

fees due, and to fulfill any applicable unsatisfied data requirements.

### V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** (56 FR 29362) June 26, 1991; [FRL 3846-4]. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

#### List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: October 16, 1997.

#### Richard D. Schmitt,

*Acting Director, Information Resources and Services Division, Office of Pesticide Programs.*

[FR Doc. 97-28659 Filed 10-28-97; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-772; FRL-5751-3]

### Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by the docket control number PF-772, must be received on or before November 28, 1997.

**ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION:** By mail: Regulatory Action Leader, Edward Allen, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460. Office location and telephone number: 5th floor CS #1, 2800 Crystal Drive, Arlington, VA 22202. Telephone No. (703) 308-8699; e-mail: allen.edward@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-772] (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 official record is located at the address in "ADDRESSES" at the beginning of this document.

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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-772] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

#### List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 15, 1997.

#### Janet L. Andersen,

*Director, Biopesticides and Pollution Prevention 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.

### 1. Auxein Corporation

PP 7F4842

EPA has received a pesticide petition (7F4842) from Auxein Corporation, P. O. Box 27519, 3125 Sovereign Drive, Suite B, Lansing, MI, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a (d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of glutamic acid in or on all food commodities.

Pursuant to the section 408 (d) (2) (A) (i) of the FFDC, as amended, Auxein Corporation has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Auxein Corporation and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

#### A. Proposed Use Practices

Glutamic acid will be incorporated into the end-use product, AuxiGro WP Plant Growth Enhancer as an active ingredient. AuxiGro is proposed for use in a variety of agricultural, horticultural, and floricultural applications to enhance plant growth and crop productivity.

Depending on the crop, the first application of AuxiGro is made at first bloom, first bud, at the 4-6 leaf stage, or other prescribed growth stage. A subsequent application, for a maximum of two (2) applications, may be made 1-3 weeks later. The rate range is 0.10 - 0.75 pounds of formulated product/acre per treatment, not to exceed a maximum of 1.5 lb/A per growing season. This equates to the application of 0.55 lb/A glutamic acid at the maximum use rate.

#### B. Product Identity/Chemistry

Glutamic acid is an amino acid found in microorganisms, tissues of animals, all food, and higher plants as free amino acid or bound in protein. The biochemical is a white, practically odorless, free flowing crystalline powder. It is slightly soluble in water, forming acidic solutions. The pH of a saturated solution is about 3.22. The specific gravity for glutamic acid is 1.538 and the decomposition point is 175° C @ 10 mm Hg.

#### C. Toxicological Profile

Glutamic acid is highly regulated in man and other organisms, the mechanisms of which are well understood. It is classified as Generally Recognized as Safe (GRAS) by the Food and Drug Administration.

Glutamate has been administered to numerous species in long term dietary studies without adverse effects. The end-use product containing glutamic acid, AuxiGro WP, has been evaluated for acute toxicity. Acute oral toxicity in rats is greater than 5,050 mg/kg (Toxicity Category IV). Acute dermal toxicity in rabbits is greater than 5,050 mg/kg (Toxicity Category IV). In an eye irritation study, all signs of irritation cleared within 24 hours (washed eyes) following administration of AuxiGro (Toxicity Category IV); in unwashed eyes, irritation cleared in 5/6 rabbits within 24 hours. Irritation cleared within 48 hours in the remaining rabbit. A rabbit dermal irritation study with AuxiGro resulted in limited signs of irritation that cleared within 24 hours (Toxicity Category IV). There was no indication of dermal sensitization in a guinea pig dermal sensitization study.

Waivers have been requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species based on glutamic acid's ubiquity in nature, long history of food uses, favorable toxicological profile in chronic toxicology studies, and inconsequential exposure resulting from label-directed use rates.

#### D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* Glutamic acid is ubiquitous in nature and is found in microorganisms, lower and higher plant species, fish, birds, insects, mammals, and natural and processed foods. It is the most prevalent amino acid in plant and animal proteins. Worldwide production of glutamic acid is over 340,000 tons/yr. Many items in the human daily diet contain appreciable quantities of free glutamic acid. For example, ripe tomatoes, mushrooms, peas, corn, potatoes, squash, cheese, eggs, poultry and meat provide from 20

to 150 mg of glutamic acid per 100 gram serving. Daily consumption for a 70-kg individual of glutamate has been previously reported to be 10.4 g per day, based on an intake of 100 grams of protein/day. Regarding the sodium salt of glutamic acid, monosodium glutamate (MSG), the Joint Expert Committee on Food Additives of the United Nations (JEFCA) has assigned an Acceptable Daily Intake of "not specified" (no numerical limitation), meaning that MSG can be used safely according to food manufacturing practices in food by people of all ages.

Dietary exposure due to topical applications of glutamic acid is difficult to estimate because of the amino acid's prevalence in nature. However, a comparison of naturally-occurring levels of glutamic acid to topically applied levels shows that the applied level is a small fraction of that found naturally. Naturally-occurring levels of glutamic acid in corn and tomatoes are estimated to be 143 lb/A and 195 lb/A, respectively. Applied levels of glutamic acid resulting from the application of AuxiGro at maximum use levels (1.5 lb/A) is 0.55 lb/A, several orders of magnitude lower than naturally-occurring levels.

Considering the low dose of AuxiGro required to achieve the desired effect, the levels of glutamic acid found naturally in the diet and the quantity consumed from processed foods, it can be concluded that incremental dietary exposure to glutamic acid resulting from AuxiGro applications is negligible.

2. *Non-dietary, non-occupational exposure.* AuxiGro is proposed for use on turf and ornamentals. Exposure from turfgrass applications is expected to be minimal because golfers will be protected by shoes and socks. Further, based on the limited frequency of use on turfgrass, this non-food use is not likely to result in potential chronic exposure and thus should not be factored into a chronic exposure assessment. Exposures resulting from application to ornamentals is also anticipated to be negligible because consumers will not be in contact with treated plants until after the foliage is dry.

#### E. Cumulative Exposure

Glutamic acid is highly regulated in plants and mammals, the mechanisms of which are well understood. This amino acid is not intended for pesticidal use and does not share a common mechanism of toxicity with currently available pesticides, thus Auxein anticipates no cumulative effects with other substances.

### F. Endocrine Disruptors

The Agency has no information to suggest that glutamic acid will adversely affect the immune or endocrine systems.

### G. Safety Considerations

Glutamic acid is classified as Generally Recognized as Safe (GRAS) for use as a direct food additive by the Food and Drug Administration (FDA) and is cleared by the EPA for use as an inert ingredient in certain pesticide products. Condensed, extracted fermentation glutamic acid is approved by the FDA for use in animal feed.

Incremental exposure resulting from application of glutamic acid is miniscule compared to levels of glutamic acid consumed from natural and processed food products. Considering the negligible contributions to the environment resulting from the application of Auxigro, the abundance and role of glutamic acid in foods and in the human body, and the prevalence of glutamic acid in nature, glutamic acid does not pose an undue risk to human health.

### H. Analytical Method

An analytical method using High Performance Liquid Chromatography (HPLC) for determining glutamic acid content in Auxigro, the end-use product, is available. However, because this amino acid is found naturally in plants, residue analysis would not yield meaningful results, i.e., the analysis would not discern whether the glutamic acid source was the plant or the product treatment.

### I. Codex Maximum Residue Level

There are no CODEX tolerances or international tolerance exemptions for glutamic acid at this time. Glutamic acid is presently listed as exempt from tolerances under 40 CFR 180.1001 when used as a plant nutrient for seed treatment.

## 2. Auxein Corporation

### PP 7F4843

EPA has received a pesticide petition (7F4843) from Auxein Corporation, P. O. Box 27519, 3125 Sovereign Drive, Suite B, Lansing, MI, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a (d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of GABA in or on all food commodities.

Pursuant to the section 408 (d) (2) (A) (i) of the FFDCFA, as amended, Auxein Corporation has submitted the following summary of information, data and

arguments in support of their pesticide petition. This summary was prepared by Auxein Corporation and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

### A. Proposed Use Practices

Gamma aminobutyric acid (GABA) will be incorporated into the end-use product, Auxigro Plant Growth Enhancer as an active ingredient. Auxigro is proposed for use in a variety of agricultural, horticultural, and floricultural applications to enhance plant growth and crop productivity.

Depending on the crop, the first application of Auxigro is made at first bloom, first bud, at the 4-6 leaf stage, or at a prescribed growth stage. A subsequent application, for a maximum of two (2) applications, may be made 1-3 weeks later. The rate range is 0.10 - 0.75 pounds of formulated product/acre per treatment, not to exceed a maximum of 1.5 lb/A per growing season. This equates to 0.4 lb/A of GABA applied at the maximum use rate.

### B. Product Identity/Chemistry

GABA is a non-protein amino acid that is ubiquitous in nature. It has been found in microorganisms, lower and higher plants, fish, birds, insects, and mammals. GABA is a white, crystalline powder with a pH of 6.5 to 7.5. It is freely soluble in water, but insoluble or poorly soluble in other solvents. The melting point for GABA is 202° C.

### C. Toxicological Profile

GABA is an ubiquitous non-protein amino acid present in all living things. It is an inhibitory neurotransmitter in brain regions and central nervous systems of mammals. Because of the inability of GABA to cross the blood-brain barrier, exogenous sources do not affect the levels in the brain.

The open literature reports studies involving prolonged chronic administration of large doses (up to 1 g/kg/day) of GABA to rats and dogs. No signs of toxicity or untoward effects were observed in these studies.

According to the literature, similar doses have been administered repeatedly to unanesthetized dogs without untoward effects. In clinical studies, daily oral doses of 8 mM/kg have been administered to humans for a year or more with no indication of chronic or cumulative toxicity.

Auxigro, the end-use product containing 29.2% GABA, has been studied for acute toxicity. Acute oral toxicity of Auxigro in rats is greater than 5,050 mg/kg (Toxicity Category IV). Acute dermal toxicity in rabbits is greater than 5,050 mg/kg (Toxicity Category IV). In an eye irritation study, all signs of irritation cleared within 24 hours (washed eyes) following administration of Auxigro (Toxicity Category IV); in unwashed eyes, irritation cleared in 5/6 rabbits within 24 hours. Irritation cleared within 48 hours in the remaining rabbit. A rabbit dermal irritation study with Auxigro resulted in limited signs of irritation that cleared within 24 hours (Toxicity Category IV). There was no indication of dermal sensitization in a guinea pig dermal sensitization study.

Waivers have been requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species based on GABA's ubiquity in nature, use as a pharmaceutical agent, favorable toxicological profile in chronic and other toxicology studies, and inconsequential exposure resulting from label-directed uses.

### D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* GABA is ubiquitous in nature. Therefore, applications of Auxigro would only incrementally add to levels occurring naturally in the environment.

GABA concentrations in plants have been reported to range from 0.03 to 32.5 uM/g, fresh weight. It is presumed that the higher levels are probably due to stress and/or localized high levels within certain plant tissues. Based on these figures, the naturally-occurring level of GABA is calculated to be 0.1 kg/A 7.15 kg/A. The high-end (maximum application rate) estimate of incremental loading of GABA resulting from application of Auxigro is 0.2 kg. Thus, applied GABA is well within the range of that found in nature.

2. *Non-dietary, non-occupational exposure.* Auxigro is proposed for use on turf and ornamentals. Exposure from turfgrass applications are expected to be minimal because golfers will be

protected by shoes and socks. Further, based on the limited frequency of use on turfgrass, this non-food use is not likely to result in potential chronic exposure and thus should not be factored into a chronic exposure assessment. Exposures resulting from application to ornamentals is also anticipated to be negligible because consumers will not be in contact with treated plants until after the foliage is dry.

#### E. Endocrine Disruptors

Auxin has no information to suggest that GABA will adversely affect the immune or endocrine systems.

#### F. Safety Considerations

GABA is naturally-occurring in food and is a pharmaceutical agent. Incremental exposure to GABA resulting from the application of Auxigro is minimal to negligible. Considering the negligible contributions of GABA to the environment resulting from the application of Auxigro, the biochemical's prevalence in nature, and its role and abundance in foods, GABA does not pose a human health risk.

#### G. Analytical Method

An analytical method using High Performance Liquid Chromatography (HPLC) for determining the GABA content in Auxigro, the end-use product, is available. However, because GABA is found naturally in plants, residue analysis would not yield meaningful results, i.e., the analysis would not discern whether the source of GABA was the plant or the product treatment.

#### H. Codex Maximum Residue Level

There are no CODEX tolerances or international tolerance exemptions for GABA.

[FR Doc. 97-28664 Filed 10-28-97; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-775; FRL-5752-2]

### Notice of Filing of Pesticide Petitions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by the docket control number PF-775, must be

received on or before November 28, 1997.

**ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Elizabeth Haeberer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 250, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-2891; e-mail: haeberer.elizabeth@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** 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 Cosmetic 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.

The official record for this notice of filing, as well as the public version, has

been established for this notice of filing under docket control number [PF-775] (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 official record is located at the address in "ADDRESSES" at the beginning of this document.

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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-775] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

#### List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 16, 1997.

**James Jones,**

*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.

**Gustafson, Inc.**

PP 4F4415

EPA has received a pesticide petition (PP 4F4415) from Gustafson, Inc., 1400 Preston Road, Suite 400, Plano, Texas 75093, proposing pursuant to section 408(d) of the Federal Food, Drug and