''ADDRESSES'' at the beginning of this document.

Written comments filed pursuant to this notice, will be available in the Public Response and Program Resources Branch, Field Operations Division at the address provided from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. It is suggested that persons interested in reviewing the application file, telephone this office at (703–305–5805), to ensure that the file is available on the date of intended visit.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: February 6, 1997.

Janet L. Andersen,

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

[FR Doc. 97–4195 Filed 2–19–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–714; FRL–5589–4]

Abbott Laboratories; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing regulations establishing tolerances for residues of the biochemical pesticide aminoethoxyvinylglycine in or on apples and pears. This notice includes a summary of the petition that was prepared by the petitioner, Abbott Laboratories.

DATES: Comments, identified by the docket control number [PF–714], must be received on or before March 24, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov or by submitting disks. Electronic comments must be submitted either in ASCII format (avoiding the use of special characters and any form of encryption) or in WordPerfect in 5.1 file format. All comments and data in electronic form must be identified by docket control number [PF–714]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. The official record for this rulemaking, as well as the public version described above, will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record, which will also include all comments submitted directly in writing.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. No CBI should be submitted through e-mail. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, Washington, DC 20460, Office location, telephone number, and e-mail address: Crystal Station I, 2800 Crystal Dr., Arlington, VA 22202. (703) 308–8263; e-mail: greenway.denise@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP–6F4632) from Abbott Laboratories, 1401 Sheridan Road, North Chicago, IL 60064–4000. The petition proposes, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR part 180 to establish tolerances for residues of the biochemical pesticide aminoethoxyvinylglycine (AVG) in or on apples and pears at 0.08 part per million (ppm). EPA has determined that the 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. The proposed analytical method is high pressure liquid chromatography (HPLC).

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (FQPA) (Pub. L. 104–170), Abbott Laboratories included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Abbott Laboratories; EPA, as mentioned above, is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Abbott Laboratories' Petition Summary

A. Residue Chemistry

1. *Plant metabolism.* AVG signifies the active ingredient *L*-alpha-(2-aminoethoxyvinyl)glycine hydrochloride in its pure form. An alternative nomenclature for AVG is [*S*]-trans-2-amino-4-[2-aminoethoxy]-3-butanoic acid hydrochloride. *N*-acetyl AVG is the primary metabolite of AVG in apples.

2. *Analytical method.* Abbott Laboratories has determined that residues of AVG are not expected in/on apples and pears at detectable levels when orchards are treated at the label use rate and pre-harvest interval. The Limit of Quantitation (LOQ) is 0.075 ppm and the Limit of Detection (LOD) is 0.03 ppm by HPLC analysis. There is no concentrating of residues in the processed commodities (*i.e.*, apple juice or wet apple pomace).

3. *Magnitude of the residue.* In the magnitude of the residue study in apples, the maximum residue at day 0 following treatment at the label use rate was 0.131 ppm. By day 21, there were no quantifiable residues present. The exposure assessments (below) indicate that there will be large margins of exposure (MOEs) from aggregate exposure to AVG. The proposed HPLC method used is deemed adequate by Abbott Laboratories to measure residues and the company argues that no additional analytical method for detecting and measuring residue levels is needed.

B. Toxicological Profile

1. *Acute toxicity.* The acute mammalian toxicological data considered in this proposed tolerance for AVG include: an acute oral toxicity study in rats, an acute dermal toxicity study in rabbits, an acute inhalation toxicity study in rats, a primary eye irritation study in rabbits, a dermal irritation study in rabbits, and a dermal sensitization study in guinea pigs.

The results of these studies indicate that AVG has an acute oral LD_{50} of 6,400

milligrams active ingredient per kilogram of body weight (mg a.i./kg bwt) in rats, an acute dermal LD_{50} greater than 2,000 mg a.i./kg bwt in rabbits, an acute inhalation LD_{50} of 1,130 mg/m^3 in rats, causes slight eye and dermal irritation in rabbits, and is not a dermal sensitizer in guinea pigs.

2. *Genotoxicity.* Abbott Laboratories concludes that AVG was not mutagenic in an Ames *Salmonella* gene mutation assay with or without metabolic activation. The company maintains that there was no mutagenic activity associated with AVG in cultures of mouse lymphoma cells (L5178Y tk ±) with or without metabolic activation. In a rat bone marrow cell micronucleus test *in vivo,* Abbott Laboratories reports that there was no indication that AVG was genotoxic.

3. *Developmental toxicity.* In a developmental toxicity study in rats by oral gavage, a no observable effect level (NOEL) of 1.77 mg a.i./kg bwt/day was determined for both developmental and maternal toxicity.

4. *Subchronic toxicity.* A Reference Dose (RfD) of 0.002 mg a.i./kg bwt/day was derived from a 90–day feeding study in rats in which there was decreased food consumption, body weight and food efficiency (body-weight gain/food consumption), and fatty changes in kidney and liver at dosage levels of 9 mg a.i./kg bwt/day or higher. The NOEL in this study was 2.2 mg a.i./kg bwt/day.

In a 21–day dermal toxicity study in rats, the NOEL was greater than 1,000 mg a.i./kg/day.

In a 28–day dietary immunotoxicity study in rats with a NOEL of 5 mg a.i./kg/day, decreases in several immune response parameters are considered secondary to the decreased food consumption, body weight, and food efficiency in the treated rats.

5. *Reproductive toxicity; chronic toxicity; animal metabolism; metabolite toxicity.* AVG is classified as a biochemical due to its proposed use pattern, its low use rate, and its natural occurrence. Due to the nature of this biochemical pesticide, the requirements for reproductive and chronic toxicity studies as well as animal metabolism and metabolite toxicity have not been triggered in the Tier Toxicity Testing approach.

C. Aggregate Exposure

Dietary exposure—food and drinking water/non-dietary exposure. Expected dietary exposures from residues of AVG would occur through apples, pears, and processed apples and pears. Spray drift may lead to exposure to residues in drinking water. There are no proposed home and garden uses for AVG. AVG is used in a commercial floral preservative. There is no exposure to infants and children through this floral preservative. The only potential exposure from this floral preservative would be dermal exposure.

For estimations of maximum anticipated residues, non-detectable residues were assigned a value one half of the LOD. For the two instances in which residues were detectable on one of the replicates, the full LOD was used. The maximum anticipated residues of AVG were calculated to be 0.018 ppm in the apple raw agricultural commodity.

The processed commodities examined were apple juice and wet apple pomace. Processing factors were calculated from apples without washing prior to processing to provide the highest possible estimate of anticipated residues in the juice and pomace. The mean apple juice processing factor was determined to be 0.8; for wet apple pomace the processing factor was 0.9.

A chronic dietary exposure analysis was conducted for AVG using the anticipated residues in apples for both apples and pears. Residues were rarely detected in field trials conducted at the maximum rate and minimum interval between application and harvest. The anticipated residue of 0.018 ppm represents about half of the LOD.

Low residues are expected in wet apple pomace, so finite residues of AVG are not expected in meat and milk; therefore, these foods were not included in the exposure analysis.

Tap water, non-tap water, and water in commercially prepared food were also included in the analysis. Residue levels in water were assumed to be 0.0012 ppm. This was based upon calculations for airblast application of AVG onto late season trees. It is estimated that a negligible amount of the applied dose could drift into nearby drinking water sources. The following table summarizes the results from the chronic aggregate exposure analysis based upon anticipated residues for the overall U.S. population and the five most highly exposed population subgroups. The exposure estimate was compared against the RfD of 0.002 mg a.i./kg bwt/day:

Population subgroup	Exposure mg a.i./kg bwt	Percent of RfD
U.S. Population	0.000055	2.5
All Infants	0.000206	10.3
Non-nursing Infants < 1 yr.	0.000258	12.9
Children 1–6 yrs	0.000099	5.0
Children 7–12 yrs	0.000077	3.8
Females 13–50 yrs ...	0.000040	2.0

As seen in the above table, even for the most highly exposed population subgroup, less than 13% of the RfD was used.

Chronic aggregate exposure to AVG also was estimated using proposed tolerance-level residues. Exposure was estimated using the same consumption data that were used for the anticipated residue exposure calculation.

The following table summarizes results of the chronic exposure analyses using proposed tolerances for the overall U.S. population and the five most highly exposed population subgroups.

Population subgroup	Exposure mg a.i./kg bwt	Percent of RfD
U.S. Population	0.000111	5.6
All Infants	0.000538	26.9
Non-nursing Infants < 1 yr.	0.000638	31.9
Children 1–6 yrs	0.000324	16.2
Children 7–12 yrs	0.000173	8.7
Females 13+/nursing	0.000133	6.7

An examination of the summary table demonstrates that chronic aggregate exposure represents no more than 32% of the chronic RfD for any population subgroup. These calculations were performed assuming that 100% of the apple and pear crops in the United States would contain AVG residues at tolerance levels. Assuming that 100% of all apple products consumed would contain tolerance-level residues is the worst-case scenario and yields a gross overestimate of dietary exposure.

An acute exposure analysis based upon anticipated residues was conducted using EPA's Tier 2 method with anticipated residues. For blended commodities (*e.g.*, apple juice and pear nectar), the mean anticipated residue level was used. For single serving commodities (*e.g.*, raw apples and pears), the LOQ of 0.075 ppm was used as a worst-case estimate of high end exposure because AVG residues were not quantifiable in the few samples in which residues were detected.

A separate exposure analysis was conducted for infants because baby foods are blended commodities. For these analyses, only raw forms of apples and pears were assumed to be consumed as single servings containing the high-end residue value of 0.075

ppm. All prepared and processed foods were assumed to be blended foods containing the mean anticipated residue of 0.018 ppm. The following table summarizes the exposure analysis at the 95th percentile:

Population subgroup	Exposure mg a.i./kg bwt	MOE
U.S. Population	0.000276	6,510
All Infants	0.000598	3,009
Non-nursing Infants < 1 yr.	0.000551	3,269
Children 1–6 yrs	0.000756	2,381
Children 7–12 yrs	0.000448	4,022
Females 13–50 yrs ..	0.000198	9,091

The MOE of the most highly exposed population subgroup, children 1 to 6 years old, is more than 23–fold higher than a level considered to provide adequate protection.

The acute exposure summary (below) in which proposed tolerance-level residues were used shows that estimated exposures provide adequate MOEs, even at the 95th percentile of exposure. In this analysis, acute exposure was calculated for the entire population rather than for consumers only, a procedure recommended by the EPA in their proposed method for acute dietary risk assessment.

Population subgroup	Exposure mg a.i./kg bwt	MOE
U.S. Population	0.000406	4,432
All Infants	0.002188	823
Non-nursing Infants < 1 yr.	0.002191	822
Children 1–6 yrs	0.001384	1,301
Children 7–12 yrs	0.000663	2,845
Females 13–50 yrs ..	0.000245	7,336

The most highly exposed population subgroup, non-nursing infants, has an estimated MOE of 822, greater than 8–fold higher than a level considered to provide adequate protection.

D. Cumulative Effects

AVG is a structurally unique biochemical pesticide and is a naturally occurring L-α-amino acid. Its proposed mode of action for mammalian toxicity is the inhibition of the enzymeγ-cystathionase. Other agents which inhibit this enzyme include naturally occurring amino acids such as alanine, cysteine, glutamic acid, and homoserine. Given the expected exposure, Abbott Laboratories maintains that inhibition of this enzyme would not occur at levels that would pose a human health risk.

E. Endocrine Effects

Abbott Laboratories reports that there have been no indications of treatment-related effects from AVG to suggest that the pesticide may have an endocrine disruption activity.

F. Safety Determination

1. *U.S. population.* AVG is a naturally occurring amino acid. Based upon expected residues in apples, pears, and water, Abbott Laboratories concludes that there is a reasonable certainty of no harm resulting from aggregate exposure of AVG to the general population.

2. *Infants and children.* The effects demonstrated in the developmental and immune toxicity studies are considered secondary to the adverse effects upon body weight gain, food consumption and food efficiency in the treated rats. These data indicate to Abbott Laboratories that AVG is not a developmental or immunological toxicant, and that infants and children are not sensitive subpopulations. The company concludes that there is a reasonable certainty that no harm will result from aggregate exposure of AVG to infants and children.

G. International Tolerances

There are no Codex maximum residue levels established for residues of AVG on apples or pears.

Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Abbott Laboratories concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of AVG, including all anticipated dietary exposure and all other non-occupational exposures.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number [PF–714].

A record has been established for this notice under docket control number [PF–714] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Authority: 21 U.S.C. 346a.

Dated: February 10, 1997.

Janet L. Anderson,

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

[FR Doc. 97–4114 Filed 2–19–97; 8:45 am]

BILLING CODE 6560–50–F

[PF-709; FRL–5588–5]

Good Bugs, Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of a temporary exemption from the requirement of the tolerance for residues of Burkholderia (pseudomonas) cepacia strain AMMD in or on American ginseng, carrots, peas, potatoes, snap beans, supersweet and sweet corn, tomatoes, and turf in California, Florida, Illinois, Minnesota, Missouri, Ohio, Washington, and Wisconsin for the 1997-1999 growing seasons. The summary of the petition was prepared by the petitioner, Good Bugs, Inc.

DATES: Comments, identified by the docket control number [PF-709], must be received on or before March 24, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Crystal Mall #2, Room