This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 9, 2005.

Debra Edwards,

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

[FR Doc. 05–5211 Filed 3–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0217; FRL–7705–2]

Imazalil; Notice of Availability of the Amendment to the Imazalil RED; Correction of Docket Number

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's amendment to the 2003 Reregistration Eligibility Decision (RED) for the pesticide imazalil and informs the public of a correction of the docket identification (ID) number.

FOR FURTHER INFORMATION CONTACT: Meghan French, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8004; fax number: (703) 308–8005; e-mail address: *french.meghan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2003–0217. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm.119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Does this Amendment and Correction Do?

The amendment to the Imazalil RED shows an updated label table that meets current EPA label language requirements. In addition, this amendment alerts the public and technical registrants that the special study to determine the availability of imazalil from treated citrus is no longer required, but that a data gap exists for OPPTS Harmonized Guideline 830.7050. EPA announced the availability of the Imazalil RED in the **Federal Register** of February 25, 2005 (70 FR 9317) (FRL–7700–9). In that document, the docket ID number was inadvertently listed as OPP–2004–0107. The correct docket ID number for imazalil is OPP–2003–0217.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 9, 2005.

Peter Caulkins,

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

[FR Doc. 05–5208 Filed 3–15–05; 8:45 am]

BILLING CODE 6560–50– S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0041; FRL–7700–2]

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 identification (ID)number [OPP–2005–0041], must be received on or before April 15, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Linda A. DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 potentially affected by this action if you an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0041. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.''. EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0041. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2005–0041. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2005–0041.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0041. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 FFDCA 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: February 25, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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

PP 4F6893

EPA has received pesticide petition (PP4F6893) from FMC Corporation, 1735 Market Street, Philadelphia, PA 19103, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.418 by establishing a tolerance for residues of the insecticide zeta-cypermethrin (±α-Cyano(3-phenoxyphenyl)methyl (±) *cis, trans* 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate and its inactive isomers) in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments at 0.05 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 supports 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 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 (Gas Chromatography with Electron Capture Detection (GC/ECD).

3. *Magnitude of residues.* A food/feed handling establishment study conducted at the maximum label rate for all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments show that the proposed zeta-cypermethrin tolerance in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments at 0.05 ppm will not be exceeded when the zeta-cypermethrin product labeled for this use are used as directed.

B. Toxicological Profile

1. *Acute toxicity.* For the purposes of assessing acute dietary risk, FMC has used the NOEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats. The LOAEL 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.

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

vivo chromosomal aberration in rat bone marrow cells; *in vitro* cytogenic chromosome aberration; unscheduled DNA synthesis; CHO/HGPTT mutagen assay; weakly mutagenic: Gene mutation (Ames).

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

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

ii. A developmental study with zeta-cypermethrin in rats demonstrated a maternal NOEL of 12.5 mg/kg/day and a LOEL of 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 highest dose level tested.

iii. A developmental study with cypermethrin 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*. Short- and intermediate-term toxicity (incidental oral exposure). The NOEL of 10.0 mg/kg/day based on clinical signs at the LEL of 50.0 mg/kg/day in the zeta-cypermethrin acute neurotoxicity study in rats would also be used for short-term %aPAD and MOE calculations (as well as acute, discussed in (1) above), and the NOEL of 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) of 0.06 mg/kg/day for zeta-cypermethrin is based on a NOEL of 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an uncertainty factor 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 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 zeta-cypermethrin, FMC has used the NOEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats with an uncertainty factor (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 acute Population Adjusted Dose (%aPAD) all fall below the EPA's level of concern (≥100%). The 95th percentile of exposure for the overall U. S. population was estimated to be 0.001177 mg/kg/day (%aRfD of 1.2); 99th percentile 0.003307 mg/kg/day (%aRfD of 3.3); and 99.9th percentile 0.012692 mg/kg/day (%aRfD of 12.7). The 95th percentile of exposure for all infants <1 year old was estimated to be 0.002441 mg/kg/day (%aRfD of 2.4); 99th percentile 0.011178 mg/kg/day (%aRfD of 11.2); and 99.9th percentile 0.029462 mg/kg/day (%aRfD of 29.5). The 95th percentile of exposure for nursing infants <1 year old was estimated to be 0.001247 mg/kg/day (%aRfD of 1.3); 99th percentile 0.004540 mg/kg/day (%aRfD of 4.5); and 99.9th percentile 0.011659 mg/kg/day (%aRfD of 11.7). The 95th percentile of exposure for non-nursing infants <1 year old (the most highly exposed population subgroup) was estimated to be 0.002786 mg/kg/day (%aRfD of 2.8); 99th percentile 0.012899 mg/kg/day (%aRfD of 12.9); and 99.9th percentile 0.033071 mg/kg/day (%aRfD of 33.1). The 95th percentile of exposure for children 1 to 6 years old and children 7 to 12 years old was estimated to be, respectively, 0.001942 mg/kg/day (%aRfD of 1.9) and 0.001244 mg/kg/day (%aRfD of 1.2); 99th percentile 0.005670 mg/kg/day (%aRfD of 5.7) and 0.003082 (%aRfD of 3.1); and 99.9th percentile 0.018280 mg/kg/day (%aRfD of 18.3) and 0.009335 (%aRfD of 9.3). The 95th percentile of exposure for females (13+/nursing) was estimated to be 0.001128 mg/kg/day (%aRfD of 1.1); 99th percentile 0.003112 mg/kg/day (%aRfD of 3.1); and 99.9th percentile 0.012903 mg/kg/day (%aRfD of 12.9). Therefore, FMC 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 and risk*. The chronic reference dose (cRfD) of 0.06 mg/kg/day for zeta-cypermethrin is based on a NOEL of 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an uncertainty factor 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 cRfD. 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 body weight (bwt)/day and utilize 0.3 percent of the cRfD for the overall U. S. population. The ARC for non-nursing infants (<1 year) (subgroup most highly exposed) are estimated to be 0.000666 mg/kg bwt/day and utilizes 1.1 percent of the cRfD, respectively. The ARC for children 1-6 years old and children 7-12 years old are estimated to be 0.000477 mg/kg bwt/day and 0.000254 mg/kg bwt/day and utilizes 0.8 percent and 0.4 percent of the cRfD, respectively. The ARC for females (13+/nursing) is estimated to be 0.000180 mg/kg bwt/day and utilizes 0.3 percent of the RfD. 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 cRfD. Therefore, FMC 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 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. Drinking water estimated concentrations (DWEC) 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 DWEC values. Thus, exposure to zetacypermethrin and cypermethrin residues in drinking water is not of concern.

US 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 FQPA Index Reservoir Screening Tool (FIRST), PRZM/EXAMS, SCIGROW and monitoring data. If monitoring data are 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 Drinking Water Level of Comparison (DWLOC) value to the Drinking Water Estimated Concentration (DWEC) value. The DWEC value results from either the monitoring data residues or modeled water residues. If the DWLOC value exceeds the DWEC 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: The DWLOC and the DWEC. The DWLOC is the drinking water level of comparison. This is the maximum allowable drinking water concentration (in ppb). The DWEC is the drinking water environmental concentration, which is derived either from monitoring studies or from modeling. If the DWLOC is greater than the DWEC, 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 DWEC surface water residues. Therefore, there is reasonable certainty that no harm will result from cumulative and aggregate (food and water) exposure to cypermethrin and zetacypermethrin 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 intends to submit information for the 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 Food Quality Protection Act.

E. Safety Determination

1. *U. S. population*. The chronic reference dose (cRfD) of 0.06 mg/kg/day for zeta-cypermethrin is based on a NOEL of 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an uncertainty factor 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 cRfD. 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 body weight (bwt)/day and utilize 0.3 percent of the cRfD for the overall U. S. population. The ARC for non-nursing infants (<1 year) (subgroup most highly exposed) are estimated to be 0.000666 mg/kg bwt/day and utilizes 1.1 percent of the cRfD, respectively. The ARC for children 1-6 years old and children 7-12 years old are estimated to be 0.000477 mg/kg bwt/day and 0.000254 mg/kg bwt/day and utilizes 0.8 percent and 0.4 percent of the cRfD, respectively. The ARC for females (13+/nursing) is estimated to be 0.000180 mg/kg bwt/day and utilizes 0.3 percent of the RfD. 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 cRfD. Therefore, FMC 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 one day or single exposure. For the purposes of assessing acute dietary risk for zeta-cypermethrin, FMC has used the NOEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats with an uncertainty factor (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 acute Population Adjusted Dose (%aPAD) all fall below the EPA's level of concern (≥100%). The 95th percentile of exposure for the overall U. S. population was estimated to be 0.001177 mg/kg/day (%aRfD of 1.2); 99th percentile 0.003307 mg/kg/day (%aRfD of 3.3); and 99.9th percentile 0.012692 mg/kg/day (%aRfD of 12.7). The 95th percentile of exposure for all infants <1 year old was estimated to be 0.002441 mg/kg/day (%aRfD of 2.4); 99th percentile 0.011178 mg/kg/day (%aRfD of 11.2); and 99.9th percentile 0.029462 mg/kg/day (%aRfD of 29.5). The 95th percentile of exposure for nursing infants <1 year old was estimated to be 0.001247 mg/kg/day (%aRfD of 1.3); 99th percentile 0.004540 mg/kg/day (%aRfD of 4.5); and 99.9th percentile 0.011659 mg/kg/day (%aRfD of 11.7). The 95th percentile of exposure for non-nursing infants <1 year old (the most highly exposed population subgroup) was estimated to be 0.002786 mg/kg/day (%aRfD of 2.8); 99th percentile 0.012899 mg/kg/day (%aRfD of 12.9); and 99.9th percentile 0.033071 mg/kg/day (%aRfD of 33.1). The 95th percentile of exposure for children 1 to 6 years old and children 7 to 12 years old was estimated to be, respectively, 0.001942 mg/kg/day (%aRfD of 1.9) and 0.001244 mg/kg/day (%aRfD of 1.2); 99th percentile 0.005670 mg/kg/day (%aRfD of 5.7) and 0.003082 (%aRfD of 3.1); and 99.9th percentile 0.018280 mg/kg/day (%aRfD of 18.3) and 0.009335 (%aRfD of 9.3). The 95th percentile of exposure for females (13+/nursing) was estimated to be 0.001128 mg/kg/day (%aRfD of 1.1); 99th percentile 0.003112 mg/kg/day (%aRfD of 3.1); and 99.9th percentile 0.012903 mg/kg/day (%aRfD of 12.9). Therefore, FMC 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 considered data from developmental toxicity studies in the rat and rabbit, and a two-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 reproductiveility 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 thresholdeffects to account for pre- and post-natal toxicity and the completeness of the database.

ii. *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 (35.0 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 12.5 mg/kg/day in rats and 100 mg/kg/day in rabbits.

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

iv. *Pre- and post-natal sensitivity*— a. *Pre-natal*. There was no evidence of developmental toxicity in the studies at the highest doses tested 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 wouldrequire an additional safety factor.

b. *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.

3. Conclusion

Based on the above, FMC concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children. As stated above, aggregate exposure assessments utilized 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, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cypermethrin residues.

4. International Tolerances

There are no Canadian, or Mexican residue limits for residues of cypermethrin or zeta-cypermethrin in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0052; FRL–7703–3]

Bacillus Thuringiensis VIP3A Insect Control Protein and the Genetic Material Necessary for its Production; Notice of Filing a Pesticide Petition to Amend an Exemption from the Requirement of a Tolerance for a Certain Pesticide Chemical in or on Food; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces a correction to the Notice of Filing of a pesticide petition proposing an amendment to an existing exemption from the requirement of a tolerance for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0052, must be received on or before April 15, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION** of the September 15, 2004, **Federal Register** Notice.

FOR FURTHER INFORMATION CONTACT: Sharlene Matten, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0514; e-mail address: *matten.sharlene@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the September 15, 2004, Notice of Filing a list of those who may be potentially affected by the action. If you have any questions regarding the applicability of this action to a particular entity, consult