

Dated: June 25, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, 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. 321(q), (346a) and 371.

2. Section 180.502 is amended by revising the entry for “Stone fruit crop group” in the table to paragraph (a) to read as follows:

§ 180.502 Aminoethoxyvinylglycine; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million	Expiration/Revocation Date
Stone fruit crop group	0.170	12/21/03

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301147; FRL-6790-7]

RIN 2070-[AB78]

Aminoethoxyvinylglycine (AVG); Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances of 0.08 part per million (ppm) for residues of aminoethoxyvinylglycine (AVG), in or on apples and pears. Valent BioSciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire on December 21, 2003.

DATES: This regulation is effective July 12, 2001. Objections and requests for hearings, identified by docket control number OPP-301147, must be received by EPA on or before September 10, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301147 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticides and Pollution Prevention Division

(7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8263; and e-mail address: greenway.denise@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>.

To access this document, on the Home Page select “Laws and Regulations”, “Regulations and Proposed Rules,” and then look up the entry for this document under the “Federal Register—Environmental Documents.” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301147. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall# 2, (CM #2) 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of March 28, 2001 (66 FR 16931) (FRL-6775-1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 6F4632, transferred from Abbott Laboratories) for tolerances by Valent BioSciences Corporation, 870 Technology Way, Suite 100,

Libertyville, IL 60048. This notice included a summary of the petition prepared by Valent BioSciences Corporation, the registrant. There were no comments received in response to the notice of filing.

New data summarized by Valent BioSciences Corporation in that petition were a rat 2-generation reproduction study. The study was a condition of registration of the subject active ingredient, and was submitted to the Agency by Abbott Laboratories on September 27, 1999. Other new data also summarized in the March 28, 2001 notice were internationally-generated residue data in apples, submitted by Valent BioSciences Corporation on May 23, 2000.

Subsequent to the March 28, 2001 notice, the Agency received from Valent BioSciences Corporation a substantial number of supplementary data in support of aminoethoxyvinylglycine. These new data have been placed in the public docket. OPP-301147.

The petition requested that 40 CFR 180.502 be amended by establishing permanent tolerances for the biochemical pesticide aminoethoxyvinylglycine, in or on apples and pears at 0.08 part per million (ppm). Instead, because the Agency has not completed its assessment of the conditional rat 2-generation reproduction study, the Agency is establishing time-limited tolerances for which the tolerances will expire on December 21, 2003.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(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(b)(2)(C) 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. For further discussion of the regulatory requirements of section 408 and a

complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for apples and pears at 0.08 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

Toxicological Profile

EPA has previously evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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.

In the **Federal Register** of May 7, 1997 (62 FR 24835) (FRL-5713-5), EPA established time-limited tolerances for residues of the plant regulator aminoethoxyvinylglycine (AVG) in or on the food commodities apples and pears at 0.08 ppm. This final rule included a summary of the Agency's assessment of the health effects data submitted in support of the establishment of the time-limited tolerances. This rule also announced that, in considering the sensitivity of infants and children, the thousand-fold safety factor includes an additional uncertainty factor of 10 for incompleteness of data until a rat 2-generation reproduction study was completed. A correction to this rule was published in the **Federal Register** of October 29, 1997 (62 FR 56089) (FRL-5751-5), which announced the correction of the reference dose (RfD) appearing on page 24836, column three, third full paragraph, line 11, from "0.0002" to "0.002." This correction did not affect the tolerance levels. The time limited tolerances expired on April 1, 2001.

Summaries of the toxicological profile and other relevant health effects data, to comply with the requirements of the FFDCA, as amended by the FQPA of 1996, were reported in the **Federal Register** publication of the final rule of May 7, 1997, establishing the time-limited tolerances. Although the Agency

has not completed its assessment of the rat 2-generation reproduction study, based on the previously submitted data outlined in the May 7, 1997, **Federal Register** final rule, and based on the same rationale included therein, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to aminoethoxyvinylglycine. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

IV. Other Considerations

A. Analytical Enforcement Methodology

The submitted analytical method, High Performance Liquid Chromatography (HPLC)/Fluorescence detector, is acceptable; it is also verified and validated.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5229.

B. International Residue Limits

There are no Codex Alimentarius Commission (CODEX) Maximum Residue Levels (MRLs) for residues of aminoethoxyvinylglycine on apples or pears, or on any other crops.

V. Conclusion

A data gap currently exists for a rat 2-generation reproduction study, because the Agency has not concluded its assessment of the data, which were submitted by Abbott Laboratories on September 27, 1999. All tolerances are time-limited because of this data gap. The Agency also has not completed its assessment of the new internationally-generated apple residue data, which were submitted by Valent BioSciences Corporation on May 23, 2000, and, the supplementary data received after the publication of the March 28, 2001, notice. The time limitation allows for review of the data. Based on the available toxicological data, the thousandfold uncertainty factor, and the levels of exposure, the EPA has determined that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the pesticide (AVG) and its residues during the period of the time-limited tolerances.

Based on the information and rationale cited in the final rule of May 7, 1999, the Agency has determined that the establishment of the time-limited tolerances by amending 40 CFR 180.502 will be safe; therefore the time-limited tolerances are established for apples and pears at 0.08 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301147 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 10, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees"

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP-301147, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and

avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances 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) (Public Law 104-4). Nor does it require any 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 OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175,

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.”

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. 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 United States prior to publication of this final rule in the **Federal Register**. This final rule 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: July 2, 2001.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, 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. 321(q), 346(a) and 371.

2. Section 180.502 is amended by revising the Expiration/revocation date for the commodities Apples and Pears in the table in paragraph (a) to read as follows:

§ 180.502 Aminoethoxyvinylglycine; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/revocation date
Apples	0.08	12/21/03
Pears	0.08	12/21/03
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[FR Doc. 01-17472 Filed 7-11-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 401

[USCG 1999-6098]

RIN 2115-AF91

Great Lakes Pilotage Rates

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard amends the rates for pilotage on the Great Lakes.

The new rates rest on an independent audit of expenses, results of the 1999 rate review, comments received in response to a Notice and a Supplemental Notice of Proposed Rulemaking, and a public meeting held in Coast Guard Headquarters on October 12, 2000. On these basis, the rates for such services increase an average of 3%, with consequent effects on the incomes of pilots.

DATES: This rule is effective August 13, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket USCG 1999-6098 and are available for inspection or copying at the Docket Management Facility, U.S.

Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call Tom Lawler, Chief Economist, Office of Great Lakes Pilotage, Commandant (G-MW-1), U.S. Coast Guard, at 202-267-1241, by facsimile 202-267-4700, or by email at tlawler@comdt.uscg.mil. If you have questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202-366-5149.