DFO. Members of the public are requested to call the DFO at the number listed below if planning to attend so that arrangements can be made to comfortably accommodate attendees as much as possible, and to facilitate security clearance to the meeting. Seating will be on a first come, first served basis.

DATES: The Local Government Advisory Committee plenary session will begin at 8:30 a.m. Thursday, March 27 and conclude at 3 p.m. on March 28.

ADDRESSES: The meetings will be held at the EPA's Region 4 Office located at 61 Forsyth Street, SW., (Sam Nunn Federal Center), Atlanta, GA 30303. Plenary sessions will be held in the Atlanta/ Augusta Rooms(3B90) in the Third floor Bridge Conference center.

Additional information can be obtained by writing the DFO at 1200 Pennsylvania Avenue, NW., (1306A), Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: The DFO for the Local Government Advisory Committee (LGAC) is Paul Guthrie (202) 564–3649.

Dated: February 25, 2003.

Paul N. Guthrie,

Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 03–5473 Filed 3–6–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0031; FRL–7290–5]

Spiroxamine; 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–2003–0031, must be received on or before April 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: 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–2003–0031. 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 on 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–2003–0031. 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–2003–0031. 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–2003–0031.

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–2003–0031. 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 pesticide petitions 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 6, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioners summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Bayer CropScience, 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

Interregional Research Project Number 4 (IR-4)

PP 0F6122, PP 3E6518, and PP 3E6538

EPA has received pesticide petitions (OF6122 and 3E6538) from Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709 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, by establishing tolerances for residues of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine in or on the raw agricultural commodities as follows:

1. PP 0F6122 proposes tolerances for grape at 1.0 parts per million (ppm) and grape, raisin at 1.3 ppm.

2. PP 3E6538 proposes a tolerance for banana at 3.0 ppm.

In addition, EPA has received a pesticide petition (3E6518) from the Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing tolerances for residues of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine in or on the raw agricultural commodity hop at 11.0 parts per million (ppm).

EPA has determined that the petitions 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 petitions. Additional data may be needed before EPA rules on the petitions.

This notice includes a summary of all three petitions prepared by Bayer CropScience, the manufacturer of spiroxamine.

A. Residue Chemistry

1. *Plant metabolism.* Banana and grape plant metabolism studies have been conducted, and the nature of the residue is adequately understood. Animal metabolism studies are not required since none of the proposed crops to be treated with spiroxamine are fed to livestock per EPA's Table 1. Raw Agricultural and Processed Commodities and Feedstuffs Derived from Crops.

2. *Analytical method.* A method to determine the total residues of spiroxamine using gas chromatography has been submitted to EPA. In addition, spiroxamine has been evaluated using the multi-residue methodologies as published in the Food and Drug Administration (FDA) Pesticide Analytical Manual, Volume I.

3. *Magnitude of residues*—i. *Grape.* Field trials were conducted at 12 locations to evaluate the quantity of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine, residues in grape (fruit) following treatment of grape vines with KWG 4168 300 CS. In the 11 harvest experiments conducted, duplicate treated and single control samples of grape (fruit) were collected at 26 to 29 days following the final application of KWG 4168 300 CS. In the single decline experiment, duplicate samples of treated grape (whole fruit) were collected at 21–28–, 34–, and 42–day pre-harvest intervals (PHIs). In all trials, the highest average field trial (HAFT) residue of spiroxamine observed in grape was 0.61 ppm.

A study to evaluate the quantity of the residues of spiroxamine in grape processed commodities following two foliar spray applications of KWG 4168 300 CS was conducted in which KWG 4168 300 CS was applied to the grape vines at 50% fruit maturity (56–day PHI), and at 80% fruit maturity (28–day PHI), using an airblast sprayer. Control and treated grapes were harvested at 28 days after the second application of KWG 4168 300 CS. The grape juice and raisins were evaluated for the residues. Total spiroxamine residues in the processed commodities were 0.434 ppm in grape juice and 0.831 ppm in raisins. The concentration factor for spiroxamine residues in raisins was 1.3X. No concentration of spiroxamine residues occurred in grape juice. Therefore, a tolerance of 1.3 ppm is being proposed for residues of spiroxamine in raisin, and no tolerance is needed for grape juice.

ii. *Hops.* IR-4 has received a request from Washington State for the use of spiroxamine on hops. To support this request, three fields trials were performed in the states of Washington, Oregon and Idaho. In each trial, four foliar applications of KWG 4168 300 CS spaced 8–14 days apart were applied to mature hops, and collected 12–14 days following the last application. Spiroxamine residue levels ranged from 1.9 to 10.9 ppm.

iii. *Banana.* Twelve field trials were conducted in commercial banana plantations of the major production areas of Latin and South America to compare the quantity of residues of spiroxamine in/on bananas following foliar applications. In 11 trials, duplicate composite samples of bananas were collected at a 0–day PHI from each of two side-by-side or super-imposed plots in which the racemes (bunches) were bagged or unbagged. In one trial, duplicate composite samples of bananas were collected at a 0–, 7–, 14–, and 21–day PHI from each of the plots containing bagged and unbagged bananas. The highest total residue value of spiroxamine in unwashed, bagged, whole bananas was 0.46 ppm at a 0–day PHI. The highest total residue value of spiroxamine in unwashed, unbagged, whole bananas was 2.44 ppm at a 0–day PHI. The total spiroxamine residues in whole bananas appeared to decline with time.

B. Toxicological Profile

1. *Acute toxicity*—i. *KWG 4168 (spiroxamine) Technical.* The acute oral LD_{50} in male rats was 595 milligrams/kilogram (mg/kg) and in female rats was >500 but <560 mg/kg. The acute dermal LD_{50} in rats was >1,600 and 1,068 mg/kg for males and females, respectively. The 4–hour inhalation LC_{50} in rats was 2.772 and 1.982 milligrams/liter (mg/L) for males and females, respectively. Irritation studies in rabbits revealed spiroxamine was severely irritating to the skin while not irritating to the eye. Spiroxamine exhibited a skin-sensitizing potential in guinea pigs in both the Magnusson/Kligman maximization test and the Buehler patch test.

ii. *Prosper 300.* The acute oral LD_{50} in rats was >2,036 and >2,028 mg/kg for males and females, respectively. The acute dermal LD_{50} in rats was >5,000 mg/kg for males and females. The 4–hour inhalation LC_{50} in rats was >2.730 mg/L for both sexes. In an eye irritation study in rabbits, minimal irritation to the iris and conjunctiva was observed with all irritation, resolving by 72 hours

post-treatment. In a dermal irritation study in rabbits, mild erythema and/or edema was observed at 72 hours post-treatment with all irritation resolving by 14 days post-treatment. Prosper 300 did not have the potential to induce dermal sensitization in guinea pigs under conditions of the Buehler patch test.

2. *Genotoxicty*. The genotoxic action of spiroxamine was studied in bacteria and mammalian cells with the aid of various *in vitro* test systems (Salmonella microsome test, forward mutation assay, cytogenetic study with Chinese hamster ovary cells and unscheduled DNA synthesis test), and in one *in vivo* test (micronucleus test). None of the tests revealed any evidence of a mutagenic or genotoxic potential of spiroxamine. The compound did not induce point mutations, DNA damage or chromosome aberrations.

3. *Reproductive and developmental toxicity*. In a reproduction study using rats, spiroxamine was administered for 2 generations at dietary concentrations of 20, 80, or 300 ppm. Reproductive effects such as reduced litter size at birth and clinical signs of toxicity occurred at the high dose in conjunction with maternal toxicity. The parental and reproductive no observed effect levels (NOELs) were 20 ppm (equal to 2.13 mg/kg body weight/day (bwt/day) and 80 ppm (equal to 9.19 mg/kg bwt/day), respectively.

In a developmental toxicity study in rats, spiroxamine was administered by oral gavage at dose levels of 0, 10, and 25 mg/kg bwt/day and in a supplemental study at doses of 0 and 150 mg/kg bwt/day. Severe maternal toxicity occurred at 150 mg/kg bwt/day resulting in the deaths of 21 of 25 animals. Embryotoxicity (palatoschisis and omphalocele) was observed at the high dose in conjunction with the severe maternal toxicity. The two lower dose levels did not reveal any maternal or developmental toxicity. The results of these studies showed that the dose of 150 mg/kg bwt/day was too high to obtain unequivocal results with respect to embryotoxicity and teratogenicity.

In another oral developmental toxicity study in rats, spiroxamine was administered by gavage during gestation at doses of 0, 10, 30, or 100 mg/kg bwt/day. Developmental toxicity occurred in conjunction with distinct maternal toxicity at the highest dose tested. The maternal NOEL was 30 mg/kg bwt/day based on reduced body weight gain and feed intake at 100 mg/kg bwt/day. The NOEL for developmental toxicity was 30 mg/kg bwt/day based on delayed ossification, slightly reduced fetal weights and three cases of palatoschisis at 100 mg/kg bwt/day.

In oral developmental toxicity studies in rabbits, spiroxamine was administered by gavage during gestation at doses of 0, 5, 20, or 80 mg/kg bwt/day and in a supplemental study at doses of 0 and 80 mg/kg bwt/day. The maternal NOEL was 20 mg/kg bwt/day based on clinical findings, reduced body weight gain, reduced food intake and lethality at 80 mg/kg bwt/day. The NOEL for developmental toxicity was 20 mg/kg bwt/day based on marginal developmental toxicity (reduced fetal weight and a slight increased rate of spontaneous malformations) at the highest dose level.

In a dermal developmental toxicity study in rats, spiroxamine was administered for 6 hours/day during gestation at doses of 0, 5, 20, or 80 mg/kg. Reduced body weight gain occurred in dams at 20 mg/kg and greater. Dose-related skin reactions were observed at all treated doses. Developmental toxicity, such as wavy ribs, occurred in conjunction with maternal toxicity at the highest dose tested. The NOELs for systemic and local maternal toxicity were 5 and <5 mg/kg, respectively. The NOEL for developmental toxicity was 20 mg/kg. Spiroxamine did not reveal any teratogenic potential associated with dermal application.

4. *Subchronic toxicity.* In subacute dermal toxicity studies, rabbits were treated with spiroxamine at doses ranging from 0.05 to 5 mg/kg bwt/day for 6 hours/day over a period of 3 weeks. Systemic effects were not observed in these studies. Local irritation, increased skin fold thickness, and histopathological findings of the skin occurred in these studies. The overall NOELs for local and systemic effects were 0.2 and 5 mg/kg bwt/day, respectively.

In a 90–day feeding study, mice were administered spiroxamine at dietary concentrations of 0, 20, 80, 320, or 1,280 ppm. Effects observed included clinical signs of toxicity, decreased body weight and food consumption, changes in hematological parameters, hyperplastic changes in the epidermis of the auricles and/or tail, and effects on the liver, kidney, and urinary bladder. The NOEL was 20 ppm (equal to 6.2 mg/kg bwt/day) for male mice based on marginally reduced body weight development at 80 ppm. The NOEL for female mice was 80 ppm (equal to 28.5 mg/kg bwt/day) based on slight morphological findings in the liver at 320 ppm.

In another subchronic mouse study, spiroxamine was administered by oral gavage at doses of 0, 60, 180 or 240 mg/kg. Effects observed included clinical signs of toxicity, and effects of the liver, urinary bladder and hyperplastic changes in the epidermis of the auricles and tails. Evidence of liver enzyme induction was seen in all treatment groups. The NOEL was <60 mg/kg bwt/day for both males and females.

Spiroxamine was administered to rats in a subchronic feeding study at dietary concentrations of 0, 25, 125, or 625 over a period of 13 weeks. Effects included clinical signs of toxicity, reduced body weight gains, changes in hematological parameters, and effects on the liver, urinary bladder, esophagus and forestomach. The NOEL both male and female was 25 ppm (equal to 1.9 and 2.7 mg/kg bw/day, respectively) based on histopathological findings in the esophagus and forestomach at 125 pwas administered at dietary concentrations of 0, 25, 750 or 1,500 ppm and at 0, 150, 250 or 500 ppm over a period of 13 weeks. Toxicological effects included changes in clinical chemistries, increased relative liver weights, and histopathological findings in the liver. The overall NOELs from these studies were 500 (equal to 16.9 mg/kg bw/day) and 750 ppm (equal to 21.29 mg/kg bw/day) for males and females, respectively, based on liver effects.

5. *Chronic toxicity*. In a chronic dog study, Spiroxamine was administered at dietary concentrations of 0, 25, 75, 1,000 or 2,000 ppm for a period of 52 weeks. Effects included opthalmological findings, changes in clinical chemistries, mild anemia, and histopathological findings (eye and liver). The NOEL for both sexes was 75 ppm (equal to 2.47 and 2.48 mg/kg bw/day for males and females, respectively) based on eye and liver effects.

Rats were administered Spiroxamine for 2 years at dietary concentrations of 0, 10, 70 or 490 ppm. Effects included reduced body weight gains, a slight increase in mortality and histopathological findings in the esophagus and urinary bladder. The NOEL for both sexes was 70 ppm (equal to 4.22 and 5.67 mg/kg bw/day for males and females, respectively) based on esophagus and urinary bladder effects.

The carcinogenicity potential of Spiroxamine was investigated in rats and mice at maximum dietary concentrations of 490 ppm (equal to 32.81 mg/kg bw/day) and 600 ppm (equal to 149.8 mg/kg bw/day), respectively. No evidence of an oncogenic potential of Spiroxamine was found in the long-term studies in rats and mice.

6. *Animal metabolism*. Rats were gavaged with 1 or 100 mg/kg radio-labeled technical Spiroxamine. Seventy percent of the oral low dose was absorbed. Within 48 hours of dosing, over 97 percent of the dose was excreted

in urine and feces. At sacrifice (48 hours post dosing), the radioactivity remaining in the body was below 1 percent in the low dose groups and approximately 1 percent and 2 percent in the male and female rats, espectively, from the high dose group. Concentrations found in tissues and organs were relatively low: i.e., they do not exceed 0.04 µg/g. The highest concentrations were found in liver, thymus and adrenals. Slightly smaller concentrations were observed in the thyroid, spleen, fat, ovaries and *uterus*. The main metabolite in all dose groups is Spiroxamine oxidized to the carboxylic acid in the t-butyl-moiety. The identification rate was approximately 77 percent of the recovered radioactivity in all dose groups.

7. *Metabolite toxicology*. Toxicological studies have been conducted on KWG 4,168 N-oxide, a plant and animal metabolite of KWG 4168. In an acute oral toxicity study on KWG 4,168 N-oxide using female rats, the LD_{50} was 707 mg/kg. In a subacute toxicity study, rats were administered KWG 4168 N-oxide at dietary concentrations of 0, 30, 150 and 1,000 ppm. The highest concentration resulted in treatment-related effects. The main targets were the epithelia of the digestive tract and the urinary bladder. A mild liver enzyme induction was observed without any correlating gross- or micropathological findings. In a subchronic study, rats were administered KWG 4168 N-oxide at dietary concentrations of 0, 25, 125 and 625 ppm, and KWG 4168 at 625 ppm. Toxic effects were observed at 625 ppm for both test substances. Similar effects included delayed body weight development, changes in clinical chemistries and micropathological findings of the esophagus and stomach. The effects were less pronounced for KWG 4168 N-oxide when compared to KWG 4168 (parent). Effects noted only in animals treated with KWG 4168 included changes in hematological parameters and micropathological findings of the urinary bladder (females). The mutagenic potential of KWG 4168 N-oxide was studied *in vitro* in bacteria and mammalian cells. It did not cause mutations *in vitro* in the Ames assay, the V-79-HPRT gene mutation assay, or produce clastogenicity in the chromosome aberration assay with or without metabolic activation.

8. *Endocrine disruption*. The toxicology database for Spiroxamine is current and complete. Studies in this database 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 Spi primary endocrine effects due to spiroxamine.

C. Aggregate Exposure

1. *Dietary exposure*. An aggregate risk assessment was conducted to assess the potential acute and chronic dietary exposure from applications of spiroxamine on grape, hop, and banana (imported). Novigen Sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM) was used to estimate the chronic and acute dietary exposure.

For the acute dietary analysis, the proposed acute reference dose (aRfD) of 0.1 mg/kg/day was used. This aRfD is based on NOELs of 10 mg/kg from an acute oral toxicity and an acute neurotoxicity screening study and applying a 100-fold uncertainty factor.

For the chronic dietary analysis, the proposed chronic reference dose cRfD of 0.02 mg/kg/day was used. This cRfD is based on a parental toxicity NOEL of 2.13 mg/kg/day from the two-generation reproduction study and the application of a 100-fold uncertainty factor.

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 spiroxamine on grape, hop, and banana.

i. *Food*. An acute dietary (food) risk assessment was conducted using the highest residue values and 100% crop treated. The estimated percent of the aRfD for the overall U.S. population (all seasons) at the 95 percentile are 8.4%. The most highly exposed population subgroup, non-nursing infants, had an exposure equal to 33.3% of the aRfD at the 95 percentile. These exposure estimates are within EPA's criteria of acceptability.

A chronic dietary analysis was conducted using average residue values and 100% crop treated. The estimated percent of the cRfD for the overall U.S. population (all seasons) was 8.8%. For the most highly exposed population subgroup, children (1–6 years), the exposure equaled 30.6% of the cRfD. These exposure estimates are within EPA's criteria of acceptability.

ii. *Drinking water*. No monitoring data are available for residues of spiroxamine in ground water, and EPA has established no health advisory levels or maximum contaminant levels for residues of spiroxamine in drinking water.

Studies show low to no soil mobility for spiroxamine and its primary metabolites. In addition, field studies show that spiroxamine and its degradates do not leach below the 6–inch depth level, and show very low potential to leach into ground water. Therefore, it can be concluded with reasonable certainty that no harm will result from acute or chronic aggregate exposure to spiroxamine residues in drinking water.

2. *Non-dietary exposure*. Spiroxamine is not registered nor are registrations pending for uses that would result in non-dietary exposure.

D. Cumulative Effects

Spiroxamine belongs to a new class of chemistry known as spiroketalamines. Therefore, for this tolerance petition, it is assumed that spiroxamine does not have a common mechanism of toxicity with other substances and only the potential risks of spiroxamine in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population*. Based on the above aggregate food exposure estimates for the overall U.S. population 8.4% of the aRfD and (8.8% of the cRfD), the low potential for spiroxamine and its degradates to leach into ground water, and the completeness of the toxicity data base, there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to spiroxamine.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of spiroxamine, data from developmental toxicity studies in mice, rats, rabbits and a 2-generation reproduction study in the rat are considered. 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.

Based on the above aggregate food exposure estimates for the most highly exposed population subgroup, non-nursing infants (33.3% of the aRfD), and children 1–6 years (30.6% of the cRfD), the low potential for spiroxamine and its degradates to leach into ground water, and on the completeness of the toxicity data base, there is reasonable certainty that no harm to infants and children will result from aggregate exposure to spiroxamine.

F. International Tolerances

There are no established codex, Canadian or Mexican maximum residue levels for spiroxamine.

[FR Doc. 03–5316 Filed 3–6–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0025; FRL–7289–8]

Pyriproxyfen; Notice of Filing Pesticide Petitions 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 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–2003–0025, must be received on or before April 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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 producers (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. 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–2003–0025. 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