triflusulfuron methyl have been conducted. However, the standard battery of required toxicology studies have been completed. These include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure to doses that far exceed likely human exposures. Based on these studies there is no evidence to suggest that triflusulfuron methyl has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. The acute dietary exposure was estimated for triflusulfuron methyl using the Dietary Exposure Evaluation Model (version 6.73) for a number of subpopulation groups. An acute Tier I dietary analysis was based upon the residues for sugar beet (root) at 0.05 ppm and sugar beet (top) at 0.05 ppm. The acute reference dose (aRfD) is 0.9 mg/kg bw/day (based upon a NOAEL of 90 mg/kg bw/day and a 100-fold safety factor). For triflusulfuron methyl, the predicated exposure for the U.S. population was 0.00460 mg/kg bw/day (0.05 % of the aRfD) at the 95th percentile. The subpopulation with the highest predicted exposure was the non-nursing infants subgroup with an exposure of 0.00166 mg/kg bw/day (0.19% of the aRfD) at the 95th percentile. Because the predicted exposures, expressed as percentages of the aRfD, are well below 100%, there is reasonable certainty that no acute effects would result from dietary exposure to triflusulfuron methyl.

The chronic dietary exposure was estimated for triflusulfuron methyl using the Dietary Exposure Evaluation Model (version 6.74) for a number of subpopulation groups. A chronic Tier I dietary analysis was based upon residues for sugar beet (root) at 0.05 ppm and sugar beet (top) at 0.05 ppm. The chronic RfD is 0.024 mg/kg bw/day (based upon a NOAEL of 2.44 mg/kg bw/day and a safety factor of 100). The estimated exposure for the U.S. population was 0.000146 mg/kg bw/day (0.6% of the RfD). For the subpopulation with the highest level of exposure (non-nursing infants), the exposure was 0.000433 mg/kg bw/day (>1.8% of the chronic reference dose (cRfD)). Because the predicted exposures, expressed as percentages of the cRfD, are well below 100%, there is reasonable certainty that no chronic effects would result from dietary exposure to triflusulfuron methyl.

Even though very conservative assumptions were made in predicting acute and chronic exposures to triflusulfuron methyl, the predicted exposures expressed as percentages of the cRfD and aRfD values were found to be well within the acceptable range.

ii. *Drinking water*. Another potential source of dietary exposure is residues in drinking water. Based on the available environmental studies conducted with triflusulfruon methyl, DuPont concludes that there is no anticipated exposure to residues of triflusulfuron methyl in drinking water. In addition, there is no established maximum concentration level (MCL) for residues of triflusulfuron methyl in drinking water.

2. *Non-dietary exposure*. Triflusulfuron methyl is not registered for any use that could result in non-occupational or non-dietary exposure to the general population.

D. Cumulative Effects

Triflusulfuron methyl belongs to the sulfonylurea class of crop protection chemicals. Other structurally similar compounds in this class are registered herbicides. However, the herbicidal activity of sulfonylureas is due to the inhibition of acetolacate synthase (ALS), an enzyme found only in plants. This enzyme is part of the biosynthesis pathway leading to the formation of branched chain amino acids. Animals lack ALS and this biosynthetic pathway. This lack of ALS contributes to the relatively low toxicity of sulfonylurea herbicides in animals. There is no reliable information that would indicate or suggest that triflusulfuron methyl has any toxic effects on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. Based on the completeness and reliability of the toxicology data base and using the conservative assumptions presented earlier, EPA has established a chronic RfD of 0.024 mg/kg/day. This was based on the NOAEL for the 2–year chronic rat study (2.44 mg/kg/day) and a 100–fold safety factor. It has been concluded that the aggregate exposure was 0.6% of the cRfD. Generally, exposures below 100% of the cRfD are of no concern because it represents the level at or below which daily aggregrate exposure over a lifetime will not pose appreciable risk to human health. Thus, there is reasonable certainty that no harm will result from aggregate exposures to triflusulfuron methyl residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of triflusulfuron methyl, data from the previously discussed developmental and multi-generation reproductive toxicity studies were considered.

Developmental studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from the prenatal and postnatal exposures to the pesticide. The studies with triflusulfuron methyl demonstrated no evidence of developmental toxicity at exposures below those causing maternal toxicity. This indicates that developing animals are not more sensitive to the effects of triflusulfuron methyl administration than adults.

FFDCA section 408 provides that EPA may apply an additional uncertainty factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on current toxicological data requirements, the data base for triflusulfuron methyl relative to prenatal and postnatal effects for children is complete.

In addition, the NOAEL of 2.44 mg/kg/day in the chronic rat study (and upon which the cRfD is based) is much lower than the NOAELs defined in the reproduction and developmental toxicology studies. The sub-population with the highest level of exposure was non-nursing infants, where exposure was < 1.8% of the cRfD. Based on these conservative analyses, there is reasonable certainty that no harm will result to infants and children from aggregate exposures to triflusulfuron methyl.

F. International Tolerances

There are no Codex Maximum Residue Levels established for triflusulfuron methyl.

[FR Doc. 99–33159 Filed 12–21–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–903; FRL–6396–2]

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–903, must be received on or before January 21, 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–903 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., 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	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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–903. 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–903 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, 401 M St., SW., 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–903. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: December 10, 1999.

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 petitioners and represent 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. Interregional Research Project Number 4 and BASF Corporation, Agricultural

9E6002 and 7F4881

EPA has received a pesticide petition (9E6002) from the Interregional Research Project Number 4 (IR-4), Center for Minor Crop Pest Management, Technology Center of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. EPA has also received a pesticide petition (7F4881) from BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709. The petitions propose, 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 tolerances for residues of pyridaben 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one in or on the raw agricultural commodities (RAC) cranberries (9E6002), and pistachio (7F4881) at 0.5 and 0.05 and parts per million (ppm). Registration for pyridaben on cranberries would be limited to areas along the eastern coast in the states of MA, NJ, ME, NY, CT, NH, VT, RI, and DE based on the geographical representation of the residue data submitted.

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 supports granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petitions prepared by, BASF Corporation, the registrant, P.O. Box 13528, Research Triangle Park, NC 27709.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the residue in plants is adequately understood. The residue of concern is pyridaben *per se* as specified in 40 CFR 180.494.

2. *Analytical method*. The proposed analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (GC/ECD).

3. *Magnitude of residues*. Three cranberry residue trials were conducted in two states. Residues of pyridaben were measured by GC/ECD. The method of detection had a limit of detection of 0.05 ppm. Residues ranged from 0.172 to 0.447. Pistachio use rates will be the same as almond which have already received a tolerance of 0.05 ppm.. Also, pending at EPA is a nut crop group tolerance petition including 6 residue trials of pecans showing all residues are below 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity*—i. *Subpopulation females 13+ years old*. The no observed adverse effect level (NOAEL) is 13 milligrams/kilograms (mg/kg). In a developmental toxicity study, Sprague-Dawley rats (22/group) from Charles River, U.K., received NC-129 Pyridaben, 98.0% active ingredient (a.i.) via gavage at dose levels of 0, 2.5, 5.7, 13.0, or 30.0 mg/kg/day from gestation day 6 through 15, inclusive. Natural mating was used. Maternal toxicity, observed at 13.0 and 30.0 mg/kg/day, consisted of decreased body weight (bwt)/weight gain and food consumption during the dosing period. Based on these effects, the maternal toxicity lowest observed adverse effect level (LOAEL) is 13.0 mg/kg/day and the maternal toxicity NOAEL is 4.7 mg/kg/day (82% of 5.7 mg/kg/day based on concentration analysis). Developmental toxicity NOAEL is 13.0 mg/kg/day based on observed decreased fetal (bwt) and increased incomplete ossification in selected bones at 30.0 mg/kg/day LOAEL. With the 100 uncertainty factor (UF) (10x for interspecies extrapolation and 10x for intraspecies variability) the chronic population adjusted dose (cPAD) for females 13+ is 0.13 mg/kg/day.

ii. *General population including infants and children*. NOAEL = 50 mg/kg. In an acute neurotoxicity study, CD Rats (10/sex/group) were administered a single oral dose (gavage) of NC-129 in 1% aqueous carboxymethyl cellulose of 0 (vehicle), 50, 100, and 200 mg/kg (a.i. equivalents: 44.3, 79.6, and 190.0 mg/kg for males and 44.5, 99.7, and 190.0 mg/kg bwt for females). The animals were observed for mortality and clinical signs of toxicity for 14 days post-dosing. During the first 5 days, compound-related decreases in bwt gain were noted in mid-dose males (17%) and females (36%) and high-dose males (74%); the high-dose females lost weight (4 g) during the first 4 days of the observation period. Food consumption was low in all treated groups on the day of dosing with severe effects seen in the high-dose males (73% lower than controls). Dose-dependent increases in clinical signs (piloerection, hypoactivity, tremors, and partially closed eyes) were seen in mid-dose males and high-dose males and females. These effects were reversible by observation day 4. Treatment-related findings in the functional observational battery consisted of lower body temperature and reduced motor activity among the high-dose males. No treatment-related gross or microscopic neuropathologic findings were present. The NOAEL for systemic toxicity is 50 mg/kg for both sexes. The LOAEL of 100 mg/kg/day is based on systemic toxicity including clinical signs and decreased food consumption and bwt gain. With the 100 UF the aPAD for the general population is calculated to be 0.5 mg/kg/day.

2. *Subchronic toxicity*. The NOAEL is 100 mg/kg/day. In a 21–day dermal toxicity study, repeated doses of pyridaben were applied topically to approximately 10% of the body surface area of rats at doses of 0, 30, 100, 300, or 1,000 mg/kg/day for 21 days.

Increased squamous cell hyperplasia and/or surface accumulation of desquamated epithelial cells were noted sporadically in the 100, 300, and 1,000 mg/kg/day dose groups. These findings appear to be due to abrasions of the skin when the powdered substance was applied onto the skin, rather than a dose-related effect. No gross dermal irritation effects were noted. Based on the results of the study, the systemic dermal toxicity NOAEL is 100 mg/kg/day. The systemic dermal toxicity LOAEL is determined to be 300 mg/kg/day based on decreased bwt in the females. The dermal irritation NOAEL is 100 mg/kg/day. Note: In agreement, a dermal equivalent dose of 94 mg/kg/day is derived if the maternal oral NOAEL of 4.7 mg/kg/day (based on decreased bwt gain and food consumption) in the rat oral developmental toxicity study is adjusted by the proposed 5% dermal absorption rate.

3. *Chronic toxicity*. EPA has established the cPAD for pyridaben at 0.005 mg/kg/day. This cPAD is based on a 1 year feeding study in dogs with a NOAEL of 0.5 mg/kg/day and an uncertainty factor of 100 based on decreased bwt, emesis, and ptyalism.

4. *Animal metabolism*. The nature of the residue in animals is adequately understood. The residue of concern is pyridaben and its metabolites PB-7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2H)-one) and PB-9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3(2H)-one) as specified in 40 CFR 180.494.

C. Aggregate exposure

1. *Dietary exposure*—i. *Food*. From the acute dietary risk assessment, the calculated exposure yields dietary percentage of the aPAD for females 13+ years old ranging from 29% for females 13+ years old--not pregnant, non-nursing, to 42% for females 13+ years old--pregnant, not nursing. The calculated exposure yields dietary percentage of the aPAD for the remainder of the population ranging from 9% for males 13–19 years old to 77% for nursing infants > 1 year old. This risk estimate should be viewed as highly conservative; refinement using anticipated residue values and percent crop-treated data in conjunction with a Monte Carlo analysis will result in a lower acute dietary exposure estimate. In conducting the chronic dietary risk assessment, the registrant has made somewhat conservative assumptions--that 100% of cranberries will contain pyridaben residues and those residues will be at the level of the tolerance plus the ratio of organosoluble residues to pyridaben, and all commodities having published and pending pyridaben tolerances will contain pyridaben regulable residues, those residues will be at the anticipated residue level for the commodity, no percent crop treated data were used, and plant anticipated residues will be adjusted using the ratio of organosoluble residues to pyridaben all of which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure estimate.

ii. *Drinking water*. Based on information currently available to EPA, pyridaben is immobile and thus unlikely to leach to ground water. There is no established maximum contaminant level for residues of pyridaben in drinking water. No health advisory levels for pyridaben in drinking water have been established. EPA uses the Generic expected environmental concentration (GENEEC) and SCI-GROW screening models to estimate surface and ground water concentrations for first-tier exposure assessments. As screening models designed to estimate the concentrations found in surface and ground water for use in ecological risk assessment, they provide upper-bound values on the concentrations that might be found in ecologically sensitive environments because of the use of a pesticide. The models predict that as much as 2.3 part per billion (ppb) and 0.0003 ppb of pyridaben may be found in surface and ground water, respectively. The modeling data were compared to the results from modeling equations used to calculate the acute and chronic drinking water levels of concern (DWLOC) for pyridaben in surface and ground water.

a. *Acute exposure and risk*. Acute DWLOCs have been calculated by EPA at the following amounts: U.S. population 14,000 g/L; adult male 20+ years old 15,000 g/L; adult female 13+, pregnant, non-nursing 2,200 g/L infant < 1g/L, nursing 1,100 g/L.

b. *Chronic exposure and risk*. Chronic DWLOCs have been calculated by EPA at the following amounts: U.S. population 140 g/L; adult male, 13–19 years old 160 g/L; adult female 13+, nursing 100 g/L; infant > 1, non-nursing 7 g/L.

2. *Non-dietary exposure*. Pyridaben is currently not registered for use on residential non-food sites.

D. Cumulative Effects

The registrant does not have, at this time, available data to determine whether pyridaben has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyridaben does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, the registrant has not assumed that pyridaben has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. Using the published and pending tolerances, the dietary percentage of the aPAD range from 9% for males 13–19 years old to 77% for nursing infants ≤ 1 year old, with the U.S. population at 18%. This risk estimate should be viewed as highly conservative; refinement using additional anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis will result in a lower acute dietary exposure estimate. The acute dietary exposure does not exceed EPA's level of concern. Pyridaben is immobile and thus, unlikely to leach to ground water. The modeling data for pyridaben in drinking water indicate levels less than EPA's DWLOC for acute exposure. Since a refined acute risk for food only would not exceed EPA's levels of concern for acute dietary exposures and the monitoring and modeling levels in water are less than the acute DWLOC, the registrant does not expect aggregate acute exposure to pyridaben will pose an unacceptable risk to human health.

ii. *Chronic risk*. Using the somewhat conservative anticipated residue contribution (ARC) exposure assumptions described in Unit III.B. of this preamble, EPA has concluded that aggregate exposure to pyridaben from food will utilize 20% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The residues of pyridaben in drinking water do not exceed EPA's DWLOC. Pyridaben does not have any residential uses. The registrant does not expect the aggregate exposure to exceed 100% of the cPAD.

iii. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor

residential uses. Since there are no residential uses, a short-term or intermediate-term aggregate risk assessment is not required.

iv. *Aggregate cancer risk for U.S. population*. Since pyridaben has been classified as a *Group E* carcinogen ''no evidence of carcinogenicity to humans,'' a cancer risk assessment is not required.

v. *Endocrine disrupter effects*. EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''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 old from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this a.i and end use products for endocrine disrupter effects.

vi. *Determination of safety*. Based on these risk assessments, the registrant concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyridaben residues.

2. *Infants and children*—i. *Safety factor for infants and children*—a. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of pyridaben, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat were considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to prenatal and postnatal effects from exposure to pyridaben, effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. FFDCA section 408 provides that EPA shall apply an additional tenfold 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and UF (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*—a. *Rats*. In a developmental toxicity study in rats, the maternal (systemic) NOAEL was 4.7 mg/kg/day. The maternal LOAEL of 13 mg/kg/day was based on decreases in bwt, bwt gain, and food consumption during the dosing period (GD 6–15). The developmental (fetal) NOAEL was 13 mg/kg/day. The developmental LOAEL of 30 mg/kg/day was based on decreased fetal bwt and increased incomplete ossification in selected bones.

b. *Rabbits*. In an oral developmental toxicity study in rabbits, the maternal (systemic) NOAEL was not established. The maternal LOAEL of 1.5 mg/kg/day was based on decreases in bwt gain and food consumption. There was no developmental toxicity observed at any dose tested. Therefore, the developmental (fetal) NOAEL is 15 mg/kg/day at the highest dose tested (HDT).

iii. *Reproductive toxicity study—rats*. In the 2-generation reproductive toxicity study in rats, the prenatal (systemic) NOAEL was 2.3 mg/kg/day. The prenatal (systemic) LOAEL of 7 mg/kg/day was based on decreased bwt, decreased bwt gains, and decreased food efficiency. The reproductive (pup) NOAEL was 7 mg/kg/day and the LOAEL was 7 mg/kg/day at the HDT.

iv. *Prenatal and postnatal sensitivity*. The toxicological data base for evaluating prenatal and postnatal toxicity for pyridaben is complete with respect to current data requirements. There are no prenatal or postnatal toxicity concerns for infants and children based on the results of the rat and rabbit developmental toxicity studies as well as the 2-generation rat reproductive toxicity study. According to the above, reliable data support removing the additional 10x safety factor for protection of infants and children.

v. *Conclusion*. There is a complete toxicity data base for pyridaben and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

a. *Acute risk*. Using the somewhat conservative exposure assumptions described above, the percentage of the aPAD that will be utilized by dietary exposure to residues of pyridaben for infants and children range from 16% for children 7-12 years old to 77% for nursing infants ≤ 1 year old. The acute DWLOC does not exceed EPA's level of concern. Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, the registrant concludes that there is a reasonable certainty that no harm will result to infants and children from acute aggregate exposure to pyridaben residues.

b. *Chronic risk*. Using the somewhat conservative exposure assumptions described above, EPA has calculated that the percentage of the cPAD that will be utilized by dietary exposure to residues of pyridaben ranges from 27% for nursing infants less than 1 year old, up to 85% for non-nursing infants less than 1 year old. The chronic DWLOC does not exceed the level of concern. There are no residential uses for pyridaben. Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, the registrant concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to pyridaben residues.

c. *Short-term or intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account chronic dietary food and water plus indoor and outdoor residential uses. Since the chronic food and chronic DWLOC do not exceed EPA's level of concern and there are currently no indoor or outdoor residential uses of pyridaben, the short-term and intermediate-term aggregate risk does not exceed EPA's level of concern.

d. *Determination of safety*. Based on these risk assessments, the registrant concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyridaben residues.

F. International Tolerances

There are no CODEX, Canadian, or Mexican Maximum Residue Limits established for pyridaben on cranberries and pistachio.

2. Interregional Research Project Number 4

9E6016, 9E6030, 9E6031, and 9E6034

EPA has received pesticide petitions (9E6016, 9E6030, 9E6031, and 9E6034) from the Interregional Project Number 4 (IR-4) Rutgers University, New Brunswick, NJ, 08903-0231 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 [bifenthrin, ((2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the RAC as follows:

1. *PP 9E6016* proposes the establishment of a tolerance for grape at 0.2 ppm.

2. *PP 9E6030* proposes the establishment of a tolerance for peppers at 0.5 ppm.

3. *PP 9E6031* proposes the establishment of a tolerance for head lettuce at 2.0 ppm.

4. *PP 9E6034* proposes the establishment of a tolerance for the caneberry subgroup at 1.0 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 supports granting of the petitions. Additional data may be needed before EPA rules on these petitions.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of bifenthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabelled bifenthrin in various crops all showing similar results. The residue of concern is the parent compound only.

2. *Analytical method*. There is a practical analytical method for detecting and measuring levels of bifenthrin in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances GC/ECD analytical method P-2132M.

3. *Magnitude of residues*. Field residue trials meeting EPA study requirements have been conducted at the maximum label rate for these crops. Results from these trials demonstrate that the proposed bifenthrin tolerances of 0.2 ppm for grape, 0.5 ppm for peppers, 2.0 ppm for head lettuce, and 1.0 ppm for the caneberry subgroup will not be exceeded when the product is applied following the proposed use directions.

B. Toxicological Profile

1. *Acute toxicity*. For the purposes of assessing acute dietary risk, FMC has used the maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats. The maternal LOAEL of this study of 2.0 mg/kg/day was based on tremors from day 7-17 of dosing. This acute dietary endpoint is used to determine acute dietary risks to all population subgroups.

2. *Genotoxicity*. The following genotoxicity tests were all negative: gene mutation in *Salmonella* (Ames); chromosomal aberrations in Chinese hamster ovary (CHO) and rat bone marrow cells; hypoxanthine guanine phophoribosyl transferase (HGPRT) locus mutation in mouse lymphoma cells; and unscheduled DNA synthesis in rat hepatocytes.

3. *Reproductive and developmental toxicity*. In the rat reproduction study, parental toxicity occurred as decreased bwt at 5.0 mg/kg/day with a NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day HDT.

4. *Subchronic toxicity*. The maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats is also used for short-term and intermediate-term MOE calculations (as well as acute, discussed in paragraph (1) above). The maternal LOAEL of this study of 2.0 mg/kg/day was based on tremors from day 7–17 of dosing.

5. *Chronic toxicity*—i. The chronic population adjusted dose (cPAD) has been established at 0.015 mg/kg/day. This cPAD is based on a 1 year oral feeding study in dogs with a NOAEL of 1.5 mg/kg/day, based on intermittent tremors observed at the LOAEL of 3.0 mg/kg/day; an uncertainty factor of 100 is used.

ii. Bifenthrin is classified as a *Group C* chemical (possible human carcinogen) based upon urinary bladder tumors in mice; assignment of a Q* has not been recommended.

6. *Animal metabolism*. The metabolism of bifenthrin in animals is adequately understood. Metabolism studies in rats with single doses demonstrated that about 90% of the parent compound and its hydroxylated metabolites are excreted.

7. *Metabolite toxicology*. The Agency has previously determined that the metabolites of bifenthrin are not of toxicological concern and need not be included in the tolerance expression.

8. *Endocrine disruption*. No special studies investigating potential estrogenic or other endocrine effects of bifenthrin have been conducted. However, no evidence of such effects were reported in the standard battery of required toxicology studies which have been completed and found acceptable. Based on these studies, there is no evidence to suggest that bifenthrin has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Tolerances have been established for the residues of bifenthrin, in or on a variety of RACs. Tolerances, in support of registrations, currently exist for residues of bifenthrin on hops; strawberries; corn grain, forage, and fodder; cottonseed; artichokes, the crop group cucurbit vegetables, the crop group legume vegetables - subgroup edible-podded legume vegetables and subgroup succulent shelled pea and bean, eggplant, the subgroup head and stem brassica, and livestock commodities of cattle, goats, hogs, horses, sheep, poultry, eggs, and milk. Pending tolerances for citrus, raspberries and sweet corn also exist. For the purposes of assessing the potential dietary exposure for the existing and pending tolerances, FMC has utilized available information on anticipated residues, monitoring data and percent crop treated.

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

2. *Non-dietary exposure*. Analyses were conducted which included an evaluation of potential non-dietary (residential) applicator, post-application

and chronic dietary aggregate exposures associated with bifenthrin products used for residential flea infestation control and agricultural/commercial applications. The aggregate analysis conservatively assumes that a person is concurrently exposed to the same active ingredient via the use of consumer or professional flea infestation control products and to chronic level residues in the diet. In the case of potential non-dietary health risks, conservative point estimates of non-dietary exposures, expressed as total systemic absorbed dose (summed across inhalation and incidental ingestion routes) for each relevant product use category (i.e., lawn care) and receptor subpopulation (i.e., adults, children 1–6 years old and infants > 1 year old) are compared to the systemic absorbed dose NOAEL for bifenthrin to provide estimates of the MOEs. Based on the toxicity endpoints selected by EPA for bifenthrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOAEL for estimating MOEs. In the case of potential aggregate health risks, the above mentioned conservative point estimates of inhalation and incidental ingestion non-dietary exposure (expressed as systemic absorbed dose) are combined with estimates (arithmetic mean values) of chronic average dietary (oral) absorbed doses. These aggregate absorbed dose estimates are also provided for adults, children 1–6 years old and infants > 1 year old. The combined or aggregated absorbed dose estimates (summed across non-dietary and chronic dietary) are then compared with the systemic absorbed dose NOAEL to provide estimates of aggregate MOEs.

The non-dietary and aggregate (non-dietary + chronic dietary) MOEs for bifenthrin indicate a substantial degree of safety. The total non-dietary (inhalation + incidental ingestion) MOEs for post-application exposure for the lawn care product evaluated was estimated to be > 194,000 for adults, 52,400 for children 1-6 years old and 56,700 for infants < 1 year old. The aggregate MOE (inhalation + incidental oral + chronic dietary, summed across all product use categories) was estimated to be 2,158 for adults, 579 for children 1-6 years old and 966 for infants (< 1 year old). It can be concluded that the potential non-dietary and aggregate exposures for bifenthrin are associated with substantial margins of safety.

D. Cumulative Effects

In consideration of potential cumulative effects of bifenthrin and other substances that may have a common mechanism of toxicity, to our knowledge there are currently no available data or other reliable information indicating that any toxic effects produced by bifenthrin would be cumulative with those of other chemical compounds; thus only the potential risks of bifenthrin have been considered in this assessment of its aggregate exposure. FMC intends to submit information for EPA to consider concerning potential cumulative effects of bifenthrin consistent with the schedule established by EPA pursuant to the Food Quality Protection Act (FQPA).

E. Safety Determination

1. *U.S. population*—i. *Chronic exposure and risk*. Based on a complete and reliable toxicology data base, the acceptable cPAD is 0.015 mg/kg/day, based on a NOAEL of 1.5 mg/kg/day from the chronic dog study and an uncertainty factor of 100. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into an analysis to estimate the anticipaded residue contribution (ARC) for 26 population subgroups. The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues. The ARC are estimated to be 0.000444 mg/kg bwt/day and utilize 3.0% of the cPAD for the overall U. S. population. The ARC for children 7–12 years old and children 1–6 years old (subgroups most highly exposed) are estimated to be 0.000650 mg/kg bwt/day and 0.001203 mg/kg bwt/day and utilizes 4.3% and 8.0% of the cPAD, respectively. Generally speaking, EPA has no cause for concern if the total dietary exposure from residues for uses for which there are published and proposed tolerances is less than 100% of the cPAD. Therefore, FMC concludes that the chronic dietary risk of bifenthrin, as estimated by the aggregate risk assessment, does not appear to be of concern.

ii. *Acute exposure and risk*. Acute dietary exposure risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. For the purposes of assessing acute dietary risk for bifenthrin, the maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats was used. The maternal LOAEL of this study of 2.0 mg/kg/day was based on tremors from day 7–17 of dosing. This acute dietary endpoint was used to determine acute dietary risks to all population subgroups. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into a Tier 3 analysis, using Monte Carlo modeling for commodities that may be consumed in a single serving. These assessments show that the MOEs are greater than the EPA standard of 100 for all subpopulations. The 99.9th percentile of exposure for the overall U. S. population was estimated to be 0.005932 mg/kg/day (MOE of 168). The 99.9th percentile of exposure for all infants < 1 year old was estimated to be 0.007331 mg/kg/day (MOE of 136). The 99.9th percentile of exposure for nursing infants < 1 year old was estimated to be 0.004599 mg/kg/day (MOE of 217). The 99.9th percentile of exposure for non-nursing infants < 1 year old was estimated to be 0.006974 mg/kg/day (MOE of 143). The 99.9th percentile of exposure for children 1 to 6 years old was estimated to be 0.009983 mg/kg/day (MOE of 100). Therefore, FMC concludes that the acute dietary risk of bifenthrin, as estimated by the dietary risk assessment, does not appear to be of concern.

2. *Infants and children*—i. *General*. In assessing the potential for additional sensitivity of infants and children to residues of bifenthrin, FMC considered data from developmental toxicity studies in the rat and rabbit, and a 2–generation reproductive study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. FFDCA section 408 provides that EPA may apply an additional margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal natal toxicity and the completeness of the data base.

ii. *Developmental toxicity studies*. In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOAEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOAEL of 4 mg/kg/day. In the rat developmental study, the maternal NOAEL was 1 mg/kg/day, based on tremors at the LOAEL of 2 mg/kg/day. The developmental (pup) NOAEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOAEL 2 mg/kg/day. There were 5/23 (22%) litters affected (5/141 fetuses since each litter only had one affected fetus) in the 2 mg/kg/day group, compared with zero

in the control, 1, and 0.5 mg/kg/day groups. According to recent historical data for this strain of rat, incidence of distended ureter averaged 11% with a maximum incidence of 90%.

iii. *Reproductive toxicity study*. In the rat reproduction study, parental toxicity occurred as decreased bwt at 5.0 mg/kg/day with a NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day HDT.

iv. *Prenatal and postnatal sensitivity*—a. *Prenatal*. Since there was not a dose-related finding of hydroureter in the rat developmental study and in the presence of similar incidences in the recent historical control data, the marginal finding of hydroureter in rat fetuses at 2 mg/kg/day (in the presence of maternal toxicity) is not considered a significant developmental finding. Nor does it provide sufficient evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

b. *Postnatal*. Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special postnatal sensitivity to infants and children in the rat reproduction study.

c. *Conclusion*. Based on the above, FMC concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children. As stated above, aggregate exposure assessments utilized less than 10% of the cPAD for either the entire U. S. population or any of the 26 population subgroups including infants and children. Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to bifenthrin residues.

F. International Tolerances

There are no Codex, Canadian, or Mexican residue limits for residues of bifenthrin in or on grape, peppers (bell and non-bell), lettuce, and caneberry.

[FR Doc. 99–33035 Filed 12–21–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–906; FRL–6398–6]

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–906, must be received on or before January 21, 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–906 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: tompkins.jim@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	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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–906. 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–906 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, 401 M St., SW., 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