Kinetic approach data from studies on Cry34Ab1 and studies with known allergens and non-allergens, as well as the Agency's allergenicity assessment of Cry34Ab1 will be presented to the FIFRA SAP. The Panel will be asked to consider the appropriateness of the kinetic approach, how digestion assays should be used in allergenicity assessments, and what assay conditions should be used for comparing the digestion of different proteins.

C. FIFRA SAP Meeting Minutes

The FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency in approximately 60 days after the meeting. The meeting minutes will be posted on the FIFRA SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 30, 2004.

Joseph Merenda, Jr,

Director, Office of Science Coordination and Policy.

[FR Doc. 04–26946 Filed 12–7–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0377; FRL–7687–4]

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–2004–0377 must be received on or before January 7, 2005.

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: Dan 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 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–2004–0377. 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, 1801 South Bell St., 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–2004–0377. 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–2004–0377. 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–2004–0377.

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, 1801 South Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0377. 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 record keeping requirements.

Dated: November 30, 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.

Arvesta Corporation

PP 4F6869

EPA has received a pesticide petition (4F6869) 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 commodities grapes at 0.5 parts per million (ppm), raisins at 1.0 ppm, and potatoes at 0.1 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. 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 (TMG) 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 chromatography (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 can also extract aged clothianidin, TZG, TZU, and ATMG-Pyr residues.

Although for the plant and animal residues this HPLC-MS/MS method is highly suitable as an 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— i. Potatoes.* Fifteen residue trials were conducted in key potato producing regions of the United States. At each trial, two different application regimes, foliar and in-furrow, were studied in separate plots. Samples were analyzed for residues of clothianidin.

Three foliar applications of 0.0661 pounds (lb) per active ingredient/acre (ai/A) were made with the 50 WDG formulation at 28, 21 and 14 days prior to harvest. Clothianidin residues ranged from ND to 0.0205 ppm for this treatment.

One in-furrow application of 0.198 lb ai/A was made with the 16 WSG formulation. Clothianidin residues ranged from less than the limit of detection (LOD) (0.007 ppm) to 0.0332 ppm for this treatment.

At one of the trial sites, two additional plots were treated at 5X the normal application rate for the processing phase of the study. Spray volumes range from 13.3 to 31.2 gallons per acre (GPA). The processing portions analyzed were whole tubers, granules, chips, and wet peel.

The foliar application of 50WDG was made at the 5X rate of 0.331 lb ai/A for the processing phase of the study. All of the clothianidin mean residues were less than limit of quantitation (LOQ) except for granules, which had mean clothianidin residues of 0.0316 ppm. The concentration factor (CF) for granules was calculated as 3.2. It was not possible to calculate a reliable CF in commodities other than granules. A residue decline study indicated that residues do not increase with longer preharvest intervals (PHI).

The in-furrow application of 16WSG was made at the 5X rate of 0.99 lb ai/A for the processing phase of the study. Clothianidin mean residues in whole tubers, granules, chips, and wet peel were 0.0258, 0.0546, 0.04 (< LOQ), and 0.007 (<LOQ) ppm, respectively. The CF for granules, chips, and wet peel were 2.1, 1.6, and <1, respectively.

ii. *Grapes*. Twelve residue trials were conducted in key grape producing regions of the United States. At each trial two different application regimes, foliar and drip irrigation, were studied in separate plots. Samples were analyzed for residues of clothianidin.

Two foliar applications of 0.0992 lb ai/A/application were made with the 50 WDG formulation at 14 and 0 days prior to normal harvest. Clothianidin residues ranged from 0.0398 to 0.410 ppm for this treatment.

At all of the trial sites except two in New York, a plot was established with one drip application of the 16 WSG formulation at 0.1984 lb ai/A at 30 days prior to harvest. Clothianidin residues ranged from ND to 0.01 ppm (<LOQ) for this treatment.

At two of the trial sites, plots received two drip applications of 16 WSG at the 0.5X rate of 0.0992 lb ai/A. Clothianidin residues were all less than the LOD, ranging from 0.0005 to 0.006 ppm.

At one of the trial sites, two additional plots were treated at 5X the normal application rate for the processing phase of the study. The processing portions analyzed were whole fruit, raisins, and juice.

Two foliar applications of 50WDG were made at the 5X rate of 0.496 lb ai/A/application for the processing phase of the study. Clothianidin mean residues in whole fruit, raisins, and juice were 0.621, 1.02, and 0.707 ppm, respectively. The concentration factor (CF) was 1.64 for raisins and 1.14 for juice. A residue decline study indicated that residues do not increase with longer preharvest intervals (PHI).

The drip irrigation application of 16WSG was made at the 5X rate of 0.992 lb ai/A for the processing phase of the study. Clothianidin mean residues in whole fruit, raisins, and juice were 0.006, 0.009, and 0.004 ppm, respectively. Since the mean residues in whole fruit and processed commodities were <LOD, it was not possible to calculate a reliable CF for either processed commodity.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral lethal dose $(LD)_{50}$ was >5,000 milligram/kilogram (mg/kg) for both male and

female rats and the acute dermal LD_{50} was >2,000 mg/kg in rats. The four-hour inhalation LC_{50} was 6.14 mg/L for male and female rats. Clothianidin was not a dermal or eye irritant in rabbits and was not a skin sensitizer 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 2–generation reproduction study with clothianidin, rats were administered dietary levels of 0, 150, 500 and 2,500 ppm. The no observed effect level (NOEL) for reproductive parameters was 2,500 ppm. The NOEL for developmental effects was 500 ppm based on decreased pup weights and the parental NOEL was 150 ppm based on decreased body weights (bw).

A developmental toxicity study was conducted in rats with clothianidin using dose levels of 0, 10, 50 and 125 mg/kg/day by gavage. The NOEL for maternal toxicity was established at 10 mg/kg and for developmental effects it was >125 mg/kg. Additionally, a developmental toxicity study was conducted with rabbits treated orally by gavage at 0, 10, 25, 75 and 100 mg/kg/day. The NOEL for maternal toxicity was 10 mg/kg and for developmental toxicity, it was 75 mg/kg.

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 NOELs were established at 500 ppm for rat and 650 ppm for the 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 NOEL 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 2,000/1,800 ppm for males and females, respectively, revealed a NOEL of 350 ppm based on reduced bw gains and increased incidence of hypercellular hypertrophy. No evidence of oncogenicity was seen in the rats 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 an overall NOEL of 325 ppm and no observed adverse effect level (NOAEL) of 650 ppm based on a 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 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 the toxicological profile showed no endocrine related toxicity or tumorgenicity. No effects on T3, T4, or TSH were observed in the subchronic rat study. In a 2–generation reproduction study in the rat, and rat and rabbit teratology studies, clothianidin did not show reproductive or teratogenic effects. The extensive database shows that clothianidin has no endocrine properties.

C. Aggregate Exposure

1. *Dietary exposure*. Tolerances are proposed for residues of clothianidin on grapes, raisins, and potatoes. For the purposes of assessing the potential dietary exposure for these proposed tolerances, an exposure assessment was conducted using Dietary Exposure Evaluation Model (DEEM™) software, consumption data derived from the 1994–1998 USDA Continuing Surveys of Food Intake by Individuals (CSFII), and residue levels at proposed tolerance levels.

i. *Food — a. Acute dietary exposure*. The acute population adjusted dose (aPAD) of 0.25 mg/kg bw/day (acute NOAEL with a 100-fold uncertainty factor) was used to assess dietary exposure. Arvesta Corporation has conducted an acute dietary exposure Tier 1 analysis with DEEM™ using the proposed tolerances for grapes, raisins, and potatoes of 0.5, 1.0, and 0.1 ppm, respectively, 100% crop treated and default processing factors for the overall US population and the following subpopulations: All infants (<1 year), children (1–2 years), females (13–49 years), and adults (50+). Arvesta has conducted an acute Tier 1 analysis from the uses on grapes and potatoes. This analysis also includes the anticipated exposure to clothianidin resulting from both Bayer's seed treatment uses and uses of thiamethoxam, of which clothianidin is a major metabolite. The results of this Tier 1 analysis indicate that the highest exposure never exceeds 18.00% of the aPAD at the 95th percentile of exposure.

b. Chronic dietary exposure. The chronic population adjusted dose (cPAD) of 0.098 mg/kg bw/day (chronic NOEL with a 100–fold uncertainty factor) was used to assess chronic dietary exposure. Arvesta has conducted a chronic Tier 1 analysis, including the anticipated exposure to clothianidin resulting from Bayer's seed treatment uses and uses of thiamethoxam, and the results indicate that the highest exposure never exceeds 13.41% of the cPAD.

ii. *Drinking water*. For drinking water, the models screening concentration in ground water (SCI-GROW) (ground water) and the Food Quality Protection Act (FQPA) index reservoir screening tool (FIRST) (surface water), were selected to calculate the potential exposure of clothianidin in drinking water. Both short-term (acute) and long-term (chronic) exposures were estimated with respect to foliar and drip-irrigation uses for grapes and foliar and in-furrow uses for potatoes. The worst case drinking water estimated concentrations (DWEC) for these applications to grapes and potatoes were 15.1 parts per billion (ppb) for the acute and 0.5 ppb for the chronic using the FIRST model. The acute and chronic drinking water levels of comparison (DWLOC) were calculated for each of the population subgroups. The acute DWLOC for the most sensitive population subgroup, children 1–2 years, was calculated to be 2,050 ppb and the chronic DWLOC for this population subgroup is 849 ppb. The acute DWLOC for the U.S. population is 8,417 ppb and the chronic DWLOC is 3,350 ppb. The calculated acute and chronic DWLOCs for the U.S. population and children 1–2 years exceed the DWECs from the models.

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 food-only exposure to clothianidin from all

proposed crop uses will be less than 3.8% of the aPAD and less than 2.34% of the cPAD for the overall U.S. population. All evaluated population subgroups had an exposure of less than 18.00% of the aPAD and less than 13.41% of the cPAD. EPA generally has no concerns for exposures below 100% of the PAD, because the PAD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. The DWLOCs exceed the DWECs as calculated by conservative models. There are no residential uses of clothianidin; therefore, aggregate exposure consists of food and drinking water exposures. Thus, 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 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 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 database. Based on the current toxicological data requirements, the toxicology database for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offspring to be more sensitive. All effects were secondary to severe maternal toxicity. The cPAD for clothianidin was calculated using the NOAEL of 9.8 mg/kg bw/day from the 2–generation rat reproduction study.

F. International Tolerances

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

[FR Doc. 04–27004 Filed 12–7–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0236; FRL–7689–3]

Ethoxyquin; Reregistration Eligibility Decision for Low Risk Pesticide; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's Reregistration Eligibility Decision (RED) for the pesticide ethoxyquin, and opens a public comment period on this document, related risk assessments, and other support documents. EPA has reviewed the low risk pesticide ethoxyquin through a modified, streamlined version of the public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0236, must be received on or before February 7, 2005.

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: Tom Brennan, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0540; fax number: (703) 308–7042; e-mail address:*brennan.thomas@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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–2004–0236. 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, 1801 S. Bell St., 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. 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