establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures. Through FOSTTA, the Chemical Information and Management Project (CIMP) focuses on EPA's chemical program and works to develop a more coordinated effort involving Federal, State, and Tribal agencies. The Pollution Prevention Project (P2) promotes the prevention ethic across society, helping companies incorporate P2 approaches and techniques and integrating P2 into mainstream environmental activities at both the Federal level and among the States and Tribes. The Tribal Affairs Project (TAP) concentrates on chemical and prevention issues that are most relevant to the Tribes, including lead control and abatement, Tribal traditional/subsistence lifeways, and hazard communications and outreach. FOSTTA's vision is to focus on major policy-level issues of importance to States and Tribes, recruit more senior State and Tribal leaders, increase outreach to all 50 States and some 560 federally recognized Tribes, and vigorously seek ways to engage the States and Tribes in ongoing substantive discussions on complex and oftentimes controversial environmental issues.

In January 2002, the Environmental Council of the States (ECOS), in cooperation with the National Tribal Environmental Council (NTEC), was awarded the new FOSTTA cooperative agreement. ECOS, NTEC, and EPA's Office of Pollution Prevention and Toxics (OPPT) are co-sponsoring the meeting. As part of a cooperative agreement, ECOS facilitates ongoing efforts of the State and Tribal leaders and OPPT to increase understanding and improve collaboration on toxic chemicals and pollution prevention issues, and to continue a dialogue on how Federal environmental programs can best be implemented among the States, Tribes, and EPA.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to the technical person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered Confidential Business Information. Requests to participate in the meeting, identified by docket ID number OPPT–2004–078, must be received on or before March 18, 2004.

IV. The Meeting

In the interest of time and efficiency, the meetings are structured to provide maximum opportunity for State, Tribal, and EPA participants to discuss items on the predetermined agenda. At the discretion of the chair, an effort will be made to accommodate participation by observers attending the proceedings. The FOSTTA representatives and EPA will collaborate on environmental protection and pollution prevention issues. The tentative agenda items identified by the States and the Tribes follow:

1. Federal budget process (TAP).
2. Pollution prevention activities (TAP).
3. Discussion on HPV challenge data base and demonstration (CIMP).
4. Joint session with TAP/CIMP to increase State and Tribal involvement (CIMP).
5. Connecting P2 with measurable results (P2).
6. P2 in schools (P2).

List of Subjects

Environmental protection, Pollution prevention, Chemical information and management.

Dated: March 3, 2004.

Barbara A. Cunningham,

Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics.

[FR Doc. 04–5373 Filed 3–9–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0414; FRL–7340–7]

Propamocarb Hydrochloride; 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–2003–0414, must be received on or before April 9, 2004.

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 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–2003–0414. 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, 1921 Jefferson Davis Hwy., 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 EPA's 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–2003–0414. 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–2003–0414. 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–2003–0414.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0414. 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 27, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's 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.

Bayer CropScience

PP 0F6123

EPA has received a pesticide petition (0F6123) from Bayer CropScience, 2TW Alexander Drive, Research Triangle Park, NC 27709, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.499 by establishing a tolerance for residues of propyl [3-(dimethylamino)propyl]carbamate mono-hydrochloride, also known as propamocarb hydrochloride, in or on the raw agricultural commodities (RACs) lettuce, leaf, at 65 parts per million (ppm), lettuce, head, at 50 ppm, wheat, grain, at 0.05 ppm, wheat, straw, at 0.10 ppm, wheat, forage, at 0.30 ppm, wheat, hay, at 0.30 ppm, vegetable, cucurbit, group 9, at 1.5 ppm, vegetable, fruiting, group 8, at 2.0 ppm, and tomato, paste, at 5.0 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 fate of propamocarb hydrochloride in plants is clearly understood. Metabolism studies in cucumbers, potatoes, and spinach demonstrated that propamocarb hydrochloride is degraded into carbon dioxide, which is reincorporated into natural plant constituents. The primary residue found in all crops, and the only residue of concern, is the parent, propamocarb hydrochloride.

2. *Analytical method.* A practical analytical method utilizing gas/liquid chromatography (GLC) and flame ionization detector *N*-(FID) or mass spectrometry detection (MSD) is available and has been validated for detecting and measuring levels of propamocarb hydrochloride in or on food. The limit of quantification (LOQ) is 0.05 milligrams/kilogram (mg/kg) (ppm).

3. *Magnitude of residues.* Residue trials have been conducted with representative applications of propamocarb hydrochloride formulations to lettuce, cucurbits, tomatoes, and peppers. In all cases, the proposed tolerances are based upon the highest residues seen at the maximum rate, minimum application interval, and minimum pre-harvest interval utilized in the studies.

For lettuce, leaf, a proposed pre-harvest interval of 2 days and tolerance of 65 ppm is proposed. For lettuce, head, a pre-harvest interval of 2 days and tolerance of 50 ppm is proposed. For vegetables, cucurbits, a proposed pre-harvest interval of 2 days and tolerance of 1.5 ppm is proposed. For vegetables, fruiting, a pre-harvest interval of 5 days and tolerance of 2.0 ppm is proposed. Based on a tomato processing study, a tolerance of 5.0 ppm is proposed for tomato paste. No tolerance is proposed for tomato, puree, because the residue in this commodity is anticipated to be less than or equal to the proposed crop group tolerance.

In the field rotational crop study, residues were present only in wheat rotated 30 days after the last propamocarb hydrochloride treatment. There were no residues in sugar or table beets, soybeans, or dried beans. Based upon the results of this study, and in conjunction with recent section 18 emergency exemptions, EPA proposed time-limited tolerances for wheat grain at 0.05 ppm (the LOQ of the analytical method), wheat straw at 0.1 ppm, and wheat forage and hay at 0.3 ppm.

B. Toxicological Profile

Much of the toxicological database supporting the registration of propamocarb hydrochloride has been evaluated by EPA as part of previous regulatory actions and is summarized below. The conclusions presented are those determined by the Agency as reported by the registrant. Additional studies have been submitted to the Agency and are awaiting review. Those studies' results are summarized below by the registrant.

1. *Acute toxicity.* There are no acute toxicity concerns with propamocarb hydrochloride. The acute rat oral lethal dose $(LD)_{50}$ was 2,900 mg/kg in males and 2,000 mg/kg in females. The acute rat dermal $(LD)_{50}$ was >3,000 mg/kg. The acute (4–hour) inhalation lethal

concentration $(LC)_{50}$ in rats was >5.54 milligrams/Liter (mg/L). Propamocarb hydrochloride was a slight skin sensitizer in guinea pigs. Propamocarb hydrochloride was previously classified as toxicity category III for acute oral and dermal toxicity and eye irritation, and category IV for acute inhalation toxicity and skin irritation.

An acute neurotoxicity study was performed in rats at dose levels of 0, 20, 200, and 2,000 mg/kg of propamocarb hydrochloride. The overall no observed adverse effect level (NOAEL) for this study was determined to be 200 mg/kg based on decreased weight gain, soiled fur and decreased motor activity in males and/or females at 2,000 mg/kg.

2. *Genotoxicity*. No evidence of genotoxicity was observed in a battery of studies including *Salmonella* and *E. coli* gene mutation assays, two mouse micronucleus assays, an *in vitro* mammalian cytogenetic assay using cultured human lymphocytes, a yeast mitotic gene conversion assay and a yeast mitotic recombination assay.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study, rats were administered propamocarb hydrochloride by gavage at dose levels of 0, 74, 221, 740, or 2,210 mg/kg/day on gestation days 6–19. The NOAEL for maternal toxicity was 740 mg/kg/day based on mortality, clinical observations and decreased body weight gain at 221 mg/kg/day. The NOAEL for developmental toxicity was 221 mg/kg/day based on increased post-implantation loss, decreased fetal weights and increased incidence of minor skeletal anomalies (retarded ossification) at 740 and/or 2,210 mg/kg/day.

In another developmental toxicity study, rabbits were administered propamocarb hydrochloride by gavage at dose levels of 0, 15, 45, 150, 300, or 600 mg/kg/day on gestation days 6–18. The NOAEL for both maternal toxicity and developmental toxicity was 150 mg/kg/day, based on decreased maternal body weight gain and increased post-implantation loss at 300 mg/kg/day.

A 3–generation reproduction study was conducted using rats fed diets containing propamocarb hydrochloride at dietary concentrations of 0, 40, 200, and 1,000 ppm (33.3 mg/kg/day) for 100 days and then continuously through three successive generations. No treatment-related effects were noted on either the parents or offspring.

A 2–generation reproduction study was conducted with albino rats. Animals received propamocarb hydrochloride at dietary concentrations of 0, 200, 1,250 and 8,000 ppm. Reduced body weights were observed in the F0 and F1 parental animals and the F1 and F2 offspring at 8,000 ppm. Based on these findings, the NOAEL is 1,250 ppm for parental and neonatal toxicity (81 mg/kg/day for males and 127 mg/kg/day for females) and 8,000 ppm for reproductive toxicity.

4. *Subchronic toxicity*. In a 90–day feeding study, propamocarb hydrochloride was administered to albino rats at concentrations of 0, 20, 50, 100, and 500/1,000 ppm. (The high dose rate was 500 ppm when the study was begun, but was raised to 1,000 ppm during the course of the study) in the diet. The only effects noted were slightly reduced food efficiency and body weight gains at 1,000 ppm.

In a 90–day feeding study in Beagle dogs, propamocarb hydrochloride was administered in the diet at concentrations of 0, 50, 100, 500, and 1,000/2,000 ppm. (The high dose rate was 1,000 ppm when the study was begun, but was raised to 2,000 ppm during the course of the study). No treatment-related findings were observed.

In a 90–day feeding study with albino mice, propamocarb hydrochloride was administered at concentrations of 0, 1,404, 2,808, 5,616 and 11,232 ppm in the diet. No treatment-related findings were observed.

A 21–day dermal toxicity study was performed with propamocarb hydrochloride in Sprague-Dawley rats at dose levels of 0, 100, 500, and 1,000 mg/kg/day, 6 hours per day, 5 days per week over a 21–day period. No treatment related effects were observed.

A 21–day dermal toxicity study was performed with propamocarb hydrochloride in rabbits at dose levels of 0, 150, 525, and 1,500 mg/kg/day, 6 hours per day, 5 days per week, over a 21–day period. The NOAEL for this study was considered by the Agency to be 150 mg/kg/day based on dose-related skin irritation in mid-dose and high-dose animals and a decrease in weight gain in mid-dose females.

A 90–day neurotoxicity study was conducted in rats at dietary concentrations of propamocarb hydrochloride of 0, 200, 2,000, and 20,000 ppm. No evidence of neurotoxicity (Functional Obervation Battery (FOB), motor activity or neuropathology) was observed at any dose level. Plasma, red blood cell (RBC) and brain cholinesterase levels were also not affected. The NOAEL was determined to be 2,000 ppm (142 mg/kg/day) based on decreased weight gain at 20,000 ppm.

5. *Chronic toxicity*. A 2–year feeding chronic toxicity/carcinogenicity study was performed in Sprague-Dawley rats with propamocarb hydrochloride at dietary concentrations of 0, 40, 200, or 1,000 ppm. There was no evidence of carcinogenicity or other treatment-related effects except for a possible reduction in food intake in female rats at the highest level tested. Thus, 1,000 ppm (41 mg/kg/day) was considered to be the NOAEL. However, this study did not satisfy the EPA's criteria for a maximum tolerated dose (MTD). In a second 2–year chronic toxicity/oncogenicity study, albino rats received diets containing propamocarb hydrochloride at concentrations of 0, 350, 2,800, and 22,400 ppm. Animals receiving 22,400 ppm exhibited decreased body weights, body weight gain and food consumption. Additionally, these animals revealed moderate vacuolation of the choroid plexus ependymal cells. There was no evidence of oncogenicity. Based on these findings, the NOAEL is 2,800 ppm (138 mg/kg/day).

A 2–year feeding chronic toxicity/carcinogenicity study was performed in CD–1 mice with propamocarb hydrochloride at dietary concentrations of 0, 20, 100, and 500 ppm. No evidence of carcinogenicity or toxicity was noted at any dose level. Thus, 1,000 ppm (53 mg/kg/day for males and females, respectively), was considered to be the NOAEL.

An 18–month mouse oncogenicity study was conducted in CD–1 mice exposed to propamocarb hydrochloride at dietary concentrations of 0, 105, 840, and 6,720 ppm. Reduced body weights were reported for animals in the 840 and 6,720 ppm groups. There was no evidence of oncogenicity. Based on these findings, the NOAEL is 105 ppm (16 mg/kg/day).

A 2–year feeding study was performed in Beagle dogs with propamocarb hydrochloride at dietary concentrations of 0, 1,000, 3,000, and 10,000 ppm. Decreased weight gain, decreased food efficiency, an increased incidence of acute gastric mucosal erosions, and/or chronic erosive gastritis were noted in all treated groups. Thus, a NOAEL for this study was not determined but was considered to be slightly lower than the lowest dose level tested (33.3 mg/kg/day, 1,000 ppm).

6. *Animal metabolism*. The absorption, distribution, metabolism, and excretion of propamocarb hydrochloride has been evaluated in rats. Propamocarb hydrochloride was rapidly absorbed, extensively metabolized, and rapidly eliminated, primarily via the urine (>90% excreted within 24 hours), following oral administration. Metabolite profiles were similar following single and repeated

oral dosing and following intravenous dosing. The primary route of metabolism was oxidative degradation with hydrolytic cleavage occurring as a secondary pathway.

The metabolism of propamocarb hydrochloride has been evaluated in ruminants. The majority of the orally administered dose was excreted via the urine and feces. Total radioactive residues in tissues and bile accounted for 0.7% of the administered dose. The majority of the residue was comprised of propamocarb hydrochloride plus *N*-oxide metabolite, an oxazolidine metabolite, and a 2–hydroxy metabolite.

7. *Endocrine disruption*. No special studies have been conducted to investigate the potential of propamocarb hydrochloride to induce estrogenic or other endocrine effects. However, the standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects yet no such effects were detected. Thus, the potential for propamocarb hydrochloride to produce any significant endocrine effects is considered to be minimal.

C. Aggregate Exposure

An aggregate exposure assessment was conducted in order to determine the total exposure for someone who would be exposed to propamocarb hydrochloride residues from both dietary and non-dietary routes. The only population subgroup of concern for residential use is females 13+, thus an aggregate assessment was conducted for this subgroup only. For the purpose of this petition only, a worst-case scenario was assumed wherein a female 13+ is exposed to an acute dietary dose (95th percentile of Tier I analysis) and enters a treated residential lawn on the same day (exposure assumptions described below). In practice, the aggregate assessment should not assume that ''worst-case'' exposures would occur simultaneously. Rather, the aggregate assessment should evaluate a realistic scenario incorporating the relative application times and use patterns (calendar-based model) along with a chronic dietary background exposure. This calendar-based model has not been used for this assessment. The aggregate methodology used here entails summation of all route-specific exposures assuming that they occur simultaneously. The dermal non-dietary exposure has been converted to oral equivalents using a dermal absorption factor. Thus the maximum aggregate exposure for a female 13+ to potential residues of propamocarb hydrochloride from food and non-dietary routes is at 11% (0.168 milligrams/kilogram of bodyweight per day (mg/kg bwt/day)) of the short-term reference dose (RfD) margin of exposure ((MOE)=891). Intermediate-term exposures would be even less. The drinking water level of comparison (DWLOC) based on this exposure value for females 13+ is 39,900 parts per billion (ppb) (39.9 ppb), still several orders of magnitude higher than the acute and chronic drinking water estimated concentrations (DWECs) described below.

1. *Dietary exposure*. Dietary exposure to propamocarb hydrochloride was estimated from residues expected on food and in drinking water.

i. *Food*. Potential dietary exposures from food were estimated using the dietary exposure evaluation model (DEEM) software system (Novigen Sciences, Inc.) and the 1994–1996 United States Department of Agriculture (USDA) consumption data. For the purposes of this assessment, Bayer CropScience has made the very conservative assumption that 100% of all commodities will contain propamocarb hydrochloride residues at the proposed and established tolerance levels. EPA has established a tolerance for propamocarb hydrochloride on potatoes of 0.06 ppm [65 FR 58399]. In the current petition the following tolerances are proposed: 2.0 ppm in fruiting vegetables and their respective processed commodities, except for 5.0 ppm in tomato paste; 1.5 ppm in cucurbits; 50 ppm in head lettuce; 65 ppm in leaf lettuce; 0.05 ppm in wheat grain; 0.1 ppm in wheat straw; and 0.3 ppm in wheat forage and hay. Results of the Tier I acute analysis for females 13+ show that 7% (0.0984 mg/kg body weight/day (bwt/day) of the acute RfD is utilized at the 95th percentile. This is a very conservative estimate and actual exposure is likely to be much less or negligible in real world situations. The Tier I chronic analysis results in 18% (0.0201 mg/kg bwt/day of the chronic RfD utilized for the U.S. population. The most highly exposed population subgroup is children 1 to 6 at 24% of the chronic RfD (0.0268 mg/kg bwt/day) consumed. As in the acute scenario these are very conservative estimates and actual exposures are likely to be much less as new data and models are developed.

ii. *Drinking water*. EPA's standard operating procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessments. These tools include water models such as screening concentration in ground water (SCI-GROW), generic expected environmental concentration (GENEEC), EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZMS/EXAMS), and monitoring data. If monitoring data is not available then the models are used to predict potential residues in surface water and ground water. In the case of propamocarb hydrochloride, monitoring data do not exist therefore SCI-GROW and PRZM/EXAMS were used to estimate water residues. The calculated drinking water level of comparison (DWLOC) for chronic and acute exposures for all adults and children exceed the DWEC from the models. The acute DWLOC for females 13+ (the only population of concern for acute exposure) is 42,000 ppb (42 ppb). The acute DWEC is 132 ppb for surface water. The chronic DWLOC for adults is 3,147 ppb. The chronic DWLOC for children/toddlers is 833 ppb. The surface water DWEC for the worst-case chronic scenario is 20 ppb.

2. *Non-dietary exposure*. Based on the labeled use patterns, a chronic exposure scenario does not exist. The endpoint of concern is short-term and intermediate-term dermal exposure to females 13+ only (based on post-implantation loss in the rabbit developmental toxicity study). The estimated dermal exposures are converted to oral equivalents using a dermal absorption factor. As a professional use turf and ornamental fungicide, propamocarb hydrochloride is used primarily (>90% of use) on golf courses for control of *Pythium* blight (BANOL Fungicide, EPA Reg. No. 45639–88). Some limited use of BANOL occurs on ornamental plants produced in greenhouses or containers, and to a very limited extent on sod farms or by professional lawn care applicators to commercial turf. No homeowner applicator exposures were assessed as the product is not sold to homeowners and only professional application would occur. There is the potential for residential post-application exposure to adults and children entering treated sites in recreational areas. No assessments for adult males and toddlers were done since the endpoint of concern is for females 13+ only. Using screening level conditions proposed in EPA's SOP for Residential Exposure Assessments (December 1997, EPA) and the proposed changes to the SOP (September, 1999, EPA), short-term exposure and risk were estimated for residential adult females. A dermal

absorption factor of 12% from a dermal penetration study in rats submitted by Bayer (MRID #44538505) was used. Based on the assumptions below and the default factors from the SOP, a MOE of 2,299 (Exp=0.07 mg/kg/day) is obtained for adult females. This is well above the level of concern (LOC) for propamocarb hydrochloride based on a MOE of 100. This analysis is a very conservative estimate based on EPA screening level procedures. Actual exposures are likely to be much lower, if they occur at all.

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.'' The precise mechanism of toxicity for propamocarb hydrochloride is unknown. Although a member of the carbamate group of pesticides, propamocarb hydrochloride is not an *n*-methyl carbamate, and demonstrated no inhibitory effects on blood or brain cholinesterase following either acute or repeated oral administrations to rats and dogs. *In vitro* studies using rat or dog blood plasma showed very slight cholinesterase inhibitory effects only at extremely high dose levels, equivalent to about 2,200 mg/kg bodyweight. This level is 20,000X the established RfD for propamocarb hydrochloride. Thus, no cumulative effects with other carbamates are anticipated. There is no other available data to determine whether propamocarb hydrochloride has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, propamocarb hydrochloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that propamocarb hydrochloride has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure to the proposed uses of propamocarb hydrochloride will utilize at most 18% of the chronic reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. The acute population of concern, female 13+ utilizes 7% of the acute RfD. Again, this is a Tier I highly conservative assessment and actual exposure is likely to be far less. A very conservative ''worst-case'' aggregate assessment for females 13+ results in utilization of 11% of the RfD. DWLOCs based on the dietary and aggregate exposures are greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food, drinking water, and non-dietary) to residues of propamocarb hydrochloride.

2. *Infants and children*. No treatment-related effects to either parental animals or offspring were noted in either a 3–generation rat reproduction study at dose levels up to 1,000 ppm (33.3 mg/kg/day) or a 2–generation rat reproduction study at dose levels up to 1,250 ppm (81 mg/kg/day in males, 127 mg/kg/day in females). No evidence of teratogenicity was noted in either rat or rabbit developmental toxicity studies, even at maternally toxic dose levels. Increased post-implantation loss was noted in the rabbit study, but only at maternally toxic dose levels. The NOAEL for both maternal and developmental toxicity in rabbits was 150 mg/kg/day.

Decreased fetal weights, increased post-implantation loss and retarded ossification were noted in rats, and the developmental NOAEL of 221 mg/kg/day was lower than the maternal NOAEL of 740 mg/kg/day.

FFDCA section 408 provides that the Agency may apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity or incompleteness of the database. The toxicology database for propamocarb hydrochloride regarding potential prenatal and postnatal effects in children is complete according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns, therefore an additional UF to protect infants and children is not needed. Using the conservative assumptions described in the exposure section above, the percent of the chronic RfD that will be used for exposure to residues of propamocarb hydrochloride in food for children 1 to 6 (the most highly exposed sub group) is 24%. Infants utilize 4% of the chronic RfD. There are no chronic non-dietary concerns for infants and children.

All DWLOCs are higher than the worst case DWECs and are expected to use well below 100% of the RfD. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of propamocarb hydrochloride.

F. International Tolerances

The Codex Alimentarius Commission (Codex) has established tolerances (maximum residue levels) for propamocarb hydrochloride in the following raw agricultural commodities: Beetroot at 0.2 ppm, brussel sprouts at 1.0 ppm, cabbage (head) at 0.1 ppm, cauliflower at 0.2 ppm, celery at 0.2 ppm, cucumber at 2.0 ppm, lettuce (head) at 10 ppm, pepper (sweet) at 1.0 ppm, radish at 5.0 ppm, strawberry at 0.1 ppm and tomato at 1.0 ppm.

[FR Doc. E4–464 Filed 3–9–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0055; FRL–7346–6]

Experimental Use Permit; Receipt of Amendment/Extension Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications 68467–EUP–7 and 29964–EUP–5 from Mycogen Seeds c/o Dow Agrosciences LLC and Pioneer Hi-Bred International requesting experimental use permit (EUP) amendment/extensions for *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17662) in corn. The Agency has determined that the applications may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on the applications.

DATES: Comments, identified by docket ID number OPP–2004–0055, must be received on or before April 9, 2004.

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**.