from developmental toxicity studies in the rat and rabbit and the two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects on the reproductive capacity of males and females exposed to the pesticide. Developmental toxicity was not observed in developmental toxicity studies using rats and rabbits. In these studies, the rat and rabbit maternal NOAELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOAEL for the rabbit was greater than 300 mg/kg/day, which was the highest dose, tested and for the rat was 600 mg/kg/day based on increased litter incidences of thickened and wavy ribs. These two findings are not considered adverse effects of treatment but related delays in rib development, which are generally believed to be reversible.

In a two-generation reproduction study in rats, no reproductive toxicity was observed under the conditions of the study at 4,000 ppm, which was the highest dose tested.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre-natal and post-natal effects for children is complete and an additional uncertainty factor is not warranted. Therefore at this time, the RfD of 0.03 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

3. *Population adjusted dose (aPAD and cPAD).* Using the conservative exposure assumptions described above, the percent of the aPAD that will be utilized by aggregate exposure to residues of carfentrazone-ethyl for non-nursing infants (<1 year old) would be < 1% (aPAD) and < 10% (cPAD); for children 1–6 years of age would be < 1% (aPAD) and < 15% (cPAD), (the most highly exposed group). Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of carfentrazone-ethyl including all anticipated dietary exposure.

F. International Tolerances

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for carfentrazone-ethyl on any crops at this time. However, MRLs for small grains in Europe have been proposed which consist of carfentrazone-ethyl and carfentrazone-ethyl-chloropropionic acid.

[FR Doc. 04–16719 Filed 7–27–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0197; FRL–7366–2]

Spiromesifen; 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 ID number OPP–2004–0197, must be received on or before August 27, 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: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food processing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturers (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 identification (ID) number OPP–2004–0197. 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. Note: Due to renumbering of buildings in area, the street address will change to 1801 South Bell Street as of June 26, 2004. 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–2004–0197. 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–2004–0197. 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–2004–0197.

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–2004–0197. Note: Due to renumbering of buildings in area, the street address will change to 1801 South Bell Street as of June 26, 2004. 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: July 9, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

I. Bayer Corporation

PP 3F6537

EPA has received a pesticide petition (3F6537) from Bayer CropScience, 2 T.W. Alexander Drive, 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 the following residues:

1. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester, and its enol metabolite; 4-hydroxy- 3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4] non-3-en-2-one in or on the raw agricultural commodities strawberry at 2.0 parts per million (ppm); vegetable, tuberous and corm, crop subgroup 1C at 0.01 ppm; vegetable, leafy greens (except Brassica), crop subgroup 4A at 10 ppm; vegetable, Brassica, head and stem, crop subgroup 5A at 2.0 ppm; vegetable, Brassica, leafy, crop subgroup 5B at 12 ppm; vegetable, fruiting, crop group 8 at 0.30 ppm; tomato, paste at 0.60 ppm; vegetable, Cucurbit, crop group 9 at 0.10 ppm; corn, field, grain at 0.01 ppm; corn, field, forage at 3.0 ppm; corn, field, stover at 5.0 ppm; cotton at 0.50 ppm; and cotton, gin byproducts at 15 ppm.

2. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester, its enol metabolite; 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non- 3-en-2-one, and its metabolites containing the 4-hydroxymethyl moiety; 4- hydroxy-3-[4-(hydroxymethyl)- 2,6-dimethylphenyl]-1-oxaspiro[4.4] non-3-en-2-one, moieties in or on the rotational crop commodities alfalfa, forage at 1.5 ppm; alfalfa, hay at 3.0 ppm; wheat, grain at 0.01 ppm; wheat, forage at 0.20 ppm; wheat, hay at 0.15 ppm; wheat, straw at 0.25 ppm; wheat, bran at 0.05 ppm; wheat, shorts at 0.03 ppm; barley, grain at 0.02 ppm; barley, hay at 0.25 ppm; barley, straw at 0.25 ppm; beet, sugar, tops at 0.20 ppm; beet, sugar, roots at 0.02 ppm; and beet, sugar, molasses at 0.05 ppm.

3. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester, and its metabolites containing the enol; 4-hydroxy- 3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4] non-3-en-2-one, or 4-hydroxymethyl; 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]- 1-oxaspiro[4.4] non-3-en-2-one, moieties in or on the raw agricultural commodities cattle, fat at 0.05 ppm; cattle, meat byproducts at 0.05 ppm; milk at 0.01 ppm; and milk, fat at 0.03 ppm.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of spiromesifen in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled spiromesifen in various crops, all showing similar results. The residue of concern is spiromesifen and its enol metabolite.

2. *Analytical method*. Adequate analytical methodology using LC/MS/MS detection is available for enforcement purposes.

3. *Magnitude of residues*. Complete residue data exists for spiromesifen on these crops and crop groupings. The data support the requested tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Oral and dermal LD_{50} values were >2,000 mg/kg bw. Inhalation LC_{50} values were >4,873 mg/m^3 air. Spiromesifen was not irritating to rabbit skin or eyes but did cause skin sensitization in the Magnusson/Kligman maximization test in guinea pigs. Acute toxicity studies for spiromesifen support an overall toxicity Category III.

2. *Genotoxicity*. Several genotoxicity tests were conducted to test for point-mutagenic activity, chromosome aberration *in vitro* and *in vivo*, and for DNA repair. All tests conducted were negative, indicating no evidence of mutagenic or genotoxic potential.

3. *Reproductive and developmental toxicity*. An oral developmental toxicity study in rat did not reveal any evidence of teratogenic potential. The maternal and developmental no observed adverse effect levels (NOAELs) were 10 mg/kg bw/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 5 mg/kg bw/day, a developmental NOAEL of 35 mg/kg bw/day and did not reveal any teratogenic potential. A 2–generation study in rats, with a parental toxicity NOAEL of 2.2 mg/kg bw/day for males and 3.8 mg/kg bw/day for females, did not reveal evidence of a primary reproductive

toxicity potential. The reproductive NOAEL was 36.6 mg/kg bw/day for males and 14.2 mg/kg bw/day in females.

4. *Subchronic toxicity*. A subchronic toxicity feeding study with rats over 90 days demonstrated a NOAEL of 6.3 and 7.7 mg/kg bw/day for males and females, respectively, based on reduced body weights, effects on the lipid metabolism (decrease of triglycerides and cholesterol) and thyroid effects (colloidal alteration, hypertrophy) at the higher dose levels. A subchronic feeding study in mice over 14 weeks demonstrated a NOAEL of 3.2 and 5.1 mg/kg bw/day based on effects on lipid metabolism (decrease of cholesterol) and adrenal effects (cytoplasmic eosinophilia). A 14-week feeding study in dogs demonstrated a NOAEL of 9.2 and 9.3 mg/kg bw/day based on liver effects (enzyme induction, increased liver weights and cytoplasmic change) and thyroid effects (decreased T4).

5. *Chronic toxicity*. A 12-month chronic feeding study in rats demonstrated a NOAEL of 6.5 and 19.3 mg/kg bw/day for males and females, respectively. A 24-month oncogenicity study in rats demonstrated a NOAEL of 6.1 and 19.5 mg/kg bw/day for males and females, respectively. An oncogenicity study in the mouse revealed a NOAEL of 3.3 and 3.8 mg/kg bw/day for males and females, respectively based on macroscopic and microscopic adrenal effects. There was no indication in the rat or mouse for an oncogenic effect of spiromesifen. A 1–year feeding study with dogs demonstrated a NOAEL of 11.5 and 10.8 mg/kg bw day for males and females, respectively based on decreased body weights, liver effects (increased liver weight, hepatocellular cytoplasmic change, vacuoles) adrenal effects (increased incidence of small cell types).

6. *Animal metabolism*. Metabolism and pharmacokinetic studies in the rat demonstrate that spiromesifen residues are rapidly absorbed, metabolized and eliminated. There was no evidence of accumulation of residues in any tissues or organs. The primary metabolites are the enol, which is formed by cleavage of the alkyl ester group, and the 4-hydroxymethyl metabolite. However, several other metabolites are also formed.

7. *Metabolite toxicology*. The residues of concern are spiromesifen, its enol metabolite and BSN 4-hydroxymethyl, which are products of metabolism in mammalian systems, as well as in the environment. Since both products are major metabolites following the oral administration of spiromesifen to rats, toxicology data for these metabolites are completely supported by data obtained for spiromesifen.

8. *Endocrine disruption*. There is no evidence to suggest that spiromesifen has any primary endocrine disruptive potential. Reproductive and developmental findings provided no evidence of an enhanced sensitivity of the young. All prospective endocrine and endocrine-related changes which were noted were considered a function of the chemical's biological mode of action, the degree of exposure, a response secondary to other changes (e.g, enhanced liver metabolism), an aging or strain-specific phenomenon, or some combination of these factors.

C. Aggregate Exposure

1. *Dietary exposure*. For the acute dietary analysis, the acute reference dose (aRfD) of 2.0 mg/kg/day was derived from a NOAEL of 200 mg/kg based on an acute neurotoxicity study in rats and the application of an uncertainty factor (UF) of 100 to account for inter-species extrapolation and intra-species variability. For the chronic dietary analysis, the chronic reference dose (cRfD), of 0.022 mg/kg/day was derived from a NOAEL of 2.2 mg/kg/day based on a 2–generation reproduction toxicity study in rats and the application of an UF of 100. Based on the moderate, exposure-driven, non-primary, and/or animal specific nature of the endocrine and neurological changes attributed to exposure to spiromesifen as well as the lack of evidence to support a primary embryotoxic or teratogenic potential for spiromesifen, an FQPA safety factor of 1 was applied to the acute and chronic toxicology values, resulting in an acute population adjusted dose (aPAD) of 2.0 mg/kg/day and a chronic population adjusted dose (cPAD) of 0.022 mg/kg/day. As a conservative measure, the aPAD and cPAD values were used for all population sub-groups when conducting the assessments.

i. *Food*. Assessments were conducted to evaluate the potential risks due to acute and chronic dietary exposure of the entire U.S. population and selected population subgroups to residues of spiromesifen. These assessments cover the proposed use of spiromesifen on brassica (head and stem, broccoli and cabbage; leafy, mustard greens), corn (field), cotton, cucurbits (cantaloupe, cucumbers, and summer squash), fruiting vegetables (peppers and tomatoes), leafy greens (head and leaf lettuce and spinach), potatoes, strawberries, and the rotational crops of alfalfa, barley, sugarbeets, and wheat. For the acute assessment, the most highly exposed population subgroup was children 1-6 years with an exposure equal to 0.4% of the acute reference dose (aPAD) at the 95th percentile. Acute exposure of the overall US population was equivalent to 0.3% of the aPAD. For the chronic dietary assessment, the most highly exposed population subgroup was children 1-6 years, with an exposure equal to 1.2% of the chronic reference dose (cPAD). Chronic exposure for the overall U.S. population equated to 0.4% of the cPAD. These Tier 2 acute and chronic dietary exposure estimates are well below EPA's level of concern for the overall U.S. population as well as the various population subgroups.

ii. *Drinking water*. Spiromesifen is immobile in soil and therefore will not leach into groundwater. Additionally, due to insolubility in water and a highly lipophilic nature, any residues in surface water will rapidly bind to soil particles and remain with sediment where it is quickly degraded, and therefore not contribute to potential dietary exposure from drinking water. Estimated environmental concentrations (EECs) of spiromesifen and its enol metabolite in surface water (Tier I) were determined using EPA's FIRST screening model (FIFRA Index Reservoir Screening Tool). EEC predictions of spiromesifen its enol metabolite in groundwater (Tier I) were made using SCI-GROW (Screening Concentration in Ground Water). Tier II EEC predictions in surface drinking water were made using the Pesticide Root Zone Model, PRZM3, in combination with the Exposure Analysis Modeling System, EXAMS II, and EPA's Index Reservoir (IR) scenario. Use of spiromesifen (Tier II) on strawberries and vegetables was simulated in Florida, potatoes in Minnesota and cotton in Texas and California. Applications of spiromesifen to field corn were also evaluated in Texas.

The highest predicted Tier I surface water EECs for spiromesifen were from use on strawberries, with peak (acute) and annual average (chronic) concentrations of 7.41 and 0.18 ppb, respectively. Corresponding surface water EECs for the enol metabolite were 37.5 and 19.4 ppb. Strawberries produced the highest EECs under the Tier I scenario due to the conservative runoff assumptions built into the model. The highest predicted EECs in ground water were 0.000 ppb for spiromesifen and 1.09 ppb for the enol, also from the strawberry use scenario. Tier II EECs were predicted to be highest for strawberries and vegetables. The highest peak, 4-day, 21-day, 60-day, 90-day, yearly upper 90th percentile (of the

annual maximums) and annual average concentrations across all use scenarios were 1.30 and 1.07 ppb for FL strawberries and 0.66, 0.35, 0.24, 0.07 and 0.05 ppb for Florida vegetables, respectively. EECs of spiromesifen enol were highest for Florida strawberries, with corresponding concentrations of 32, 30, 26, 17, 11, 3.9, and 1.7 ppb, respectively.

The highest acute and chronic concentrations (spiromesifen and enol in surface water combined) across all use scenarios were used to assess human health risk from drinking water. Potential risk was estimated by comparing estimated drinking water concentrations to the acute and chronic Population Adjusted Dose (PAD) values, while accounting for differences in body weight and drinking water consumption between adults and children. These calculations result in risk estimates in the form of percentages of the acute and chronic PAD values. Tier I acute risk for adults and children were estimated at 0.06 and 0.23%, respectively, while Tier II acute estimates were 0.05 and 0.17%, respectively. Maximum Tier I chronic risk was estimated at 2.5% for adults and 8.9% for children. Corresponding Tier II chronic risk was estimated at 0.52% for adults and 1.8% for children (0.81% for children using the mean of the annual average concentrations over the simulation period).

2. *Non-dietary exposure*. Exposure assessments were prepared for both mixer/loader-applicators and reentry workers based on use of spiromesifen on various field crops, vegetables and strawberries. Agricultural worker margins of exposure (MOE) estimates were conservatively based on a no-observable-effect level (NOEL) of 1.06 mg/kg/day, maximum label rates, and a dermal absorption value of 2.25%. An occupational exposure uncertainty factor of 100 was used in the assessment. All margins of exposure (total) exceeded 100, indicating that these uses of spiromesifen pose no significant risk to workers who mix, load and apply this product, or to those who reenter treated areas to perform post-application activities. These data support the use of a single layer of clothing for mixer/loaders and applicators, gloves for mixer/loaders, and a 12-hour REI for reentry workers.

Exposure assessments were also conducted for both applicators and reentry based on use of spiromesifen for ornamentals, greenhouse and nursery applications. There are no indoor residential uses for spiromesifen, and therefore no assessments were performed for indoor residential use. All margins of exposure (total) exceeded 100, indicating that these uses of spiromesifen pose no significant risk to workers who mix, load and apply this product, or to those who reenter treated areas to perform post-application activities. These data support the use of a single layer of clothing for mixer/loaders and applicators, gloves for mixer/loaders, and reentry activities to be performed immediately after the application spray dries.

D. Cumulative Effects

Spiromesifen represents a new class of chemistry, ketoenoles. There are no known registered chemicals within this class. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects of spiromesifen consistent with the schedule established by EPA at 62 FR 42020 (Aug. 4, 1997) (FRL–5734–6) and other EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to spiromesifen from all label uses will utilize less than 10 percent of the RfD for chronic dietary exposures and that margins of exposure in excess of 100 exist for aggregate exposure to spiromesifen for non-occupational exposure. EPA generally has no concerns for exposures below 100 percent of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Margins of exposure of 100 or more also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to spiromesifen residues.

2. *Infants and children*. In assessing the potential for increased sensitivity of infants and children, data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity. None of these studies conducted with spiromesifen indicated developmental or reproductive effects. The toxicology data which support these uses of spiromesifen include the following: An oral developmental toxicity study in rat that did not reveal any evidence of teratogenic potential. Maternal and developmental NOAELs were 10 mg/kg bw/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 5 mg/kg bw/day, a developmental NOAEL of 35 mg/kg bw/day and did not reveal any teratogenic potential. A two-generation study in rats, with a parental toxicity NOAEL of 2.2 mg/kg bw/day, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 14.2 mg/kg bw/day. FFDCA Section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when prenatal and postnatal threshold effects were observed in studies or to account for incompleteness of the toxicity database. Based on the toxicological data requirements, the data relative to prenatal and postnatal effects in children is complete. No indication of increased susceptibility of younger animals was observed in any of the above studies. For the population with the highest exposure, children 1-6 years old, the acute dietary exposure at the 95th percentile was 0.4% of the aPAD, equivalent to an MOE of 24845. Acute exposure of the overall US population was equivalent to 0.3% of the aPAD. For the chronic dietary analysis, the most highly exposed population subgroup was children 1-6 years old, with an exposure equal to 1.2% of the cPAD. Chronic exposure for the overall U.S. population equated to 0.4% of the cPAD.

F. International Tolerances

Codex maximum residue levels (MRLs) are not yet established for spiromesifen.

[FR Doc. 04–16720 Filed 7–27–04; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0221; FRL–7371–5]

Experimental Use Permit; Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application 67979–EUP–L from Syngenta Seeds, Inc. - Field Crops - NAFTA requesting an experimental use permit (EUP) for the plant-incorporated