

Rocky Ridge Road, Lovell, ME 04051.
Product name: Leg Up Coyote Urine.
Type of product: Repellent. *Active ingredient:* Coyote Urine at 97.0%.
Proposed classification/Use: Animal repellent.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: June 14, 2005.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 05-12200 Filed 6-21-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0105; FRL-7710-1]

Fenpropimorph; 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 reannounces the 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-2005-0105, must be received on or before July 22, 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: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are 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-2005-0105. 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-2005-0105. 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-2005-0105. 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-2005-0105.

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-2005-0105. 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: May 27, 2005.

Betty Shackelford,

Acting 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.

BASF Corporation

PP 7E4874

EPA has received a pesticide petition (PP 7E4874) from BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528, 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 fenpropimorph, (+)-cis-4-(3-((4-tert-butylphenyl))-2-methylpropyl)-2,6-dimethylmorpholine in or on the raw agricultural commodity banana at 1.5 parts per million (ppm) of which no more than 0.3 ppm is found in the pulp. This petition was previously published in the **Federal Register** on December 7, 1998 (63 FR 67476) (FRL-6047-2), identified by the docket control number PF-848. 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 results of the banana metabolism study indicate that fenpropimorph constitutes the total toxic residue. All other significant portions of the total radioactive residue are due to natural products, predominately carbohydrates. Therefore, for regulatory purposes, the residue of concern determined by the analytical method consists only of fenpropimorph.

2. *Analytical method.* The method of analysis includes extraction, liquid/liquid partition, column clean-up, and quantitation by gas chromatography/nitrogen-phosphorus detector. The overall fortification recoveries from the unpeeled, whole banana, and the peeled (pulp) samples together averaged 87.1% $\pm$ 9.3% (N=76).

3. *Magnitude of residues.* Fifteen crop residue trials were conducted in the banana growing regions of Mexico, South and Central America including three sites in Colombia, four sites in Costa Rica, four sites in Ecuador, one site in Guatemala, two sites in Honduras, and one site in Mexico. Four sequential applications were made at the target rate of 545 gram/hectares (g/ha) to both bagged and unbagged bananas at each site. Fruit from both the bagged and unbagged treatments were

harvested at 0 days following the last application.

Whole fruit (peel and pulp) samples and pulp only samples were analyzed for all treatments at all sites. Under typical practices, bagged banana residues in the whole fruit ranged from the limit of quantitation (LOQ) 0.050 milligrams/kilogram (mg/kg) to a maximum of 0.4 mg/kg. Banana pulp residues from bagged bananas ranged from the < LOQ (0.050 mg/kg to 0.20 mg/kg and averaged 0.0518 mg/kg). The average value was calculated by assuming all values below the LOQ were equal to one-half the < LOQ or 0.025 mg/kg. Under worst-case practices, unbagged bananas residues in the whole fruit ranged from < the LOQ (0.050 mg/kg to a maximum of 1.4 mg/kg). Banana pulp residues from unbagged bananas ranged from < the LOQ (0.050 mg/kg to 0.43 mg/kg and averaged 0.1149 mg/kg). The average value was calculated by assuming all values below the LOQ were equal to one-half the LOQ or 0.025 mg/kg.

B. Toxicological Profile

Based on review of the available data, BASF believes the reference dose (RfD) for fenpropimorph will be based on a 2-year feeding study in rats with a threshold no observed adverse effect level (NOAEL) of 0.3 milligrams/kilogram/day (mg/kg/day). Using an uncertainty factor of 100, the RfD is calculated to be 0.003 mg/kg/day. A summary of the available mammalian toxicology data is given in the following sections.

1. *Acute toxicity.* Based on available acute toxicity data, fenpropimorph does not pose any acute toxicity risks. These studies are not required for an import tolerance, but we have provided the following information to demonstrate that fenpropimorph is not an acute toxicant. The acute toxicity studies place technical fenpropimorph in acute toxicity category III for acute oral, dermal, inhalation, and skin irritation; and in acute toxicity category IV for eye irritation and the technical material is not a skin sensitizer.

2. *Genotoxicity.* The following genotoxicity tests were performed with fenpropimorph: A modified Ames Test (2 studies; point mutation) - Negative; *In Vitro* CHO/HPRT Mammalian Cell Mutation Assay (1 study; point mutation) - Negative; *In Vitro* Cytogenetic test in Chinese Hamster V79 cells (1 study; chromosome aberrations) - non-activated negative, activated equivocal; *In Vitro* Cytogenetics-Human lymphocytes (1 study; chromosome aberrations) - Negative; *In Vivo* Mouse Micronucleus Assay (2 studies;

chromosome aberrations) - Negative; *In Vitro* UDS Test Using Rat Hepatocytes (1 study; DNA damage and repair): Negative; *In Vivo* dominant lethal test in mice (1 study; chromosome aberrations in germ cells) - Negative. Fenpropimorph has been tested in a total of nine genetic toxicology assays. These assays were performed both *in vitro* and *in vivo*. The weight of the evidence from these nine studies indicates that fenpropimorph is not genotoxic.

3. *Reproductive and developmental toxicity* — i. A developmental prenatal toxicity study was conducted via oral gavage in rats at doses of 0, 2.5, 10, 40, and 160 mg/kg/day from day 6 to 15 of gestation with a developmental toxicity NOAEL of 40 mg/kg/day and a maternal toxicity NOAEL of 10 mg/kg/day based on the following: (a) Signs of maternal toxicity, in the form of decreased body weights (bwt) and/or clinical signs observed at dose levels > 40 mg/kg/day; (b) maternal animals in the 160 mg/kg/day dose group showed an increased incidence of vaginal bleeding from day 10 to 19 of gestation and increased placental weight; (c) maternal animals in the 160 mg/kg/day dose group showed an increase in the number of resorptions as compared to controls; (d) decreases in fetal body weights and size and number of viable fetus were observed at 160 milligrams/kilogram body weight/day (mg/kg bwt/day); (e) a significant number of fetuses had a finding of cleft palate at 160 mg/kg bwt/day; and (f) litters from animals treated at the lower doses remained entirely unaffected.

ii. A perinatal developmental toxicity study was conducted via oral gavage in rats at doses of 0, 2.5, 10, 40, and 160 mg/kg/day from gestation day 15 to day 21 post partum with a developmental and maternal toxicity NOAEL of 40 mg/kg/day based on the following: (a) Four high dose maternal animals died on days 1 to 6 after delivery; (b) signs of maternal toxicity, in the form of decreased body weight and/or clinical signs observed at the top dose level; (c) at birth, body weight was significantly reduced in the pups of the top dose group; (d) the brood care at the top dose group animals was generally unsatisfactory and led to a high perinatal mortality of the fetuses with only 30 viable fetuses left on day 1 post partum, the dead fetuses showed no increased incidence of malformations; (e) the few surviving pups of the dams at the 160 mg/kg/day dose group showed decreases in fetal body weight and size was retarded, no disturbances were found in the functional and behavioral tests that were conducted on

the surviving pups; (f) at necropsy, all dams showed comparable number of implantations and the animals sacrificed as scheduled revealed no treatment-related changes and also the mean organ weights were similar in treated and untreated groups; and (g) litters from animals treated at the lower doses remained entirely unaffected and no pathological findings were also noted in these pups.

iii. A series of two developmental toxicity studies were conducted via gavage with rabbits. In the first study, rabbits were treated at dose levels of 0, 2.4, 12, 36, and 60 mg/kg/day and in the second study the dose levels were 0, 7.5, 15, and 30 mg/kg/day. Considering both studies, the maternal and developmental toxicity NOAEL's were 15 mg/kg/day based on the following: (a) Severe clinical signs and/or mortality were observed at dose levels > 30 mg/kg/day; (b) decreased body weight, food consumption, and absorption/premature delivery in the 36 and 60 mg/kg/day dose groups which survived to the end of the studies; (c) fetal effects consisted of a high number of dead fetuses and several gross malformations (pseudo ancylosis, syndactylia, micromelia, aplasia of the twelfth rib) at the highest dose tested; and (d) pseudo ancylosis was also seen in 1 fetus from the 12 mg/kg/day dose group and in 6 fetuses in the 36 mg/kg/day dose level, but this finding is known to occur spontaneously in rabbits of this strain used and the contractures usually normalize during early stages of life. Due to the severe maternal effect at the high dose level (HDL), these effects were not considered to represent a specific teratogenic effect of the treatment.

iv. A 2-generation reproduction study was conducted with rats fed dosages of 0, 0.625, 1.25, and 2.5 mg/kg/day average mg/kg/day dose levels for both male and female rats with a reproductive NOAEL of 2.5 mg/kg/day and with a parental NOAEL of 2.5 mg/kg/day based on: (a) Significant body weight changes in adults; (b) no effects were observed on parameters of fertility and gestation, or macro- or histopathological changes for the parental F₀ and F₁ animals at all dose levels tested; (c) in the F₁ litters, a slight increased incidence of stillborn pups, unfolding of the ear, and slight reduced body weight development during lactation were observed in the 2.5 mg/kg/day dose level group, but this was not reproduced in the F₂ litters; and (d) in the F₂ litters, no treatment-related effects were observed at all dose levels tested.

4. *Subchronic toxicity.* The short-term toxicity of fenpropimorph was

investigated in an oral 28-day range-finding study in rats as well as in 3-month studies in rats and dogs. In addition, the short-term toxicity following dermal exposure was determined in a 21-day study in rabbits and the short-term inhalation toxicity was studied in a 28-day inhalation study in rats.

The signs of toxicity observed in rats and dogs tested orally were overall similar with the liver as the target organ. The effects observed typically included the increase in one or more serum liver enzymes, changes in cholesterol and increased liver weight. No pathological changes were observed in any organ. Plasma cholinesterase was decreased in the highest doses tested in rats. Brain and RBC cholinesterase were unaffected by treatment.

Severe dermal irritation with repeated dosing limited the highest dose tested for 3 weeks in rabbits to 8.5 mg/kg bwt/day. No substance-related systemic findings were detected up to the highest dose. Rats were exposed via inhalation for 28 days at concentrations up to 160 mg/m³. The NOAEL was determined to be 10 mg/m³ based on serum liver enzyme and cholesterol changes and reduced plasma cholinesterase at higher concentrations.

5. *Chronic toxicity* —i. A combined chronic feeding/oncogenicity study was performed in rats being fed doses of 0, 0.2, 0.3, 1.7, and 8.8 mg/kg/day (males) and 0, 0.2, 0.4, 2.1, and 11.2 mg/kg/day (females) with a NOAEL of 0.3 mg/kg/day (males) and 0.4 mg/kg/day (females) based on the following effects: (a) Decreased body weights were observed in both male and female rats at dose levels > 1.7 mg/kg/day; (b) decreased food consumption in female rats at the 11.2 mg/kg/day; (c) significantly lower activities of plasma cholinesterase were noted in male and female rats in the high dose whereas no effect was found for red blood cell and brain cholinesterase values; (d) at terminal sacrifice, reduced activities of brain cholinesterase were detected in males, only, at the 1.7 and 8.8 mg/kg/day dose levels groups tested; (e) increased liver weights for females at dose levels > 2.1 mg/kg/day and in males of the top dose group; (f) microscopic findings were observed in the liver of male and female rats in both sexes of the two highest dose groups consisting of enlargement of the centriobular hepatocytes and increased incidences of multinucleate hepatocytes; and (g) no increased incidence of neoplasms occurred at any dose levels tested in this study.

ii. A carcinogenicity study in mice fed doses of 0, 0.5, 3.0, 16, and 106 mg/kg/day (males) and 0, 0.5, 3.5, 17, and 118

HDT mg/kg/day (females) with a NOAEL of 3.0 and 3.5 mg/kg/day for male and female mice, respectively, based on the following effects: (a) Decreased body weights were observed with no effect on food consumption in both male and female mice at the highest dose tested; (b) decreased cholinesterase activities were observed in red blood cells for female mice in the 17 and 118 mg/kg/day dose level tested at terminal sacrifice; (c) at the high dose, increased liver weights were observed for female mice at terminal sacrifice and in males at interim sacrifice after 52 weeks; and (d) no increased incidence of neoplasms occurred at any dose levels tested in this study.

iii. A 1 year feeding study in dogs fed doses of 0, 0.8, 3.2, or 12.7 mg/kg/day with a NOAEL of 3.2 mg/kg/day based on the following effects: (a) No changes in body weights nor food consumption for both the high dose male and female dogs were observed at all tested dose levels as compared to controls; (b) blood biochemistry values were slightly increased in high dose males (alkaline phosphatase) and females (alanine aminotransferase); (c) the cholinesterase from plasma, red blood cells, and brain showed comparable activities in treated and untreated dogs; and (d) neither organ weight analyses nor macro- and histopathological examinations demonstrated any treatment-related effects as compared to controls.

6. *Animal metabolism.* Fenpropimorph was well absorbed orally (>90%) and extensively metabolized by rats. Excretion was rapid (plasma half-life of 16–24 hours) occurring by urine and bile. By 48 hours after treatment, essentially all of the administered dose was eliminated by all routes. Levels in tissues were small and rapidly declined, and there was no evidence for a bioaccumulation potential. Fenpropimorph was eliminated exclusively in the form of metabolites. Significant amounts of the metabolites were in conjugated form.

7. *Metabolite toxicology.* There were no metabolites identified in plant commodities which require regulation.

8. *Endocrine disruption.* No specific tests have been performed with fenpropimorph to determine whether the chemical may have an effect in humans that is similar to an effect produced by naturally occurring estrogen or other endocrine effects. However, there are significant findings in other relevant toxicity studies, i.e., teratology, and multi-generation reproductive studies, that would suggest fenpropimorph produces endocrine-related effects.

C. Aggregate Exposure

1. *Dietary exposure.* A dietary assessment was conducted to evaluate the potential risk due to chronic dietary exposure of the U.S. population and all sub-populations to residues of fenpropimorph. Fenpropimorph is not registered in the United States so no tolerances have previously been established.

This dietary analysis was conducted to evaluate the proposed import tolerance for banana pulp at 0.3 ppm. The dietary assessment was conducted using tolerance level residues, default processing factors, and 100% crop treated factors. These assumptions are conservative because it assumes all bananas imported into the United States will be at tolerance level and 100% of all the import bananas will have been treated with fenpropimorph. Inadvertent residues in animal commodities (i.e., meat, meat byproducts, milk, eggs) were not considered because imported bananas will not be used as an animal feed commodity.

i. *Food.* Acute dietary exposure assessment for fenpropimorph. BASF believes there is no concern regarding acute dietary risk since the available toxicity data do not indicate any evidence of significant toxicity from a 1 day or single, event exposure by the oral route.

ii. *Chronic dietary exposure assessment.* A chronic assessment was conducted for all subpopulations. The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with Food Commodity Intake Database (DEEM-FCID). The chronic population adjusted dose (cPAD) used for all subpopulations was 0.003 mg/kg bwt/day. Using the exposure assumptions discussed above, fenpropimorph chronic dietary exposure from food is less than 19% cPAD for all subpopulations. The most highly exposed subpopulation was children 1-2 years old and utilized 18.4 % of the cPAD. The results of the chronic dietary assessment are presented in Table 1.

TABLE 1.— SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR FENPROPIMORPH.

Population Subgroups	Exposure Estimate (mg/kg bw/day)	%cPAD
U.S. population	0.0001140	3.8

TABLE 1.— SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR FENPROPIMORPH.—Continued

Population Subgroups	Exposure Estimate (mg/kg bw/day)	%cPAD
All Infants	0.0004320	14.4
Children (1-2 years)	0.0005520	18.4
Children (3-5 years)	0.0002880	9.6
Children (6-12 years)	0.0001200	4.0
Females (13-19 years)	0.0000720	2.4
Youth (13-19 years)	0.0000480	1.6

Results of the chronic dietary exposure analysis demonstrate a reasonable certainty that no harm to the general U.S. population or any subpopulation would result from importing bananas treated with fenpropimorph.

iii. *Drinking water.* Fenpropimorph is not registered for use within the United States and therefore exposure through drinking water will not occur.

An aggregate exposure assessment for fenpropimorph is not needed because the only exposure to fenpropimorph will occur from the dietary food route. Fenpropimorph is not registered within the United States for any uses. The dietary assessment conducted above demonstrates that there are no safety concerns for any subpopulation, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

2. *Non-dietary exposure.* Fenpropimorph is not registered for use within the United States. Thus, residential exposure is not possible.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Results for toxicity studies indicate that toxic effects produced by fenpropimorph would not be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population.* Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to the general population from the aggregate exposure to fenpropimorph residues.

2. *Infants and children.* Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants or children from the aggregate exposure to fenpropimorph.

F. International Tolerances

A maximum residue level has not been established under Codex Alimentarius Commission for fenpropimorph in bananas.

[FR Doc. 05-12079 Filed 6-21-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0032; FRL-7718-7]

Propazine; 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-2005-0032, must be received on or before July 22, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5697; e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or