

What Dockets Are Currently Open for Public Comment?

The following is a list of rules/notices that are expected to be open for public comment during the scheduled docket closure periods. This listing, which identifies the docket ID number for the item, is not expected to be complete and the program docket should be contacted if a more detailed and current listing of open dockets is necessary.

OAR Docket

- A-2000-50: National Emission Standards for Hazardous Air Pollutants for Refractory Products Manufacturing
- A-97-52: National Emission Standards for Hazardous Air Pollutants; Surface Coating of Wood Building Products

OPPT Docket

- OPPT-2002-0040: Certain New Chemicals; Receipt and Status Information

OSWER Docket

- RCRA-1999-0011: Management of Cement Kiln Dust—Notice of Data Availability
- RCRA-2002-0019: NESHAP: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors (Final Replacement Standards and Phase II)—Notice of Data Availability
- RCRA-2002-0021: Agency Collection Activities: Continuing Collection; Comment Request; Notification of Regulated Waste Activity
- RCRA-2002-0022: Agency Collection Activities: Proposed Collection; Comment Request; National Waste Minimization Partnership Program
- RCRA-2002-0023: Agency Information Collection Activities: Continuing Collection; Comment Request; Information Collection Request for RCRA Reporting and Recordkeeping Requirements for Incinerators, Boilers and Industrial Furnaces Burning Hazardous Waste
- SFUND-2002-004: Contaminated Sediments Science Plan—Notice

OW Docket

- W-99-18: Standards for the Use or Disposal of Sewage Sludge
- W-02-06: Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category
- W-00-27: Notice of Data Availability; National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitations Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO)

Dated: July 30, 2002.
 Mark Luttner,
 Office of Information Collection, Office of Environmental Information.
 [FR Doc. 02-19565 Filed 8-1-02; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0134; FRL-7185-9]

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 ID number OPP-2002-0134, must be received on or before September 3, 2002.

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 ID number OPP-2002-0134 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda A. DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5428; e-mail address: deluise.linda@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	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	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," "Regulations and Proposed Rules" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0134. 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 ID number OPP-2002-0134 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 ID number OPP-2002-0134. 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 ID 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: July 23, 2002.

Peter Caulkins,

Acting 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

2F6444

EPA has received a pesticide petition (2F6444) from FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 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 zeta-cypermethrins-Cyano(3-phenoxyphenyl)methyl (\pm) *cis, trans* 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate and its inactive isomers) in or on the raw agricultural commodities (RACs) root and tuber vegetables, roots at 0.10 part per million (ppm); peanuts at 0.05 ppm; and cucurbit vegetables at 0.10 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 cypermethrin in plants are 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 (LOD) that allows monitoring of food with residues at or above the levels set in these tolerances (gas chromatography with electron capture detection (GC/ECD)).

3. *Magnitude of residues.* Crop field trial residue data from studies conducted at the maximum label rates for root and tuber vegetables, peanuts, and cucurbit vegetables show that the proposed zeta-cypermethrin tolerances on root and tuber vegetables, roots at 0.10 ppm; peanuts at 0.05 ppm; and cucurbit vegetables at 0.10 ppm will not be exceeded when the zeta-cypermethrin products labeled for these uses are used as directed.

B. Toxicological Profile

1. *Acute toxicity.* For the purposes of assessing acute dietary risk, FMC Corporation has used the no observed adverse effect levels (NOAEL) at 10.0 milligram/kilograms/day (mg/kg/day) from the zeta-cypermethrin acute neurotoxicity study in rats. The lowest observed adverse effect levels (LOAEL) at 50.0 mg/kg/day was based on clinical signs. This acute dietary endpoint is used to determine acute dietary risks to all population subgroups.

2. *Genotoxicity.* The following genotoxicity tests were all negative:

i. *In vivo* chromosomal aberration in rat bone marrow cells.

ii. *In vitro* cytogenetic chromosome aberration.

iii. Unscheduled DNA synthesis (UDS).

iv. Chinese hamster ovary/hypoxanthine guanine phosphoribosyl transferase (CHO/HGPRT) mutagen assay; weakly mutagenic: Gene mutation (Ames).

3. *Reproductive and developmental toxicity.* No evidence of additional sensitivity to young rats was observed following prenatal or postnatal exposure to zeta-cypermethrin.

i. A 2-generation reproductive toxicity study with zeta-cypermethrin in rats demonstrated a NOAEL at 7.0 mg/kg/day and the LOAEL at 27.0 mg/kg/day for parental/systemic toxicity based on body weight (bwt), organ weight, and clinical signs. There were no adverse effects in reproductive performance. The NOAEL for reproductive toxicity was considered to be >45.0 mg/kg/day (the highest dose tested (HDT)).

ii. A developmental study with zeta-cypermethrin in rats demonstrated a maternal NOAEL at 12.5 mg/kg/day and a LOAEL at 25 mg/kg/day based on decreased maternal body weight gain, food consumption and clinical signs. There were no signs of developmental toxicity at 35.0 mg/kg/day, the HDT.

iii. A developmental study with cypermethrin in rabbits demonstrated a maternal NOAEL at 100 mg/kg/day and a LOAEL at 450 mg/kg/day based on decreased body weight gain. There were no signs of developmental toxicity at 700 mg/kg/day, the HDT.

4. *Subchronic toxicity.* Short-term and intermediate-term toxicity (incidental oral exposure). The NOAEL at 10.0 mg/kg/day based on clinical signs at the lowest effect level (LEL) at 50.0 mg/kg/day in the zeta-cypermethrin acute neurotoxicity study in rats would also be used for short-term percent of the acute population adjusted dose (aPAD) and margin of exposure (MOE) calculations (as well as acute, discussed

in paragraph (1) above), and the NOAEL at 5.0 mg/kg/day based on decreased motor activity in the zeta-cypermethrin subchronic neurotoxicity study in rats, would be used for intermediate-term MOE calculations.

5. *Chronic toxicity*—i. The chronic reference dose (RfD) at 0.06 mg/kg/day for zeta-cypermethrin is based on a NOAEL at 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an uncertainty factor (UF) of 100. The endpoint effect of concern was based on clinical signs.

ii. 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 nor in the risk exposure assessments.

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

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Permanent tolerances, in support of registrations, currently exist for residues of zeta-cypermethrin on: alfalfa hay, alfalfa forage, alfalfa seed, aspirated grain fractions, sugar beets (roots and tops), head, stem, and leafy Brassica vegetables, cabbage, field corn grain, pop corn grain, field corn forage, field corn stover, pop corn stover, sweet corn (K+CWHR), sweet corn forage, sweet corn stover, cottonseed, dried shelled peas, and beans, edible podded legume vegetables, fruiting vegetables (except Cucurbits), leafy vegetables, head lettuce, bulb, and green onions, pecans, rice grain, rice hulls, rice straw, sorghum forage, sorghum grain, sorghum stover, soybean seed, succulent shelled peas and beans, sugarcane,

wheat forage, wheat grain, wheat hay, wheat straw, meat, fat, and meat byproducts of cattle, goats, hogs, horses, and poultry, eggs, milk, and milk fat. For the purposes of assessing the potential dietary exposure for these existing and the subject proposed 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 1 day or single exposure. For the purposes of assessing acute dietary risk for zeta-cypermethrin, FMC Corporation has used the NOAEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats with an UF of 100 (acute RfD = 0.10 mg/kg/day). The LEL of 50.0 mg/kg/day was based on clinical signs. This acute dietary endpoint is 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 percent of acute PAD all fall below EPA's level of concern (LOC) ($\geq 100\%$). The 95th percentile of exposure for the overall U.S. population was estimated to be 0.001012 mg/kg/day (percent of the acute RfD at 1.01); 99th percentile 0.002913 mg/kg/day (percent of the acute RfD at 2.91); and 99.9th percentile 0.012145 mg/kg/day (percent of the acute RfD at 12.14). The 95th percentile of exposure for all infants <1 year old was estimated to be 0.000716 mg/kg/day (percent of the acute RfD at 0.72); 99th percentile 0.005735 mg/kg/day (percent of the acute RfD at 5.74); and 99.9th percentile 0.027673 mg/kg/day (percent of the acute RfD of 27.67). The 95th percentile of exposure for nursing infants 1 year old was estimated to be 0.000420 mg/kg/day (percent of the acute RfD at 0.42); 99th percentile 0.001087 mg/kg/day (percent of the acute RfD at 1.09); and 99.9th percentile 0.004944 mg/kg/day (percent of the acute RfD at 4.94). The 95th percentile of exposure for non-nursing infants <1 year old (the most highly exposed population subgroup) was estimated to be 0.000826 mg/kg/day (percent of the acute RfD at 0.83); 99th percentile 0.011124 mg/kg/day (percent of the acute RfD at 11.12); and 99.9th percentile 0.031431 mg/kg/day (percent of the acute RfD of 31.43). The 95th percentile of exposure for

children 1 to 6 years old and children 7 to 12 years old was estimated to be, respectively, 0.001228 mg/kg/day (percent of the acute RfD at 1.23) and 0.001001 mg/kg/day (percent of the acute RfD at 1.0); 99th percentile 0.003716 mg/kg/day (percent of the acute RfD at 3.72) and 0.002724 (percent of the acute RfD at 2.72); and 99.9th percentile 0.015244 mg/kg/day (percent of the acute RfD at 15.24) and 0.008805 (percent of the acute RfD at 8.81). The 95th percentile of exposure for females (13+/nursing) was estimated to be 0.001051 mg/kg/day (percent of the acute RfD at 1.05); 99th percentile 0.003029 mg/kg/day (percent of the acute RfD at 3.03); and 99.9th percentile 0.013146 mg/kg/day (percent of the acute RfD at 13.15). Therefore, FMC Corporation concludes that the acute dietary risk of zeta-cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

iii. *Chronic exposure risk.* The chronic RfD at 0.06 mg/kg/day for zeta-cypermethrin is based on a NOAEL of 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an UF of 100. The endpoint effect of concern was based on clinical signs. A chronic dietary exposure/risk assessment has been performed for zeta-cypermethrin using the above chronic 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 are estimated to be 0.000184 mg/kg bwt/day and utilize 0.3% of the chronic RfD for the overall U.S. population. The ARC for nursing infants (<1 year) and non-nursing infants (<1 year) (subgroup most highly exposed) are estimated to be 0.000052 mg/kg bwt/day and 0.000380 mg/kg bwt/day and utilizes 0.1% and 0.6% of the chronic RfD, respectively. The ARC for children 1 to 6 years old and children 7 to 12 years old are estimated to be 0.000337 mg/kg bwt/day and 0.000203 mg/kg bwt/day and utilizes 0.6% and 0.3% of the chronic RfD, respectively. The ARC for females (13+/nursing) are estimated to be 0.000177 mg/kg bwt/day and utilizes 0.3% of the RfD. 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 chronic RfD. Therefore, FMC Corporation concludes that the chronic dietary risk of zeta-cypermethrin, as

estimated by the dietary risk assessment, does not appear to be of concern.

iv. *Drinking water.* Laboratory and field data have demonstrated that cypermethrin is immobile in soil and will not leach into ground water. Other data show that cypermethrin 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. Drinking water estimated concentrations (DWE) and the corresponding drinking water level of comparison (DWLOC) values were calculated for chronic and acute exposures. The results show that all DWLOC values exceed the DWE values. Thus, exposure to zeta-cypermethrin and cypermethrin residues in drinking water is not of concern. EPA's draft SOP for Incorporating Estimates of Drinking Water Exposure into Aggregate Risk Assessments was used to perform a drinking water analysis. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as the Food Quality Protection Act/Index Reservoir Screening Tool (FQPA)(FIRST), EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), Screening Concentration in Ground Water (SCIGROW), and monitoring data. If monitoring data is not available, then the models are used to predict potential residues in drinking water. The technique recommended in the drinking water SOP compares a calculated DWLOC value to the drinking water estimated concentration (DWE) value. The DWE value results from either the monitoring data residues or modeled water residues. If the DWLOC value exceeds the DWE value, then there is reasonable certainty that no harm will result from the acute or chronic aggregate exposure.

In the case of cypermethrin and zeta-cypermethrin, monitoring data do not exist. Therefore, the FIRST model was used to estimate a surface water residue. The risk assessment for drinking water compares two values:

a. The DWLOC and the DWE. The DWLOC is the drinking water level of comparison. This is the maximum allowable drinking water concentration (in parts per billion). The DWE is the drinking water environmental concentration, which is derived either from monitoring studies or from modeling.

b. If the DWLOC is greater than the DWE, then the overall exposure from water, food, and residential is

considered to be acceptable. The calculated DWLOC values for acute and chronic exposures for all adults, adult females, and children exceed the modeled DWE surface water residues. Therefore, there is reasonable certainty that no harm will result from cumulative and aggregate (food and water) exposure to cypermethrin and zeta-cypermethrin residues.

2. *Non-dietary exposure.* Zeta-cypermethrin is registered for agricultural crop applications only, therefore non-dietary exposure assessments are not warranted.

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

E. Safety Determination

1. *U.S. population.* The chronic RfD at 0.06 mg/kg/day for zeta-cypermethrin is based on a NOAEL at 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an UF of 100. The endpoint effect of concern was based on clinical signs. A chronic dietary exposure/risk assessment has been performed for zeta-cypermethrin using the above chronic 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 0.000184 mg/kg bwt/day and utilize 0.3% of the chronic RfD for the overall U.S. population. The ARC for nursing infants (<1 year) and non-nursing infants (<1 year) (subgroup most highly exposed) are estimated to be 0.000052 mg/kg bwt/day and 0.000380 mg/kg bwt/day and utilizes 0.1% and 0.6% of the chronic RfD, respectively. The ARC for children 1 to 6 years old and children 7 to 12 years old are estimated to be 0.000337 mg/kg bwt/day

and 0.000203 mg/kg bwt/day and utilizes 0.6% and 0.3% of the chronic RfD, respectively. The ARC for females (13+/nursing) are estimated to be 0.000177 mg/kg bwt/day and utilizes 0.3% of the RfD. 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 chronic RfD. Therefore, FMC Corporation concludes that the chronic dietary risk of zeta-cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

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 zeta-cypermethrin, FMC Corporation has used the NOAEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats with an UF of 100 (acute RfD = 0.10 mg/kg/day). The LEL of 50.0 mg/kg/day was based on clinical signs. This acute dietary endpoint is 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 percent of acute PAD all fall below EPA's LOC ($\geq 100\%$). The 95th percentile of exposure for the overall U.S. population was estimated to be 0.001012 mg/kg/day (percent of the acute RfD at 1.01); 99th percentile 0.002913 mg/kg/day (percent of the acute RfD at 2.91); and 99.9th percentile 0.012145 mg/kg/day (percent of the acute RfD at 12.14). The 95th percentile of exposure for all infants <1 year old was estimated to be 0.000716 mg/kg/day (percent of the acute RfD at 0.72); 99th percentile 0.005735 mg/kg/day (percent of the acute RfD at 5.74); and 99.9th percentile 0.027673 mg/kg/day (percent of the acute RfD at 27.67). The 95th percentile of exposure for nursing infants <1 year old was estimated to be 0.000420 mg/kg/day (percent of the acute RfD at 0.42); 99th percentile 0.001087 mg/kg/day (percent of the acute RfD at 1.09); and 99.9th percentile 0.004944 mg/kg/day (percent of the acute RfD at 4.94). The 95th percentile of exposure for non-nursing infants <1 year old (the most highly exposed population subgroup) was estimated to be 0.000826 mg/kg/day (percent of the acute RfD at

0.83); 99th percentile 0.011124 mg/kg/day (percent of the acute RfD at 11.12); and 99.9th percentile 0.031431 mg/kg/day (percent of the acute RfD at 31.43). The 95th percentile of exposure for children 1 to 6 years old and children 7 to 12 years old was estimated to be, respectively, 0.001228 mg/kg/day (percent of the acute RfD at 1.23); and 0.001001 mg/kg/day (percent of the acute RfD at 1.0); 99th percentile 0.003716 mg/kg/day (percent of the acute RfD at 3.72); and 0.002724 (percent of the acute RfD at 2.72); and 99.9th percentile 0.015244 mg/kg/day (percent of the acute RfD of 15.24); and 0.008805 (percent of the acute RfD at 8.81). The 95th percentile of exposure for females (13+/nursing) was estimated to be 0.001051 mg/kg/day (percent of the acute RfD at 1.05); 99th percentile 0.003029 mg/kg/day (percent of the acute RfD at 3.03); and 99.9th percentile 0.013146 mg/kg/day (percent acute RfD at 13.15). Therefore, FMC Corporation concludes that the acute dietary risk of zeta-cypermethrin, 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 zeta-cypermethrin, FMC Corporation considered data from developmental toxicity studies in the rat, rabbit, and a 2-generation reproductive study in the rat. The data demonstrated no indication of increased sensitivity of rats to zeta-cypermethrin or rabbits to cypermethrin *in utero* and/or postnatal exposure to zeta-cypermethrin or 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 (MOS) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base.

ii. *Developmental toxicity studies*. In the prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the HDT (35.0 mg/kg/day in rats and 700 mg/kg/day in rabbits). Decreased body weight gain was observed at the maternal LOAEL in each study; the maternal NOAEL was established at 12.5 mg/kg/day in rats and 100 mg/kg/day in rabbits.

iii. *Reproductive toxicity study*. In the 2-generation reproduction study in rats, offspring toxicity (body weight), parental toxicity (body weight, organ weight, and clinical signs), were observed at 27.0 mg/kg/day and greater. The parental systemic NOAEL was 7.0 mg/kg/day and the parental systemic LOAEL was 27.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 45.0 mg/kg/day, HDT.

iv. *Prenatal and postnatal sensitivity*—a. *Prenatal*. There was no evidence of developmental toxicity in the studies at the HDT in the rat (70.0 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.

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.

v. *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 significantly less than 1% 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 cypermethrin residues.

F. *International Tolerances*

There are no Canadian, or Mexican residue limits for residues of cypermethrin or zeta-cypermethrin in or on cucurbit vegetables, peanuts, root, and tuber vegetables. The Codex maximum residue levels for cypermethrin are cucumbers 0.2 ppm; peanuts 0.05 ppm; and for root and tuber vegetables 0.05 ppm.

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EXPORT-IMPORT BANK OF THE UNITED STATES

Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated to the Public by the Export-Import Bank of the U.S. (Ex-Im Bank)

AGENCY: Export-Import Bank of the United States (Ex-Im Bank).

ACTION: Notice of draft guidelines.

SUMMARY: The Export-Import Bank (Ex-Im Bank) is seeking comments on the draft Information Quality Guidelines that follow.

ADDRESSES: Export-Import Bank of the United States, 811 Vermont Avenue, NW., Washington, DC 20571.

FOR FURTHER INFORMATION CONTACT:

Kalesha Malloy, Office of the Chief Information Officer Information Management & Technology Group, 811 Vermont Avenue, NW., Room 763, Washington DC 20571; by e-mail at kalesha.malloy@exim.gov, by phone at (202) 565-3857; or by fax at (202) 565-3424.

DATES: Comments should be received on or before August 16, 2002.

SUPPLEMENTARY INFORMATION:

Dated: July 29, 2002.

Carlista D. Robinson,

Agency Clearance Officer.

Introduction and Purpose

The Export-Import Bank (Ex-Im Bank) is seeking comments on the draft Information Quality Guidelines that follow. These draft Information Quality Guidelines describe Ex-Im Bank's pre-dissemination information publicly disseminated by Ex-Im Bank. Ex-Im Bank will post its draft Information Quality Guidelines on its Web site at <http://www.exim.gov/omb/dataquality.doc> and encourages public comment on the report. Please submit comments to Kalesha Malloy, Office of the Chief Information Officer, Information Management & Technology Group, 811 Vermont Ave, NW., Room 763, Washington, DC 20571, by phone at (202) 565-3857, by e-mail at kalesha.malloy@exim.gov or by fax at (202) 565-3424. Comments should be received on or before August 16, 2002.

These guidelines are drafted in accordance with "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" ("Agency-wide guidelines") published by the Office of Management and Budget ("OMB") in 66 FR 49718 on Friday, September 28, 2001, updated in

67 FR 369 on Thursday, January 3, 2002 and corrected in 67 FR 8452 on February 22, 2002. These published guidelines were issued pursuant to Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106-554). In accordance with these provisions, each Federal Agency is obligated to:

1. Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency no later than October 1, 2002;

2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines; and

3. Report annually to the Director of OMB, beginning January 1, 2004, the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

Consistent with the Agency-wide Guidelines, Ex-Im Bank's draft guidelines rely on its existing practices, to the extent they are consistent with the recently published guidelines, while adopting a new administrative mechanism to satisfy the new procedural requirements. Ex-Im Bank's guidelines reflect its internal procedures for reviewing and substantiating information to maximize quality, including the objectivity, utility, and integrity of information, before it is disseminated. The administrative mechanism allows affected persons to seek and obtain, where appropriate correction of information disseminated by Ex-Im Bank that does not comply with these guidelines or with the Agency-wide Guidelines.

Ex-Im Banks draft guidelines follow:

Background

Ex-Im Bank publishes these guidelines in accordance with the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (Agency-wide guidelines) published by the Office of Management and Budget in 66 FR 49718 on Friday, September 28, 2001, updated in 67 FR 369 on Thursday, January 3, 2002 and corrected in 67 FR 8452 on February 22, 2002. These published guidelines were issued pursuant to Section 515 of the Paperwork Reduction Act (44 U.S.C. 3502(1) et seq.) In response to the

legislation and the published guidelines, Ex-Im Bank identifies the following policies and procedures for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Ex-Im Bank; and it hereby establishes additional procedures for affected persons to seek and obtain correction of information maintained and disseminated by Ex-Im Bank that does not comply with standards set out in the Agency-wide Guidelines.

Ex-Im Bank is an independent U.S. Government agency that helps finance the overseas sales of U.S. goods and services. In 65 years, Ex-Im Bank has supported more than \$300 billion in U.S. exports. Ex-Im Bank's mission is to create jobs through exports. It provides guarantees of working capital loans for U.S. exporters, guarantees the repayment of commercial export loans, or makes loans to foreign purchasers of U.S. goods and services. Ex-Im Bank also provides credit insurance that protects U.S. exporters against the risks of non-payment by foreign buyers for political or commercial reasons. Ex-Im Bank does not compete with commercial lenders, but assumes the risks they cannot accept. Ex-Im Bank must always conclude that there is reasonable assurance of repayment on every transaction financed. Ex-Im Bank takes pride in the quality, objectivity, utility, and integrity of the information that it disseminates to the public.

1. Procedures for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Prior to Dissemination

In Agency-wide Guidelines, "quality" is defined as a term comprising utility, objectivity, and integrity.

(a) Objectivity of Information

(i) As defined in Section IV, below, "objectivity" is a measure of whether disseminated information "accurate, clear, complete, and unbiased;"

"utility" refers to the usefulness of the information to its intended audience. Ex-Im Bank is committed to disseminating reliable and useful information. Before disseminating information, appropriate Ex-Im Bank staff and officials will review the information.

(ii) It is the primary responsibility of the Office drafting information intended for dissemination to pursue the most knowledgeable and reliable sources reasonably available to confirm the objectivity of such information and to ensure appropriate technical and policy clearance before public dissemination. Clearance procedures will vary with the