data to further refine the risk assessment, such as percent crop treated information or submission of residue data from food processing studies, or could address the Agency's risk assessment methodologies and assumptions as applied to this specific chemical. Comments should be limited to issues raised within the preliminary risk assessment and associated documents. EPA will provide other opportunities for public comment on other science issues associated with the pesticide tolerance reassessment program. Failure to comment on any such issues 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 should be submitted by April 16, 2001 using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION.** Comments will become part of the Agency record for atrazine.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: February 8, 2001.

Jack E. Housenger,

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

[FR Doc. 01–3844 Filed 2–12–01; 2:53 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–998; FRL–6768–7]

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–998, must be received on or before March 16, 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–998 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6100; e-mail address: larocca.george@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–998. 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–998 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–998. Electronic comments

may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data 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: January 31, 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 petitioner. 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.

FMC Corporation

0E6216

EPA has received a pesticide petition (0E6216) from FMC Corporation, 1735 Market Street, Philadelphia, PA 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 raw agricultural commodity (RAC) bananas at 0.1 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

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 gas chromatography with electron capture detection (GC/ECD) analytical method P–2132M, (PP) 0E3921, MRID 41658601.

3. *Magnitude of residues*. Field residue trials meeting EPA study requirements have been conducted at the maximum label rate for the crop bananas. Results from these trials demonstrate that the highest bifenthrin residues found will not exceed 0.1 (ppm) 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 Corporation has used the maternal no observed adverse effect level (NOAEL) of 1.0 milligram/kilogram (mg/kg)/day from the oral developmental toxicity study in rats. The maternal lowest effect level (LEL) 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 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*. i. In the rat reproduction study, parental toxicity occurred as decreased body weight (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 (highest dose tested (HDT)).

ii. 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.

4. *Subchronic toxicity—Short- and intermediate-term toxicity*. The maternal NOAEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats is also used for short- and intermediate-term margin of exposure (MOE) calculations (as well as acute, discussed in (1) above). The maternal LEL of this

study of 2.0 mg/kg/day was based on tremors from day 7–17 of dosing.

5. *Chronic toxicity*. i. The reference dose (RfD) has been established at 0.015 mg/kg/day. This RfD 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 (UF) 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 was 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, sweet corn, cottonseed, artichokes, the crop group cucurbit vegetables, the crop group legume vegetables - subgroup edible-podded legume vegetables, and subgroup succulent shelled pea, eggplant, the subgroup head and stem brassica, and livestock commodities of cattle, goats, hogs, horses, sheep, poultry, eggs, and milk. Pending tolerances for citrus, bananas, grapes, peanuts, pears, potatoes, caneberries, peppers (bell and non-bell), lettuce (head), and herbs also exist. For the purposes of assessing the potential dietary exposure for these existing and pending tolerances FMC Corporation has utilized available information on anticipated residues, monitoring data and percent crop treated as follows:

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 one 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 LEL 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 99.9^{th} percentile of exposure for the overall U. S. population was estimated to be 0.005506 mg/kg/day (MOE of 181). The 99.9^{th} percentile of exposure for all infants <1–year old was estimated to be 0.005825 mg/kg/day (MOE of 171). The 99.9^{th} percentile of exposure for nursing infants <1–year old was estimated to be 0.004056 mg/kg/day (MOE of 246). The 99.9^{th} percentile of exposure for non-nursing infants <1–year old was estimated to be 0.005910 mg/kg/day (MOE of 169). The 99.9^{th} percentile of exposure for children 1 to 6 years old (the most highly exposed population subgroup) was estimated to be 0.009741 mg/kg/day (MOE of 102). Therefore, FMC Corporation concludes that the acute dietary risk of bifenthrin, as estimated by the dietary risk assessment, does not appear to be of concern.

iii. *Chronic exposure and risk*. The acceptable reference dose (RfD) is based on a NOAEL of 1.5 mg/kg/day from the chronic dog study and an UF of 100 is 0.015 mg/kg/day. The endpoint effect of concern was tremors in both sexes of dogs at the LEL of 3.0 mg/kg/day. A chronic dietary exposure/risk assessment has been performed for bifenthrin using the above RfD. The chronic exposures are estimated to be 0.000186 mg/kg bwt/day and utilize 1.2% of the RfD for the overall U. S. population; children 7-12 years old and children 1-6 years old (subgroups most highly exposed) are estimated to be 0.000229 mg/kg bwt/day and 0.000371 mg/kg bwt/day and utilizes 1.5% and 2.5% of the RfD, respectively. Generally speaking, the 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 RfD. Therefore, FMC Corporation concludes that the chronic dietary risk of bifenthrin, as estimated by the dietary risk assessment, does not appear to be of concern.

iv. *Drinking water*. Laboratory and field data have demonstrated that bifenthrin is immobile in soil and will not leach into groundwater. Other data show that bifenthrin is virtually insoluble in water and extremely lipophilic. As a result, FMC Corporation 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 ($PRZM^3$). Based on this screening assessment, the potential concentrations of a pyrethroid in groundwater at depths of 1 and 2 meters are essentially zero (<<0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using $PRZM^3$ 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 analysis, the contribution of water to the dietary risk estimate is negligible. Therefore, FMC Corporation concludes that together these data indicate that residues are not expected to occur in drinking water.

2. *Non-dietary exposure*. Analysis 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 and infants <1–year) 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 and infants <1–year. 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. The aggregate MOE (inhalation + incidental oral + chronic dietary, summed across all product use categories) was estimated to be 4,878 for adults, 1,117 for children 1-6 years old and 1,361 for infants (<1–year). It can be concluded that the potential non-dietary and aggregate (non-dietary + chronic dietary) 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 Corporation intends to submit information for the EPA to consider concerning potential cumulative effects of bifenthrin consistent with the schedule established by EPA in the Federal Register at 62 FR 42020 (August 4, 1997), FRL–5734–6 and other EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population*. For the overall U.S. population, the calculated MOE at the 95th percentile was estimated to be 650, 359 at the 99th percentile; and 181 at the 99.9th percentile. For all infants <1–year old, the calculated MOE at the 95th percentile was estimated to be 540; 241 at the 99th percentile; and 171 at the 99.9th percentile. For nursing infants <1–year old, the calculated MOE at the 95th percentile was estimated to be 1,311; 451 at the 99th percentile; and 246 at the 99.9th percentile. For non-nursing infants <1–year old, the calculated margins of exposure MOE at the 95th percentile was estimated to be 476, 197 at the 99th percentile; and 169 at the 99.9th percentile. For the most highly exposed population subgroup, children 1-6 years old, the calculated MOE at the 95th percentile was estimated to be 330, 214 at the 99th percentile; and 102 at the 99.9th percentile. Therefore, FMC Corporation concludes that there is reasonable certainty that no harm will result from acute exposure to bifenthrin.

2. *Infants and children*—a. *General*. In assessing the potential for additional sensitivity of infants and children to residues of bifenthrin, FMC Corporation 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 toxicity and the completeness of the data base.

b. *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 was 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 (1992–1994) for this strain of rat, incidence of distended ureter averaged 11% with a maximum incidence of 90%.

c. *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.

d. *Prenatal and postnatal sensitivity*—i. *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. 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.

e. *Conclusion*. Based on the above, FMC Corporation concludes that reliable data support use of the standard 100–fold UF, and that an additional UF is not needed to protect the safety of infants and children. As stated above, aggregate exposure assessments utilized less than 10% of the RfD 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 bananas.

[FR Doc. 01–3621 Filed 2–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–996; FRL–6765–8]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).