old (nursing). Acute dietary risk was calculated for females 13+ years old because the endpoint upon which the acute PAD is based on developmental effects. Estimated drinking water levels were calculated using drinking water models (SCI-GROW and GENEEC), and the values are considered overestimates due to the conservative assumptions built into the models. Estimated concentrations for trifloxystrobin residues in surface and ground water are lower than EPA's DWLOCs. Therefore, it is not expected that acute aggregate risk to trifloxystrobin residues from acute food and drinking water sources will exceed EPA's level of concern for acute aggregate risk.

Exposure to trifloxystrobin and the free form of its acid metabolite, CGA–321113 residues in food will occupy less than 0.5% of the chronic PAD for adult population subgroups (females 13+/nursing) and no more than 2.0% of the chronic PAD for infant/children subgroups (highest subgroup: non-nursing infants). Estimated concentrations of trifloxystrobin residues in surface and ground water are lower than EPA's DWLOCs. Estimated drinking water levels were calculated using drinking water models, and the values are considered overestimates due to the conservative assumptions built into the models. EPA has previously determined chronic residential exposure of trifloxystrobin is not expected. The established and pending uses of trifloxystrobin when combined in a chronic aggregate risk assessment for food, water, and residential sources will not exceed EPA's level of concern for chronic aggregate risk. Bayer concludes that there is a reasonable certainty that no harm will result from aggregate exposure to trifloxystrobin residue.

2. *Infants and children.* On June 21, 1999, EPA FQPA safety factor committee determined the 10x safety factor for the protection of infants and children should be removed for trifloxystrobin. The Committee's rationale for removing the FQPA safety factor is as follows:

i. The trifloxystrobin toxicology data base is complete for FQPA assessment.

ii. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin. In the development and reproductive toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

Using the same exposure assumptions as employed for the determination in the general population, it has been calculated that the percent of the RfD that will be utilized by aggregate exposure to residues of trifloxystrobin is <2.0% for non-nursing infants (<1 year) (the most impacted sub-population). Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Bayer concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to trifloxystrobin residues.

F. International Tolerances

No Codex MRLs have been established for residues of trifloxystrobin.

[FR Doc. 01–28199 Filed 11–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1055; FRL–6809–7]

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 control number PF–1055, must be received on or before December 14, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1055 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis McNeilly, Insecticide Rodenticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at *http://www.epa.gov/*. To access this document, on the homepage select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person.* The Agency has established an official record for this action under docket control number PF–1055. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is

available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1055 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1055. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 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: November 2, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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 Corporation

1F6315

EPA has received a pesticide petition (1F6315) from Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120 proposing, pursuant to section 408(d) of the 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 canola, seed; corn, grain; corn, fodder; corn, forage; meat and meat by-products, and milk at 0.01, 0.01, 0.10, 0.10, 0.02, and 0.01 parts per million (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 aminothiazol methylguanidine-pyridine (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 MS/MS detection. In an extraction efficency testing, the plant residues method has also demonstrated the ability to extract aged clothianidin residue.

In anamial 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–i. Corn*. A total of 27 field trials were conducted to evaluate the quantity of clothianidin in field, pop, and sweet corn. Corn seed was treated with clothianidin at a rate of 2 mg active ingredient (a.i.)/seed. The highest average field trial was 0.06 ppm in sweet corn forage with ears at 75 days pre-harvest interval (PHI), 0.03 ppm in late dough-stage corn forage at 85 days PHI, and 0.05 ppm in corn fodder at 136 days PHI. All grain and sweet corn ear samples contained<0.01 ppm clothianidin residue. The corn processing study indicated no concentration in any corn processed-commodities following the proposed seed treatment use.

ii. *Canola*. A total of 22 field trials was conducted to determine the residue level in canola following the planting of canola seed treated with clothianidin at a rate of 600 g a.i./100 kg seed. All canola seed samples contained <0.01 ppm clothianidin residue. The canola processing study indicated no concentration in any canola processed commodities following the proposed seed treatment use.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} was >5,000 milligrams/kilograms/body weight (mg/kg bw) for both male and female rats. The acute dermal LD_{50} was greater than 2,000 mg/kg bw in rats. The 4–hour inhalation LC_{50} was 6.14 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 2-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. The parental NOAEL was 150 ppm, based on the decreased body weights.

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

Developmental toxicity studies showed no primary developmental toxicity and no teratogenic potential was evident.

4. *Subchronic toxicity*. Ninety–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 2–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 a 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 an overall NOAEL of 325 ppm and NOAEL of 650 ppm based on slight decrease in alanine aminotransferase activity (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 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 the rat, 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 bw/day (acute NOAEL with a uncertainty factor) was used to assess acute dietary exposure. 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 >1,000,000 at the 95th percentile.

The chronic reference dose (cRfD) of 0.097 mg/kg bw/day (chronic NOAEL with a 100-fold uncertainty factor) was used to assess chronic dietary exposure. Bayer's chronic dietary analysis estimated the percent of the cRfD 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 analysis, all evaluated population subgroups had an exposure equal to 0% of the cRfD. The corresponding MOE was >1,000,000.

i. *Food.* Since clothianidin is not currently registered, projected percent crop treated values were used for the chronic and acute dietary analyses.

ii. *Drinking water.* For drinking water, the models SCI-GROW (ground water), and FIRST (surface water), were selected to calculate the potential exposure of clothianidin in drinking water. Each model generated an acute water concentration, and the higher of the two concentrations was selected to represent the acute exposure, and similarly for the chronic exposure. The acute environmental exposure was determined to be 3.24 µg/L (from surface water), and the chronic environmental exposure was 0.724 µg/L (from ground water). Both exposures result from clothianidin used as a seed treatment on corn. Based on the standard exposure scenarios for drinking water (70 kg adult - 2 L/day; 10 kg child - 1 L/day), the human exposure and risk can be estimated. Using the acute (0.60 mg/kg/day) and chronic (0.097 mg/kg/day) RfDs, the human risk from exposure to clothianidin in drinking water was determined to be less than 0.03% of the RfD in adults, and less than 0.08% of the RfD in children (the maximum human exposure was 0.32 µg/kg/day, for acute exposure for children).

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 equal to 0% of the RfD for the overall U.S. population. All evaluated population subgroups had an expousre equal to 0% 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, 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 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 2–year chronic/oncogenicity study. This NOAEL is lower than the NOAEL from the 2-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 clothiandin was established at a level 0.097 mg/kg/day, a value that offers a measure of safety that is still 1.7-fold higher than the highest RfD (imidacloprid at 0.057 mg/kg/day) of the 10 competitive compounds compared in this report.

F. International Tolerances

No CODEX Maximum Residue Levels have been established for residues of clothianidin on any crops at this time.

[FR Doc. 01–28524 Filed 11–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1052; FRL–6808–9]

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 control number PF–1052, must be received on or before December 14, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1052 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be