enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone.

Dated: December 5, 1997.

A. Stan Meiburg,

Acting Regional Administrator.

Chapter I, title 40, *Code of Federal Regulations,* is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart B—Alabama

2. Section 52.50 is amended by adding paragraph (c)(71) to read as follows:

§ 52.50 Identification of plan.

* * * * *

(c)* * *

(71) The State of Alabama submitted revisions to the ADEM Administrative Code for the Air Pollution Control Program on October 30, 1996. These revisions involve changes to Chapters 335–3–1, 335–3–3 and 335–3–6.

(i) Incorporation by reference. Chapters 335–3–1–.02(gggg)(24–27), 335–3–3–.01(9) and 335–3–6–.16 except for (5) were adopted on August 19, 1997.

(ii) Other material. None.

[FR Doc. 98–357 Filed 1–6–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300599; FRL–5764–5]

RIN 2070–AB78

Gamma Aminobutyric Acid; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biochemical gamma aminobutyric acid (GABA) in or on all food commodities, when applied as a plant growth and crop yield enhancer in accordance with good agricultural practices. This exemption was requested by Auxein Corporation.

DATES: This regulation becomes effective February 6, 1998. Objections and requests for hearings must be received by EPA on or before March 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300599], 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–300599], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300599]. 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 (7511W), 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 22202, Telephone No. (703) 308-8699), e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Auxein Corporation, P.O. Box 27519, 3125 Sovereign Drive, Suite B, Lansing, MI 48911 had requested in pesticide petition 7F4843, the establishment of an exemption from the requirement of a tolerance for residues of the biochemical gamma aminobutyric acid (GABA). A notice of filing (PF–772) was published in the **Federal Register** of October 29, 1997 (62 FR 57170; FRL–5751–3), and the notice announced that the comment period would end on November 28, 1997; no comments were received. 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.

I. Summary

A. Proposed Use Practices

Gamma aminobutyric acid (GABA) will be incorporated into the end-use product, AuxiGro™ WP Plant Growth Enhancer as an active ingredient. AuxiGro WP 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/acre per growing season. This equates to 0.4 lb/acre (0.2 kg) 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 degrees C on rapid heating.

II. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special

consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the scientific data and other relevant information in support of this action and considered its validity, completeness, reliability, and relationship to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

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 (0.8 g/kg) have been administered to humans for a year or more with no indication of chronic or cumulative toxicity.

AuxiGro WP, 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 48 hours following administration of AuxiGro (Toxicity Category III). 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. Waivers were accepted based on GABA's natural occurrence, use as a pharmaceutical agent, favorable toxicological profile in chronic toxicology studies, and inconsequential exposure resulting from label-directed uses.

They were accepted based on the following rationale: (a) low acute toxicity in mammalian species, (b) natural occurrence and lack of persistence in the environment, and (c) natural occurrence in plants and ability to promote growth of numerous plant species.

IV. 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 innature. Therefore, applications of AuxiGro WP 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 (0.000005 g to 0.0000325 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/acre - 7.15 kg/acre. The high-end (maximum application rate) estimate of incremental loading of GABA resulting from application of AuxiGro is 0.2 kg/acre. Thus, applied GABA is well within the range of that found in nature.

2. *Non-dietary, non-occupational exposure.* AuxiGro WP is proposed for use on turf and ornamentals. Exposure from turfgrass applications are expected to be minimal to non-existent because of the low application rates. 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.

V. Cumulative Effects

GABA has a very low toxicity to humans. Because of its low toxicity, low rate of application, and use patterns, the Agency believes that there is no reason to expect any cumulative effects from GABA and other substances.

VI. Endocrine Disruptors

The Agency has no information to suggest that GABA 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 after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

VII. Safety Determination for U.S. Population, Infants and Children

Based on the information discussed above, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of GABA. 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, the toxicity of GABA to mammals is very low and under reasonably foreseeable circumstances it does not pose a risk.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that GABA is practically non-toxic to mammals, including infants and children, and, thus, a margin of exposure (safety) approach is not needed to protect adults or infants and children.

VIII. Analytical Method

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for GABA.

IX. Codex Maximum Residue Level

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

X. 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 GABA. 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 GABA resulting from label-directed use is inconsequential, does not cross the blood-brain barrier, and is consumed daily by the human population from naturally-occurring sources. As a result, EPA establishes an exemption from the requirement of a tolerance pursuant to FFDCA section 408(c) for GABA, on the condition that it be used in accordance with use directions provided on the product label.

XI. 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 section 408(e) as was provided in the old 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 objecitons. 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.

XII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket number [OPP–300599] (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 (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may 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 document.

XIII. 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.

XIV. 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: December 30, 1997.

Janet L. Andersen,

Acting Director, Office of Pesticide Programs.

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 180.1188 is revised to read as follows:

§ 180.1188 Gamma aminobutyric acid; exempt from the requirement of a tolerance.

Gamma aminobutyric acid is exempt from the requirement of a tolerance on all food commodities when used as a plant growth enhancer in accordance with good agricultural practices.

[FR Doc. 98–360 Filed 1–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300598; FRL–5764–4]

RIN 2070–AB78

Glutamic Acid; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biochemical glutamic acid in or on all food commodities, when applied as a plant growth and crop yield enhancer in accordance with good agricultural practices. This exemption was requested by Auxein Corporation.

DATES: This regulation becomes effective February 6, 1998. Objections and requests for hearings must be received by EPA on or before March 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300598], may 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 should be identified by the document control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300598]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of 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 (7511W), 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 22202, Telephone No. (703) 308–8699, e-mail: allen.edward@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Auxein Corporation, P.O. Box 27519, 3125 Sovereign Drive, Suite B, Lansing, MI 48911 had requested in pesticide petition 7F4842, the establishment of an exemption from the requirement of a tolerance for residues of the biochemical glutamic acid. A notice of filing (PF–772) was published in the **Federal Register** of October 29, 1997 (62 FR 56268, FRL–5751–3), and the notice announced that the comment period would end on November 28, 1997; no comments were received. 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.

I. Summary

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 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/acre per growing season. This equates to 0.4 lb/acre (0.2 kg) of glutamic acid applied at the maximum use rate.

B. Product Identity/Chemistry

Glutamic acid is an amino acid found in microorganisms, tissues of animal, 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 degrees C @ 10 millimeters (mm) mercury (Hg).

II. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.