ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300546; FRL–5741–3]

RIN 2070–AB78

Glutamic Acid; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical glutamic acid, when used to enhance the growth, vegetable quality, and yield of the following crops: broccoli, cabbage, cauliflower, cotton, green peppers, lettuce, peanuts, potatoes, snap beans, spinach, and tomatoes.

DATES: This regulation is effective September 5, 1997. Objections and requests for hearings must be received by EPA on or before November 4, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300546], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300546], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300546]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Edward Allen, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: 5th floor, Crystal Station #1, 2800 Crystal Drive, Arlington, VA, telephone: (703) 308–8699; e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Auxein Corporation, 3125 Sovereign Drive, Suite B, Lansing, MI 48911 has requested in pesticide petition (PP) 7G4839 the establishment of a temporary exemption from the requirement of a tolerance for residues of the biochemical glutamic acid. A notice of filing (FRL–5728–9) was published in the **Federal Register** (62 FR 36063, July 3, 1997), and the notice announced that the comment period would end on August 4, 1997; no comments were received. This temporary exemption from the requirement of a tolerance will permit the marketing of the above food commodities when treated in accordance with the provisions of experimental use permit (EUP) 70810–EUP–1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170.

I. Summary

A. Proposed Use Practices

The experimental program will be conducted in the states of Alabama, Arizona, California, Florida, Georgia, Idaho, Maine, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Washington, and Wisconsin. Crops to be treated are broccoli, cabbage, cauliflower, cotton, green peppers, lettuce, peanuts, potatoes, snap beans, spinach, and tomatoes. Depending on the crop, application is made at first bloom, first bud or at the 5–6 leaf stage. Subsequent applications, for a maximum of three applications, are at 1– to 3–week intervals. The rate range is 0.125–0.75 pounds (lbs) of formulated product/acre(A) per treatment, not to exceed a maximum of 1.5 lbs/A per growing season. The proposed EUP program would utilize 462 lbs of active ingredients (231 lbs of gamma aminobutyric acid and 231 lbs of glutamic acid) in 793 lbs of formulated product. A total of 822 lbs of formulated product will be shipped. A maximum of 790 acres will be treated under this EUP. The experimental program is intended for evaluation of plant growth, yield and vegetable quality.

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. Glutamic acid 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 @ 20/4 C and the decomposition point is 175° C @ 10 millimeters (mm) mercury (Hg).

II. Toxicological Profile

Glutamic acid is highly regulated in man and other organisms, the mechanisms of which are well understood. 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 milligram (mg)/kilogram (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 were requested for genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species. Waivers were accepted based on glutamic acid's natural occurrence, long history of food

uses, favorable toxicological profile in chronic toxicology studies, and inconsequential exposure resulting from label-directed use rates.

A. 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*. Dietary exposure due to topical applications of glutamic is difficult to estimate because of its prevalence in nature; applications associated with the EUP would be minuscule compared to levels found in nature. Glutamic acid in the environment is readily utilized by microorganisms. Furthermore, glutamic acid is presently consumed by humans in the form of glutamate in relatively high quantities. The low toxicity, low application rate, and the use pattern leads the Agency to conclude that residues from use of the biochemical glutamic acid will not pose a dietary risk of concern under reasonable foreseeable circumstances. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure under this temporary exemption.

2. *Non-dietary, non-occupational exposure*. Increased non-dietary exposure to glutamic acid via lawn care, topical insect repellents, etc., is not applicable to this EUP.

B. Cumulative Exposure

Glutamic acid is ubiquitous in nature. Incremental exposure resulting from this EUP program are miniscule when compared to the high levels of glutamic found naturally occuring in food.

C. Endocrine Disruptors

The Agency has no information to suggest that glutamic acid will adversely affect the immune or endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years (yrs) after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

D. Safety Considerations

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 (g) 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 g of protein/day.

Glutamic acid is listed 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 this EUP 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, the Agency concludes that application of glutamic acid to the aforementioned vegetable crops does not pose a dietary risk.

E. 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, the Agency has determined that 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.

F. 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.

G. Conclusion

Based on its abundance in nature and long history of use by humans without deleterious effects, there is reasonable certainty that no harm will result from aggregate exposure to the U. S. population, including infants and children, to residues of glutamic acid. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, exposure to glutamic acid resulting from the EUP label-directed use is inconsequential, and it is consumed daily by the human population from both naturally occurring sources and from processed foods. As a result, EPA establishes a temporary exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for glutamic acid, on the condition that it be used in accordance with the experimental use permit 70810–EUP–1, with the following provisions:

The total amount of the active ingredients to be used must not exceed the quantity authorized by the EUP.

Auxein Corporation must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of product, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration (FDA).

This temporary exemption from the requirement of a tolerance expires and is revoked August 27, 1998. Residues remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the biochemical is legally applied during the term of, and in accordance with, the provisions of the EUP and temporary exemption from the requirement of a tolerance. This temporary exemption from the requirement of a tolerance may be revoked if the EUP is revoked or if any experience with or scientific data on this biochemical indicate that the tolerance exemption is not safe.

III. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance exemption regulation issued by EPA under new FFDCA section 408(e) as was provided in the old FFDCA section 408. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may within 60 days after

publication of this document in the **Federal Register** file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under ''ADDRESSES'' at the beginning of this rule (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP Docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request 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. A copy of the information 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.

IV. Public Record

A record has been established for this rulemaking under the docket control number [OPP–300546] (including any comments and data submitted electronically). 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 Information and Records Integrity Branch, Information Resources and Services 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 any copies of objections and hearing requests 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 rule.

V. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:August 27, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1187 is added to subpart D to read as follows:

§ 180.1187 Glutamic acid; exemption from the requirement of a tolerance.

The biochemical glutamic acid is temporarily exempted from the requirement of a tolerance for residues when used on crops including: snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage to enhance crop yields. This temporary exemption from the requirement of a tolerance will permit the marketing of the food commodities in this paragraph when treated in accordance with the provisions of

experimental use permit 70810–EUP–1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked August 27, 1998. This temporary exemption from the requirement of a tolerance may be revoked at any time if the EUP is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

[FR Doc. 97–23629 Filed 9–4–97; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300547; FRL–5741–4]

RIN 2070–AB78

Gamma Aminobutyric Acid; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This rule establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical gamma aminobutyric acid when used to increase yields of the following crops: snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage.

DATES: This regulation is effective September 5, 1997. Objections and requests for hearings must be received by EPA on or before November 4, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300547], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300547], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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FOR FURTHER INFORMATION CONTACT: By mail: Edward Allen, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: 5th floor CS 1, 2800 Crystal Drive, Arlington, VA, telephone: (703) 308–8699; e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Auxein Corporation, 3125 Sovereign Drive, Suite B, Lansing, MI 48911 has requested in pesticide petition # 7G4838 the establishment of a temporary exemption from the requirement of a tolerance for residues of the biochemical gamma aminobutyric acid (GABA). A notice of filing was published in the **Federal Register** on July 3, 1997 (62 FR 36063)(FRL–5728–9), and the notice announced that the comment period would end on August 4, 1997; no comments were received. This temporary exemption from the requirement of a tolerance will permit the marketing of the above food commodities when treated in accordance with the provisions of experimental use permit 70810–EUP–1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170.

I. Summary

A. Proposed Use Practices

The experimental program will be conducted in the states of Alabama, Arizona, California, Florida, Georgia, Idaho, Maine, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Washington, and Wisconsin. Crops to be treated are snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage. Depending on the crop, application is made at first bloom, first bud or at the 5-6 leaf stage. Subsequent applications, for a maximum of three applications, are at 1– to 3–week intervals. The rate range is 0.125–0.75 pounds of formulated product/acre per treatment not to exceed a maximum of 1.5 lbs/A per growing season. The proposed EUP program would utilize 462 pounds of active ingredients (231 pounds of gamma aminobutyric acid and 231 pounds of glutamic acid) in 793 pounds of formulated product. A total of 822 pounds of formulated product will be shipped. A maximum of 790 acres will be treated under this EUP. The experimental program is intended for evaluation of plant growth, yield and vegetable quality.

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 on rapid heating.

II. Toxicological Profile

GABA is a ubiquitous non-protein amino acid present in all living things. It is an inhibitory neurotransmitter in many brain regions and central nervous systems of mammals. Due to GABA's role in the nervous system, it has been administered to humans with the aim of improving central GABA-mediated transmission and to control Huntington's disease, Parkinson's disease, schizophrenia and other seizure states. AuxiGro, the end-use formula 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