interval between application and harvest (''pre-harvest intervals''), modifications in use, or suggest alternative measures to reduce residues contributing to dietary exposure. For occupational risks, commenters may suggest personal protective equipment or technologies to reduce exposure to workers and pesticide handlers. For ecological risks, commenters may suggest ways to reduce environmental exposure, e.g., exposure to birds, fish, mammals, and other non-target organisms. EPA will provide other opportunities for public participation and comment on issues associated with the organophosphate pesticide tolerance reassessment program. Failure to participate or comment as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments and proposals must be received by EPA on or before May 1, 2000 at the addresses given under the **ADDRESSES** section. Comments and proposals will become part of the Agency record for the organophosphate pesticides specified in this notice.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: February 22, 2000.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 00–4789 Filed 2–29–00; 8:45 am]

BILLING CODE 6450–01–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–916; FRL–6489–9]

Notice of Filing a Pesticide Petition 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 pesticide petitions 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–916, must be received on or before March 31, 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–916 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Tracy Keigwin, Registration Support Branch, Registration Division (7505), 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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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–916. 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, 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–916 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, Crystal Mall #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–916. 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 Comestic 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: February 17, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announce 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.

1. Bayer Corporation

EPA has received a pesticide petition (PP5F4475) from Bayer Corporation, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120-0013 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of cyfluthrin, cyano (4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2- in or on the raw agricultural commodity (RAC) cereal grains group; corn, starch; corn, refined oil (wet milling); corn, flour; corn, refined oil (dry milling); wheat, bran; corn, milled by-products; rice, hulls; wheat, milled by-products at 2.0, 3.0, 12, 4.0, 15, 3.0, 4.0, 9.0, 3.0 parts per million (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 cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

2. *Analytical method*. Adequate analytical methodology (gas/liquid chromatography with an electron capture detector (GLC/EC) is available for enforcement purposes.

3. *Magnitude of residues*. Cyfluthrin is the active ingredient (a.i.) in the registered end-use product Tempo 2E Grain, Bin and Warehouse Insecticide , EPA FR 3125-ULO. Data to support the proposed tolerances have been submitted to the Agency.

B. Toxicological Profile

1. *Acute toxicity*. There is a battery of acute toxicity studies for cyfluthrin supporting an overall toxicity Category II for the active ingredient.

2. *Genotoxicty*. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary (CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis (UDS) assay in rat hepatocytes. All tests were negative for genotoxicity.

3. *Reproductive and developmental toxicity*. An oral developmental toxicity study in rats with a maternal and fetal no observed adverse effect level (NOAEL) of 10 milligrams/kilograms body weight/day (mg/kg bwt/day) highest dose tested (HDT). An oral developmental toxicity study in rabbits with a maternal NOAEL of 20 mg/kg bwt/day and a maternal lowest effect level (LEL) of 60 mg/kg bwt/day, based on decreased bwt gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg bwt/day and a fetal LEL of 60 mg/kg bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss. A 3–generation reproduction study in rats with systemic toxicity NOAELs of 7.5 and 2.5 mg/kg bwt/day for parental animals and their offspring, respectively. At highest dose levels (HDLs), the bwts of parental animals and their offspring were reduced.

4. *Subchronic toxicity*. A subchronic toxicity feeding study using rats demonstrated a NOAEL of 22.5 mg/kg bwt/day, the HDT. A 6–month toxicity feeding study in dogs established a NOAEL of 5 mg/kg bwt/day. The LEL

was 15 mg/kg bwt/day based on clinical signs and reduced thymus weights.

5. *Chronic toxicity*. A 12–month chronic feeding study in dogs established a NOAEL of 4 mg/kg bwt/day. The LEL for this study is established at 16 mg/kg bwt/day, based on slight ataxia, increased vomiting, diarrhea, and decreased body weight. A 24–month chronic feeding/carcinogenicity study in rats demonstrated a NOAEL of 2.5 mg/kg bwt/day and LEL of 6.2 mg/kg bwt/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females. A 24–month carcinogenicity study in mice was conducted. Under the conditions of the study there were no carcinogenic effects observed. A 24–month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism*. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Metabolite toxicology*. No toxicology data have been required for cyfluthrin metabolites. The residue of concern is cyfluthrin.

8. *Endocrine disruption*. There is no evidence of endocrine effects in any of the studies conducted with cyfluthrin, thus, there is no indication at this time that cyfluthrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure was estimated using Novigen's Dietary Exposure Evaluation Model (DEEM) software; results from field trial and processing studies; consumption data from the Department of Agricultural (USDA) Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1994 through 1996; and information on the percentages of crops treated with cyfluthrin. Cyfluthrin is currently registered for use in alfalfa, carrots, citrus, cotton, sweet corn, sorghum, sunflower, sugarcane, potatoes, peppers, radishes, and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments and in combination with another active ingredient, for use in field corn, pop corn, and sweet corn. Chronic dietary exposure estimates with the current label uses plus the proposed uses on stored grain, field and pop corn, soybeans, hops, peas and lentils, lettuce, head and stem brassica, and mustard greens for the overall U.S. population were 5% of the population adjusted dose (PAD) (0.008 mg/kg bwt/day). For the most highly exposed population subgroup, children 1 to 6 years of age, the exposure was estimated to be 15% of the PAD. Acute dietary exposure estimates with the current label uses plus the proposed uses on stored grain, field and pop corn, soybeans, hops, peas and lentils, lettuce, head and stem brassica, and mustard greens for the overall U.S. population were 11% of the aPAD (0.07 mg/kg bwt/day). For the most highly exposed population subgroup, children 1 to 6 years of age, the exposure was estimated to be 18% of the aPAD.

ii. *Drinking water*. Cyfluthrin is immobile in soil, therefore, will not leach into ground water. Additionally, due the insolubility and lipophilic nature of cyfluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore, not contributing to potential dietary exposure from drinking water. A screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM3). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at 2 meters are essentially zero (<0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 52 parts per trillion (ppt). Concentration in actual drinking water would be much lower. Based on these analyses, the contribution of water to the dietary risk estimate is negligible.

2. *Non-dietary exposure*. Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Pursuant to the requirements of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended by the Food Quality Protection Act (FQPA) of 1996 non-dietary and aggregate risk analyses for cyfluthrin were conducted. The analyses include evaluation of potential non-dietary acute application and post-application exposures. Non-occupational, non-dietary exposure was assessed based on the assumption that a flea infestation control scenario represents a ''worst case'' scenario. For the flea control infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose NOAEL. Results for each potential exposed subpopulation (of adults, children 1-6 years, and infants <1 year) were compared to the systemic absorbed dose NOAEL for cyfluthrin to provide estimates of margins of exposure (MOE). The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,700, and 2,500 for adults, children (1-6 years), and infants (<1 year), respectively. The aggregate MOE for adults is approximately 3,700 and the MOEs for infants and children exceed 2,400. The non-dietary methods used in the analyses can be characterized as highly conservative. This is due to the conservatism inherent in the calculation procedures and input assumptions. An example of this is the conservatism inherent in the jazzercise methodology's over-representation of residential post-application exposures. It is important to acknowledge that these MOEs are likely to significantly underestimate actual MOEs due to a variety of conservative assumptions and biases inherent in the derivatization of exposure by this method. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the FQPA of 1996 for the current label uses. The additional use of cyfluthrin on field corn and soybean crops will have no impact on the analysis for non-dietary exposure.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA at 62 FR 42020 (August 4, 1997) (FRL–5734-6) and other EPA publications pursuant to the FQPA.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to cyfluthrin from all label uses will utilize less than 20% of the RfD for chronic dietary exposures and that MOE in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-cupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. MOE of 100 or more (300 for infants and children) also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2–generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through 2–generations, as well as any observed systemic toxicity. The toxicology data which support these uses of cyfluthrin include: A rat oral developmental toxicity study in which maternal and fetal NOAELs of 10 mg/kg bwt/day HGT were observed. An oral developmental toxicity study in which rabbits had a maternal NOAEL of 20 mg/kg bwt/day and a maternal LEL of 60 mg/kg bwt/day, based on decreased bodyweight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg bwt/day and a fetal LEL of 60 mg/kg bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss. An oral developmental toxicity study performed with beta-cyfluthrin, the resolved isomer mixture of cyfluthrin, has been submitted to the Agency and is currently under review. A developmental toxicity study in rats exposed via inhalation to liquid aerosols of cyfluthrin revealed developmental toxicity, but only in the presence of maternal toxicity. The developmental NOAEL was 0.46 mg/m^3 on the basis of reduced placental and fetal weights, and delayed ossification. The NOAEL for overt maternal toxicity was <0.46 mg/m^3, the LDT. In a rat 3–generation reproduction study, systemic toxicity NOAELs of 7.5 and 2.5 mg/kg bwt/day for parental animals and their offspring, respectively, were observed. At HDL, the bwts of parental animals and their offspring were reduced. Another multiple-generation reproduction study in rats has been submitted to the Agency and is currently under review. To assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups, the Agency has used the rabbit developmental toxicity study which had a maternal NOAEL of 20 mg/kg bwt/day. Because the toxicological endpoint is one of developmental toxicity, the population group of concern for this analysis was women aged 13 and above. This subgroup most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOAEL to the exposure. The Agency calculated the MOE to be over 600. Generally, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when prenatal and postnatal threshold effects were observed in studies or to account for incompleteness of the toxicity data base. The results of the 3–generation study in rats provided evidence suggesting that, with respect to effects of cyfluthrin on body weight, pups were more sensitive than adult rats. Thus, the Agency determined that an additional 3-fold uncertainty factor (UF) should be used in risk assessments to ensure adequate protection of infants and children. Generally, EPA considers MOEs of at least 100 to indicate an adequate degree of safety. With an additional 3x uncertainty factor, this would be 300 for infants and children.

F. International Tolerances

There is a Codex maximum residue level (MRLs) for maize of 0.05 ppm. There is a Codex MRL for sweet corn of 0.02 ppm.

2. *Bayer Corporation.* EPA has received a pesticide petition (PP0F6084) from Bayer Corporation, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120-0013 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of cyfluthrin, cyano (4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2- in or on the RAC, mustard greens, greens; lettuce, head; lettuce, leaf; head and stem brassica subgroup (5A) at 7.0, 2.0, 3.0, 2.0 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 cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

2. *Analytical method*. Adequate analytical methodology GLC/EC detector is available for enforcement purposes.

3. *Magnitude of residues*. Cyfluthrin is the active ingredient in the registered end-use product Baythroid 2 Emulsifiable Pyrethroid Insecticide, EPA FR 3125-351. Data to support the proposed tolerances have been submitted to the Agency.

B. Toxicological Profile

1. *Acute toxicity*. There is a battery of acute toxicity studies for cyfluthrin supporting an overall toxicity Category II for the active ingredient.

2. *Genotoxicity*. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a CHO/HGPRT assay; a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an UDS assay in rat hepatocytes. All tests were negative for genotoxicity.

3. *Reproductive and developmental toxicity*. An oral developmental toxicity study in rats with a maternal and fetal NOAEL of 10 mg/kg bwt/day HDT. An oral developmental toxicity study in rabbits with a maternal NOAEL of 20 mg/kg bwt/day and a maternal LEL of 60 mg/kg bwt/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg bwt/day and a fetal LEL of 60 mg/kg bwt/day were also observed in this study. The LEL was based on increased resorptions and increased post-implantation loss. A 3–generation reproduction study in rats with systemic toxicity NOAELs of 7.5 and 2.5 mg/kg bwt/day for parental animals and their offspring, respectively. At HDLs, the body weights of parental animals and their offspring were reduced.

4. *Subchronic toxicity*. A subchronic toxicity feeding study using rats demonstrated a NOAEL of 22.5 mg/kg bwt/day, the HDT. A 6–month toxicity feeding study in dogs established a NOAEL of 5 mg/kg bwt/day. The LEL was 15 mg/kg bwt/day based on clinical signs and reduced thymus weights.

5. *Chronic toxicity*. A 12–month chronic feeding study in dogs established a NOAEL of 4 mg/kg bwt/day. The LEL for this study is established at 16 mg/kg bwt/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight. A 24–month chronic feeding/carcinogenicity study in rats demonstrated a NOAEL of 2.5 mg/kg bwt/day and LEL of 6.2 mg/kg bwt/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females. A 24–month carcinogenicity study in mice was conducted. Under the conditions of the study there were no carcinogenic effects observed. A 24–month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism*. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Metabolite toxicology*. No toxicology data have been required for cyfluthrin metabolites. The residue of concern is cyfluthrin.

8. *Endocrine disruption*. There is no evidence of endocrine effects in any of the studies conducted with cyfluthrin, thus, there is no indication at this time that cyfluthrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure was estimated using Novigen's Dietary Exposure Evaluation Model (DEEM) software; results from field trial and processing studies; consumption data from the USDA Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1994 through 1996; and information on the percentages of crops treated with cyfluthrin. Cyfluthrin is currently registered for use in alfalfa, carrots, citrus, cotton, sweet corn, sorghum, sunflower, sugarcane, potatoes, peppers, radishes, and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments and in combination with another active ingredient, for use in field corn, pop corn, and sweet corn. Chronic dietary exposure estimates with the current label uses plus the proposed uses on stored grain, field and pop corn, soybeans, hops, peas and lentils, lettuce, head and stem brassica, and mustard greens for the overall U.S. population were 5% of the PAD (0.008 mg/kg bwt/day). For the most highly exposed population subgroup, children 1 to 6 years of age, the exposure was estimated to be 15% of the PAD. Acute dietary exposure estimates with the current label uses plus the proposed uses on stored grain, field and pop corn, soybeans, hops, peas and lentils, lettuce, head and stem brassica, and mustard greens for the overall U.S. population were 11% of the aPAD (0.07 mg/kg bwt/day). For the most highly exposed population subgroup, children 1 to 6 years of age, the exposure was estimated to be 18% of the aPAD.

ii. *Drinking water*. Cyfluthrin is immobile in soil, therefore, will not leach into ground water. Additionally, due the insolubility and lipophilic nature of cyfluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore, not contributing to potential dietary exposure from drinking water. A screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM3). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at 2 meters are essentially zero (<0.001 ppb). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using Standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 52 ppt. Concentration in actual drinking water would be much lower. Based on these analyses, the contribution of water to the dietary risk estimate is negligible.

2. *Non-dietary exposure*. Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Pursuant to the requirements of FIFRA as amended by the FQPA of 1996 non-dietary and aggregate risk analyses for cyfluthrin were conducted. The analyses include evaluation of potential non-dietary acute application and post-application exposures. Non-occupational, non-dietary exposure was assessed based on the assumption that a flea infestation control scenario represents a ''worst case'' scenario. For the flea control infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose NOAEL. Results for each potential exposed subpopulation (of adults, children 1-6 years, and infants <1 year) were compared to the systemic absorbed dose NOAEL for cyfluthrin to provide estimates of MOE. The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,700, and 2,500 for adults, children (1-6 years), and infants (< 1 year), respectively. The aggregate MOE for adults is approximately 3,700 and the MOEs for infants and children exceed 2,400. The non-dietary methods used in the analyses can be characterized as highly conservative. This is due to the conservatism inherent in the calculation procedures and input assumptions. An example of this is the conservatism inherent in the jazzercise methodology's over-representation of residential post-application exposures. It is important to acknowledge that these MOEs are likely to significantly underestimate actual MOEs due to a variety of conservative assumptions and biases inherent in the derivatization of exposure by this method. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the FQPA of 1996 for the current label uses. The additional use of cyfluthrin on field corn and soybean crops will have no impact on the analysis for non-dietary exposure.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA at 62 FR 42020 (August 4, 1997) (FRL–5734-6) and other EPA publications pursuant to the FQPA.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to cyfluthrin from all label uses will utilize less than 20% of the RfD for chronic dietary exposures and that MOEs in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. MOE of 100 or more (300 for infants and children) also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2–generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through 2–generations, as well as any observed systemic toxicity. The toxicology data which support these uses of cyfluthrin include: A rat oral developmental toxicity study in which maternal and fetal NOAELs of 10 mg/kg bwt/day HDT were observed. An oral developmental toxicity study in which rabbits had a maternal NOAEL of 20 mg/kg bwt/day and a maternal LEL of 60 mg/kg bwt/day, based on decreased bwt gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg bwt/day and a fetal LEL of 60 mg/kg bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss. An oral developmental toxicity study performed with beta-cyfluthrin, the resolved isomer mixture of cyfluthrin, has been submitted to the Agency and is currently under review. A developmental toxicity study in rats exposed via inhalation to liquid aerosols of cyfluthrin revealed developmental toxicity, but only in the presence of maternal toxicity. The developmental NOAEL was 0.46 mg/m^3 on the basis of reduced placental and fetal weights, and delayed ossification. The NOAEL for overt maternal toxicity was < 0.46 mg/m^3, the LDT. In a rat 3–generation reproduction study, systemic toxicity NOAELs of 7.5 and 2.5 mg/kg bwt/day for parental animals and their offspring, respectively, were observed. At HDL, the body weights of parental animals and their offspring were reduced. Another multiple-generation reproduction study in rats has been submitted to the Agency and is currently under review. To assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups, the Agency has used the rabbit developmental toxicity study which had a maternal NOAEL of 20 mg/kg bwt/day. Because the toxicological endpoint is one of developmental toxicity, the population group of concern for this analysis was women aged 13 and above. This subgroup most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOAEL to the exposure. The Agency calculated the MOE to be over 600. Generally, MOEs greater than 100 for data derived from animal studies are regarded as showing no appreciable risk. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when prenatal and postnatal threshold effects were observed in studies or to account for incompleteness of the toxicity data base. The results of the 3–generation study in rats provided evidence suggesting that, with respect to effects of cyfluthrin on body weight, pups were more sensitive than adult rats. Thus, the Agency determined that an additional 3-fold uncertainty factor (UF) should be used in risk assessments to ensure adequate protection of infants and children. Generally, EPA considers MOEs of at least 100 to indicate an adequate degree of safety. With an additional 3x UF, this would be 300 for infants and children.

F. International Tolerances

There are currently no Codex maximum residue levels for mustard greens, lettuce or head and stem brassicas.

[FR Doc. 00–4791 Filed 2–29–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50862; FRL–6388–7]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits (EUPs) to the following pesticide applicants. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: By mail: Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In person or by telephone: Contact the designated person at the following address at the office location, telephone number, or e-mail address cited in each experimental use permit: 1921 Jefferson Davis Highway, Arlington, VA.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

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

You may obtain electronic copies of this document from the EPA Internet Home Page at http://www.epa.gov/. 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/.

II. EUPs

EPA has issued the following EUPs:

70515–EUP–1. Amendment. J.P. BioRegulators, Inc., IR–4 Project Rutgers University, Cook College, P.O. Box 231, New Brunswick, NJ 08903–0231. This experimental use permit allows the use of 72 kilograms each year of the