D. Cumulative Effects

According to Valent there are no other pesticidal compounds that are structurally related to pyriproxyfen and have similar effects on animals. In consideration of potential cumulative effects of pyriproxyfen and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by pyriproxyfen would be cumulative with those of other chemical compounds. Thus, only the potential risks of pyriproxyfen have been considered in this assessment of aggregate exposure and effects. Valent will submit information for EPA to consider concerning potential cumulative effects of pyriproxyfen consistent with the schedule established by EPA at 62 Federal Register 42020 (August 4, 1997) and other subsequent EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population*—i. *Chronic dietary exposure and risk*. Using the Tier I dietary exposure assessment, calculated chronic dietary exposure resulting from residue exposure from existing and proposed uses of pyriproxyfen is minimal. The estimated chronic dietary exposure from food for the overall U.S. Population and many non-child/infant subgroups is from 0.000338 to 0.000652 mg/kg bw/day, 0.097 to 0.186 per cent of the RfD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above) increases exposure by only 4.57×10^{-6} mg/kg bw/day and does not change the maximum occupancy of the RfD significantly. Generally, the Agency has no cause for concern if total residue contribution is less than 100 percent of the RfD. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. Population and infants and children from aggregate, chronic exposure to pyriproxyfen residues.

ii. *Acute dietary exposure and risk*. An acute dietary dose and endpoint was not identified. Thus, the risk from acute aggregate exposure is considered to be negligible.

iii. *Non-dietary exposure and aggregate risk*. Acute, short term, and intermediate term dermal and inhalation risk assessments for residential exposure are not required due to the lack of significant toxicological effects observed.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of pyriproxyfen, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to ten-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicological data base for evaluating pre- and post-natal toxicity for pyriproxyfen is complete with respect to current data requirements. There are no special pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2–generation reproductive toxicity study in rats. Valent concludes that reliable data support use of the standard 100–fold uncertainty factor and that an additional uncertainty factor is not needed for pyriproxyfen to be further protective of infants and children.

F. International Tolerances

There are no Codex MRLs for pyriproxyfen.

[FR Doc. 01–8140 Filed 4–3–01;8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1013; FRL–6772–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical 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 a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1013, must be received on or before May 4, 2001.

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–1013 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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,'' ''Regulations and Proposed Rules,'' 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–1013. 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–1013 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, 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–1013. 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 support 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: March 20, 2001.

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.

Interregional Research Project Number 4 (IR-4)

0E6184 and 0E6075

EPA has received pesticide petitions (0E6184 and 0E6075) from the Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, 681 US Highway #1 South, North Brunswick, NJ 08902–3390 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 tolerances for residues of the insecticide, cyfluthrin, (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate in or on southern pea at 0.23 parts per million (ppm) and dry peas (pigeon peas, chickpeas/garbanzo beans, lentils) at 0.05 ppm. EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on these petitions. This notice contains a summary prepared by the registrant, Bayer Corporation, Box 4913, Kansas City, MO 64120–0013.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of cyfluthrin in plants is adequately

understood. The residue of concern is cyfluthrin.

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

3. *Magnitude of residues.* Complete residue data for cyfluthrin on southern pea and dry peas have been submitted. The data support the requested tolerances.

B. Toxicological Profile

1. *Acute toxicity.* The required toxicity studies for acute oral lethal dose $(LD)_{50}$ ≥16.2 milligrams/kilograms (mg/kg), dermal LD_{50} >5,000 mg/kg, inhalation lethal concentration $(LC)_{50}$ ≥ 0.468 mg/Liter (L), primary eye irritation (category III), primary dermal irritation (category IV), and dermal sensitization have been conducted. Cyfluthrin is not a dermal sensitizer.

2. *Genotoxicity.* Mutagenicity tests were conducted including three reverse mutation assays (*Salmonella typhimurium, E. coli* and *Saccharomyces cerevisiae*); one reverse mutation, mitotic recombination and conversion assay in *Saccharomyces cerevisiae*; one Chinese hamster ovary/hypoxanthine guanine phophoribosyl transferase (CHO/HGPRT) assay; one sister chromatid exchange assay in CHO cells; and one unscheduled DNA synthesis (UDS) assay in primary rate hepatocytes. All studies were negative for mutagenicity.

3. *Developmental and reproductive toxicity*— i.*Oral developmental study in rats/rabbits.* Cyfluthrin was administered via gavage to pregnant female rats during days 6–15 of gestation at dose levels of 0, 1, 3, or 10 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) was not observed. The maternal no observed adverse effect level (NOAEL) is ≥10 mg/kg/day. A developmental LOAEL was not observed. The developmental NOAEL is ≥10 mg/kg/day.

ii. *Developmental studies via inhalation in rats.* In the first study, pregnant female rats at day 0 gestation were exposed head-only to cyfluthrin concentrations of 0, 1.1, 4.7 or 23.7 mg/m^3/day for 6 hours/day on gestation days 6–15.

In the second study, the dams were exposed to analytical concentrations of 0, 0.09, 0.25, 0.59 or 4.2 mg/m^3 of the test material. The dams were sacrificed on day 20 and their pups removed by caesarian section. Based on reduced motility, dyspnea, piloerection, ungroomed coats and eye irritation, the maternal NOAEL was 1.1 mg/m^3 and the maternal LOAEL was 4.7 mg/m^3. The developmental NOAEL was 0.59 mg/m^3 and the developmental LOAEL was 1.1 mg/m^3 based on increases in the incidence of runts and skeletal anomalies in the sternum (at 1.1 mg/m^3 (and higher)). Increases in post-implantation losses and decreases in pup weights were observed at 4.7 mg/m^3 (and higher), and increased incidences of late embryonic deaths, in skeletal anomalies in the extremities, pelvis, skull and microphthalmia was observed at 23.7mg/m^3.

In a third study, cyfluthrin was administered to female rats at 0.46, 2.55, 11.9 or 12.8 mg/m^3 exposure levels for gestational days 6–15 in a nose only inhalation chamber. The rats were exposed to the test material 6 hr/day, 7 days/week. Both the maternal NOAEL and LOAEL were <0.46 mg/m^3 based on decreased body weight gain and reduced relative food efficiency. The developmental NOAEL and LOAEL were 0.46 mg/m^3 and 2.55 mg/m^3 respectively, based on reduced fetal and placental weight, reduced ossification in the phalanx, metacarpals and vertebrae.

Cyfluthrin was administered in the diet to male and female rats in dose levels of 0, 50, 150, or 450 ppm (actual animal intake; 0, 2.5, 7.5, or 22.5 mg/kg/day). The LOAEL for parental toxicity was 450 ppm (22.5 mg/kg/day) based on decreased body weight gains. The NOAEL for parental toxicity is 150 ppm (7.5 mg/kg/day). The LOAEL for reproductive toxicity was 150 ppm (7.5 mg/kg/day) based on decreased viability and lactational indices and decreased pup body weight gains. The reproductive NOAEL was 50 ppm (2.5 mg/kg/day).

4. *Subchronic toxicity—28 day oral toxicity studies in rats.* Cyfluthrin was administered to SPF-Wistar rats via gavage at 0, 5, 20, or 80 (40) mg/kg/day. The high dose was 80 mg/kg/day during the first and third weeks and 40 mg/kg/day during the second and fourth weeks. The LOAEL was 80 (40) mg/kg/day in both sexes based on clinical signs of nerve toxicity, decreases in body weight gain, and changes in liver and adrenal weights. The NOAEL was 20 mg/kg/day.

Rats were dosed with cyfluthrin in the diet at 0, 100, 300, or 1,000 ppm (equivalent to 0, 5, 15,or 50 mg/kg/day). The LOAEL was 15 mg/kg/day in both sexes based on decreased blood glucose. The NOAEL was 5 mg/kg/day.

i. *Three–month rat feeding study.* SPF-Wistar rats were dosed with cyfluthrin in the diet at 0, 30, 100, or 300 ppm (equivalent to 0, 1.5, 5, or 15 mg/kg/day) for 3 months. No treatment related effects were observed at any of the levels tested, thus the NOAEL for this 3–month rat feeding study was 15 mg/kg/day for both sexes.

ii. *Six–month dog feeding study.* Cyfluthrin was administered in the diet to dogs at 0, 65, 200 or 600 ppm (equivalent to 0, 1.62, 5 or 15 mg/kg/day) for 26 weeks. The LOAEL for this study was 15 mg/kg/day for both sexes, based on neurological effects (hindlimb abnormalities) and gastrointestinal disturbances. The NOAEL was 5 mg/kg/day for males and females.

iii. *Twenty-one–day dermal study in rats.* In a 21–day repeated dose dermal toxicity study, male and female rats were treated with cyfluthrin by dermal occlusion at target doses of 0, 100, 340, or 1,000 mg/kg/day for 6 hours/day (average actual dose levels were 0, 113, 376, or 1,077 mg/kg/day). No mortality was observed, and there were no treatment-related effects on body weight, ophthalmology, organ weights, clinical biochemistry, or hematology. The LOAEL for dermal effects was 376 mg/kg/day for male and female Sprague-Dawley rats based on gross and histological skin lesions. The NOAEL for dermal effects for technical Baythroid was 113 mg/kg/day. The LOAEL for systemic effects was 1,077 mg/kg/day based on decreased food consumption, red nasal discharge and urine staining. The NOAEL for systemic effects was 376 mg/kg/day.

iv. *Three–week inhalation toxicity studies in rats.* SPF-Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin at concentrations of 0, 2.3, 11.5, or 69.6 mg/kg/day for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOAEL was 2.3 mg/m^3, based on the treatment-related effects on body weight and temperature observed during the 3–week exposure period. A NOAEL was not established; therefore this study was repeated using lower doses.

SPF-Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin at concentrations of 0, 0.4, 1.4, or 10.5 mg/m^3 for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOAEL was 10.5 mg/m^3, based on the treatment-related behavioral effects as well as effects on body and organ (spleen) weights. The NOAEL is 1.4 mg/m^3.

v. *Thirteen–week inhalation study in rats.* Rats were dynamically exposed by head-only inhalation to cyfluthrin at concentrations of 0, 0.09, 0.71, or 4.51 mg/m^3 for 6 hours/day, 5 consecutive days/week for 13 weeks. All animals survived the 13–week study, and no treatment-related changes were observed in organ weight, gross

pathology and histopathology. The LOAEL was 0.71 mg/m^3, based on the treatment-related behavioral effects in females as well as the increased urinary protein in males. The NOAEL was 0.09 mg/m^3.

5. *Chronic toxicity—1–year dog study*. Cyfluthrin was fed to beagle dogs at 0, 40, 160, or 640 ppm (equivalent to 0, 1, 4, or 16 mg/kg/day) for 52 weeks. The NOAEL was 4 mg/kg body weight/day. The LOAEL was 16 mg/kg body weight/day for both sexes, based on slight ataxia in two dogs on single occasions, decreased body weight in males, and on observations of increased vomiting and diarrhea at the high dose. The NOAEL is 4 mg/kg body weight/day.

i. *Chronic/carcinogenicity rat*. Cyfluthrin was administered for 24 months in the diet to rats at dose levels of 0, 50, 150, or 450 ppm (equivalent to 2.02, 6.19, or 19.20 mg/kg body weight/day in males and 2.71, 8.15, or 25.47 mg/kg/day in females based on food consumption and body weights). The chronic LOAEL was 150 ppm (equivalent to 6.19 mg/kg/day in males and 8.15 mg/kg/day in females) based on decreased body weights in the high-dose animals and the mid-dose males. The chronic NOAEL was 50 ppm (equivalent to 2.02 mg/kg/day in males and 2.71 mg/kg/day in females). Under the conditions of this study, there was no evidence of carcinogenic potential.

ii. *Chronic/carcinogenicity mouse*. Cyfluthrin was administered in the diet for 23 months to mice at dose levels of 0, 50, 200, or 800 ppm (equivalent to 11.6, 45.8, or 194.5 mg/kg/day in males and 15.3, 63.0, or 259.9 in females based on food consumption and body weights). There were no treatment related changes noted in the clinical observation, food consumption, hematology, gross observation, organ weight, and microscopic data. The chronic LOAEL is 50 ppm (equivalent to 11.6 mg/kg/day in males and 15.3 mg/kg/day in females) based on increased alkaline phosphatase activity in the dosed males. A chronic NOAEL was not established in male and female mice. Under the conditions of this study, there was no evidence of carcinogenic potential.

6. *Animal metabolism*. Metabolism studies 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*. Cyfluthrin is pyrethroid insecticide currently registered for use in alfalfa, citrus, sweet corn, cotton, sorghum, sunflower, sugarcane, carrots, peppers, radishes, potatoes and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments. These assessments include contributions from crops with established tolerances and proposed uses on dry peas (including pigeon peas, chick peas/garbanzo beans, lentils) and southern peas.

i. *Food*. For purposes of assessing the potential acute and chronic dietary exposure, Bayer has estimated acute and chronic exposure for all registered crops, uses pending with the EPA for soybeans and field corn, and new proposed uses on dry peas and southern peas.

Novigen Sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM®), which is licensed to Bayer, was used to estimate the chronic and acute dietary exposure. This software used the food consumption data for the 1994–1996 USDA Continuing Surveys of Food Intake by Individuals (CSFII 1994–1996).

a. *Acute*. The acute dietary (food) risk assessment was conducted using a Monte Carlo analysis (Tier 3). The anticipated residue values used were determined from field trial data reflecting maximum application rates and minimum preharvest intervals. Field trial residue distributions were used in the Monte Carlo simulation for those foods identified as single-serving commodities. For those foods considered to be blended or processed, mean field trial residues were calculated. For the analysis current registered uses plus the added contribution for dry garden peas, lentils, pigeon peas, garbanzo beans/chick peas and southern peas were used.

Bayer's acute Monte Carlo dietary exposure assessment estimated percent of the aPAD and corresponding margins of exposure (MOE) for the overall U.S. population, (all seasons), and the subpopulations all infants (< 1 year), nursing infants (< 1 year), non-nursing infants (<1 year), children (6–12 years), children (7–12 years), females (13–19 years) and males (13–19 years). In this acute analysis, the most highly exposed population subgroup, non-nursing infants (< 1 year), had an exposure equal to 2.84% of the aPAD and a MOE of 10,062 at the 99.9th percentile. The exposure estimates in this dietary analysis are within EPA's criteria of acceptability of the 99.9th percentile.

b. *Chronic*. In the analysis for the chronic dietary (food only) risk assessment the anticipated residue values used were determined from field trail data conducted at maximum application rates and minimum preharvest intervals. Mean anticipated residues values were calculated substituting half of the limit of quantitation (LOQ) for those samples for which residues were reported below the LOQ. For the analysis current registered uses plus the added contribution for dry garden peas, lentils, pigeon peas, garbanzo beans/chick peas and southern peas were used.

Bayer's chronic dietary analysis estimated the chronic population adjusted dose (cPAD) for the overall U. S. population (all seasons) and the subpopulations nursing infants (< 1 year), non-nursing infants (< 1 year), all infants (< 1 year), children (1–6 years), children (7–12 years), females (13–19 years), males (13–19 years). In this chronic analysis, the most highly exposed population subgroup, children (1–6 years), the exposure was estimated to be 3.4% of the cPAD. Chronic dietary exposure estimates for the overall U.S. population were 1.2% of the cPAD (0.008 mg/kg bw/day).

Results from the acute and chronic dietary exposure analyses demonstrate a reasonable certainty that no harm to the overall U. S. population or any population subgroup will result from the use of cyfluthrin on currently registered and the pending IR-4 uses on dry peas, pigeon peas, chick peas/garbanzo beans, lentils, and southern peas.

ii. *Drinking water*. Cyfluthrin is immobile in soil, therefore, will not leach into groundwater. 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.

The EPA estimates potential concentrations of cyfluthrin in water using the Pesticide Root Zone Model (PRZM 1) and Exposure Analysis Modeling System (EXAMS) computer models. The estimated environmental concentration (EECs) of cyfluthrin residues are 0.236 part per billion (ppb) for acute surface water and 0.044 ppb for chronic surface water.

The comparison of EECs to the back-calculated human health drinking water levels of comparison (DWLOCs) for

acute and chronic exposures are summarized in the following tables 1 and 2:

TABLE 1.—DRINKING WATER LEVELS OF COMPARISON FOR ACUTE EXPOSURE TO CYFLUTHRIN

Population Category	aPAD mg/kg/day	Food Exposure mg/kg/day	Max. Water Exposure mg/kg/day	DWLOC µg/L	Estimated Environmental Concentration (acute Surface Water)
U.S. Population Male	0.07	0.001336	0.0687	2404	0.236
U.S. Population Female	0.07	0.001336	0.0687	2061	0.236
Infant (non-nursing, <1 yr)	0.07	0.001988	0.0501	501	0.236

TABLE 2: DRINKING WATER LEVEL OF COMPARISON FOR CHRONIC EXPOSURE TO CYFLUTHRIN

Population Category	cPAD mg/kg/day	Food Exposure mg/kg/day	Max. Water Exposure mg/kg/day	DWLOC µg/L	Estimated Environmental Concentration (chronic Surface Water)
U.S. Population Male	0.008	0.000095	0.0079	277	0.044
U.S. Population Female	0.008	0.000095	0.0079	237	0.044
Children (1–6 yrs)	0.008	0.000271	0.0077	77	0.044

As indicated in Tables 1 and 2 above, the environmental concentrations of cyfluthrin residues for acute and chronic surface water are less than the calculated drinking water level of comparisons for acute and chronic exposure and demonstrates a reasonable certainty that no harm to the overall U. S. population or any population subgroup will result from the use of cyfluthrin on currently registered and the pending IR-4 uses on dry peas, and southern peas.

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 Food Quality Protection Act of 1996 (FQPA), 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 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.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA on August 4, 1997 (62 FR 42020) (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 1.2% of the cPAD for chronic dietary exposures and that margins of exposure in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-occupational exposure. EPA generally has no concerns for exposures below 100 percent of the reference dose (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. Margins of exposure 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*. 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 database.

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, the EPA considers margins of exposure 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. Using the exposure assessments described above and based on the described toxicity data aggregate exposure to infants and children indicate a margin of exposure in excess of 3,800. Thus, it can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

F. International Tolerances

There are Codex Maximum residue level (MRLs) for maize of 0.05 ppm, and sweet corn of 0.02 ppm.

[FR Doc. 01–8142 Filed 4–3–01; 8:45 am]

BILLING CODE 6560–50–S