ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0213; FRL–7343–2]

Spirodiclofen; Notice of Filing a Pesticide Petition to Establish a 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 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–2003–0213, must be received on or before March 19, 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: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address:*kumar.rita@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–2003–0213. 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–2003–0213. 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–2003–0213. 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–2003–0213.

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–2003–0213. 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: January 27, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by 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

PP 2F6469

EPA has received a pesticide petition (PP 2F6469) 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 a tolerance for residues of Spirodiclofen; 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro [4,5]dec-3-en-4-yl ester 2,2-dimethyl-butanoic acid, in or on the raw agricultural commodities citrus fruit group at 0.3 parts per million (ppm), citrus pulp, dried, at 0.4 ppm, citrus oil at 20 ppm, pome fruit group at 0.8 ppm,

pome fruit pomace, wet, at 6.0 ppm, stone fruit group at 1.0 ppm, tree nut group at 0.05 ppm, almond hulls at 20 ppm, pistachios at 0.05 ppm, grape at 2.0 ppm and grape, raisin at 4.0 ppm. Spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl ester 2,2-dimethyl-butanoic acid, and/or its enol metabolite, 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro [4,5]dec-3-en-2-one, in or on the raw agricultural commodities cattle, fat, at 0.01 ppm and cattle, meat by-products, at 0.05 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

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

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 spirodiclofen 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 milligrams/kilogram body weight (mg/kg bwt). Inhalation LC_{50} values were >5,030 mg/m^3 air. Spirodiclofen 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 spirodiclofen 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 1,000 mg/kg bwt/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 100 mg/kg bwt/day and did not reveal any teratogenic potential. A two-generation study in rats, with a parental toxicity NOAEL of 5.2 mg/kg bwt/day, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 26.2 mg/kg bwt/day based on various clinical and histopathological findings at higher dose levels.

4. *Subchronic toxicity*. A subchronic toxicity feeding study with rats over 90 days demonstrated a NOAEL of 32.1 and 8.1 mg/kg bwt/day for males and females, respectively, based on effects on the lipid metabolism (decrease of triglycerides and cholesterol), liver effects (increase in transaminases) and adrenal effects (vacuolation) at the higher dose levels. A subchronic feeding study in mice over 13–weeks revealed no clinical toxicological signs. A NOAEL of 30.1 mg/kg bwt/day for females was observed (a clear NOAEL was not established for males). A 14–week feeding study in dogs demonstrated a NOAEL of 7.7 mg/kg bwt/day.

5. *Chronic toxicity*. A 24–month combined chronic feeding/carcinogenicity study in rats demonstrated a NOAEL of 14.7 mg/kg bwt/day. An oncogenicity study in the mouse revealed a NOAEL of 4.1 mg/kg bwt/day. Uterine and testicular oncogenicity was noted in the rat and hepatic neoplasia was observed in the mouse. A 1–year feeding study with dog demonstrated a NOAEL of 1.38 mg/kg bwt/day based on adrenal effects (vacuolization) as well as changes in circulating cholesterol and prostate weight at higher dose levels.

6. *Animal metabolism*. Metabolism and pharmacokinetic studies in the rat demonstrate that spirodiclofen residues are rapidly absorbed, metabolized and eliminated. The primary metabolite is the enol, which is formed by cleavage of the alkyl ester group, but numerous other metabolites are also formed.

7. *Metabolite toxicology*. The residue of concern is spirodiclofen and its enol metabolite, which is a product of hydrolysis in mammalian systems, as well as in the environment. Since the enol is inherently present after administration, toxicology data for this metabolite is completely supported by data obtained for spirodiclofen.

8. *Endocrine disruption*. The mammalian mode of action for spirodiclofen includes that classified as inhibitory to steroid biosynthesis, resulting in an indirect and endogenously-mediated toxicological response. Effects do not have an impact on fertility, reproduction, developmental or neuropathological parameters. Additional mechanistic studies with the chemical indicated that there is no direct effect on the endocrine system as there is no interaction with hormone receptors.

C. Aggregate Exposure

1. *Dietary exposure*. For the acute dietary analysis, the acute reference dose (aRfD), of 1.0 mg/kg/day was derived from a NOAEL of 100 mg/kg based on a prenatal developmental toxicity study in rabbits 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 cRfD, of 0.0138 mg/kg/day was derived from a NOAEL of 1.38 mg/kg/day based on a 1–year feeding study in dogs and the application of an UF of 100. An FQPA safety factor of 3 was also applied to the acute and chronic toxicology values, resulting in an acute population adjusted dose (aPAD) of 0.33 mg/kg/day and a chronic population adjusted dose (cPAD) of 0.0046 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 spirodiclofen. These analyses cover the proposed uses on citrus fruits (grapefruits, lemons, and oranges), pome fruits (apples and pears), stone fruits (cherries, peaches, and plums), tree nuts (almonds and pecans) and grapes. For the acute dietary assessment, 100% crop treated and the highest or highest average field trial residues were assumed. For the chronic assessment, anticipated market share and average residue values were assumed. For the acute analysis, the most highly exposed population subgroup was non-nursing infants (< 1–year) with an exposure equal to 2.3% of the aPAD at the 95th percentile. Acute exposure of the overall U.S. population was equivalent to 0.45% of the aPAD. For the chronic dietary analysis, the most highly exposed population subgroup was children 1–6 years, with an exposure equal to 1.9% of the cPAD. Chronic exposure for the overall U.S. population equated to 0.6% of the cPAD. These 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*. Spirodiclofen is immobile in soil; and therefore, will not leach into ground water. Additionally, due to insolubility in water and a highly lipophilic nature, any residues in

surfacewater 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. The estimated environmental concentration (EEC) values for spirodiclofen and the enol metabolite were calculated using the tier I screening concentration in ground water (SCI-GROW), screening model for ground water estimates, and the tier II PRZM/EXAMS, models with index reservoir (IR) and percent crop area (PCA) factor for surface water estimates. The potential EEC levels were determined for the maximum usage intensity for each crop. The acute and chronic percent of population adjusted dose (%PAD) values associated with drinking water exposure were calculated based on a NOAEL of 100 mg/kg/day for acute exposure and 1.38 mg/kg/day for chronic exposure. The uncertainty factor (UF) considered in the analysis was 100X, and an additional Food Quality Protection Act (FQPA) safety factor of 3X was used both for acute and chronic calculations. The SCI-GROW estimated maximum ground water EEC level for spirodiclofen and enol combined was 0.003 ppb, suggesting that the compounds have a low potential to leach and contaminate the ground water under normal use. The highest estimate of the total acute concentration in surface water for spirodiclofen and enol combined was 6.04 parts per billion (ppb). The highest estimate of the total chronic concentration in surface water for spirodiclofen and enol combined was 0.67 ppb. The maximum %PAD calculated, 1.46%, was for infant/children chronic exposure. The low %PAD indicates that the human health risk associated with the presence of spirodiclofen and/or its enol metabolite in drinking water is minimal.

2. *Non-dietary exposure*. There are no indoor residential, indoor commercial or outdoor residential uses for spirodiclofen. Exposure and risk assessments were prepared for both mixer/loader-applicators and reentry workers during use of spirodiclofen on citrus, tree nuts and pome/stone fruit. Worker margins of exposure (MOE) estimates were conservatively based on a NOAEL of 1.38 mg/kg/day, maximum label rates, and a dermal absorption value of 2.3%. An occupational exposure uncertainty factor of 100 was used in the assessment. Margins of exposure total ranged from 360 to 69,000, indicating that the use of spirodiclofen poses 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, and gloves for mixer/loaders, and a 12–hour REI for reentry workers.

D. Cumulative Effects

Spirodiclofen represents a new class of chemistry, ketoenoles. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects of spirodiclofen consistent with the schedule established by EPA at 62 **Federal Register** 42020 (Aug. 4, 1997) 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 spirodiclofen from all label uses will utilize less than 5% of the RfD for chronic dietary exposures and that margins of exposure in excess of 360 exist for aggregate exposure to spirodiclofen for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Margins of exposure of 100 or more (300 for infants and children) 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 spirodiclofen 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 spirodiclofen indicated developmental or reproductive effects. The toxicology data which support these uses of spirodiclofen include the following: An oral developmental toxicity study in rat that did not reveal any evidence of teratogenic potential. Maternal and developmental NOAELs were 1,000 mg/kg bwt/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 100 mg/kg bwt/day and did not reveal any teratogenic potential. A two-generation study in rats, with a parental toxicity NOAEL of 5.2 mg/kg bwt/day, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 26.2 mg/kg bwt/day based on various clinical and histopathological findings at higher dose levels. 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, non-nursing infants <1 year old, the acute dietary exposure at the 95th percentile was 2.3% of the aPAD, equivalent to an MOE of 13,167. For the population described as children 1–6 years old, the exposure was 1.2% of the aPAD, equivalent to an MOE of 25,638. Acute exposure of the overall U.S. population was equivalent to 0.45% 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 1.9% of the cPAD. Chronic exposure for the overall U.S. population equated to 0.6% of the cPAD.

F. International Tolerances

Codex maximum residue levels MRLs are not yet established for spirodiclofen.

[FR Doc. E4–270 Filed 2–17–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0026; FRL–7344–4]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only