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

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (1)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### X. Submission to Congress and the General Accounting Office

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

### List of Subjects in 40 CFR Part 180

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

Dated: October 17, 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. In § 180.474, paragraph (b)(1) is amended by alphabetically adding the following commodities to the table to read as follows:

**§ 180.474 Tebuconazole; tolerances for residues.**

* * * * *

(b) *Section 18 emergency exemptions.* (1) * * *

| Commodity | Parts per million | Expiration/Revocation Date |
|---|---|---|
| * * * | * * | * * |
| Sunflower oil | 0.4 | 9/30/98 |
| Sunflower seed | 0.2 | 9/30/98 |
| * * * | * * | * * |

* * * * *

[FR Doc. 97–28656 Filed 10–28–97; 8:45 am]

**BILLING CODE 6560–50–F**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300555; FRL–5745–5]**

**RIN 2070–AB78**

## Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of lambda-cyhalothrin and its epimer in or on barley grain, barley bran, barley hay and straw, canola seed, and sugarcane. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on barley, canola, and sugarcane in Louisiana and Montana. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin in the above-mentioned 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.

**DATES:** This regulation is effective October 29, 1997. Objections and requests for hearings must be received by EPA on or before December 29, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, OPP–300555, 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–300555], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 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–300355. 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: Virginia Dietrich, 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) 308–9359, e-mail: dietrich.virginia@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the insecticide lambda-cyhalothrin and its epimer, in or on barley grain, barley bran, barley hay and straw, canola seed and sugarcane at 0.05, 0.2, 2.0, 0.10, and 0.03 part per million (ppm), respectively. These tolerances will expire and are revoked on August 30, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

## I. Background and Statutory Authority

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

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

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

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

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

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

Cutworms are serious pests of small grains in Montana. Infestations can result in severe damage from the voracious feeding by the larvae. Since the cancellation of endrin, barley production has remained unprotected with an effective registered chemical. Unusually high levels of moths caught during Montana fall cutworm surveys demonstrated the potential for infestation at levels that could result in significant economic losses. This spring, levels of cutworm infestation exceeded the threshold for treatment and the Montana Department of Agriculture declared a crisis exemption on May 16, 1997.

Feeding on canola by Diamondback moth larvae is expected to result in economically significant losses of 40% in canola grown in Montana unless adequately controlled. A rapid knock-down of the larvae is necessary to prevent significant yield loss which occurs within 2 or 3 days after the larvae begin feeding on the seed pod. The registered alternatives, endosulfan and methyl parathion, both take a week or longer to match the efficacy of lambda-cyhalothrin. Another alternative, ethyl parathion, while effective in controlling this pest, is unavailable to most canola growers in Montana because there are few commercial applicators with the required closed loading system.

Sugarcane yield loss from the sugarcane borer is estimated at 60% unless adequately controlled. Registered alternatives either are more toxic to aquatic environments or cause secondary outbreaks of aphids due to toxicity to non-target arthropods (parasites and predators). After having reviewed these submissions, EPA concurs that emergency conditions exist for these states. EPA has authorized under FIFRA section 18 the use of lambda-cyhalothrin on barley, canola, and sugarcane for control of cutworm in barley, Diamondback moth in canola, and Sugarcane borer in sugarcane in Montana and Louisiana.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of lambda-cyhalothrin in or on barley, canola, and sugarcane. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on August 30, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on barley, canola, and sugarcane after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether lambda-cyhalothrin meets EPA's registration requirements for use on barley, canola, and sugarcane or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for

registration of lambda-cyhalothrin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Montana and Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for lambda-cyhalothrin, contact the Agency's Registration Division at the address provided above.

## III. Risk Assessment and Statutory Findings

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

### *A. Toxicity*

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

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

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

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

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

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 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.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants less than 1 year old) was not regionally based.

## IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of lambda-cyhalothrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of lambda-cyhalothrin and its epimer on barley grain, barley bran, barley hay and straw, canola seed and sugarcane at 0.05, 0.2, 2, 0.10, and 0.03 ppm, respectively. 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*. EPA's Office of Pesticide Programs (OPP) is currently reassessing time-limited tolerances for residues of lambda-cyhalothrin in or on over a dozen commodities established for conditional registrations. These tolerances are due to expire November 15, 1997. On July 31, 1997, as part of this reassessment, the OPP's Hazard Identification Assessment Review Committee identified an acute toxicity endpoint and recommended use of the NOEL of 0.5 mg/kg/day for an acute dietary endpoint, based on gait abnormalities in dogs in a 1 year oral toxicity study. The following assessment for the tolerances in this document uses this recommended endpoint of concern as a basis to evaluate acute dietary risk to population subgroups.

2. *Short - and intermediate-term toxicity*. For short- and intermediate-term margin of exposure (MOE) calculations, EPA's Office of Pesticide Programs (OPP) selected use of the NOEL of 0.3 ug/l (0.05 milligrams/kilogram/day (mg/kg/day) from the 21-day inhalation toxicity study in rats. The LEL of 3.3 ug/l was based on decreased body weight gains and clinical signs of toxicity including paw flicking, tail erections, and tiptoe gait.

In the 21-day dermal toxicity study, the NOEL was >1000 mg/kg/day (limit dose) and therefore the Office of Pesticide Programs did not select an endpoint.

3. *Chronic toxicity*. EPA has established the RfD for lambda-cyhalothrin at 0.001 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*. Lambda-cyhalothrin has been classified by the Office of Pesticide Programs as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity.''

### *B. Exposures and Risks*

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.438, 185.3765, and 186.3765) for the combined residues of lambda-cyhalothrin and its epimer, in or on a variety of raw agricultural commodities at levels ranging from 0.01 to 6.0 ppm. A food additive tolerance has been established under 40 CFR 185.1310 for residues on dried hops. Tolerances with the expiration date of November 15, 1997, have been established under 40 CFR 185.3765 for sunflower hulls, corn grain flour, and tomato pomace. Time-limited tolerances have been established for various animal products under 40 CFR 185.3765. Risk assessments were conducted by EPA to assess dietary exposures and risks from lambda-cyhalothrin as follows:

i. *Acute exposure and risk*. The registrant, Zeneca Ag Products, has submitted a ''Monte Carlo'' analysis assessing acute dietary risk for lambda-cyhalothrin to support extension of tolerances due to expire in November 1997. The results of the analysis are summarized below.

Table 1.—Acute Dietary Exposure and Risk Analysis Results

| Population | Exposure (mg/kg/day) 99.9th percentile | MOE 99.9th percentile |
|---|---|---|
| U.S. Population | 0.002108 | 237 |
| Children 1 - 6 Years | 0.003789 | 132 |
| Children 7 - 12 Years | 0.001893 | 264 |
| Non-Nursing Infants | 0.003281 | 152 |
| Nursing Infants | 0.000969 | 516 |
| Women, 13+ Years | 0.000831 | 601 |

The Monte Carlo analysis provided by the registrant has not undergone a thorough review in the Agency. However, given the emergency nature of the section 18 requests, the Agency will consider the results of the registrant's analysis to support the section 18 use of lambda-cyhalothrin on barley, canola, and sugarcane.

ii. *Chronic exposure and risk*. The existing lambda-cyhalothrin tolerances plus the proposed section 18 use resulted in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

U.S Population—22%
Nursing Infants (<1 year old)—25%
Non-Nursing Infants (<1 year old)—71%
Children (1-6 years old)—50%
Children (7-12 years old)—33%
Hispanics—25%
Non-Hispanic Others—27%
Northeast Region—23%
Western Region—24%

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). Further refinement using percent crop-treated data for all commodities would result in lower dietary exposure estimates.

2. *From drinking water.* Office of Pesticide Program studies indicate lambda-cyhalothrin is moderately persistent and mobile in surface water, but not ground water. There is no established Maximum Contaminant Level (MCL) for residues of lambda-cyhalothrin in drinking water. No health advisory levels for lambda-cyhalothrin in drinking water have been established. There is no entry for lambda-cyhalothrin in the ''Pesticides in Groundwater Database.''

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 pest control (crack/crevice/spot), termiticide, landscape, turf ornamentals, commercial ornamentals, golf course turf, and unoccupied agricultural premises.

The Agency lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including lambda-cyhalothrin. However, because: (1) Lambda-cyhalothrin has a low vapor pressure (2 x $10^{-10}$ torr); (2) no acute toxicity endpoints were identified by the Toxicity End-Point Selection Committee; (3) no short- or intermediate-term dermal toxicity endpoint was identified; (4) for occupationally exposed workers, high MOEs for inhalation exposure were calculated (ranging from 1,200 to 13,000); and (5) the low percentage of the RfD that is occupied for the general population by the pending and registered uses of this chemical; in the best scientific judgement of OPP, non-dietary, non-occupational uses of lambda-cyhalothrin should not pose a risk that exceeds OPP's level of concern.

4. *Cumulative exposure to substances with a 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 mechanisms of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether lambda-cyhalothrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. 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 risk.* OPP has concluded that exposure from existing uses results in MOE estimates that are not likely to exceed the Agency's acceptable level (less than 100) for acute exposure. OPP also believes adding the proposed section 18 tolerances would still result in acceptable MOEs. Therefore, the Agency has concluded that these new temporary tolerances meet the reasonable certainty of no harm finding for acute risk. A discussion of the factors considered for this decision follows.

Emergency exemptions for three commodities, sugarcane, barley, and canola, were issued earlier this year. At that time, no acute exposure endpoint had been identified in the Agency's risk assessment for the emergency exemption. However, as a result of review of new data submitted to support the extension of temporary tolerances established for conditional registrations, an acute exposure endpoint for lambda-cyhalothrin was identified (see Unit IV.A.1. of this document). OPP therefore revisited the acute risk assessment for the emergency exemptions. A preliminary review of the new information using the Agency's best professional judgement supported the reasonable certainty of no harm finding. EPA's conclusions regarding this risk analysis may change following a more thorough review.

The basis for this risk assessment is an acute dietary exposure analysis using a ''Monte Carlo'' model which reflects the distribution of possible residues on the commodities considered in the analysis as well as percent of crop treated information. This model was applied to both food and feed commodities covered under existing temporary tolerances. Although this analysis did not consider the commodities treated under the emergency exemption, the Agency believes that these tolerances are adequately protective for the following two reasons. Direct consumption of lambda-cyhalothrin through these commodities (barley, sugarcane, and canola) is expected to be lower than tolerance levels since the commodities are consumed as the processed product and not as the raw agricultural commodity. Exposure from secondary residues, those consumed through eating products from animals fed these raw agricultural commodities, is nearly all accounted for because the current analysis includes wheat, corn, and rice as well as peanut oil, corn oil, cottonseed oil, and soybean oil. These items comprise a much greater portion of animals diets than do barley, canola, or sugarcane.

2. *Chronic risk*. Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize 22 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-Nursing Infants (<1 year old) and is discussed later in this document under Determination of Safety for Infants and Children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to lambda-cyhalothrin in drinking water and from non-dietary, non-occupational exposure, 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.

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.

*D. Aggregate Cancer Risk for U.S. Population*

Lambda-cyhalothrin has been classified by OPP as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity.'' For this reason, this risk assessment was not considered appropriate and was not conducted.

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

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

FFDCA section 408 provides that EPA shall apply an additional 10-fold 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 data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard safety factor.

b. *Developmental toxicity studies*—i. *Rats*. 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).

2. *Rabbit*. 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).

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

d. *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.

e. *Conclusion*. 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.

2. *Acute risk*. OPP has concluded that exposure from existing uses results in MOE estimates that are not likely to exceed the Agency's acceptable level (less than 100) for acute exposure. OPP also believes adding the proposed section 18 tolerances would still result in acceptable MOEs. Therefore, the Agency has concluded that these new temporary tolerances meet the reasonable certainty of no harm finding for acute risk. A discussion of the factors considered for this decision can be found in Unit IV.C.1. of this preamble.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize from 25% for nursing infants less than 1 year old, up to 71% for non-nursing infants less than 1 year old of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to lambda-cyhalothrin in drinking water and from non-dietary, non-occupational exposure, 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 to infants and

children from aggregate exposure to lambda-cyhalothrin residues.

## V. Other Considerations

### *A. Metabolism in Plants and Animals*

OPP has determined that the nature of the residue in plants and animals is adequately understood based on metabolism studies conducted on cotton, cabbage, soybeans, and wheat. The residue of concern is lambda-cyhalothrin and its epimer.

### *B. Analytical Enforcement Methodology*

Adequate methods are available for the enforcement of the current tolerance expression. The analytical method (GC/ECD) for determination of lambda-cyhalothrin is ICI Method 81 which has been validated by the Agency and was found to be adequate for regulatory purposes.

The petitioner has determined recoveries of lambda-cyhalothrin and its metabolites PP890, and 3-PBAcid under FDA's multi-residue protocols.

### *C. Magnitude of Residues*

Time-limited tolerances for combined residues of lambda-cyhalothrin and its epimer should be established as follows to support this section 18 exemption:

Barley, grain—0.05 ppm
Barley, bran—0.2 ppm
Barley, straw—2 ppm
Barley, hay—2 ppm
Canola seed—0.10 ppm
Sugarcane—0.03 ppm

Barley grain, straw, and hay are livestock feed items. The dietary burden resulting from potential lambda-cyhalothrin residues in/on barley feedstuffs is comparable to that resulting from other livestock feedstuffs which have lambda-cyhalothrin tolerances (such as corn forage at 1.0 ppm and corn grain at 0.05 ppm). Thus, secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this section 18 use.

### *D. International Residue Limits*

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of lambda-cyhalothrin in/on barley. Therefore, international harmonization is not an issue for this section 18 use.

### *E. Rotational Crop Restrictions*

Studies submitted in support of lambda-cyhalothrin registration showed 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.

## VI. Conclusion

Therefore, the tolerance is established for combined residues of lambda-cyhalothrin and its epimer in barley grain, barley bran, barley hay and straw, canola seed and sugarcane at 0.05, 0.2, 2, 0.10, and 0.03 ppm, respectively.

## VII. Objections and Hearing Requests

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

Any person may, by December 29, 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 CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

## VIII. Public Docket

EPA has established a record for this rulemaking under docket control number OPP–300555 (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 (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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

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

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

## IX. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency 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.

### X. Submission to Congress and the General Accounting Office

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

### List of Subjects in 40 CFR Part 180

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

Dated: October 21, 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. In § 180.438, by adding paragraph (b) to read as follows:

### § 180.438 Lambda-cyhalothrin tolerance for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the insecticide lambda-cyhalothrin (a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclo-propanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclo-propanecarboxylate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

| Commodity | Parts per million | Expiration/Revocation Date |
|---|---|---|
| barley bran | 0.2 | 8/30/98 |
| barley grain | 0.05 | 8/30/98 |
| barley hay | 2 | 8/30/98 |
| barley straw | 2 | 8/30/98 |
| canola seed | 0.1 | 8/30/98 |
| sugarcane | 0.03 | 8/30/98 |

* * * * *

[FR Doc. 97–28655 Filed 10–28–97; 8:45 am]
**BILLING CODE 6560–50–F**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–300564; FRL–5749–2]**

**RIN 2070–AB78**

### Ferric Phosphate; Establishment of an Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final Rule.

**SUMMARY:** This rule establishes an exemption from the requirement of a tolerance for residues of ferric phosphate, when used as a molluscicide in or on all food commodities. W. Neudorff GmbH KG submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this molluscicide in or on all food commodities.

**DATES:** This regulation is effective on October 29, 1997. Objections and requests for hearings must be received by December 29, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300564], 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–300564], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental