ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0087; FRL–7350–6]

Clothianidin; 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 identification (ID) number OPP–2004–0087, must be received on or before July 16, 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: Stephanie Nguyen, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0702; e-mail address: *nguyen.stephanie@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–2004–0087. 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 areavailable 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 EPA's 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 EPAidentifies 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–2004–0087. 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–2004–0087. 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–2004–0087.

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–2004–0087. 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: May 27, 2004.

Lois Rossi,

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 3F6792

EPA has received a pesticide petition (3F6792) 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 clothianidin in or on the raw agricultural commodities sorghum, grain at 0.01 part per million (ppm); sorghum, forage at 0.01 ppm; and sorghum, stover at 0.01 ppm, respectively. 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*. In plants, the metabolism of clothianidin is adequately understood for the purposes of establishing these proposed tolerances. Unchanged parent clothianidin was the predominant residue in all crop matrices (14.4% to 64.5% in corn, 66.1% to 96.6% in tomatoes, 4.3% to 24.4% in sugar beets, and 24.3% to 63.3% in apples), with the exception of sugar beet leaves. In sugar beet leaves, the main components were the methylguanidine and thiazolylmethylguanidine metabolites, accounting for 28.6% and 27.7%, respectively. All metabolites found in plants were also found in the animal metabolism studies. In animals, parent clothianidin was the major component in liver, muscle, and fat. Based on the available metabolism data, parent clothianidin, thiazolyl-guanidine (TZG), thiazolyl-urea (TZU), and (ATMG-Pyr) aminothiazolyl methylguanidine-pyridine are proposed to be considered as the residues of concern in livestock matrices.

2. *Analytical method*. In plants and plant products, the residue of concern, parent clothianidin, can be determined using high performance liquid chromotography (HPLC) with electrospray mass spectroscopy/mass molecular size (MS/MS) detection. In an extraction efficiency testing, the plant residues method has also demonstrated the ability to extract aged clothianidin residue.

Although the plant residues lethal dose (LC)-MS/MS method is highly suitable for enforcement method, an LC-ultraviolet (UV) method has also been developed which is suitable for enforcement (monitoring) purposes in all relevant matrices.

3. *Magnitude of residues in sorghum*. A total of 12 field trials was conducted to evaluate the quantity of clothianidin in sorghum forage, stover, and grain. Sorghum seed was treated with TI–435 600 fecal streptococci (FS) at a rate of 250 grams active ingredient/100 kilograms (kg) seed. The highest average field trial was less than 0.01 ppm in sorghum forage, stover, and grain when collected at normal harvest of 97 to 167 days after planting of treated seed. In a sorghum processing study sorghum seed was treated at a 2X rate of 500 grams active ingredient/100 kg seed. No residues at or above the limit of quantitation (LOQ) of 0.01 ppm were found in the sorghum grain. Therefore, a sorghum processing study was not conducted.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral lethal dose $(LD)_{50}$ was >5,000 milligrams/kilogram/body weight (mg/kg/bwt) for both male and female rats. The acute dermal LD_{50} was greater than 2,000 mg/kg/bwt in rats. The 4–hour inhalation LC_{50} was 5.538 miligrams/Liters (mg/L) for male and female rats. Clothianidin was not irritating to rabbit skin and only slightly irritating to the eyes and did not cause skin sensitization in guinea pigs.

2. *Genotoxicity*. Extensive mutagenicity studies were conducted with clothianidin. Based on the weight of evidence clothianidin was considered negative for genotoxicity.

3. *Reproductive and developmental toxicity*. In a 2–generation reproduction study, rats were administered dietary levels of 0, 150, 500, and 2,500 ppm. The no observed effect level (NOAEL) for reproductive parameters was 500 ppm (31.2/36.8 mg/kg/day; for male and female), while the NOAEL for developmental effects was 150 ppm (9.8/11.5 mg/kg/day; for male and female. The parental systemic NOAEL was 500 ppm (31.2/36.8 mg/kg/day; for male and female).

A developmental toxicity study was conducted in rats with clothianidin using dose levels of 0, 10, 50, and 125 mg/kg/bwt by gavage. The NOAEL for maternal toxicity was established at 10 mg/kg/bwt and for developmental effects it was >125 mg/kg bwt. Additionally, a developmental toxicity study was conducted with rabbits treated orally by gavage at 0, 10, 25, 75, and 100 mg/kg/bwt. The NOAEL for maternal toxicity was 25 mg/kg/bwt and for developmental toxicity it was 75 mg/kg/bwt. Developmental toxicity studies showed no primary developmental toxicity and no teratogenic potential was evident.

4. *Subchronic toxicity*. A 90–day feeding study was conducted in rats and dogs. The rat study was conducted at dietary levels of 0, 150, 500, and 3,000 ppm and the dog study was conducted at 0, 325, 650, and 1,500 ppm. The NOAELs were established at 500 ppm (27.9/34.0 mg/kg/day; for the male and female rat, and 650 ppm (19.3 mg/kg/day) for the male dog, and 1,500 ppm (42.1 mg/kg/day) for the female dog.

5. *Chronic toxicity*. A 2–year combined rat chronic/oncogenicity study conducted at dietary levels of 0, 150, 500, 1,500, and 3,000 ppm demonstrated a NOAEL of 500 ppm (27.9/34.0 mg/kg/day) based on reduced weight gains and non-neoplastic histomorphological changes. A 78–week mouse oncogenicity study conducted at dose levels of 0, 100, 350, 1,250, and 2,000, and 1,800 ppm for males and females, respectively, revealed a NOAEL of 350 ppm (47.2/65.1 mg/kg/day; for males and females based on reduced body weight gains and increased incidence of hypercellular hypertrophy. No evidence of oncogenicity was seen in the rat or the mice. A 52–week chronic toxicity study in dogs conducted at dietary levels of 0, 325, 650, 1,500, and 2,000 ppm revealed a NOAEL of 2,000 ppm (46.4 mg/kg/day) for the male dog and 1,500 ppm (40.1 mg/kg/day) for the female dog.

6. *Animal metabolism*. The nature of the clothianidin residue in livestock is adequately understood. In animals, parent clothianidin was the major component in liver, muscle, and fat. Based on the available metabolism data, parent clothianidin, TZG, TZU, and ATMG-Pyr are proposed to be considered as the residues of concern in livestock matrices.

7. *Metabolite toxicology*. Eight *in vivo* metabolites of clothianidin identified in the rat were investigated for acute oral endpoint mutagenic activity. None of the metabolites were mutagenic either with or without activation and the LD_{50} values range from <500 to >2,000 mg/kg, showing low to moderate toxicity.

8. *Endocrine disruption*. All guideline studies conducted to characterize toxicological profile showed no endocrine related toxicity or tumorgenicity. No effects on triiodothyronine (T3), throxine (T4), or thyroid stimulating hormone (TSH) were observed in the subchronic rat study. In a 2–generation reproduction study in rat; and rat and rabbit teratology studies, clothianidin did not show reproductive or teratogenic effects. The extensive data base shows that clothianidin has no endocrine properties.

C. Aggregate Exposure

1. *Dietary exposure*. There are no residential uses for clothianidin, therefore aggregate exposure consists of dietary (food and drinking water) exposures. The acute population adjusted dose (PAD) of 0.025 mg/kg bwt/day based on an acute NOAEL of 25 with an uncertainty factor (UF) of 1,000 was used to assess acute dietary exposure. The chronic (PAD) of 0.0098 mg/kg/bwt/day based on a chronic NOAEL of 9.8 with an UF of 1,000 was used to assess chronic exposure.

i. *Food*. In the clothianidin pesticide tolerance action for corn and canola, the

Federal Register notice of May 30, 2003 (68 FR 32390) (FRL–7306–8), EPA conducted Tier I acute and chronic dietary assessments for clothianidin. These assessments included residues of clothianidin that arise from the uses of thiamethoxam which has clothianidin as a common metabolite. Based on these assessments, a tolerance of 0.01 ppm for sorghum use for clothianidin was added to the analysis. No significant contribution was seen from this use. The U.S. population utilized 8.4% (0.00211 mg/kg/bwt/day, 95th percentile) of the acute PAD and 6.5% (0.000635 mg/kg/bwt/day) of the chronic PAD. The most highly exposed subpopulation is children 1 to 2 at 19.1% (0.004772 mg/kg/bwt/day, 95th percentile) of the acute PAD and 19.1% (0.001874 mg/kg/bwt/day) of the chronic PAD.

ii. *Drinking water*. EPA's Standard Operating Procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessment. These tools include water models such as Screening Concentration in Groundwater (SCI-GROW), FQPA Index Reservoir Screening Tool (FIRST), EPA's Pesticide Root Zone Model/ Exposure Analysis Modeling System (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 and the highest is assumed to be the drinking water residue. In the case of clothianidin, monitoring data do not exist therefore SCI-GROW and FIRST were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for acute chronic exposure for all adults and children exceed the drinking water estimated concentrations (DWEC) from the models. The chronic DWLOC for adults is 321 parts per billion (ppb) and the acute DWLOC is 801 ppb. The chronic DWLOC for children 1 to 2 is 79 ppb and the acute DWLOC is 202 ppb. The DWEC for the worst case chronic scenario is 2.14 ppb FIRST and the acute DWEC FIRST is 3.97 ppb. The DWLOC are based on conservative dietary (food) exposures and are expected to be much higher in real world situations.

2. *Non-dietary exposure*. Clothianidin products are not labeled for residential uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational exposure.

D. Cumulative Effects

Clothianidin is a metabolite of thiamethoxam. Therefore, residues of clothianidin resulting from use of thiamethoxam were included in the above risk assessment. There are no data available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that aggregate exposure to residues of clothianidin present a reasonable certainty of no harm. Exposure from residues in crops utilize 8.4% of the acute PAD and 6.5% of the chronic PAD. EPA generally has no concerns for exposures below 100% of the PAD. DWLOC are well above the estimated drinking water concentrations as calculated by conservative models. There are no residential uses so aggregate exposure consists of food and drinking water exposures. The conservative Tier I assessments demonstrate a reasonable certainty of no harm will result from uses of clothianidin for the U.S. population.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a 2–generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through 2–generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA section 408 provides that EPA may apply an additional UF for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity data base. Based on the current toxicological data requirements the toxicology data base for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. Therefore, no additional safety or UF is justified.

F. International Tolerances

No CODEX maximum residue levels have been established for residues of clothianidin on any crops at this time.

[FR Doc. 04–13411 Filed 6–15–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Meeting Cancellation

Board Action: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in October 1999, notice is hereby given of the cancellation of the meeting of the Federal Accounting Standards Advisory Board (FASAB), scheduled for Friday, June 25, 2004, at the GAO Building in room 7C13.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G St., NW., Mail Stop 6K17V, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. 92–463.

Dated: June 10, 2004.

Wendy M. Comes,

Executive Director.

[FR Doc. 04–13538 Filed 6–15–04; 8:45 am]

BILLING CODE 1610–01–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

June 8, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Pub. L. No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of