C. How and To Whom Do I Submit Comments?

To submit comments, or access the official public docket, please follow the detailed instructions as provided in Unit I.C. of the **Federal Register** of the January 29, 2003 document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What Action is EPA Taking?

This document reopens the public comment period established in the **Federal Register** of January 29, 2003. In that document, EPA announced the availability of the preliminary comparative ecological assessment for nine rodenticides and invited comment on issues directly associated with the nine rodenticides that were included in the assessment. Due to the many requests received for additional time to comment, EPA is hereby reopening the comment period, which was set to end on March 31, 2003, to May 30, 2003.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: April 8, 2003.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 03–10070 Filed 4–22–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0129; FRL–7303–1]

Fluoxastrobin; 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–2003–0129, must be received on or before May 23, 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: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address: mcneilly.dennis@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 identification (ID) number OPP–2003–0129. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public

docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0129. 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–2003–0129. 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–2003–0129.

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–2003–0129. 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: April 15, 2003.

Debra Edwards,

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.

Bayer CropScience

PP 3F6556

EPA has received a pesticide petition (3F6556) 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 a tolerance for residues of fluoxastrobin; 2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl (5,6-dihydro-1,4,2-dioxazin-3-yl)methanone-O-methyloxime in or on the raw agricultural commodities (RACs) alfalfa, forage at 0.05 parts per million (ppm), alfalfa, hay at 1.0 ppm, cotton, gin byproducts at 0.02 ppm, grain, cereal, forage at 0.10 ppm, grain, cereal, hay at 0.10 ppm, grain, cereal, straw at 0.10 ppm, grain, cereal, stover at 0.10 ppm, grass, forage at 0.10 ppm, grass, hay at 0.50 ppm, legume, seed at 0.01 ppm, legume, forage at 0.05 ppm, legume, hay at 0.05 ppm, peanut at 0.01 ppm, peanut, hay at 20 ppm, peanut, refined oil at 0.10 ppm, tomato, paste at 2.0 ppm, vegetable, fruiting, group at 1.0 ppm, vegetable, leafy, petioles, except brassica, subgroup at 5.0 ppm, and vegetable, tuberous and corm, subgroup at 0.01 ppm. Fluoxastrobin; 2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl (5,6-dihydro-1,4,2-dioxazin-3-yl)methanone-O-methyloxime, and its phenoxy-hydroxypyrimidine metabolite; 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol in or on the RACs cattle, fat at 0.10 ppm, cattle, meat at 0.05 ppm, cattle, meat byproducts at 0.20 ppm, milk at 0.01 ppm, and milk, fat at 0.10 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 fluoxastrobin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled fluoxastrobin in peanut, tomato, spring wheat, and various representative rotational crops, all showing similar results. The residue of concern is parent fluoxastrobin (sum of E and Z isomers).

2. *Analytical method*. Adequate analytical methodology using liquid chromatography/mass spectrometer/mass spectromer (LC/MS/MS) detection is available for enforcement purposes.

3. *Magnitude of residues*. Complete residue data exists for fluoxastrobin on these crops and crop groupings. Magnitude of residue trials were conducted on peanut, potato, celery, tomato, pepper, and the rotational crops of alfalfa, cotton, cereal grains (corn, rice, sorghum and wheat), soybeans, other legume vegetables, and grasses. A cattle feeding study was performed in order to determine residues in meat and milk commodities. The data support the proposed tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Oral and dermal lethal dose $(LD)_{50}$ values were >2,000 milligrams/kilogram bodyweight (mg/kg) (bwt). Inhalation lethal concentrations $(LC)_{50}$ values were >4,998 milligrams/meters (mg/m^3) air. Fluoxastrobin technical was not irritating to rabbit skin, was moderately irritating to eyes in rabbits, and was non-sensitizing dermally in the Magnusson/Kligman maximization test in guinea pigs. Acute toxicity studies for fluoxastrobin 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 no observed adverse effect level (NOAEL) was 300 mg/kg and the developmental NOAEL was 1,000 mg/kg bwt/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 25 mg/kg bwt/day, a developmental NOAEL of 100 mg/kg bwt/day and did not reveal any teratogenic potential. A 2-generation study in rats, with a parental toxicity NOAEL of 73.7 mg/kg bwt/day for males and 86.7 mg/kg bwt/day for females, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 763.6 mg/kg bwt/day for males and 806.5 mg/kg bwt/day in females.

4. *Subchronic toxicity*. A subchronic toxicity feeding study with rats over 90 days demonstrated a NOAEL of 7.3 and 18.3 mg/kg bwt/day for males and females, respectively, based on reduced body weights and alterations in several urinary tract-related clinical chemistry parameters, at the higher dose levels. In a subchronic feeding study in mice over 14 weeks, a NOAEL was not established based on decreased alanine aminotransferase (ALAT) and increased absolute and relative liver weights at the low dose level (21.7 and 35.3 mg/kg bwt/day for males and females respectively). A 14-week feeding study in dogs demonstrated a NOAEL of 3.0 mg/kg bwt/day based on decreased body weights and food consumption, and liver effects (enzyme induction, increased liver weights, cytoplasmic change), and thyroid effects (decreased T3)

5. *Chronic toxicity*. A 24-month chronic/oncogenicity feeding study in rats demonstrated a NOAEL of 53.0 and 35.2 mg/kg bwt/day for males and females, respectively. An oncogenicity study in the mouse revealed a NOAEL of 18.5 and 29.5 mg/kg bwt/day for males and females, respectively based on liver effects. There was no indication in the rat or mouse for an oncogenic effect of fluoxastrobin. A 1-year feeding study with dogs demonstrated a NOAEL of 1.7 and 1.5 mg/kg bwt/day for males and females, respectively based on decreased body weights and slight liver effects (increased alkaline phosphatase (Aph) and liver weights).

6. *Animal metabolism*. Metabolism and pharmacokinetic studies in the rats, lactating goats, and laying hens demonstrate that fluoxastrobin residues are rapidly absorbed, metabolized, and eliminated. There was no evidence of accumulation of residues in any tissues or organs. The metabolic pattern was always complex and numerous metabolites were identified. The main metabolic reactions, however, are very comparable for all tested animal species and most metabolites were present at low levels. Based on the available metabolism data, fluoxastrobin and phenoxy-hydroxypyrimidine are the proposed residues of concern in animals.

7. *Metabolite toxicology*. The residues of concern are fluoxastrobin its

phenoxy-hydroxypyrimidine metabolite. This metabolite was investigated for acute oral toxicity and point mutagenic activity in a bacterial reverse mutation assay. The phenoxy-hydroxypyrimidine metabolite did not show mutagenic activity in the reverse mutation assay and the oral LD_{50} was >300 <500 mg/kg body weight.

8. *Endocrine disruption*. There is no evidence to suggest that fluoxastrobin has any primary endocrine disruptive potential. Reproductive and developmental findings provided no evidence of an enhanced sensitivity of the young.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Acute and chronic dietary analyses were conducted to estimate exposure to potential fluoxastrobin residues in/on the following crops and crop groups: celery, fruiting vegetables, peanuts, and potatoes. Rotational crops included in the analysis are alfalfa, grasses, legume vegetables, foliage of legume vegetables, cereal grains, and cotton. Tier I analysis were conducted for both the acute and chronic scenarios using the Dietary Exposure Evaluation Model (DEEM) (Exponent, Inc.) software. The acute dietary exposure estimates at the 95th percentile of exposure for the U.S. population was 1.4% of the acute reference dose (RfD). The population subgroup with the highest exposure was children 1 to 6 at 2.7% of the acute RfD. Chronic dietary exposure estimates from potential residues of fluoxastrobin for the U.S. population was 6.5% of the chronic RfD. The subpopulation with the highest exposure was children 1 to 6 with 12.7% of the chronic RfD used. Tier I assessments use tolerance residue values and 100% crop treated. These can be considered very conservative values.

ii. *Drinking water*. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water analysis for fluoxastrobin. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as Screening Concentration in Groundwater (SCI-GROW), Generic Estimate Exposure Concentration (GENEEC), Pesticide Root Zone Model-Exposure Analysis Modeling Systems (PRZM/EXAMS), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water. In the case of fluoxastrobin, monitoring data do not exist, therefore, PRZMS/EXAMS and SCI-GROW models were used to estimate a drinking water residue. The calculated drinking water levels of comparison (DWLOC) for acute and chronic exposures for all adults and children exceed the modeled fluoxastrobin drinking water estimated concentrations (DWECs). The acute DWLOC values are 8,624 parts per billion (ppb) for adults and 2,433 ppb for children. The worst-case DWEC for acute scenarios is calculated to be 58 ppb using the PRZMS/EXAMS surface water model. The chronic DWLOC values are 491 ppb for adults and 131 ppb for children. The DWEC for the worst-case chronic scenario is 28 ppb PRZM/EXAMS.

2. *Non-dietary exposure*. Residential (non-dietary) exposure is limited to post-application exposure of fluoxastrobin from professional applications to residential turf and golf courses. Using the very conservative EPA SOPs for residential exposure a margin of exposure (MOE) of 7,143 was calculated for the youth golfer scenario. Adult and toddler reentry to treated turf MOEs were 784 and 468 respectively.

Aggregate exposure considers all exposures from food, drinking water, and residential uses together. Probabilistic models and methods as well as refined data for these scenarios are under development. In the interim, as a screening level analysis a worst-case deterministic calculation can be considered. For fluoxastrobin this would consist of a child (1 to 6) who has a chronic dietary exposure to potential residues in food and also plays on a maximally treated lawn (after 4 applications) on a particular day. The childs lawn exposure includes estimates of dermal exposure and oral exposure from hand to mouth, object to mouth and soil ingestion SOP scenarios. The childs estimated dose from the lawn exposure is 0.0194 mg/kg bwt/day. The child 1 to 6 chronic dietary exposure estimate is 0.001907 mg/kg bwt/day. The total dose for a child 1 to 6 with this worst-case exposure is 0.0213 mg/kg bwt/day or 8.5% of the acute RfD. The resulting aggregate acute DWLOC is 2,287 ppb still well above the acute DWEC of 58 ppb. Total adult exposure (average dietary and dermal lawn) is 0.004804 mg/kg bwt/day or 1.9% of the acute RfD. The resulting aggregate acute DWLOC for adults is 17,164 ppb.

D. Cumulative Effects

Fluoxastrobin is a novel strobilurin analog. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects of fluoxastrobin consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL–5734–6), and other EPA publications pursuant to the Food Quality Protection Act (FQPA).

E. Safety Determination

1. *U.S. population*. Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data it is concluded that aggregate exposure to the proposed uses of fluoxastrobin will utilize at most 1.9% of the RfD for the U.S. population, and is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. DWLOC based on this exposure are much greater than conservative estimated concentrations, and would be expected to be well below the 100% level, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to fluoxastrobin.

2. *Infants and children*. Consideration of the toxicology data base as described above leads to no additional concerns for infants and children. Therefore the FQPA safety factor can be established at 1X. Using the conservative exposure assumptions described in the exposure section above, the percent of the RfD that will be used for short-term aggregate exposure to residues of fluoxastrobin will be 8.5% for children 1 to 6 (the most highly exposed sub-group). This value is based on a worst-case aggregate exposure calculation of a child 1 to 6 who has a background dietary exposure to potential residues and plays on a maximally treated lawn. As in the adult situation, DWLOC are much higher than the worst-case DWECs and would be expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of fluoxastrobin.

F. International Tolerances

Codex maximum residue levels are not yet established for fluoxastrobin.

[FR Doc. 03–9746 Filed 4–22–03; 8:45 am]

BILLING CODE 6560–50–S