Dated: January 22, 2003.

Linda Vlier Moos,

Acting Director, Information Resources Services Division, Office of Pesticide Programs.

[FR Doc. 03–2772 Filed 2–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0081; FRL–7287–5]

Imidacloprid; Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0081, must be received on or before March 7, 2003.

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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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 categories and 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in OPP–2002–0081. 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 identification (ID) number OPP–2002–0081. 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 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. 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–2002–0081. 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–2002–0081. 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–2002–0081.

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–2002–0081. 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. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this notice.

8. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of 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 these petitions contain 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: January 24, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner's summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summaries of the petitions were prepared by Bayer Corporation and represents the view of the company. The petitions summaries announce 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. The Interregional Research Project No. 4 (IR–4) assembled and submitted the petitions to EPA on behave of the Bayer Corporation.

Interregional Research Project Number 4 and Bayer Corporation

PP 1E6268, PP 1E6254, PP 1E6237, PP 1E6225, PP 0E6203, PP 2E6403, PP 2E6406, PP 2E6409, PP 2E6417, PP 2E6421, PP 2E6435, PP 2E6414, PP 2E6458, and PP 2E6506

EPA has received pesticide petitions from the Interregional Research Project Number 4 (IR–4), Technology Centre and Rutgers State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.472 by establishing tolerances for the combined residues of imidacloprid, 1-(6-chloro-3-pyridinyl)methyl-*N*-nitro-2-imidazolidinimine, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on the raw agricultural commodities as follows:

1. PP 1E6268 proposes tolerances for bushberry subgroup 13B and lingonberry, juneberry, and salal at 3.5 parts per million (ppm).

2. PP 1E6254 proposes a tolerance for okra at 1.0 ppm.

3. PP 1E6237 proposes a tolerance for watercress at 3.5 ppm.

4. PP 1E6225 proposes a tolerance for artichoke at 2.5 ppm.

5. PP 0E6203 proposes a tolerance for cranberry at 0.05 ppm.

6. PP 2E6403 proposes a tolerance for vegetable, legume, except soybean, group 6 at 4.0 ppm.

7. PP 2E6406 proposes tolerances for avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote at 1.0 ppm, and lychee, longan, Spanish lime, rambutan, pulasan, and persimmon at 3.0 ppm.

8. PP 2E6409 proposes a tolerance for vegetable, leaves of root and tuber, group 2 at 4.0 ppm.

9. PP 2E6417 proposes a tolerance for strawberry at 0.5 ppm.

10. PP 2E6421 proposes a tolerance for fruit, stone, group 12 at 3.0 ppm.

11. PP 2E6435 proposes tolerances for guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 1.0 ppm.

12. PP 2E6414 proposes tolerances for corn, pop, grain at 0.05 ppm and corn, pop, stover at 0.2 ppm.

13. PP 2E6458 proposes a tolerance for mustard seed at 0.05 ppm.

14. PP 2E6506 proposes a tolerance for vegetable, root, and tuber, except sugar beet, group 1 at 0.4 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions. Bayer Corporation, Crop Protection, Kansas City, MO 64120–0013 produces the imidacloprid product(s) of concern for these pending tolerances.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the imidacloprid residue in plants and livestock is adequately understood. The residues of concern are combined residues of imidacloprid and it metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid.

2. *Analytical method*. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary gas chromatography/mass spectrometry (GC/MS) selective ion monitoring. This method has successfully passed a petition method validation in EPA labs. There is a confirmatory method specifically for imidacloprid and several metabolites utilizing GC/MS and high performance liquid chromotography/ using ultra-violet detection (HPLC/UV) which has been validated by EPA as well. Imidacloprid and its metabolites are stable for at least 24 months in the commodities when frozen.

3. *Magnitude of residues*. Bushberry subgroup, lingonberry, juneberry, and salal. IR–4 has received requests from Maine for imidacloprid use on lowbush blueberries and from New Jersey, Delaware, Michigan, and South Carolina for use on high bush blueberries. Two field trials were performed on lowbush blueberries and nine trials on highbush blueberries to support the requested tolerance of 3.5 ppm.

- *Okra*. No data was submitted in support of this tolerance petition; rather, IR–4 proposes that EPA, utilizes the registrant's fruiting vegetable data (peppers and tomatoes). IR–4 believes this approach is justified based upon the similarities of okra to members of the fruiting vegetable crop group. It is noteworthy that okra is classified as a fruiting vegetable under CODEX.
- *Watercress*. IR–4 received a request from the Florida Agricultural Experiment Station for the registration of imidacloprid on watercress. No watercress data were presented in support of this petition; rather, IR–4 requests that EPA utilizes the registrant's head and leaf lettuce data to support the proposed watercress tolerance of 3.5 ppm.
- *Artichoke*. IR–4 has received requests from California for the use of imidacloprid on artichoke. To support this request and the proposed tolerance of 2.5 ppm, magnitude of residue data were collected from three field trials in California.
- *Cranberry*. IR–4 received a request from Massachusetts for the use of imidacloprid on cranberries. To support this request and the proposed tolerance for strawberry at 0.05 ppm. IR–4 conducted five field trials in the states of Massachusetts, New Jersey, Wisconsin, and Oregon.
- *Peas*. IR–4 received a request from Washington, Oregon, and Delaware for the use of imidacloprid on peas. In support of this request, field trials were conducted in Wisconsin, Ohio, Washington, Maryland, New Jersey, and California.
- *Mamey sapote*. IR–4 received a request from Florida for the use of imidacloprid on mamey sapote. In support of this request, two field trials were conducted in southern Florida.
- *Leaves of root and tuber crop group*. IR–4 received a request from Oregon and California for the use of imidacloprid on beets. In support of this request, magnitude of residue data were collected from field trials conducted in Texas, Ohio, New Jersey, Oregon, and Indiana. Data from beet tops were combined with the previously submitted petition for turnip tops to support a tolerance for leaves of root and tuber vegetables.
- *Stone fruit*. IR–4 received requests from Utah, Washington, Michigan, and Oregon for the use of imidacloprid on cherries, Michigan and Washington for the use of imidacloprid on peaches, and Michigan for the use of imidacloprid on plums. Magnitude of residue data were collected on these crops to support a stone fruit crop group tolerance.
- *Strawberry*. IR–4 received requests from Oregon, Mississippi, Michigan, Wisconsin, and North Carolina for the use of imidacloprid on strawberries. In support of this requested tolerance, magnitude of residue trials were conducted in Florida, California, New Jersey, Wisconsin, and Oregon.
- *Dry beans*. IR–4 received requests from New York, Washington, Wisconsin, Georgia, California, and Idaho for the use of imidacloprid on dry beans. In support of this request, magnitude of residue trials were conducted in Washington, North Dakota, New York, Wisconsin, and California.
- *Guava and related crops (feijoa, jaboticaba, wax jambu, starfruit,*

passion fruit, and acerola). IR–4 received a request from Florida for the use of imidacloprid on guava. Magnitude of the residue data were collected from Florida on guava to support a tolerance on guava and related crops.

- *Corn, pop.* No crop-specific data were submitted with the petition proposing imidacloprid tolerances on popcorn. IR–4 proposes that EPA translates residue data from field corn to popcorn in order to establish the requested tolerances.
- *Mustard seed*. No crop-specific data are being submitted with this petition proposing an imidacloprid tolerance on mustard seed. IR–4 proposes that EPA translates residue data from canola to mustard seed in order to establish the tolerance based upon the botanical and cultural similarities of the crops. Additionally, Canada has a crop group for oil seeds (crop group 20) which contains mustard seed and has canola as one of the representative commodities.

B. Toxicological Profile

EPA has evaluated the available imidacloprid toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the reliability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imidacloprid is discussed in Unit II.A. of the final rule on imidacloprid pesticide tolerances published in the **Federal Register** of September 18, 1998 (63 FR 49837) (FRL–6027–1). Please refer to this document should you desire detailed toxicological information on imidacloprid.

1. *Animal metabolism*. The metabolism of NTN 33893 (imidacloprid) in rats was reported in seven studies. The data show that imidacloprid was rapidly absorbed and eliminated in the excreta (90% of the dose within 24 hours), demonstrating no biologically significant differences between sexes, dose levels, or route of administration. Elimination was mainly renal (70–80% of the dose) and fecal (17–25%). The major part of the fecal activity originated in the bile. Total body accumulation after 48 hours consisted of 0.5% of the radioactivity with the liver, kidney, lung, skin, and plasma being the major sites of accumulation. Therefore, bioaccumulation of imidacloprid is low in rats. Maximum plasma concentration was reached between 1.1 and 2.5 hours. Two major routes of biotransformation were proposed for imidacloprid. The first route included an oxidative cleavage of the parent compound rendering 6-chloronicotinic acid and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second route included the hydroxylation followed by elimination of water of the parent compound rendering NTN 35884. A comparison between [methylene-^{14}C-]imidacloprid and [imidazolidine-4,5-^{14}C]imidacloprid showed that while the rate of excretion was similar, the renal portion was higher with the imidazolidine-labeled compound. In addition, accumulation in tissues was generally higher with the imidazolidine-labeled compound.

A comparison between imidacloprid and one of its metabolites, WAK 3839, showed that the total elimination was the same for both compounds. The proposed metabolic pathways for these two compounds were different. WAK 3839 was formed following pretreatment (repeated dosing) of imidacloprid.

2. *Endocrine disruption*. The toxicology data base for imidacloprid is current and complete. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short- or long-term exposure. These studies revealed no primary endocrine effects due to imidacloprid.

C. Aggregate Exposure

1. *Dietary exposure*. Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U.S. population and selected population subgroups to residues of imidacloprid. These analyses cover all registered crops including rotational crops; uses pending with EPA Registration Division's 2002 work plan including dry beans, peas, bushberries, lingonberry, juneberries, salal, carrots, turnips, okra, cranberries, artichoke (globe), watercress, beet roots, leaves of root and tuber vegetables, stone fruit, mamey sapote, guava, feijoa, jaboticaba, wax jambu, starfruit, passion fruit, acerola, strawberry, cucumber (greenhouse), and tomato (greenhouse), and an import tolerance petition on bananas, active and proposed section 18 uses on blueberries, cranberries, table beets, strawberries and turnips.

Novigen sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM™), which is licensed to Bayer Corporation, was used to estimate the chronic and acute dietary exposure. This software uses the food consumption data from the 1994–1998 United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFII).

The endpoint for acute dietary risk assessments is based on neurotoxicity characterized by decreases in motor or locomotor activity in female rats at 42 milligrams/kilogram body weight/day (mg/kg bwt/day) (the lowest observed adverse effect level (LOAEL) from an acute neurotoxicity study). Based on an uncertainty factor (UF) of 10x for interspecies and 10x for intraspecies, the acute reference dose (RfD) = 0.42 mg/kg bwt/day. EPA has determined that an additional UF for FQPA (reduced to 3x) applies to all population subgroups for acute risk. Application of the additional 3x safety factor results in an acute population adjusted dose (aPAD) 0.14 mg/kg bwt/day or a margin of exposure (MOE) of 300.

For chronic dietary analyses, EPA has established the RfD for imidacloprid at 0.057 mg/kg/day based on a no-observed adverse effect level (NOAEL) of 5.7 mg/kg bwt/day from a rat chronic toxicity carcinogenicity study and UF of 10x for interspecies and 10x for intraspecies. EPA has determined that an additional UF for FQPA (reduced to 3x) applies to all population subgroups for chronic risk. Application of the additional 3x safety factor results in a chronic population adjusted dose (cPAD) of 0.019 mg/kg bwt/day.

The registrant believes that results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of imidacloprid on currently registered and pending uses.

i. *Food*. Acute and chronic (Tier 3) risk assessments were made using the results of field trials conducted at maximum label application rates and the shortest pre-harvest intervals. For some of the vegetable crops, the residue data were collected at 1.5x or greater than the maximum label rate of 0.5 lb active ingredient/acre per season. In addition, no adjustments were made to account for dissipation of residues during storage, transportation from the field to the consumer, washing or peeling. Therefore, the actual dietary exposure will be less than that presented here.

For the chronic analysis, mean field trial residues were calculated. For the acute Monte Carlo analysis, the entire distribution of residue field trial data were used for the ''non-blended'' and ''partially blended'' foods as determined by EPA's standard operating procedure (SOP) 99.6. For the foods considered as

''blended'' by EPA's Health Effects Division (HED) SOP 99.6, mean field trial residue data were used. As allowed in EPA's draft guidance for submission of probabilistic human health exposure assessments one half limit of detection limit of detection (LOD) limit of quantitation (LOQ) values were used for all non-detected values (values below the sensitivity of the method).

ii. *Acute*. Bayer Corporation's acute Monte Carlo dietary exposure assessment estimated percent of the aPAD and corresponding MOE for the overall U.S. population (all seasons) and various subpopulations. In this analysis, the exposure for the total U.S. population was equal to 7.73% of the aPAD at the 99.9th percentile. The most highly exposed population subgroup, children (1 to 6 yrs), had an exposure equal to 16.42% of the aPAD at the 99.9th percentile. Therefore, the acute dietary exposure estimates are below EPA's level of concern (LOC) for the overall U.S. population as well as the various subpopulations.

iii. *Chronic*. The Bayer Corporation chronic dietary exposure estimated the percent of the cPAD for the overall U.S. population (all seasons) and various subpopulations. In this analysis, the exposure for the total U.S. population was equal to 1.4% of the cPAD. The most highly exposed population subgroup, children (1 to 6 yrs), had an exposure equal to 3.0% of the cPAD. Therefore, the chronic exposure estimates are below EPA's LOC for the overall U.S. population as well as the various subpopulations.

iv. *Drinking water*. EPA, as published in the **Federal Register** of April 10, 2001 (69 FR 18554) (FRL–6777–6), calculated acute and chronic drinking water levels of concern (DWLOC) and compared them with the estimated environmental concentrations (EECs) for surface water and ground water. Based on this comparison, they determined that acute exposure and chronic exposure would not be expected to exceed the aPAD and cPAD, respectively. It is not expected that the additional exposure from the minor crops pending in EPA's 2002 work plan would significantly change EPA's water assessment.

2. *Non-dietary exposure*—i. *Residential turf*. Bayer Corporation has conducted an exposure study to address the potential exposures of adults and children from contact with imidacloprid treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides are applied are young children. Margins of safety (MOS) of 7,587–41,546 for 10–year old children and 6,859–45,249 for 5–year old children were estimated by comparing dermal exposure doses to the imidacloprid no-observable effect level of 1,000 mg/kg/day established in a 15–day dermal toxicity study in rabbits. The estimated safe residue levels of imidacloprid on treated turf for 10–year old children ranged from 5.6 - 38.2 grams/centimeters (g/cm^2) and for 5–year old children from 5.1 - 33.5 g/cm^2. This compares with the average imidacloprid transferable residue level of 0.080 g/cm^2 present immediately after the sprays have dried. The data indicate that children can safely contact imidacloprid-treated turf as soon after application as the spray has dried.

ii. *Termiticide*. Imidacloprid is registered as a termiticide. Due to the nature of the treatment for termites, exposure would be limited to that from inhalation and was evaluated by EPA and the Bayer Corporation. Data indicate that the MOS for the worst case exposures for adults and infants occupying a treated building who are exposed continuously (24 hours/day) are 8.0 x 10^7 and 2.4 x 10^8, respectively - and exposure can thus be considered negligible.

iii. *Tobacco smoke*. Studies have been conducted to determine residues in tobacco and the resulting smoke following treatment. Residues of imidacloprid in cured tobacco following treatment were a maximum of 31 ppm (7 ppm in fresh leaves). When this tobacco was burned in a pyrolysis study only 2% of the initial residue was recovered in the resulting smoke (main stream plus side stream). This would result in an inhalation exposure to imidacloprid from smoking of approximately 0.0005 mg per cigarette. Using the measured subacute rat inhalation NOAEL of 5.5 milligrams/meters (mg/m^3), it is apparent that exposure to imidacloprid from smoking (direct exposure and/or indirect exposure) would not be significant.

iv. *Pet treatment*. Human exposure from the use of imidacloprid to treat dogs and cats for fleas has been addressed by EPA. Bayer Corporation believes, that due to the fact that imidacloprid is not an inhalation or dermal toxicant and that while dermal absorption data are not available, imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

Imidacloprid is a chloronicotinyl insecticide. At this time, EPA has not made a determination that imidacloprid and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for these tolerance petitions, Bayer Corporation assumes that imidacloprid does not have a common mechanism of toxicity with other substances and only the potential risks of imidacloprid in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population*. EPA has considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. These studies are discussed in the toxicological profile section of Unit II. of the **Federal Register** dated September 18, 1998 (63 FR 49837). The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margin of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard UF (usually 100 for combined interspecies and intraspecies variability) and not the additional ten-fold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/SF.

Although developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, no increased sensitivity in pups as compared to adults was seen in the 2–generation reproduction toxicity study in rats, and the toxicology data base is complete as to core

requirements, EPA has determined that the additional SF for the protection of infants and children will be retained but reduced to 3x based on the following weight-of-the-evidence considerations relating to potential sensitivity and completeness of the data:

- There is concern for structure activity relationship. Imidacloprid, a chloronicotinyl compound, is an analog to nicotine and studies in the published literature suggest that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*.
- There is evidence that imidacloprid administration causes neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2–year carcinogenicity study.
- The concern for structure activity relationship along with the evidence of neurotoxicity dictates the need of a developmental neurotoxicity study for assessment of potential alterations on functional development.

Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, EPA has applied the additional UF for FQPA for all population subgroups, and in both acute and chronic risk assessments.

Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, Bayer Corporation has concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 7.73% of the aPAD at the 99.9th percentile and 1.4% of the cPAD for the U.S. population. Thus, Bayer Corporation has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children*. Based on the exposure assessments described above for the safety determination of the U.S. population and on the completeness and reliability of the toxicity data, Bayer Corporation has concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 16.42% of the aPAD at the 99.9th percentile and 3.0% of the cPAD for the most sensitive population subgroup, children 1 to 6 years. Thus, Bayer Corportion has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

F. International Tolerances

No Codex maximum residue levels have been established for residues of imidacloprid on any crops currently pending at EPA.

FR Doc. 03–2773 Filed 2–4–03; 8:45 a m]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7448–3]

Jack Goins Waste Oil Superfund Site/ Cleveland,Tennessee; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: Under section 122(h)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Environmental Protection Agency (EPA) has proposed to settle claims for response costs at the Jack Goins Waste Oil Superfund Site (Site) located in Cleveland, Tennessee, with Jack L. Goins, Susie T. Goins, Jack Goins Waste Oil Pumping Service, and Frances L. Lockmiller. EPA will consider public comments on the proposed settlement for thirty days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region IV, Waste Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8887.

Written comment may be submitted to Mr. Greg Armstrong at the above address within 30 days of the date of publication.

Dated: January 15, 2003.

Anita L. Davis,

Acting Chief, CERCLA Program Services Branch, Waste Management Division.

[FR Doc. 03–2769 Filed 2–4–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011510–017.

Title: West African Discussion Agreement.

Parties: Atlantic Bulk Carriers, Ltd., HUAL AS, A.P. Moller Maersk Sealand, Mediterranean Shipping Company, P&O Nedlloyd Limited, Safmarine Container Lines NV, Zim Israel Navigation Company Ltd.

Synopsis: The amendment adds Safmarine Container Lines as a party to the agreement effective February 1, 2003.

Agreement No.: 011802–001.

Title: Evergreen/Lloyd Triestino/ Hatsu Marine Alliance-WTSA Bridging Agreement.

Parties: The Evergreen/Lloyd Triestino/Hatsu Marine Alliance Agreement, Westbound Transpacific Stabilization Agreement.

Synopsis: The amendment updates the membership of the Westbound Transpacific Stabilization Agreement.

Agreement No.: 011839.

Title: Med-Gulf Space Charter Agreement.

Parties: Compania Chilena de Navegacion Interoceanica, Compania Sud-Americana de Vapores S.A., Lykes Lines Limited LLC.

Synopsis: The proposed agreement authorizes Lykes to charter space to the other parties in the trade between U.S. Gulf ports, including Miami, Florida, and San Juan, Puerto Rico, on the one hand, and ports in Spain, Italy, and Mexico, on the other hand.

Agreement No.: 201026–002.

Title: Port of New Orleans/P&O Ports Lease.

Parties: Port of New Orleans, P&O Ports Louisiana, Inc.

Synopsis: The modification expands the leased premises under the basic lease. The additional space may be used on an as-needed basis.

By Order of the Federal Maritime Commission.

Dated: January 31, 2003.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–2791 Filed 2–4–03; 8:45 am]

BILLING CODE 6730–01–P