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.

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.

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 milligrams per kilogram (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). 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.

Humans have the capacity to rapidly metabolize ingested glutamate (the expected exposure route) to keep plasma glutamate levels constant: no adverse effects on neurological or hepatic function were observed in humans administered levels up to 137 g daily for 14–41 days, which is much higher than the rate applied to plants. The blood brain barrier further protects the brain from large infusions of glutamate. Likewise, the placental barrier protects the developing fetus against up to twentyfold increases in maternal glutamate levels.

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.

Waivers were also requested for acute avian oral toxicity, nontarget plants, avian dietary, and nontarget insects. 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.* 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/acre and 195 lb/acre, respectively. Applied levels of glutamic acid resulting from the application of AuxiGro at maximum use levels (1.5 lb/acre) is 0.4 lb/acre, 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 from animal and vegetable proteins 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 professional 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.

V. Cumulative Effects

Glutamic acid 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 glutamic acid and other substances.

VI. 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 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 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, the toxicity of glutamic acid 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 glutamic acid 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.

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.

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 glutamic acid.

IX. Codex Maximum Residue Level

There are no CODEX tolerances or international tolerance exemptions for glutamic acid 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 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 of the preponderance of data from the open literature supporting the safe use of glutamate in foods, the supporting acute toxicity data on AuxiGro, and inconsequential resulting from its application to crops. As a result, EPA establishes an exemption from the requirement of a tolerance pursuant to FFDCA section 408(c) for glutamic acid.

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 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.

XII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300598] (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), EPA 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 in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(a).

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 180.1187 is revised to read as follows:

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

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

[FR Doc. 98–359 Filed 1–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL–5944–9]

Technical Amendments to Ocean Dumping; Amendment of Site Designation; Correction of Effective Date Under Congressional Review Act (CRA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction of effective date under CRA.

SUMMARY: On December 30, 1996 (61 FR 68963), the Environmental Protection Agency published in the **Federal Register** a final rule concerning an amendment to the ocean dumping site designation for the San Francisco Deep Ocean Site, which established an effective date of December 30, 1996. This document corrects the effective date of the rule to December 30, 1997 to be consistent with sections 801 and 808 of the Congressional Review Act (CRA), enacted as part of the Small Business Regulatory Enforcement Fairness Act.

EFFECTIVE DATE: December 30, 1997.

FOR FURTHER INFORMATION CONTACT: Cynthia Puskar at (202) 260–8532.

SUPPLEMENTARY INFORMATION:

A. Background

Section 801 of the CRA precludes a rule from taking effect until the agency promulgating the rule submits a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the General Accounting Office (GAO). EPA recently discovered that it had inadvertently failed to submit the above rule as required; thus, although the rule was promulgated December 30, 1996, by operation of law, the rule did not take effect on December 30, 1996 as stated. After EPA discovered its error, the rule was submitted to both Houses of Congress and the GAO on December 11, 1997. This document amends the effective date of the rule consistent with the provisions of the CRA.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since December 30, 1996, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

Because the delay in the effective date was caused by EPA's inadvertent failure to submit the rule under the CRA, EPA does not believe that affected entities that acted in good faith relying on the effective date stated in the December 30, 1996 **Federal Register** should be penalized if they were complying with the rule as promulgated.

B. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the December 30, 1996 **Federal Register** document.

Pursuant to 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA will submit 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; however, in accordance with 5 U.S.C. 808(2), this rule became effective on December 30, 1997. This rule is not a ''major rule'' as defined in 5 U.S.C 804(2).