conservative assumption was made that residues would be at the tolerance level. Use of the tolerances rather than actual field measurements will result in an overestimate of human dietary exposure. The existing metsulfuron methyl tolerances with the addition of the sorghum tolerance result in a theoretical maximum residue level (TMRC) that is equivalent to the following percentages of the RfD:

U.S. Population 0.3%
Nursing Infants (<1 year old) 0.1%
Non-Nursing Infants (<1 year old) 0.4%
Children (1–6 years old) 0.8%
Children (7–12 years old) 0.5%

Thus, the estimated exposure for the U.S. population and all subpopulation was less than 1% of the RfD. Metsulfuron methyl RfD (0.3 mg/kg/day)is based on the NOEL for the 2–year rat study. The most sensitive chronic toxicity/oncogenicity study. The subpopulation with the highest exposure was children ages 1–6 years (0.8% of the RfD). Based on the residue data, potential for dietary exposure is extremely low. Residue studies have shown no residue above LOQ (0.05 or 0.02 ppm) in sorghum samples evaluated including the sorghum grain processed fractions. No dietary exposure is anticipated from secondary residues in meat or milk. Although sorghum is considered a major foodstuff for cattle and poultry, residue studies and metabolism studies in the laying hen and lactating goat and cattle feeding studies showed residues below LOQ of processed fractions and less than 2% of the administered concentration in edible meat and eggs. Only traces of metsulfuron methyl were found in some goat meat and milk (0.008–0.009).

Direct human consumption of sorghum grain as a food commodity in the U.S. is extremely low. At the above levels of exposure, there is a reasonable certainty that no harm will result from dietary exposure to metsulfuron methyl.

3. *Drinking water*. Another potential source of dietary exposure to pesticides are residues in drinking water. There is no established Maximum Contaminant Level (MCL) for metsulfuron methyl in water. Based on the low use rate of metsulfuron methyl and a use pattern that is not widespread, DuPont does not anticipate residues of metsulfuron methyl in drinking water and exposure from this route is unlikely.

4. *Non-dietary exposure*. Metsulfuron methyl is registered for use in weed and brush control in non-crop situations including industrial, unimproved turf areas. Metsulfuron methyl is not to be used on lawns, walks, drive ways, tennis courts, golf courses, athletic fields, commercial sod operations, or other high maintenance, fine turf grass areas, or similar areas. Any non-occupational exposure to metsulfuron methyl in the unimproved areas is likely to be negligible.

D. Cumulative Effects

Metsulfuron methyl belongs to the sulfonylurea class of compounds. The herbicidal activity of the sulfonylurea is due to the inhibition of acetolactase synthase (ALS), an enzyme only found in plants. ALS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack ALS and this biosynthetic pathway. This lack of ALS contributes to the low toxicity of the sulfonylurea compounds in animals. We are aware of no information to indicate or suggest that metsulfuron methyl has any toxic effects on mammals that would be cumulative with those of any other chemicals.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, and based on the most sensitive chronic NOEL of 25 mg/kg/day and an RfD of 0.3 mg/kg/day, the aggregate dietary exposure will utilize less than 1% of the RfD for the U.S. population. Generally, exposure below 100% of the RfD are of no concern because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose risk to human health. We therefore conclude that there is a reasonable certainty that no harm will result from aggregate exposure to metsulfuron methyl residues.

Although no formal acute dietary margin of exposure (MOE) determinations were made, it is highly unlikely that the MOE would exceed a level of concern due to the low acute mammalian toxicity of this compound].

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of metsulfuron methyl, data were considered from developmental toxicity studies in the rat and the rabbit, and a multi-generation reproduction study in the rats. These studies proved that metsulfuron methyl was not a teratogenic or a developmental toxin.

Using the conservative exposure assessment described above, the percent of the RfD that will be utilized ranges from 0.1 to 0.8% for infants and young children. Based on this we conclude that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metsulfuron methyl residues.

Although no formal acute dietary margin of exposure determinations were made, it is highly unlikely that the MOE would exceed a level of concern due to the low mammalian toxicity of this compound.

F. International Tolerances

There are no Canadian, Mexican, or Codex Maximum Residue Level (MRLs) for metsulfuron methyl on sorghum grain.

[FR Doc. 98–7141 Filed 3–18–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–796; FRL–5776–6]

Notice of Filing of Pesticide Petitions

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 agricultural commodities.

DATES: Comments, identified by the docket control number PF–796, must be received on or before April 20, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public

inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager/Petition No.	Office location/telephone number/e-mail address	Address
Bipin Gandhi (PM 5); (PP 7E4918).	Rm. 4W53, Crystal Station, 703–308–8380, e-mail: gandhi.bipin@epamail.epa.gov.	2800 Crystal Dr., Arlington, VA
Sidney Jackson (PM 5); (PP 5E4463).	Rm. 233, CM #2, 703–305–7610, e-mail: jackson.sidney@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA

SUPPLEMENTARY INFORMATION: 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 raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic 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 grantinig of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–796 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF–796 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 21 U.S.C. 346a.

List of Subjects

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

Dated: March 5, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. 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.

1. Hercon Environmental Corporation

PP 7E4918

EPA has received a pesticide petition (PP 7E4918) from Hercon Environmental Corporation, Aberdeen Road, P.O. box 467, Emigsville, PA 17318-0467, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for Trioctyl Trimellitate (TOTM) as an inert ingredient under 40 CFR 180.1001(c).

A. Product Identity/Chemistry

Tris(2-ethylhexyl)1,2,4-benzenetricarboxylate, the chemical name for TOTM, CAS # [3319–31–1], has a molecular formula of C_{33} H_{45} O_6, and a molecular weight of 546.8.

TOTM is a primary plasticizer used in applications requiring good elongation retention such as high-temperature PVC wire coatings. Its excellent resistance to soapy water extraction also makes it attractive for use in vinyl film and vinyl-coated fabrics. Its stereochemical properties make it especially attractive in pheromone formulations as a control-release agent, and its extremely low vapor pressure (0.7×10^{-7} mm Hg), assures its retention in the formulation to perform its intended purpose.

B. Residue Chemistry

No residue chemistry data are available. However, arguments provided above relative to modes of exposure, support the lack of potential for any residues of TOTM to be present in raw agricultural product of the foods from them.

Since this petition requests an exemption from the requirement of a tolerance, Hercon believes that an analytical method for the detection and measurement of TOTM residues is not necessary. The low rate of application and the fact that it is encapsulated in the product leads to the conclusion that TOTM will not migrate into a food from the treatment of crops to any degree that would be detectable.

C. Toxicological Profile

Hercon has submitted to the EPA acute toxicological information and studies of chronic toxicology which exhibit the low toxicity of TOTM. In addition, it was determined from a manufacturer that no reports have been submitted on TOTM under TSCA 8(e) Substantial Risk Notification requirements.

1. *Acute toxicity*. Acute toxicology studies conducted with the ''neat'' material show:

Acute Toxicity: At most only slightly toxic. Slight skin irritant. LD^{50} >3200 mg/kg.

Skin Absorption and Irritation: No evidence of skin absorption. LD^{50} >20 mg/kg

Skin Sensitization: Sensitized 0/5 guinea pigs in drop-on test.

Inhalation: At lowest exposure of 0.23 mg/l, no mortality was experienced.

Eye Irritation: In unwashed eye, there was an initial moderate effect after 1 hour, but the effect disappeared after 48 hours. No effects reported in the washed eye.

2. *Genotoxicty*. — a. *TOTM evaluation in the CHO/HGPRT forward mutation assay*. TOTM was considered to be inactive under the conditions of testing in this assay. The test material did not induce dose-related increases in the mutant frequency at the HGPRT locus in CHO cell cultures. TOTM was not toxic to CHO cells at concentrations up to 5,000 nl/ml either with or without S9 metabolic activation. Mutation assays were performed in duplicate both with

a nd without S9 metabolic activation using 6 concentrations of TOTM ranging from 10.0 nl/ml to 200 nl/ml.

b. *Evaluation of TOTM in the rat primary hepatocyte unscheduled DNA synthesis assay.* The test material did not induce significant changes in the nuclear labeling of primary rat hepatocytes for an applied concentration range of 5000 nl/ml to 250 nl/ml. Little or no toxicity was observed (88.4% to 102.2% survival) but higher concentrations could not be assayed because of the insoluble nature of TOTM in medium. None of the criteria used to indicate UDS were approached by the treatments, and no dose-related response was observed. Therefore, the test material was evaluated as inactive in the Primary Rat Hepatocyte UDS Assay.

3. *Subchronic toxicity.* Twenty-eight Day Toxicity Study with TOTM in the Rat: The results of this study demonstrates that TOTM caused slight peroxisome proliferation but was less potent than DEHP [di(2-ethylhexyl) phthalate], with 2.0% TOTM producing less effects than 0.67% DEHP. There was no effect of feeding TOTM on the body weight or food intakes of the male rats. The females fed 2.0% TOTM showed an initial rejection of the diet which did not have any marked effect on their weight gain.

4. *Chronic toxicity.* Chronic Toxicity of TOTM to Daphnia magna Under Flow-Through Test Conditions: The daphnid lengths in all TOTM mean measured concentrations after 21 days of testing were not significantly different (a = 0.05) from the control. Statistical analysis of survival for Daphnia magna after a 21 days exposure to TOTM indicated that survival rates in all the mean measured test concentrations were not significantly different from the control. The mean young/adult/reproduction day after 21 days was not significantly affected in a deleterious manner in all mean measured test concentrations of TOTM. Based on the statistical analysis of adult mean length, survival and young/adult/ reproduction day from the 21 day Daphnia magna dynamic life cycle study, the MATC (Maximum Acceptable Toxicant Concentration) limits were estimated to be greater than the TOTM mean measured concentration of 82 µg/ l.

5. *Metabolite toxicology.* Study No. 4: Absorption and Metabolism of [Hexyl-2-14C] TOTM: TOTM is called TEHT in this study. These studies show that TEHT was hydrolyzed to a limited extent in the gastrointestinal tract and was largely excreted unchanged in the feces. Sixteen percent was excreted in the urine as metabolites and 1.9% was expired as CO_2.

D. Aggregate Exposure

Hercon's pheromone formulations containing TOTM will not result in an application rate of product in which more than 25 grams/acre of TOTM on food related crops will result. Depending on an extended or delayed infestation of target pests, no more than 3 applications per crop should be necessary.

It must be remembered that this amount of TOTM is contained in the formulated device, a 0.05 square inch laminated PVC flake, and therefore the TOTM itself does not come into direct contact with the plants or crops treated. At the maximum application rate, there are approximately 0.26 flakes per square foot. This equates to approximately 0.5 mg TOTM / sq.ft. At the lowest recommended application rate, this amount is halved.

To present a worst case scenario for dietary exposure to humans, Hercon has selected applications to a sugar cane crop. This worst case scenario hypothetically presumes that all available TOTM in the product is finally present in the processed sugar.

At an application rate corresponding to 0.5 mg TOTM/sq.ft, and a harvest resulting in 3.3 tons of sugar per acre, the available concentration of TOTM in the sugar would calculate to be 8.4 mg TOTM / Kg of sugar.

The assumption of an intake of 20 gms of sugar per day, would equate to a daily intake of 0.168 mg of TOTM. This hypothetical intake is much lower than the NOEL from a 28 day Chronic oral study in the male rat of 185 mg/kg/ day noted in the MSDS.

Actually, it is expected that since the TOTM is contained in the formulated devise, that no detectable TOTM would be found in the sugar.

Exposure to drinking water will be minimal. Hercon's products containing TOTM are not sprayed on lawns or gardens, around swimming pools, etc., and due to the low rates of application, even drift from an agricultural application to lakes or waterways, will not affect drinking water.

Data, calculations, low exposure potential and low toxicity discussed and presented in this petition request, precludes a concern for significant dietary or non-dietary exposure to infants and children.

Non-dietary exposure to TOTM will be mitigated through the use of personal protective equipment which is described on the label of products for personnel which may be around or in a treated field.

E. Cumulative Exposure

No cumulative mode of exposure is expected. Again, the application rate is extremely low, and encapsulation of the TOTM in the product prevents direct exposure.

Normal use patterns will not lead to accumulation of TOTM in the environment.

F. Safety Determinations

Hercon believes that the use of pheromone products containing TOTM, which is of low toxicity and which is used in such low concentrations, is compatible with EPA's objectives to register reduced risk pesticides.

In an absorption and metabolism study on rats, which is included in this package, 75% of the dose was excreted in the feces, 16% in the urine, and 1.9% was expired as CO2. Less than 0.6% remained in the tissues.

At an acute oral LD^{50} toxicity level of >3200 mg/kg in the rat and mouse, TOTM is a low level toxin with at most a class III toxicity rating. A 28 day Chronic Oral toxicity study resulted in a NOEL of 184 mg/kg/day.

Mutagenicity and Genotoxicity data showed negative results in Salmonella typhimurium assay, DHO/HGPRT assay and the Unscheduled DNA synthesis assay.

Because of the low toxcicity of TOTM and the low rate of application, and encapsulation in the product, and more importantly because no residue is expected in the final food product, a determination can be made that there is little or no exposure to the general population or to children and infants.

G. List of International Tolerances

The petitioner understands that therte are no current or known established residue levels for TOTM.

H. Environmental Fate Summary

This summary is taken directly from the Material Safety Data Sheet from Eastman Chemical Co.

''Data for this material have been used to estimate its environmental impact. It has the following properties: a low biochemical oxygen demand and little potential to cause oxygen depletion in aqueous systems, a low potential to affect aquatic organisms, a low potential to biodegrade (high persistence) with acclimated microorganisms from activated sludge, a low potential to bio-concentrate. After dilution with a large amount of water, followed by secondary waste treatment, this material is not expected to cause adverse environmental effects.''

2. IR-4 Project

PP 5E4463

EPA has received a pesticide petition (PP 5E4463) from the Interregional Research Project Number 4 (IR-4), proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR Part 180 by establishing a tolerance for residues of the insecticide cypermethrin ((+) alpha-cyano(3-phenoxyphenyl)methyl (+) cis, trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the raw agricultural commodity green onions at 6.0 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition. This notice contains a summary of the petition submitted by FMC Corporation, the registrant.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of cypermethrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabelled cypermethrin 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 cypermethrin 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. The analytical method is Gas Chromatography with Electron Capture Detection (GC/ECD).

3. *Magnitude of residues*. Field residue trials meeting EPA study requirements have been conducted at the maximum label rate for the crop green onions. Results from these trials demonstrate that the proposed cypermethrin tolerance on green onions at 6.0 ppm will not be exceeded when the product is applied following the proposed use directions. These data have previously been reviewed and classified by the Agency as supportive of this tolerance.

B. Toxicological Profile

1. *Acute toxicity*. The required battery of acute toxicity studies has been submitted and found adequate. The findings were as follows: oral toxicity, lethal dose $(LD)_{50}$ of 263 milligram (mg) per kilogram (kg); dermal toxicity, LD_{50} 2,460 mg/kg; inhalation toxicity lethal concentration LC_{50} 2.5 mg/liter (L); primary eye irritation is Toxicity Category III; primary dermal irritation is Toxicity Category IV. Cypermethrin is considered to be a dermal sensitizer.

2. *Genotoxicity*. All reported results from the following genotoxicity tests were all negative: gene mutation (Ames); chromosome aberration in Chinese hamster bone marrow cells; host mediated assay in mice; dominant lethal assay in mice.

3. *Reproductive and developmental toxicity*. No evidence of additional sensitivity to young rats or rabbits was reported following pre- or postnatal exposure to cypermethrin.

a. A 3-generation reproductive toxicity study in rats demonstrated a no observed effect level (NOEL) of 2.5 mg/kg/day and a lowest observed effect level (LOEL) of 7.5 mg/kg/day for parental/systemic toxicity based on decreased body weight gain in both sexes. There were no adverse effects in reproductive performance. The NOEL for reproductive toxicity was considered to be 37.5 mg/kg/day, the highest dose level tested.

b. A developmental study in rats demonstrated a maternal NOEL of 17.5 mg/kg/day and a LOEL of 35 mg/kg/day based on decreased body weight gain. There were no signs of developmental toxicity at 70 mg/kg/day, the highest dose level tested.

c. A developmental study in rabbits demonstrated a maternal NOEL of 100 mg/kg/day and a LOEL of 450 mg/kg/day based on decreased body weight gain. There were no signs of developmental toxicity at 700 mg/kg/day, the highest dose level tested.

4. *Subchronic toxicity*. The systemic NOEL of 5.0 mg/kg/day from the chronic toxicity study in dogs is also used for short- and intermediate-term margin of exposure (MOE) calculations (as well as acute toxicity, discussed in (1) above). This NOEL was based on neurotoxic clinical signs observed in the first week of treatment of the study.

5. *Chronic toxicity*. The Reference Dose (RfD) has been established at 0.010 mg/kg/day. This RfD is based on a chronic toxicity study in dogs with a NOEL of 1.0 mg/kg/day, based on gastrointestinal disturbances observed at the LOEL of 5.0 mg/kg/day during the first week of the study; an uncertainty factor of 100 is used.

Cypermethrin is classified as a Group C chemical (possible human carcinogen with limited evidence of carcinogenicity in animals) based upon limited evidence for carcinogenicity in female mice; assignment of a Q* has not been recommended.

6. *Animal metabolism*. The metabolism of cypermethrin in animals is adequately understood. Cypermethrin has been shown to be rapidly absorbed, distributed, and excreted in rats when administered orally. Cypermethrin is metabolized by hydrolysis and oxidation.

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

8. *Endocrine disruption*. No evidence of potential estrogenic or other endocrine effects of cypermethrin 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 cypermethrin has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. a. *Food*. Tolerances have been established for the residues of cypermethrin, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of cypermethrin on cottonseed; pecans; lettuce, head; onions, bulb; cabbage; Brassica, head and stem; Brassica, leafy and livestock commodities of cattle, goats, hogs, horses, and sheep as well as this pending tolerance for green onions. For the purposes of assessing the potential dietary exposure for these existing and pending tolerances, FMC has utilized available information on anticipated residues, monitoring data and percent crop treated as follows:

i. 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 cypermethrin, the maternal NOEL of 1.0 mg/kg/day from the chronic toxicity study in dogs was used. The LOEL of this study of 5.0 mg/kg/day was based on gastrointestinal disturbances observed in the first week of the study. 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 significantly greater than the EPA standard of 100 for all subpopulations. The 95th percentile

of exposure for the overall U. S. population was estimated to be 0.000488 mg/kg/day (MOE of 2,047); 99th percentile 0.002014 mg/kg/day (MOE of 496); and 99.9th percentile 0.004438 mg/kg/day (MOE of 225). The 95th percentile of exposure for all infants < one year old was estimated to be 0.00007 mg/kg/day (MOE of 14,240); 99th percentile 0.000345 mg/kg/day (MOE of 2,902); and 99.9th percentile 0.000997 mg/kg/day (MOE of 1,003). The 95th percentile of exposure for nursing infants < one year old was estimated to be 0.000033 mg/kg/day (MOE of 30,026); 99th percentile 0.000241 mg/kg/day (MOE of 4,144); and 99.9th percentile 0.001400 mg/kg/day (MOE of 714). The 95th percentile of exposure for non-nursing infants < one year old was estimated to be 0.000075 mg/kg/day (MOE of 13,331); 99th percentile 0.000375 mg/kg/day (MOE of 2,667); and 99.9th percentile 0.000748 mg/kg/day (MOE of 1,337). The 95th percentile of exposure for children 1 to 6 years old (the most highly exposed population subgroup) was estimated to be 0.000361 mg/kg/day (MOE of 2,767); 99th percentile 0.002088 mg/kg/day (MOE of 479); and 99.9th percentile 0.005465 mg/kg/day (MOE of 183). Therefore, FMC concludes that the acute dietary risk of cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

ii. Chronic exposure and risk. The acceptable RfD is based on a NOEL of 1.0 mg/kg/day from the chronic dog study and an uncertainty factor of 100 is 0.010 mg/kg/day. The endpoint effect of concern was based on gastrointestinal disturbances observed in the first week of the study at the LOEL of 5.0 mg/kg/day. A chronic dietary exposure/risk assessment has been performed for cypermethrin using the above RfD. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into the analysis to estimate the anticipated residue contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues. The ARC is estimated to be 0.000025 mg/kg body weight (bwt)/day and utilize 0.3 percent of the RfD for the overall U. S. population. The ARCs for non-nursing infants (<1 year) and children 1–6 years old (subgroups most highly exposed) are estimated to be 0.000014 mg/kg bwt/day and 0.000042 mg/kg bwt/day and utilizes 0.1 percent and 0.4 percent 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 percent of the RfD. Therefore, FMC concludes that the chronic dietary risk of cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

b. *Drinking water.* Laboratory and field data have demonstrated that cypermethrin is immobile in soil and will not leach into groundwater. Other data show that cypermethrin 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 groundwater at depths of 1 and 2 meters are essentially zero (<<0.001 parts per billion). 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 parts per billion(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, FMC believes that the contribution of water to the dietary risk estimate is negligible. Therefore, FMC concludes that together these data indicate that residues of cypermethrin 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 cypermethrin 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 for each product use category (indoor total release fogger and lawn care) and exposed population group (adults, children 1–6 years, and infants < 1 year) are compared to the systemic absorbed dose NOEL for cypermethrin to provide estimates of the MOEs. Based on the toxicity endpoints selected by EPA for cypermethrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOEL for estimating MOEs.

In the case of potential aggregate health risks, the above mentioned conservative point estimates of 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 NOEL to provide estimates of aggregate MOEs.

The total non-dietary MOEs (combined across all product use categories) for the inhalation plus incidental oral routes are 97,000 for adults, 2,100 for children 1–6 years old, and 1,900 for infants (< 1 year). The aggregate MOE (inhalation + incidental oral + chronic dietary, summed across all product use categories) was estimated to be 65,000 for adults, 2,000 for children 1–6 years old and 1,900 for infants (<1 year). FMC concludes that the potential non-dietary and aggregate (non-dietary + chronic dietary) exposures for cypermethrin are associated with substantial margins of safety.

D. Cumulative Effects

In consideration of potential cumulative effects of cypermethrin 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 cypermethrin would be cumulative with those of other chemical compounds; thus only the potential risks of cypermethrin have been considered in this assessment of its aggregate exposure. FMC intends to submit information for the EPA to consider concerning potential cumulative effects of cypermethrin consistent with the schedule established by EPA at in the **Federal Register** of August 4, 1997, (62 FR 42020), and other EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population*. Based on a complete and reliable toxicology database, the acceptable reference dose RfD is 0.010 mg/kg/day, based on a LOEL of 5.0 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 Anticipated 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 0.000025 mg/kg body weight (bwt)/day and utilize 0.3 percent of the RfD for the overall U. S. population. The ARC for non-nursing infants (<1 year) and children 1–6 years old (subgroups most highly exposed) are estimated to be 0.000014 mg/kg bwt/day and 0.000042 mg/kg bwt/day and utilizes 0.1 percent and 0.4 percent 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 percent of the RfD. Therefore, FMC concludes that the chronic dietary risk of cypermethrin, as estimated by the aggregate risk assessment, does not appear to pose significant risk.

For the overall U.S. population, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 2,047; 496 at the 99th percentile; and 225 at the 99.9th percentile. For all infants < one year old, the calculated MOE at the 95th percentile was estimated to be 14,240; 2,902 at the 99th percentile; and 1,003 at the 99.9th percentile. For nursing infants < one year old, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 30,026; 4,144 at the 99th percentile; and 714 at the 99.9th percentile. For non-nursing infants < one year old, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 13,331; 2,667 at the 99th percentile; and 1,337 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 2,767 ; 479 at the 99th percentile; and 183 at the 99.9th percentile. Therefore, FMC concludes that there is reasonable certainty that no harm will result from acute exposure to cypermethrin.

2. *Infants and children*. —a. *General.* In assessing the potential for additional sensitivity of infants and children to residues of cypermethrin, FMC considered data from developmental toxicity studies in the rat and rabbit, and a three-generation reproductive study in the rat. The data demonstrated no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to cypermethrin. 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 pre- and post-natal toxicity and the completeness of the database.

b. *Developmental toxicity studies.* In the prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the highest doses tested (70 mg/kg/day in rats and 700 mg/kg/day in rabbits). Decreased body weight gain was observed at the maternal LOEL in each study; the maternal NOEL was established at 17.5 mg/kg/day in rats and 100 mg/kg/day in rabbits.

c. *Reproductive toxicity study.* In the 3-generation reproduction study in rats, offspring toxicity (reduced mean litter weight gain) was observed only at the highest dietary level tested (37.5 mg/kg/day), while toxicity in the parental animals was observed at the lower treatment levels. The parental systemic NOEL was 2.5 mg/kg/day and the parental systemic LOEL was 7.5 mg/kg/day. There were no developmental (pup) or reproductive effects up to 37.5 mg/kg/day (highest dose tested).

d. *Pre- and post-natal sensitivity. —i. Pre-natal.* There was no evidence of developmental toxicity in the studies at the highest doses tested in the rat (70 mg/kg/day) or in the rabbit (700 mg/kg/day). Therefore, there is no evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

ii. Post-natal. Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

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 significantly less than 1 percent of the RfD for either the entire U. S. population or any of the 26 population subgroups including infants and children. Therefore, FMC concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cypermethrin residues.

F. International Tolerances

There are no codex, Canadian, or Mexican residue limits for residues of cypermethrin in or on green onions.

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FEDERAL HOUSING FINANCE BOARD

Announcing an Open Meeting of the Board

TIME AND DATE: 10:00 a.m., Wednesday, March 25, 1998.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:

- FHLBank Investment Practices and Implications for Finance Board Investment Policy .
- Final Rule: Eligibility for Membership and Advances.
- Proposed Rule: Elections Regulations.
- Office of Finance—Board Compensation Policy Approval.
- Office of Finance—Board Appointments.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

William W. Ginsberg,

Managing Director.

[FR Doc. 98–7313 Filed 3–17–98; 2:47 pm]
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FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).