§ 3001.196 Requests to recommend a Negotiated Service Agreement that is functionally equivalent to a previously recommended Negotiated Service Agreement.

(a) This section governs Postal Service requests for a recommended decision in regard to a Negotiated Service Agreement that is proffered as functionally equivalent to a Negotiated Service Agreement previously recommended by the Commission and currently in effect. The previously recommended Negotiated Service Agreement shall be referred to as the baseline agreement. The purpose of this section is to establish procedures that provide for accelerated review of functionally equivalent Negotiated Service Agreements. The Postal Service request shall include:

(1) A detailed description of how the proposed Negotiated Service Agreement is functionally equivalent to the baseline agreement;

(2) A detailed description of how the proposed Negotiated Service Agreement is different from the baseline agreement;

(3) Identification of the record testimony from the baseline agreement docket, or any other previously concluded docket, on which the Postal Service proposes to rely, including specific citation to the locations of such testimony;

(4) All available special studies developing information pertinent to the proposed Negotiated Service Agreement;

(5) If applicable, the identification of circumstances unique to the request; and

(6) If applicable, a proposal for limitation of issues in the proceeding, except that the following issues will be relevant to every request predicated on a functionally equivalent Negotiated Service Agreement:

(i) The financial impact of the Negotiated Service Agreement on the Postal Service over the duration of the agreement;

(ii) The fairness and equity of the Negotiated Service Agreement in regard to other users of the mail; and

(iii) The fairness and equity of the Negotiated Service Agreement in regard to the competitors of the parties to the Negotiated Service Agreement.

(b) When the Postal Service submits a request predicated on a functionally equivalent Negotiated Service Agreement, it shall provide written notice of its request, either by hand delivery or by First-Class Mail, to all participants in the Commission docket established to consider the baseline agreement.

(c) The Commission will schedule a prehearing conference for each request. Participants shall be prepared at the prehearing conference to address whether or not it is appropriate to proceed under § 3001.196, and to identify any issue(s) that would indicate the need to schedule a hearing. After consideration of the material presented in support of the request, and the argument presented by the participants, if any, the Commission shall promptly issue a decision on whether or not to proceed under § 3001.196. If the Commission's decision is to not proceed under § 3001.196, the request will proceed under § 3001.195.

(d) The Commission will treat requests predicated on functionally equivalent Negotiated Service Agreements as subject to accelerated review consistent with procedural fairness. If the Commission determines that it is appropriate to proceed under § 3001.196, a schedule will be established which allows a recommended decision to be issued not more than:

(1) 60 days after the determination is made to proceed under § 3001.196, if no hearing is held; or

(2) 120 days after the determination is made to proceed under § 3001.196, if a hearing is scheduled.

§ 3001.197 Requests to renew previously recommended Negotiated Service Agreements with existing participant(s). [Reserved]

§ 3001.198 Requests to modify previously recommended Negotiated Service Agreements. [Reserved]

[FR Doc. 04–3440 Filed 2–17–04; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

OPP–2003–0389; FRL–7341–6]

Aminoethoxyvinylglycine hydrochloride (aviglycine HCl); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl) in or on apple, pear and the stone fruits crop group 12, excepting cherries. Valent BioSciences Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective February 18, 2004. Objections and requests for hearings, identified by docket ID number OPP–2003–0389, must be received on or before April 19, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address:*greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0389. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public

docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of November 13, 2003 (68 FR 64343) (FRL–7333–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 6F4632, transferred from Abbott Laboratories) by Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048. That 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.

In the **Federal Register** of November 19, 2003 (68 FR 65281) (FRL–7334–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 3F6772) by Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048. That 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.

The petitions requested that 40 CFR 180.502 be amended by establishing permanent tolerances for residues of the biochemical pesticide aminoethoxyvinylglycine hydrochloride (aviglycine HCl), formerly designated as aminoethoxyvinylglycine (AVG), in or on apple and pear at 0.08 parts per million (ppm) (PP 6F4632), and in or on the stone fruits crop group 12, excepting cherries, at 0.170 ppm (PP 3F6772). Data submitted and summarized by Valent BioSciences Corporation in these petitions include: Domestically and internationally generated residue data; another acute inhalation toxicity study; and subchronic toxicity (rat, mouse and dog), and metabolism (rat and comparative mouse and rat) studies, as well as a Tier III biochemical pesticide toxicity study (rat carcinogenicity), and additional studies (rabbit developmental toxicity and rat chronic toxicity) to refine assessments of subpopulation sensitivities and carcinogenic potential.

Previously, in support of both time-limited and temporary tolerances issued by EPA for residues of aviglycine HCl in or on apple, pear, and the stone fruits crop group 12 (May, 7, 1997, 62 FR 24835, FRL–5713–3, corrected on October 29, 1997, 62 FR 56089, FRL–5751–5; June 10, 1999, 64 FR 31124, FRL–6080–4; July 12, 2001, 66 FR 36477, FRL–6788–7; and July 12, 2001, 66 FR 36481, FRL–6790–7), residue studies and toxicity data consistent with the Tier I biochemical pesticide toxicity data requirements, as described in 40 CFR 158.690(c), were submitted. That data included acute oral, dermal and inhalation toxicity studies; eye and skin irritation studies; dermal sensitization and one genotoxicity study (Ames test); and subchronic (immunotoxicity) and developmental toxicity studies in the rat. Several additional toxicity studies, although not required for biochemical pesticides, also were submitted previously, including two mammalian mutagenicity studies (Tier II rat micronuclei and mouse lymphoma) and subchronic studies (including 21–day dermal toxicity) in the rat. In addition, a conditionally required 2–generation rat reproduction study was submitted previously to reduce the uncertainties associated with the assessment of susceptibility of infants and children to potential hazards from aviglycine HCl exposure. All of this toxicity data on aviglycine HCl, both the new data submitted with the new petitions considered in this final rule and the data previously submitted and mentioned above has been considered and factored into the action taken in this final rule.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA 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) of FFDCA, 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) of FFDCA, for tolerances for residues of aviglycine HCl on apple and pear at 0.08 ppm, and on the stone fruits crop group 12, excepting cherries, at 0.170 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has 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. The nature of the toxic effects caused by aviglycine HCl

are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

The acute toxicity studies indicated low toxicity for technical aviglycine HCl, placing it into Toxicity Category III for dermal toxicity, and Toxicity Category IV for oral toxicity and eye and skin irritation. A new acute inhalation toxicity study considered as part of this action changed the technical grade material's classification from Toxicity Category III to Toxicity Category IV. Dermal sensitization studies also indicated that aviglycine HCl is a non-sensitizer. Finally, in order to comply with the statutory requirements under FIFRA section 6(a)(2) and EPA's data requirements (40 CFR section 158.690(c)), any incident of hypersensitivity associated with use of aviglycine HCl must be reported to the Agency.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity-rat	NOAEL = 2.2 milligram/kilogram/day (mg/kg/day) for females, 9.2 mg/kg/day (highest dose tested) for males LOAEL = 9.4 mg/kg/day (the highest dose tested for females) based on reduced body weight gain, food consumption and food efficiency; increased severity and incidence of reversible kidney and liver effects; and discoloration of the liver
870.3100	90–Day oral toxicity-rat	NOAEL = 0.4 mg/kg/day for males and females LOAEL = 4.0 mg/kg/day for males and females, based on increased incidence of periportal hepatocellular vacuolation in the liver
870.3100	90–Day oral toxicity-mouse	NOAEL = 9.5 mg/kg/day for males and 9.6 mg/kg/day for females LOAEL = 23.4 mg/kg/day for males and 23.2 mg/kg/day for females based on clinical signs in both sexes, decreased mean body weight and body weight gain in males, decreased relative spleen and kidney weights in males, histopathology in the adrenal glands of females, and increased testicular atrophy in males
870.3150	90–Day oral toxicity-dog	NOAEL = 0.6 mg/kg/day LOAEL = 1.2 mg/kg/day based on decreased body weight gain, food consumption, uterine weights, and liver pathology
870.3200	21–Day dermal toxicity-rat	NOAEL = 1,000 mg/kg/day (limit dose) A LOAEL was not determined. Limit doses are as high a dose level as can practically be tested; when there are no effects, a LOAEL is not needed
870.3700	Prenatal developmental-rat	Maternal NOAEL = 1.77 mg/kg/day LOAEL = 8.06 mg/kg/day based on decreased body weight gain, food consumption, defecation, and the presence of perinasal red material Developmental NOAEL = 1.77 mg/kg/day LOAEL = 8.06 mg/kg/day based on decreased mean fetal body weights and developmental skeletal variants
870.3700	Prenatal developmental-rabbit	Maternal NOAEL = 0.4 mg/kg/day LOAEL = 0.7 mg/kg/day based on decreased body weight gains and food consumption Developmental NOAEL = 0.2 mg/kg/day LOAEL = 0.4 mg/kg/day based on the presence of developmental malformations
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 0.8 mg/kg/day for males, 2.5 mg/kg/day for females LOAEL = 2.5 mg/kg/day based on decreased absolute body weight and body weight gain, and periportal hepatocellular vacuolation in the liver in F_0 and F_1 adult males; 4 mg/kg/day for females based on decreased absolute body weights, body weight gain and food consumption in F_1 generation Reproductive NOAEL = 4 mg/kg/day LOAEL = 8 mg/kg/day based on decreased testicular weight, changes in sperm morphology, etc., and increased incidence of testicular histopathology Offspring NOAEL = 2.5 mg/kg/day LOAEL = 4 mg/kg/day based on decreased viability of F_1 pups and retarded growth in F_1 and F_2 pups

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4100	Chronic toxicity-rat (1–year feeding)	NOAEL = 0.7 mg/kg/day for males and females LOAEL = 7.0 mg/kg/day for males and females based on the increased incidence of testicular atrophy in males and chronic renal nephropathy in females, and decreased food consumption and body weight gain in both sexes
870.4200	Carcinogenicity-rat	NOAEL = 0.7 mg/kg/day LOAEL = 7.0 mg/kg/day based on decreased absolute body weights, body weight gains, and food consumption, decreased survival and earlier deaths in males, clinical signs (unkempt coat, hunched posture, rolling gait, piloerection, and/or walking on tip toes), cataracts, adverse effects on male reproductive organs (testicular degeneration, atrophied seminal vesicles, and decreased prostate weight), adverse effects on the exocrine pancreas in females (lobular/acinar cell atrophy, focal hyperplasia, and focal basophilic alteration), and an increased incidence of focal medullary cell hyperplasia of the adrenal gland in females. For further discussion, see Unit III.C.iii. of this final rule.
870.5100 Ames	Gene mutation	There was no mutagenic activity
870.5300 Mouse lymphoma	Gene mutation	There was no mutagenic activity
870.5395 Micronuclei	Cytogenetics	There was no evidence of chromosomal damage
870.7800	Immunotoxicity-rat	NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on the decreased primary antibody (IgM) response to sheep red blood cells; decreased absolute and relative thymus weights; decreased body weight, food consumption and food efficiency at the high dose level. (While this study did not fully meet the requirements outlined in the Pesticide Assessment Guidelines Subdivision M OPPTS Series 152–18, because a NOAEL and LOAEL were determined, and found to be consistent with those from other repeat-dose studies, EPA determined that the study need not be repeated.)
	Special studies: Reporter Gene Assays Using Human Estrogen and Androgen Receptors, Non-guideline Study	No significant changes in the level of reporter activity was associated with any concentration of aviglycine HCl when tested with or without estrogenic or androgenic inhibitors. Aviglycine HCl was not cytotoxic at any concentration.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of

the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for aviglycine HCl used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AVIGLYCINE HCL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF[1] and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–49 years of age)[2]	NOAEL = 0.2 mg/kg/day UF = 100 Acute RfD = 0.002 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.002 mg/kg/day	Rabbit Developmental Toxicity Developmental LOAEL = 0.4 mg/kg/day based on increased occurrence of developmental malformations (i.e. lobular agenesis of right lung) in the high and medium dose groups
Acute Dietary (General population including infants and children)	NOAEL = 0.2 mg/kg/day UF = 100 Acute RfD = 0.002 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.002 mg/kg/day	Endpoints from rabbit developmental study utilized as a worst case estimate, even though no acute toxicological endpoints resulting from a single dose were identified for populations other than females 13–49 years of age.
Chronic Dietary (All populations)	NOAEL= 0.8 mg/kg/day UF = 100 Chronic RfD = 0.008 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷FQPA SF = 0.008 mg/kg/day	Rat 2–generation Reproductive Toxicity LOAEL = 2.5 mg/kg/day based on decreased absolute body weight and body weight gain, and periportal hepatocellular vacuolation in the liver in F_0 and F_1 adult males.
Carcinogenicity (general population)	Non-linear Effects NOAEL = 0.7 mg/kg/day UF = 1,000 (includes 10X for database uncertainty[3]) Cancer RfD = 0.0007 mg/kg/day	FQPA considerations have been accounted for in discussions involving threshold non-carcinogenic effects[3]	Rat carcinogenicity LOAEL = 7.0 mg/kg/day based on increased incidence of benign testicular interstitial cell adenomas, benign adrenal pheochromocytoma, and adrenal medullary cell hyperplasia. Decreased number of animals with tumors, with benign tumors, and with malignant tumors were also observed. These decreases were evident as mammary fibroadenomas, thyroid C-cell adenomas, and anterior pituitary adenomas.

[1] The reference to the FQPA safety factor refers to any additional safety factor retained due to concerns unique to the FQPA. (See discussion on FQPA safety factor under Unit III.B. of this Final Rule.)

[2] The only acute endpoint was identified in pregnant rabbits; therefore, it applies to females 13–49 years of age, which includes potentially pregnant individuals. Fetal malformations observed in the developmental study are presumed to occur after maternal exposure to a single dose. Utilization of the acute developmental endpoint for other populations (general U.S., children 1–2 years old, etc.) substantially over-estimates risk because resultant malformations are unique to particular stages of fetal development and will not occur in these other populations.

[3] Data are inadequate for the determination of human carcinogenic potential. As a result, an additional 10X uncertainty factor (UF) was incorporated into hazard estimates for aviglycine HCl's threshold carcinogen effects in order to compensate for this inadequacy, increasing the overall UF to 1,000. When applied to the NOAEL of 0.7 mg/kg/day, it resulted in a cancer RfD of 0.0007 mg/kg/day. Justification for the utilization of an additional 10X uncertainty factor for database insufficiencies in cancer risk assessments included: (i) A cancer study in a second species (mouse) was absent, (ii) carcinogenic properties were associated with excessive toxicity, (iii) tumor evidence was inconsistent/equivocal, (iv) carcinogenicity potential was not confirmed with mutagenicity, endocrine, or immunotoxicity studies, and (v) resultant tumors were not associated with target organ (liver) or mechanism of action (pyridoxal 5′-phosphate-dependent enzyme inhibition).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.502) for the residues of aviglycine HCl, in or on a variety of raw agricultural commodities. Time-limited tolerances for apple and pear, and a temporary tolerance for the stone fruits crop group 12 (all expired on December 21, 2003), were established previously (July 12, 2001, 66 FR 36481, FRL–6790–7 (apple and pear) and July 12, 2001, 66 FR 36477, FRL–6788–7 (stone fruits crop group12)). In response to Valent BioSciences Corporation's petitions for permanent tolerances, an updated risk assessment was conducted by EPA to assess dietary exposures from aviglycine HCl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary

Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The residue of concern for the acute analysis is aviglycine HCl. The assessment assumed 100% of the proposed crops were treated, and that all treated crops had residues of concern at the requested tolerance levels. Anticipated residues were not used. Acute dietary risks for the 95th percentile of females 13–49 years old and the general U.S. population were minimal and did not exceed EPA's LOC. Acute dietary risks for children 1–2 years old technically exceeded EPA's LOC by a small margin. These risks represented a worst case scenario using toxicologic endpoints that only occurred *in utero*. Therefore, the calculated risks were illustrative at best. See footnote 2 of Table 2 for further explanation of acute endpoint utilized by EPA.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The residue of concern for the chronic analysis is aviglycine HCl. Conservative chronic dietary assessments utilized tolerance-level concentrations for crops (i.e., 0.08 ppm for apple and pear and 0.170 ppm for stone fruits crop group 12, excepting cherries). Chronic dietary risk for the U.S. population, and children 1–2 years old did not exceed 1.6%, and 10.5%, respectively, of the chronic Population Adjusted Dose (cPAD, 0.008 mg/kg/day). Therefore, chronic dietary risks were minimal and did not exceed EPA's LOC.

iii. *Carcinogenicity*. Conflicting evidence for carcinogenicity has been reported for aviglycine HCl. Mutatgenicity, immunotoxicology, endocrine, subchronic, and chronic feeding studies strongly suggest that aviglycine HCl does not induce cancer. Effects observed in the carcinogenicity study, such as a threshold-response and reduction in the number of animals with tumors, with benign tumors, and with malignant tumors also support non-carcinogenic conclusions. In contrast, increased incidence of benign testicular interstitial cell adenomas, benign adrenal pheochromocytoma, and adrenal medullary cell hyperplasia suggest that aviglycine HCl may induce cancer. These effects, however, were seen only at an excessively toxic dose and may have been mediated indirectly through generic toxic mechanisms such as glutathione depletion and resultant oxygen radical-induced cell damage, rather than by aviglycine HCl. Dosing with excessive aviglycine HCl, therefore, weakened support for carcinogenic activity.

In the end, weight-of-evidence suggests that aviglycine HCl is non-carcinogenic. However, definitive statements of carcinogenicity can not be made at the current time, because information meeting rigorous criteria for defining it as non-carcinogenic (such as a second cancer study in a different species and strong non-conflicting evidence) is absent. These studies are not typically required in the testing of biochemical pesticides. To account for this, an additional database uncertainty factor of 10X was integrated with other UFs (100X) (increasing the overall uncertainty factor to 1,000) and the NOAEL established in the carcinogenesis study (0.7 mg/kg/day) to conservatively account for this deficiency (RfD = 0.0007 mg/kg/day).

Carcinogenic dietary risks for the U.S. population did not exceed 18.3% of the cancer RfD. The cancer risks from chronic exposure to aviglycine HCl in food and surface or ground water, therefore, were not unreasonable.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for aviglycine HCl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of aviglycine HCl.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to aviglycine HCl they are further discussed in the aggregate risk sections in Unit E.

Based on the GENEEC and SCI-GROW models, the EECs of aviglycine HCl acute peak exposures are estimated to be 0.582 parts per billion (ppb) for surface water and 0.00028 ppb for ground water. The EECs for chronic 90 day exposures are estimated to be 0.0194 ppb for surface water and 0.00028 ppb for ground water. Acute EECs did not exceed DWLOCs for the subpopulation females 13–49 years of age (49.05 ppb) or for the general U.S. population (47.32 ppb). Acute DWLOCs were not calculated for other subpopulations because of a lack of relevance to the sensitive developmental endpoint. EECs also did not exceed DWLOCs for any population considered in chronic (Table 4) or cancer estimates (Table 5). Aggregate cancer risks and the risks from aggregate acute or chronic exposure to aviglycine HCl in food and surface or ground water, therefore, are not unreasonable.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in

this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Aviglycine HCl is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether aviglycine HCl has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to aviglycine HCl and any other substances and aviglycine HCl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that aviglycine HCl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. EPA initially had concern for aviglycine HCl-induced prenatal and postnatal toxicity. This concern arose from 5 incidents of fetal toxicity (developmental malformations) that occurred at doses lower than that which induced maternal toxicity in rabbits (LOAEL = 0.4 mg/kg/day versus 0.7 mg/kg/day) and from an apparent increase in the severity of effects in rat offspring when compared to similarly dosed adults. A Degree of Concern Analysis was initiated to further investigate these issues and determine if an additional FQPA safety factor should be applied to risk equations to account for differential prenatal or postnatal sensitivities.

After investigation, the degree of concern was determined to be low for prenatal and postnatal aviglycine HCl-induced toxicity. This determination was justified for prenatal effects by:

i. The observation that the same number of similar fetal malformations in rabbits (5) also occurred at maternally toxic doses (0.7 mg/kg/day);

ii. The conclusion that 0.4 and 0.7 mg/kg/day dose differences in the rabbit study were more-than-likely without biological significance; and

iii. The utilization of the developmental endpoint (i.e., females aged 13–49), an endpoint relevant to prenatal toxicity, as a means for risk comparison. This determination also was justified for postnatal effects by:

a. The observation that toxic doses for adult rats were ultimately less than that for offspring (LOAEL = 2.5 versus 4.0 mg/kg/day);

b. The observation that increased severity of effects noticed in rat offspring may have been due to an inexplicable total loss of three litters;

c. The observation that offspring LOAELs were partially influenced by body weight decrements in parents; and

d. The observation that increased prenatal or postnatal sensitivities were not evident in rat developmental studies.

In summary, adequate characterization of prenatal and postnatal effects and the choice of a sensitive developmental endpoint for comparison to exposure data satisfied our concerns related to prenatal and postnatal effects.

3. *Conclusion*. There is a complete toxicity database for aviglycine HCl and exposure data are complete or are estimated based on data that reasonably accounts for potential prenatal and postnatal exposures to offspring and parents. A developmental NOAEL of 0.2 mg/kg/day was established in a rabbit study based on fetal effects at a dose of 0.4 mg/kg/day which was below the maternal LOAEL of 0.7 mg/kg/day. The maternal and developmental LOAELs were the same in the rat developmental study indicating no differences in susceptibility to aviglycine HCl toxicity. The multigeneration reproduction study also showed no differences in susceptibility of parents and their offspring (LOAEL = 2.5 mg/kg/day). All of these studies indicate that the special FQPA safety factor can be reduced to 1X for purposes of the current assessment.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable water exposure (mg/kg/day) = PAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable

data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to aviglycine HCl will occupy18.25 % of the aPAD for females 13–49 years old. As a worst case estimate, dietary risks for the general U.S. population and population subgroups were also estimated using the acute developmental endpoint (0.002 mg/kg/day). Exposures to aviglycine HCl were marginally above EPA's LOC for children 1–2 years old (163%), but below for the general U.S. population (32.4%). The risks posed to children 1–2 years old represented a worst case scenario using toxicologic endpoints that only occurred *in utero*. Therefore, the calculated risks were demonstrative at best. In addition, there is potential for acute dietary exposure to aviglycine HCl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit. The risks from acute aggregate exposure to aviglycine HCl in food and surface or ground water, therefore, are not unreasonable.

TABLE 3. —AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AVIGLYCINE HCL

Population Subgroup	Dietary Exposure (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U. S. Population[1]	0.000648	32.4	0.582	0.00028	47.32
Females 13–49 years old	0.000365	18.25	0.582	0.00028	49.05
Children 1–2 years old[1]	0.003266	163			

[1] These exposure estimates and risk characterizations exaggerate the risk because the majority of individuals in the general population and in this subpopulation are not likely to be susceptible to aviglycine HCl's developmental effects (i.e., not likely to be pregnant).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to aviglycine HCl from food will utilize 1.6% of the cPAD for the U.S. population, 10.1% of the cPAD for all infants (<1 year old), and 10.5% of the cPAD for children 1–2 years old, as shown in Table 4 of this unit. There are no uses for aviglycine HCl that result in chronic residential exposure to aviglycine HCl. There is potential for chronic dietary exposure to aviglycine HCl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit. The risks from chronic aggregate exposure to aviglycine HCl in food and surface or ground water, therefore, are not unreasonable.

TABLE 4. —AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AVIGLYCINE HCL

Population Subgroup	Dietary Exposure mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.000128	1.6	0.0194	0.00028	0.276
All Infants (<1 year old)	0.000807	10.1	0.0194	0.00028	
Children 1–2 years old	0.000840	10.5	0.0194	0.00028	0.072
Children 3–5 years old	0.000503	6.3	0.0194	0.00028	
Children 6–12 years old	0.000186	2.3	0.0194	0.00028	
Youth 13–19 years old	0.000064	0.8	0.0194	0.00028	
Adults 20–49 years old	0.000049	0.6	0.0194	0.00028	
Adults 50+ years old	0.000072	0.9	0.0194	0.00028	
Females 13–49 years old	0.000058	0.7	0.582	0.00028	0.238

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Aviglycine HCl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).Aviglycine HCl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum

of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions generated from cancer endpoints (RfD = 0.0007 mg/kg/day) and chronic durations of exposure, EPA has concluded that exposure to aviglycine HCl from food will utilize 18.3% of the cancer RfD for the U.S. population. There are no uses for aviglycine HCl that result in carcinogenic residential exposure. There is, however, the potential for exposure to aviglycine HCl in drinking water. After calculating a cancer DWLOC and comparing it to EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cancer RfD, as shown in Table 5 of this unit. The cancer risks from chronic aggregate exposure to aviglycine HCl in food and surface water or ground water, therefore, are not unreasonable.

TABLE 5.—AGGREGATE CANCER RISK ASSESSMENT FOR EXPOSURE TO AVIGLYCINE HCL

Population Subgroup	Dietary Exposure mg/kg/day	% of Cancer RfD	Surface Water EEC (ppb)	Cancer DWLOC
U.S. Population	0.000128	18.3	0.0194	20.02

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to aviglycine HCl residues at the established tolerance levels.

IV. Other Considerations

A. Endocrine Disruptors

Incubation with aviglycine HCl did not change reporter gene activity induced by estradiol (estrogen) and dihydrotestosterone (androgen) and inhibited by 4-hydroxytamoxifen (anti-estrogen) and hydroxyflutamide (anti-androgen) at non-cytotoxic doses. Aviglycine HCl-induced pathologies of organs associated with the endocrine system were not observed consistently at non-toxic doses. Aviglycine HCl, therefore, was qualified as a non-endocrine disrupting compound.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography-fluorescence detector) that has been EPA-validated is available to enforce the apple and pear tolerance expression. The method may be requested from: Christine Olinger, Acting Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

In addition, enforcement methodologies are available to enforce the stone fruits crop group 12, excepting cherries, tolerance expression. Preliminary review of the proposed enforcement methods for residues of aviglycine HCl on stone fruits crop group 12, excepting cherries, has indicated that they appear to be suitable for enforcement purposes. Given that the methods for the stone fruits crop group 12, excepting cherries, reflect only minor modification of the EPA-validated method, and that the registrant has provided the Agency with concurrent fortification data to demonstrate that the methods are adequate for data collection purposes and with an independent Laboratory Validation, coupled with the EPA's preliminary review, EPA concludes that the methods are suitable as enforcement methods to support tolerances associated with this action. Those methods may be requested from: Sheryl K. Reilly, Chief, Biochemical Pesticides Branch, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001, telephone number: (703) 308–8269; e-mail address: reilly.sheryl@epa.gov.

C. International Residue Limits

There are no Codex Alimentarius Commission (CODEX) maximum residue levels for residues of aviglycine HCl.

D. Conditions

Time-limited tolerances (May 7, 1997, 62 FR 24835, FRL–5713–5 and July 12, 2001, 66 FR 36481, FRL–6790–7) were established for the biochemical pesticide aviglycine HCl in connection with conditional section three registrations (June 13, 1997, 62 FR 32325, FRL–5721–4). All tolerances were time-limited because of the existence of a rat 2–generation reproduction study data gap. The time-limitation allowed for development and review of the data. Based on the available toxicological data, the thousandfold uncertainty factor, and the levels of exposure, the EPA determined at that time that there was a reasonable certainty that no harm would result to the U.S. population, including infants and children, from aggregate exposure to aviglycine HCl and its residues during the period of the time-limited tolerances. The rat 2–generation reproduction study, imposed by EPA to augment the results of the rat developmental toxicity study, was submitted to the Agency by Abbott Laboratories on September 27, 1999. It has now been reviewed and found by EPA to satisfy the 1997 condition of registration. Therefore, there currently are no data gaps associated with aviglycine HCl. A new database uncertainty factor applied to carcinogenic endpoints has now been established and is based on a review of submitted cancer data. This additional uncertainty factor has not affected current tolerance levels or crop uses. Additional cancer studies may be required in the future, however, should the registrant propose to alter tolerance levels, crop uses, application rates, pre-harvest intervals, or other factors important to human exposure.

V. Conclusion

Therefore, establishment of tolerances for residues of aviglycine HCl, in or on apple and pear at 0.08 ppm, and in or on the stone fruits crop group 12, excepting cherries, at 0.170 ppm, is appropriate.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2003–0389 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 April 19, 2004.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2003–0389, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 under 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 section 408(d) of FFDCA, such as the tolerance 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 section 408(n)(4) of FFDCA. 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. Congressional Review Act

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: February 5, 2004.

Sheryl K. Reilly

acting 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 section heading and paragraph (a) to read as follows:

§ 180.502 Aminoethoxyvinylglycine hydrochloride (aviglycine HCl); tolerances for residues.

(a) *General.* Tolerances are established for residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl) in or on the following food commodities:

Commodity	Parts per million
Apple	0.08
Fruit, stone, group 12, except cherry	0.170
Pear	0.08

* * * * *

[FR Doc. 04–3371 Filed 2–17–04; 8:45 am]

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