

(1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (202) 564-4558; FAX (202) 501-0582; or via e-mail at miller.tom@epa.gov. Requests for oral comments must be in writing (e-mail, fax or mail) and received by Mr. Miller no later than noon Eastern Time on May 30, 2000.

3. SAB Executive Committee (EC) Teleconference—June 12, 2000

The Executive Committee (EC) of US EPA's Science Advisory Board will conduct a public teleconference meeting on Monday, June 12, 2000 between the hours of 1 and 3 pm Eastern Daylight Time. The meeting will be coordinated through a conference call connection in Room 6013 in the USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW, Washington, DC. The public is encouraged to attend the meeting in the conference room noted above. However, the public may also attend through a telephonic link, to the extent that lines are available. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Priscilla Tillery-Gadsen no earlier than one week prior to the meeting (beginning on May 29) at (202) 564-4533, or via e-mail at tillery.priscilla@epa.gov.

Purpose of the Meeting—In this meeting, the Executive Committee plans to review reports from some of its Committees/Subcommittee, most likely including the following:

(a) EC Subcommittee on Data from the Testing of Human Subjects: *"Report on Data from the Testing of Human Subjects"*

(b) EC Subcommittee on Review of Cancer Guidelines: *"Applicability of the Agency's Cancer Risk assessment Guidelines to Children"*

(c) Environmental Engineering Committee (EEC): *"Commentary on Measures of Environmental Technology Performance."*

Availability of Review Materials—

Drafts of the reports that will be reviewed at the meeting should be available to the public at the SAB website (<http://www.epa.gov/sab>) by close-of-business on May 25, 2000.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments must contact Dr. Donald Barnes, Designated Federal Officer, Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (202) 564-4533; FAX (202) 501-0323; or via e-mail at barnes.don@epa.gov. Requests for oral

comments must be in writing (e-mail preferred) and received by Dr. Barnes no later than noon Eastern Time on June 5, 2000.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

Oral Comments: In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. **Written Comments:** Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

General Information—Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (<http://www.epa.gov/sab>) and in The FY1999 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

Meeting Access—Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the DFO at least five business days prior to

the meeting so that appropriate arrangements can be made.

Dated: May 5, 2000.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 00-12021 Filed 5-11-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[PF-926; FRL-6497-1]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF-914, must be received on or before June 12, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-926 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Tracy Keigwin, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6605; e-mail address: keigwin.tracy@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112	Crop production Animal production

Cat-egories	NAICS codes	Examples of poten-tially affected entities
	311 32532	Food manufacturing Pesticide manufac-turing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-926. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-926 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-926. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version

of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 2, 2000.

James Jones,
Director, Registration Division, Office of
Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition

was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Zeneca Ag Products

0F6092

EPA has received a pesticide petition (0F6092) from Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE, 19850-5458 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.438, by establishing a tolerance for residues of lambda-cyhalothrin, (S)-alpha-cyano-3-phenoxybenzyl- (Z)- (1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl- (Z)- (1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimethylcyclopropanecarboxylate and the epimer of lambda-cyhalothrin, (S)-alpha-cyano-3-phenoxybenzyl- (Z)- (1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl- (Z)- (1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimethylcyclopropanecarboxylate in or on the raw agricultural commodities (RAC) canola seed, almond hulls, and the crop groupings pome fruit, stone fruit and tree nuts at 0.15, 1.5, 0.3, 0.5, 0.05 parts per million (ppm), respectively, and on the processed commodity apple pomace, wet at 2.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of lambda-cyhalothrin has been studied in cotton, soybean, cabbage and wheat plants. The studies show that the metabolism generally follows that of other pyrethroid insecticides. The ester linkage is cleaved to form cyclopropanecarboxylic acids and the corresponding phenoxybenzyl alcohol. Overall the studies show that

unchanged lambda-cyhalothrin is the principal constituent of the residue on edible portions of these crops.

2. *Analytical method.* An adequate analytical method (gas liquid chromatography with an electron capture detector) is available for enforcement purposes.

3. *Magnitude of residues.* Crop field trial residue data from canola, pome fruit, stone fruit and tree nuts studies show that the proposed tolerances on these commodities will not be exceeded when lambda-cyhalothrin is used as directed. A market basket survey of residues of lambda-cyhalothrin in samples of whole milk collected across the contiguous United States over a period of 1 year was conducted during 1998-99. Nearly 80% of the 360 samples collected had non-detectable (<0.0003 µg/L) levels of lambda-cyhalothrin with the remaining 20% having trace levels (<0.001 µg/L). These levels are substantially less than the established tolerance for whole milk of 0.2 milligrams/kilograms (mg/kg).

No increase in the dietary burden of poultry and ruminants is expected from use on canola, pome fruit, stone fruit, or tree nuts. Therefore, any secondary residues that might result in milk, meat, poultry, and eggs would be covered by the existing tolerances on these commodities.

B. Toxicological Profile

1. *Acute toxicity.* Acute toxicity studies with the technical grade of the active ingredient lambda-cyhalothrin: oral lethal dose (LD)₅₀ in the rat of 79 mg/kg (males) and 56 mg/kg (females), dermal LD₅₀ in the rat of 632 mg/kg (males) and 696 mg/kg females, primary eye irritation study showed mild irritation and primary dermal irritation study showed no irritation.

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

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

respectively, based on decreased pup weight gain during weaning.

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

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

4. *Subchronic toxicity.* A 90-day feeding study in rats fed doses of 0, 10, 50 and 250 ppm with a NOAEL of 50 ppm and a LOAEL of 250 ppm based on body weight gain reduction.

A study where lambda-cyhalothrin in olive oil was applied to the skin of rats for 21 successive days at dose rates of 1, 10, or 100 (reduced to 50 after 2-3 applications) mg/kg/day. A NOAEL of 10 mg/kg/day is based on clinical signs of slight general toxicity at 50 mg/kg/day.

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

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

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

6. *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.

Human metabolism of lambda-cyhalothrin was assessed by administering 5 mg lambda-cyhalothrin orally to six male volunteers (average dose was 0.06 mg/kg) and dermally at 20 mg/800 centimeters² to five volunteers. No adverse effects were noted in the individuals given an oral dose, and only mild signs of parasthesia were noted in individuals receiving a dermal dose. Absorption by these two routes of exposure were determined by analysis of urinary metabolites. An average amount of 59% of the oral dose was absorbed. Dermal absorption was extremely low, and estimated to be 0.12% (range 0.04–0.19%).

7. *Metabolite toxicology.* The Agency has previously determined that the metabolites of lambda-cyhalothrin are not of toxicological concern and need not be included in the tolerance expression. Given this determination, it is concluded that there is no need to discuss metabolite toxicity.

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

C. Aggregate Exposure

1. *Dietary exposure.* For the purposes of assessing the potential chronic dietary exposure for all existing and pending tolerances for lambda-cyhalothrin, Zeneca has utilized available information on anticipated residues (FDA monitoring data, average field trial residues and processing data)

and percent crop treated. For the acute dietary assessment, a Monte Carlo method was used to estimate exposure.

i. *Food—a. Acute dietary exposure.* An acute dietary exposure assessment was made using the dietary exposure evaluation model (DEEM) computer software (Novigen Sciences Inc.) and the USDA Continuing Surveys of Individual Intakes (CSFII) 1994–96. Acute dietary exposure was based on all crops with tolerances for lambda-cyhalothrin established at 40 CFR 180.438 together with crops in this petition, canola, and the crop groupings pome fruit, stone fruit and tree nuts. Anticipated residues were estimated from field trial data and from the lambda-cyhalothrin national milk survey together with estimates of percent crop treated for each crop. The predicted acute exposure for the U.S. population was 0.001269 mg/kg/body weight/day (mg/kg/bwt/day). The population subgroup with the highest predicted level of acute exposure was non-nursing infants (<1 year old) with an exposure of 0.003599 mg/kg/bwt/day (99.9th percentile). Based on an acute NOAEL of 0.5 mg/kg/bwt/day from a 1-year dog feeding study, and a 100-fold safety factor, the acute reference dose (aRfD) is 0.005 mg/kg/bwt/day. For the U.S. population the predicted exposure is equivalent to 25% of the aRfD. For the population subgroup non-nursing infants (<1 year old) the exposure is equivalent to 72% of the aRfD. Because the predicted exposures, expressed as the percentages of the aRfD, are well below 100%, there is reasonable certainty that no acute effects would result from the dietary exposure to lambda-cyhalothrin.

b. *Chronic dietary exposure.* A chronic dietary exposure assessment was made using the DEEM computer software (Novigen Sciences Inc.). Chronic dietary exposure was based on all crops with tolerances for lambda-cyhalothrin established at 40 CFR 180.438 together with crops in this petition, canola, and the crop groupings pome fruit, stone fruit and tree nuts. Anticipated residues were estimated from field trial data and from the lambda-cyhalothrin national milk survey together with estimates of percent crop treated for each crop. The predicted chronic exposure for the U.S. population was 0.000062 mg/kg/bwt/day. The population subgroup with the highest predicted level of chronic exposure was non-nursing infants with an exposure of 0.000132 mg/kg/bwt/day. Based on a chronic NOAEL of 0.1 mg/kg/bwt/day from a 1-year dog feeding study, and a 100-fold safety factor, the chronic reference dose (cRfD) is 0.001 mg/kg/bwt/day. For the U.S.

population the predicted exposure is equivalent to 6.2% of the cRfD. For the population subgroup non-nursing infants the exposure is equivalent to 13.2% of the cRfD. Because the predicted exposures, expressed as the percentages of the aRfD, are well below 100%, there is reasonable certainty that no chronic effects would result from the dietary exposure to lambda-cyhalothrin.

ii. *Drinking water.* Laboratory and field data have demonstrated that lambda-cyhalothrin and its degradates are immobile in soil and will not leach into ground water. Surface water estimates were made by EPA using the GENEEC model (Tier I). The predicted peak, average and annual values (56 days) are, respectively, 0.095 parts per billion (ppb), 0.003 ppb and <0.003 ppb. EPA uses drinking water levels of comparison (DWLOCs) as a surrogate measure to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations. The acute DWLOC for lambda-cyhalothrin was calculated for the subpopulation of concern, non-nursing infants (<1 year old), to be 14 ppb. The chronic DWLOC was calculated for this subpopulation to be 9 ppb. The predicted maximum concentration of lambda-cyhalothrin in drinking water is 0.095 ppb which is much lower than the acute DWLOC. Therefore one can conclude with reasonable certainty that residues of lambda-cyhalothrin do not contribute significantly to the aggregate acute human health risk. The chronic DWLOC for the most sensitive subpopulation, non-nursing infants (<1 year old), is 9 ppb. This DWLOC is substantially higher than the predicted average concentration of lambda-cyhalothrin in surface water of 0.003 ppb. Therefore one can conclude with reasonable certainty that residues of lambda-cyhalothrin do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure.* Other potential sources of exposure are from non-occupational sources such as structural pest control and ornamental plant and lawn use of lambda-cyhalothrin. A risk assessment was performed by EPA published in the **Federal Register** January 29, 1999 (64 FR 4584) (FRL-6056-2), for post application activities on lawns treated

with lambda-cyhalothrin which is considered to be a worse case estimate of exposure from residential uses. Results from EPA's short-term exposure and risk assessments showed that the oral MOE (margin of exposure) for infants and children was 3,500, the dermal MOEs were 1.5 million for the U.S. population and 7,810 for infants and children, and the inhalation MOEs were 15,000 for the U.S. population and 4,800 for infants and children. For intermediate-term exposure and risk assessments, EPA concluded the oral MOEs for infants and children was 700, the dermal MOEs were 1.5 million for the U.S. population and 7,810 for infants and children, and the inhalation MOEs were 15,000 for the U.S. population and 4,800 for infants and children. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the non-dietary and overall aggregate risk assessments for lambda-cyhalothrin clearly indicates a reasonable certainty of no harm.

D. Cumulative Effects

Zeneca Ag Products will submit information for EPA to consider concerning potential cumulative effects of lambda-cyhalothrin consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL-5734-6), and other EPA publications pursuant to the Food Quality Protection Act. At this time, Zeneca cannot make a determination based on available and reliable information that lambda-cyhalothrin and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore for purposes of this request it is appropriate only to consider the potential risks of lambda-cyhalothrin in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population.* Based on the completeness and reliability of the lambda-cyhalothrin toxicology data base and using the conservative aggregate exposure assumptions presented earlier, it is concluded that lambda-cyhalothrin products may be used with a reasonable certainty of no harm relative to exposures from food and drinking water. A chronic dietary exposure and risk assessment has been performed for lambda-cyhalothrin using EPA's cRfD of 0.001 mg/kg/bwt/day. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into the analysis to estimate the Anticipated Residue Contribution (ARC). The ARC is generally considered a more realistic

estimate than an estimate based on tolerance level residues. The ARC from established tolerances and the current and pending actions are estimated to be 0.000062 mg/kg/bwt/day and utilize 6.2% of the cRfD. An acute dietary exposure and risk assessment has been performed for lambda-cyhalothrin using EPA's aRfD of 0.005 mg/kg/bwt/day. The ARC from established tolerances and the current and pending actions are estimated to be 0.001269 and utilize 25% of the aRfD. The acute and chronic DWLOC for lambda-cyhalothrin for the U.S. population are 131 ppb and 33 ppb, respectively. The maximum concentrations in drinking water predicted by EPA are substantially lower than either the acute or chronic DWLOC. Therefore, one can conclude with reasonable certainty that residues of lambda-cyhalothrin in drinking water would not contribute significantly to the aggregate acute or chronic human health risk. In conclusion, there is a reasonable certainty of no harm to the general population resulting from either acute or chronic aggregate exposure to lambda-cyhalothrin.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOAEL in the animal study appropriate to the particular risk assessment. This hundred-fold uncertainty (safety) factor/margin of exposure is designed to account for combined interspecies and intraspecies variability. EPA believes that reliable data support using the standard hundred-fold margin/factor and not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants and children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

In assessing the potential for additional sensitivity of infants and children to residues of lambda-cyhalothrin, EPA considered the data from oral developmental toxicity studies in the rat and rabbit, as well as data from a multi-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects in the developing organism resulting from pesticide exposure during prenatal development

in the mothers. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

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

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

EPA have concluded in its 1997 review of lambda-cyhalothrin that the toxicity endpoints from the data on developmental and reproductive toxicity tests do not indicate any increased prenatal or postnatal sensitivity. Therefore, EPA concluded that reliable data support use of a hundred fold safety factor and that an additional tenfold safety factor is not needed.

Based on this information, the ARC for children aged 1 to 6 years old, and non-nursing infants (subgroups most highly exposed) utilizes 0.000127 mg/kg/bwt/day (12.7% of the cRfD) and 0.000132 mg/kg/bwt/day (13.2% of the cRfD), respectively. Generally speaking, the Agency has no cause for concern if the anticipated residues contribution for all published and proposed tolerances is less than the 100% of the cRfD.

For the acute dietary assessment the ARC for children aged 1 to 6 years old, and non-nursing infants (subgroups most highly exposed) utilizes 0.002363 mg/kg/bwt/day (47.3% of the aRfD) and

0.003599 mg/kg/bwt/day (72% of the aRfD), respectively. Generally speaking, the Agency has no cause for concern if the anticipated residues contribution for all published and proposed tolerances is less than the 100% of the aRfD. The acute and chronic DWLOC for lambda-cyhalothrin for non-nursing infants are 14 ppb and 9 ppb, respectively. The maximum concentrations in drinking water predicted by EPA are substantially lower than either the acute or chronic DWLOC. Based on these exposure estimates it may be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposures to lambda-cyhalothrin.

F. International Tolerances

There are Codex maximum residue levels (MRL) established or pending for residues of cyhalothrin, as the sum of all isomers, in or on the following crops and commodities.

Crop	MRL (mg/kg)
Apricots	0.2
Cabbage, head	0.2
Cherries	0.2
Cotton seed	0.02
Cotton seed, oil	0.02
Oil seed (including rapeseed oil).	0.02
Peaches	0.2
Plums	0.1
Pome fruit	0.1
Potatoes	0.02
Tree nuts (shelled and unshelled).	0.05

Canadian MRLs of 0.1 ppm for pome fruit, stone fruit and canola are established in Canada for lambda-cyhalothrin based on the "negligible" residue clause of Canadian Food & Drug Act Regulations (B.15.002(1)).

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BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

May 3, 2000.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as

required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before July 11, 2000. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, 445 12th Street, SW., Room 1-A804, Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418-0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060-0783.

Title: Section 90.176 Coordination notification requirements on frequencies below 512 MHz.

Form Number: N/A.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents: 15.

Estimated Time Per Response: .25 hours.

Total Annual Burden: 975 hours.

Total Annual Cost: 0.

Needs and Uses: The reporting requirement in section 90.176 is a result of comments sought in the Report and Order and Further Notice of Proposed Rule Making in PR Dck No. 92-235 and requires each Private Land Mobile frequency coordinator provide, within one business day, a listing of their frequency recommendations to all other frequency coordinators in their respective pool, and, if requested, an

engineering analyses. This requirement is necessary to avoid situations where harmful interference is created because two or more coordinators recommend the same frequency in the same area at approximately the same time to different applicants.

OMB Approval Number: 3060-0798.

Title: FCC Application for Wireless Telecommunications Bureau Radio Service Authorization.

Form Number: FCC 601.

Type of Review: Revision of an existing collection.

Respondents: Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 240,320.

Estimated Time Per Response: 1.25 hours.

Total Annual Burden: 210,280 hours.

Needs and Uses: FCC 601 is used as the general application (long form) for market based licensing and site-by-site licensing in the Wireless Telecommunications Radio Services. The purpose of this revision is to make the necessary changes for the 700 MHz Band and 700 MHz Guard Band Auctions and to convert the Land Mobile Services (Part 90) to ULS. We sought emergency clearance on these changes in order to allow form changes to be in place for the auctions scheduled for the beginning of June and are now seeking a 3 year clearance. The information is used by the Commission to determine whether the applicant is legally, technically and financially qualified to be licensed.

Respondent costs are estimated to be \$48,364,000, which includes application filing fees.

OMB Control Number: 3060-0773.

Title: Marketing of RF Devices Prior to Equipment Authorization—Section 2.830.

Form Number: N/A.

Type of Review: Extension of currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents: 6,000.

Estimated Time Per Response: .5 hour.

Total Annual Burden: 3,000 hours.

Total Annual Cost: N.A.

Needs and Uses: FCC rules permit the display and advertising of radio frequency devices prior to equipment authorization or a determination of compliance with the rules, providing that the advertising or display contains a conspicuous notice as specified by the rules. The notice that must be displayed is defined in section 2.803©. A notice that applies specifically to prototype equipment is defined in section