ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0366; FRL–7334–2]

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 ID number OPP–2003–0366, must be received on or before January 30, 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: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address:*kenny.dan@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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–2003–0366. 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–2003–0366. 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–2003–0366. 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–2003–0366.

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–2003–0366. 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: December 5, 2003.

Peter Caulkins,

Acting 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 Arvesta Corporation 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.

Arvesta Corporation

PP 1F6342

EPA has received a pesticide petition (1F6342) from Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105 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 commodity apples and pears at 1.0 parts per million (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*. 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, TZG, TZU, and ATMG-Pyr 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 (MS/MS) detection. In an extraction efficiency testing, the plant residues method has also demonstrated the ability to extract aged clothianidin residue.

In animal matrices, the residues parent clothianidin, TZG, TZU, and ATMG-Pyr can also be determined using HPLC with electrospray MS/MS detection. In an extraction efficiency testing, the animal residues method has also demonstrated the ability to extract aged clothianidin, TZG, TZU, and ATMG-Pyr residues.

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

3. *Magnitude of residues*. For apples, a total of 13 field trials were conducted to evaluate the magnitude of the residues of clothianidin in apples. Apple trees were treated with clothianidin at a rate of 0.2 lb active ingredient (a.i./acre). The highest average field trial residue found was 0.174 ppm in apple at 7 days pre-harvest interval (PHI). The apple processing study conducted at the exaggerated rate of 3X rate indicated no concentration in any processed commodities including apple juice and wet pomace. A residue decline study was conducted, and an estimated half-life value was obtained at 5.9 days.

For pears, a total of seven field trials were conducted to determine the residue level in pear following one single treatment with clothianidin at a rate of 0.2 lb a.i./acre. The highest average field trial clothianidin residue was 0.163 ppm in pears. A residue decline study was conducted, and an estimated half-life value was obtained at 11.5 days for pears.

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 liquid chromatography $(LC)_{50}$ 6.14 milligrams per liter (mg/L) for male and female rats. Clothianidin was not irritating to rabbit skin or eyes and did not cause skin sensitization in guinea pigs.

2. *Genotoxicty*. 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 two-generation reproduction study, rats were administered dietary levels of 0, 150, 500 and 2,500 ppm. The no observed adverse effect level (NOAEL) for reproductive parameters was 2,500 ppm. The NOAEL for developmental effects was 500 ppm based on decreased pup weights and the parental NOAEL and 150 ppm based on the decreased body weights.

A developmental toxicity study was conducted in rats with clothanidin 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 was conducted with rabbits treated orally by gavage at 0, 10, 25, 75 and 100 mg/kg bwt. The NOAEL for maternal toxicity was 10 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*. 90–day feeding studies were 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 for rat and 650 ppm for the dog.

5. *Chronic toxicity*. A two–year combined rat chronic/oncogenicity conducted at dietary levels of 0, 150, 500, 1,500 and 3,000 ppm demonstrated a NOAEL of 150 ppm 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 NOAEL of 350 ppm 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 on overall NOAEL of 325 ppm based on slight decrease in ALT.

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 lethal dose $(LD)_{50}$ 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 T_3, T_4, TSH were observed in the subchronic rat study. In a two-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*. The acute reference dose (aRfD) of 0.6 mg/kg bwt/day (acute NOAEL with a 100–fold uncertainty factor) was used to assess acute dietary exposure.

Seed treatment use. Bayer has conducted an acute dietary exposure Tier 2 assessment estimating the percent of the aRfD and corresponding margins

of exposure (MOE) for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this refined Tier 2 analysis, all evaluated population subgroups had an exposure equal to 0% of the aRfD with a corresponding MOE of >1 million at the 95th percentile.

Foliar application use (pome fruit). Tomen has conducted an acute dietary exposure Tier 1 analysis with Dietary Exposure Evaluation Model (DEEM) using proposed tolerance of 1 ppm, 100% crop treated and no adjustment of processing factor for the overall U.S. populations and the following subpopulations: all infants, nursing infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), and females (13–50 years). The results of Tier 1 analysis from foliar use of pome fruit indicated that the highest exposure never exceeds 5.42% of the aRfD at the 95th percentile.

The chronic reference dose (cRfD) of 0.097 mg/kg bwt/day (chronic NOAEL with a 100–fold uncertainty factor) was used to assess chronic dietary exposure.

Seed treatment use. Bayer's chronic dietary analysis estimated the percent of the cRfD and corresponding MOE for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this analysis, all evaluated population subgroups had an exposure equal to 0% of the cRfD. The corresponding MOE was >1 million.

Foliar application use. Tomen has conducted a chronic Tier 1 analysis and the results indicated that the highest exposure never exceeds 8.7% of the cRfD at the 95th percentile.

i. *Food. See* above discussion.

ii. *Drinking water.* For drinking water, the models SCI-GROW (ground water), and generic expected environmental concentration (GENEEC) (surface water), were selected to calculate the potential exposure of TM–444 in drinking water. Both short-term (acute) and long-term (chronic) exposures were estimated with respect to foliar uses on apples and pears. The predicted ground water concentrations for foliar application of apples and pears were 1.17 and 1.30 µ/L, respectively. The highest estimated acute and chronic exposures from surface water were 9.10 and 3.07 µ/L, respectively. Based on the standard exposure scenarios for drinking water (70kg adult- 2L/day; 10 kg child- 1L/day), the potential human exposure and risk can be estimated. Using the acute (0.60 mg/kg/day) and chronic (0.097 mg/kg/day) reference doses (RfD), the human risk from exposure to TM-444 in drinking water is estimated. The risk to adults and children from ground water exposure ranged from 0.006 to 0.019% of the acute RfD and from 0.038 to 0.134% of the chronic RfD; from surface water, the estimated risk ranged from 0.039% to 0.152% of the acute RfD and 0.081 to 0.316% of the chronic RfD respectively.

2. *Non-dietary exposure.* Clothianidin is currently not registered for use on any residential non-food site. Therefore, residential exposure to clothianidin residues will be through dietary exposure only.

D. Cumulative Effects

There is no information 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 total aggregate exposure to clothianidin from all proposed uses will be less than 9% of the RfD for the overall U.S. population. All evaluated population subgroups had an exposure less than 9% of the RfD. 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. Thus, Arvesta believes that it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to clothianidin residues.

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 two-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 two 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 uncertainty factor 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. The RfD for clothianidin was calculated using the NOAEL of 9.7 mg/kg bw/day from the two–year chronic/oncogenicity study. This NOAEL is lower than the NOAEL from the two–generation reproduction study, the developmental studies, and the developmental neurotoxicity study. Moreover, using a toxicologically justified UF of 100, the RfD for a non-oncogenic clothianidin was established at a level 0.097 mg/kg/day, a value that offers a measure of safety that is the highest among the other alternative compounds for control of apple and pear pests.

F. International Tolerances

No CODEX maximum residue levels (MRL's) have been established for residues of clothianidin on any crops at this time.

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OW–FRL–7605–2]

National Recommended Water Quality Criteria for the Protection of Human Health

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 304(a) of the Clean Water Act (CWA), the Environmental Protection Agency (EPA) is announcing the availability of updated national recommended water quality criteria for the protection of human health for the following fifteen pollutants: chlorobenzene; cyanide; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,1-dichloroethylene; 1,3-