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 OPP–30506. 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. Offer alternative ways to improve the registration activity.

7. Make sure to submit your comments by the deadline in this notice.

8. 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. Registration Applications

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

A. Products Containing Active Ingredients Not Included in Any Previously Registered Products

File Symbol: 73176-R. Applicant: AgriVir, LLC 1625 K Street, NW., Suite 1000, Washington, DC 20006. Product name: Nut GuardV/Fruit GuardV. Product type: Biological pesticide. Active ingredient: Indian Meal Moth Granulosis Virus and larval parts on milled wheat bran carrier at 96.4. Proposed classification/Use: for use on dried fruit, in shell and shelled nuts, for crack and crevice treatment of processing, packing and storage areas.

List of Subjects

Environmental protection, Pesticides and pest.

Dated:August 17, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 01–22022 Filed 8–30–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1040;FRL–6797–6]

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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–1040, must be received on or before October 1, 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–1040 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7704; e-mail address:giles-parker.cynthia@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	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 Home Page at http://www.epa.gov/. To access this document, on the Home Page 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–1040. 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–1040 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.

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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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 supports 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: August 16, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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

0F6121

Summary of Petitions

EPA has received a pesticide petition (0F6121) from Bayer Corporation, 8400 Hawthorne Road, P. O. Box 4913, Kansas City, MO 64121–0013 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 trifloxystrobin in or on the raw agricultural commodity barley grain at 0.05 parts per million (ppm), straw at 0.05 ppm, barley hay at 0.2 ppm, citrus fruits group at 0.3 ppm, citrus oil at 7.0 ppm, corn forage at 0.05 ppm, corn stover at 7.0 ppm, aspirated grain fractions at 0.1 ppm, popcorn grain at 0.05 ppm, popcorn stover at 7.0 ppm, pecans at 0.05 ppm, rice grain at 3.5 ppm, rice straw at 7.5 ppm, stone fruits crops group at 2.0 ppm, and poultry (fat, kidney, liver, meat by-products, meats at 0.5 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. *Residue metabolism*. The metabolism of trifloxystrobin in plants (cucumbers, apples, wheat, sugar beets and peanuts) is well understood. Identified metabolic pathways are substantially similar in plants and animals (goat, rat and hen). EPA has determined that trifloxystrobin parent and its metabolite CGA–321113 are the residue of concern for tolerance setting purposes.

2. *Analytical method*. A practical analytical methodology for detecting and measuring levels of trifloxystrobin in or on raw agricultural commodities has been submitted. The limit of detection (LOD) for each analyte of this method is 0.08 ng injected, and the limit of quantitation (LOQ) is 0.02 ppm. The method is based on crop specific cleanup procedures and determination by gas chromatography with nitrogen-phosphorous detection.

3. *Magnitude of residues*. Residue trials were performed for trifloxystrobin on a full geography of Citrus Fruit Crop Group (with oranges, lemons and grapefruit as representative citrus fruit crops), field corn, popcorn, and rice as representative crops from the cereal grain group, pecans, and Stone Fruits Crop Group (with peaches, plums, tart and sweet cherries as representative stone fruit crops). A study was conducted on indicator crops to assay for secondary residues in rotational crops. A three-level ruminant and poultry study was completed to determine the rate of transfer of residues of trifloxystrobin from residues in animal feed to ruminant and poultry commodities.

B. Toxicological Profile

1. *Acute Toxicity*. Studies conducted with the technical material of trifloxystrobin:

- Rat acute oral toxicity study with a LD_{50} >5,000 mg/kg
- Mouse acute oral toxicity study with a LD_{50} >5,000 mg/kg
- Rabbit acute dermal toxicity study with a LD_{50} >2,000 mg/kg
- Rat acute dermal toxicity study with a LD_{50} >2,000 mg/kg
- Rat acute inhalation toxicity study with a LC_{50} >4.65 mg/L
- Rabbit eye irritation study showing slight irritation (Category III)
- Rabbit dermal irritation study showing slight irritation (Category IV)
- Guinea pig dermal sensitization study with Buehler's method showing negative findings
- Guinea pig dermal sensitization study with the Maximization method showing some positive findings

2. *Genotoxicity*. No genotoxic activity is expected of trifloxystrobin under *in vivo* or physiological conditions. The compound has been tested for its potential to induce gene mutation and chromosomal changes in five different test systems. The only positive finding was seen in the *in vitro* test system (Chinese hamster V79 cells) as a slight increase in mutant frequency at a very narrow range (250 – 278 µg/ml) of cytotoxic and precipitating concentrations (compound solubility in water was reported to be 0.61 µg/ml; precipitation was visually noted in culture medium at 150 µg/ml). The chemical was found to be non-mutagenic in the *in vivo* system or all other *in vitro* systems. Consequently, the limited gene mutation activity in the V79 cell line is considered a nonspecific effect under non-physiological *in vitro* conditions and not indicative of a real mutagenic hazard.

3. *Reproductive and developmental toxicity*. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database on trifloxystrobin relative to pre- and post-natal effects for children is complete.

In assessing the potential for additional sensitivity of infants and children to residues of trifloxystrobin, data were considered from teratogenicity studies in the rat and the rabbit and a 2-generation reproduction studies in the rat. The teratogenicity studies were designed to evaluate adverse effects on the developing embryo as a result of chemical exposure during the period of organogenesis. Reproduction studies provide information on effects from chemical exposure on the reproductive capability of mating animals and systemic and developmental toxicity from *in-utero* exposure.

In the rat teratology study, reductions in body weight gain and food consumption were observed in the dam at ≥100 mg/kg. No teratogenic effects or any other effects were seen on pregnancy or fetal parameters except for the increased incidence of enlarged thymus, which is a type of variation, at 1,000 mg/kg. The developmental NOAEL was 100 mg/kg.

In the rabbit teratology study, body weight loss and dramatically reduced food consumption were observed in the dam at ≥2,050 mg/kg. No teratogenic effects or any other effects were seen on pregnancy or fetal parameters except for the increase in skeletal anomaly of fused sternebrae-3 and -4 at the top dose level of 500 mg/kg. This finding is regarded as a marginal effect on skeletal development that could have resulted from the 40–50% lower food intake during treatment at this dose level. The developmental NOAEL was 250 mg/kg.

In the 2-generation rate reproduction study, body weight gain and food consumption decreased at ≥750 ppm, especially in females during lactation. Consequently, the reduced pup weight gain during lactation (≥750 ppm) and the slight delay in eye opening (1,500 ppm) are judged to be a secondary effect of maternal toxicity. No other fetal effects or any reproductive changes were noted. The low developmental NOAEL, 50 ppm (5 mg/kg), seen in this study was probably due to the lack of intermediate dose levels between 50 and 750 ppm. Based on an evaluation of the dose-response relationship for pup weight at 750 ppm and 1,500 ppm, the NOAEL should have already been nearly ten-fold higher if such a dose was available.

Based on all these teratology and reproduction studies, the lowest NOAEL for developmental toxicity is 5 mg/kg while the lowest NOAEL in the subchronic and chronic studies is 2.5 mg/kg/day (from the rat chronic study). Therefore, no additional sensitivity for infants and children to trifloxystrobin is suggested by the database.

4. *Subchronic toxicity*. In subchronic studies, several mortality related changes were reported for the top dose in dogs (500 mg/kg) and rats (800 mg/kg). At these dose levels, excessive toxicity has resulted in body weight loss and mortality with the associated and nonspecific changes in several organs

(such as atrophy in the thymus, pancreas, bone morrow, lymph node, and spleen) which are not considered specific target organs for the test compound. In the dog, specific effects were limited to hepatocellular hypertrophy at ≥150 mg/kg and hyperplasia of the epithelium of the gall bladder at 500 mg/kg. Target organ effects in the rat were noted as hepatocellular hypertrophy (≥200 mg/kg) and the related liver weight increase (≥50 mg/kg). In the mouse, target organ effects included single cell necrosis (≥300 mg/kg) and hypertrophy (1,050 mg/kg) in the liver and extramedullary hematopoiesis (≥300 mg/kg) and hemosiderosis in the spleen (1,050 mg/kg).

In general, definitive target organ toxicity, mostly in the liver, was seen at high feeding levels of over 100 mg/kg for an extended treatment period. At LOAEL, no serious toxicity was observed other than mostly non-specific effects including a reduction in body weight and food consumption or liver hypertrophy.

5. *Chronic toxicity*. The liver appears to be a major primary target organ based on the chronic studies conducted in mice, rats, and dogs. It was identified as a target organ in both the mouse and the dog studies with trifloxystrobin. However, no liver effect was seen in the chronic rat study which produced the lowest NOAEL of 2.5 mg/kg based on reduced body weight gain and food consumption seen at higher dose levels.

The compound did not cause any treatment-related increase in general tumor incidence, any elevated incidence of rare tumors, or shortened time to the development of palpable or rapidly lethal tumors in the 18–month mouse and the 24–month rat studies. Dosages in both studies were sufficient for identifying a cancer risk. In the absence of carcinogenicity, a Reference Dose approach is appropriate for quantitation of human risks.

6. *Animal metabolism*. Trifloxystrobin is moderately absorbed from the gastrointestinal tract of rats and is rapidly distributed. Subsequent to a single oral dose, the half life of elimination is about 2 days and excretion is primarily via bile. Trifloxystrobin is extensively metabolized by the rat into about 35 metabolites, but the primary actions are on the methyl ester (hydrolysis into an acid), the methoxyimino group (O-demethylation), and the methyl side chain (oxidation to a primary alcohol). Metabolism is dose dependent as it was almost complete at low doses but only about 60% complete at high doses.

In the goat, elimination of orally administered trifloxystrobin is primarily via the feces. The major residues were the parent compound and the acid metabolite (CGA–321113) plus its conjugates. In the hen, trifloxystrobin is found as the major compound in tissues and in the excreta, but hydroxylation of the trifluormethyl-phenyl moiety and other transformations, including methyl ester hydrolysis and demethylation of the methoxyimino group, are also seen. In conclusion, the major pathways of metabolism in the rat, goat, and hen are the same.

7. *Metabolite toxicology*. Metabolism of trifloxystrobin has been well characterized in plants, soil, and animals. In plants and soil, photolytically induced isomerization results in a few minor metabolites not seen in the rat; however, most of the applied materials remained as parent compound as shown in the apple and cucumber studies. All quantitatively major plant and/or soil metabolites were also seen in the rat. The toxicity of the major acid metabolite, CGA–321113 (formed by hydrolysis of the methyl ester), has been evaluated in cultured rat hepatocytes and found to be 20-times less cytoxic than the parent compound. Additional toxicity studies were conducted for several minor metabolites seen uniquely in plants and/or soil. The studies indicate that these metabolites, including CGA–357261, CGA–373466, and NOA–414412, are not mutagenic to bacteria and are of low acute toxicity (LD_{50} >2,000 mg/kg). In conclusion, the metabolism and toxicity profiles support the use of an analytical enforcement method that accounts for parent trifloxystrobin.

8. *Endocrine disruption*. CGA–279202 does not belong to a class of chemicals known for having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and reproduction study in rats gave no indication that CGA–279202 might have any effects on endocrine function related to development and reproduction. The subchronic and chronic studies also showed no evidence of a long-term effect related to the endocrine system.

i. *Dietary exposure*— a. *Food*. Acute and chronic dietary exposure assessments were performed on the crops that are the subject of this petition using field trial residue values on the citrus and stone fruit crop groups, corn, rice, barley, and pecans. In addition, established uses on sugar beets, almonds, fruiting vegetable (crop group), pome fruit (crop group), cucurbits (crop group), bananas, grapes, peanuts, potatoes, hops, and wheat were included in the assessment. All residues were generated from field trials conducted with a minimum pre-harvest interval and maximum application rate. In addition, if market share data were available, residues were adjusted for the percent crop treated. The residues in processed potatoes, sugar beets (molasses), tomatoes, oranges (juice), apples (juice), corn, rice, wheat fractions, peanuts, and grapes (juice) were adjusted using experimentally determined processing factors generated from processing studies. For all other processed fractions, USDA default processing factors were utilized. Residues in animal commodities were calculated from theoretical dietary burden calculations and transfers factors obtained from livestock and poultry feeding studies. Assessments were conducted utilizing the Dietary Exposure Evaluation Model (DEEM®) from Novigen Sciences and the 1994–96 Continuing Survey of Food Intake by Individuals (CSFII). Acute exposure for the U.S. population and all population subgroups were compared to an acute reference dose (aRfD) of 2.5 mg/kg/day based on a developmental no-observable adverse effect level (NOAEL) in rabbits and a 100–fold uncertainty factor. Although this endpoint is applicable to females only in the strictest sense, the developmental NOAEL was used for all populations due to the lack of a suitable toxicological endpoint. Chronic exposure was compared to a chronic RfD of 0.05 mg/kg/day based on a chronic study in dogs and a 100–fold uncertainty factor. Both acute and chronic toxicological endpoints were taken from the final pesticide tolerance rule for trifloxystrobin published in the **Federal Register** of September 27, 1999 (OPP–300922; FRL–6382–5).

Both acute and chronic exposure was minimal in all population subgroups. The acute results were obtained from a probabilistic, 1,000–iteration Monte Carlo assessment. Acute exposure was expressed at the 99.9th percentile of exposure and ranged from 0.17% to 0.08% of the aRfD with non-nursing infants (less than 1 year old) as the most sensitive population subgroup (0.80% of the RfD). The chronic exposure assessment was conducted by taking the mean field trial residue values and comparing to average daily consumption values. Chronic exposure ranged from 0.2% to 1.2% of the chronic RfD and the most sensitive population was non-nursing infants (less than 1 year old).

b. *Drinking water—Estimated surface water concentration*. The generic expected environmental concentration (GENEEC) estimated surface water

concentrations for trifloxystrobin uses contributed little to the over exposure. These estimated concentrations were not adjusted for the estimated market share of percentage of use area. The highest day–56 expected environmental concentration (EEC) value was 0.27 parts per billion (ppb) provided by the established trifloxystrobin turf use. According to the EPA ''OPP's Interim Approach for Addressing Drinking Water Exposure,'' the average day–56 value is divided by three when correcting for overestimation of the GENEEC model. The EPA has accepted that the average day–56 EEC value is divided by six in the case when the product is applied to turf and accounts for the effects of grass/turf in decreasing runoff (EPA, 1998. EPA–730–F97–2, PB97–137806, page 15). This division by six was used to calculate the potential exposure via surface water from the trifloxystrobin turf application, 0.27 ppb/6=0.045 ppb.

Estimated ground water concentrations. The SCI-GROW estimated ground water concentrations for trifloxystrobin uses also contributed little to the overall exposure. The estimated concentrations were not adjusted for the estimated market share or percentage of use area. In each use scenario, the concentration of trifloxystrobin in ground water was predicted to be below 1 part per trillion. The highest estimated concentration of trifloxystrobin in the ground water was 0.000859 ppb provided by the trifloxystrobin turf use.

c. *Drinking water levels of concern—Acute exposure*. Based on the EPA's ''Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' document (drafted 12/2/97), acute drinking water levels of comparison ($DWLOC_{acute}$) were calculated for trifloxystrobin. The lowest acceptable Margin of Exposure (MOE) for any pesticide is 100. This value was used in the DWLOC calculations. Based on this analysis, the maximum estimated trifloxystrobin surface water at Peak Day-0 (2.54 ppb) and ground water (0.000859 ppb) concentrations, human drinking water exposures do not exceed the calculated acute DWLOC values (µg/L:24,8000 to 87,325). Therefore, acute human drinking water exposures to trifloxystrobin from the existing and newly proposed uses would not exceed the exposure allowable by the risk cup. From the acute dietary exposure analysis provided for the trifloxystrobin dietary assessment, the acute drinking water levels of comparison ($DWLOC_{acute}$) were calculated for CGA–32113. Based on this analysis, the maximum estimated CGA–32114 in surface water at Peak Day-0 (38.73 ppb) and in ground water (4.944316 ppb) concentrations, human drinking water exposures do not exceed the calculated acute DWLOC values (µg/L:24800 to 87150). Therefore, acute human drinking water exposures to CGA–32114 from the existing and newly proposed trifloxystrobin uses would not exceed the exposure allowable by the risk cup.

Chronic exposure. The chronic drinking water levels of comparison ($DWLOC_{chronic}$) were calculated for trifloxystrobin. The maximum estimated trifloxystrobin surface water (0.09 ppb) and ground water (0.000859 ppb) concentrations do not exceed the calculated chronic DWLOC values (µg/L:494 to 1747). Therefore, chronic human drinking water exposures to the existing and newly proposed trifloxystrobin uses would not exceed the exposure allowable by the risk cup. From the chronic dietary exposure analysis provided for the trifloxystrobin dietary assessment, the chronic drinking water levels of comparison ($DWLOC_{chronic}$) were calculated for CGA–32113. Based on this analysis, the maximum estimated CGA–32113 in surface water at Day 56/3 (12.24 ppb) and in ground water (0.989 ppb) concentrations, human drinking water exposures do not exceed the calculated chronic DWLOC values (µg/L:494 to 1,745). Therefore, chronic human drinking water exposures to the existing and newly proposed trifloxystrobin uses would not exceed the exposure allowable by the risk cup.

ii. *Non-dietary exposure*. Non-dietary exposure to trifloxystrobin is considered negligible as the chemical is intended primarily for commercial and agricultural use. Post-application re-entry exposure to homeowners from professional use on residential ornamentals is considered negligible. For workers handling this chemical, acceptable margins of exposure (in the range of thousands) have been obtained for both acute and chronic scenarios.

D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by trifloxystrobin would be cumulative with those of any other types of chemicals. Furthermore, the oximinoacetate is a new type of fungicide and no compound in this general chemical class currently has a significant market share. Consequently, aggregate risk is the only potential exposure to trifloxystrobin.

E. Safety Determination

1. *U.S. population*. To calculate acute aggregate risk, high-end exposures from food and drinking water sources are compared to the acute population adjusted dose (aPAD). Exposure to trifloxystrobin residues and the free form of its acid metabolite, CGA–321113 in food will occupy <1% of the aPAD for females 13+ years old (nursing). Acute dietary risk was calculated for females 13+ years old because the endpoint upon which the aPAD is based is 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 of 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.

Chronic exposure to residues of trifloxystrobin and the free form of its acid metabolite, CGA–321113, in food will occupy less than 0.5% of the chronic population adjusted dose (cPAD) for adult population subgroups (females 13+/nursing) and no more than 2.0% of the cPAD 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, the 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 database is complete for FQPA assessment.

ii. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin.

In the developmental 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 old)(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. 01–22025 Filed 8–30–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1041; FRL–6796–1]

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–1041, must be received on or before October 1, 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–1041 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: tompkins.jim@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 Home Page at http://www.epa.gov/. To access this document, on the Home Page 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–1041. 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–1041 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–1013. Electronic comments