

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 31, 2003.

**Phil Hutton,**

*Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

### Valent BioSciences Corporation

PP 6F4632

EPA has received a pesticide petition (6F4632) transferred from Abbott

Laboratories and from Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing permanent tolerances for residues of the biochemical pesticide aminoethoxyvinylglycine hydrochloride (aviglycine HCl), formerly designated as aminoethoxyvinylglycine (AVG), in or on the food commodities apple and pear at 0.08 part per million (ppm). EPA issued a final rule, published in the **Federal Register** of July 12, 2001 (66 FR 36481) (FRL-6790-7), which announced that it established time-limited tolerances for residues of the plant regulator AVG in or on the food commodities apples and pears at 0.08 ppm, with an expiration date of December 21, 2003. EPA issued a final rule, published in the **Federal Register** of May 7, 1997 (62 FR 24835) (FRL-5713-5), which announced that it established time-limited tolerances for residues of the plant regulator AVG in or on the food commodities apples and pears at 0.08 ppm, with an expiration date of April 1, 2001. 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." Because of a then-existing data gap, all initial tolerances were time-limited. The time limitation was established to provide sufficient time for the development and review of additional data, specifically a rat 2-generation reproduction study. Abbott Laboratories submitted such a study on September 27, 1999. The Agency had also not completed its assessment of new internationally-generated apple residue data (submitted by Valent BioSciences Corporation on May 23, 2000), and of supplementary data received before and after the publication of the July 12, 2001 rule.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Abbott Laboratories submitted a summary of information, data, and arguments in support of their pesticide petition, which was published in the **Federal Register** of February 20, 1997 (62 FR 7778) (FRL-5589-4). EPA has not republished the summary of information initially submitted by Abbott Laboratories and published in the **Federal Register** of February 20, 1997 except where EPA believes such information would be helpful in understanding the new data. Valent BioSciences Corporation is, however,

relying on the previously submitted information in addition to the new data summarized below in support of this pesticide petition to establish permanent tolerances. EPA will take into account all available data when giving due consideration to Valent BioSciences Corporation's petition. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Valent BioSciences Corporation has submitted the following summary of new information, data, and arguments in support of their pesticide petition. This summary was prepared by Valent BioSciences Corporation and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

### A. Product Name and Proposed Use Practices

Aminoethoxyvinylglycine hydrochloride (aviglycine HCl), which was previously designated as aminoethoxyvinylglycine (AVG), is a plant growth regulator used in the harvest management of apples and pears. Applied once a season at 4 weeks prior to the anticipated beginning of the normal harvest period, it is used at the rate of 50 grams active ingredient per acre.

### B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* A study designed to determine whether uptake, translocation and metabolism of aminoethoxyvinylglycine hydrochloride occurs in apples identified seven minor metabolites in addition to the primary metabolite, *N*-acetylaminoethoxyvinylglycine. The study was not meant as a measure of the amount of *N*-acetylaminoethoxyvinylglycine hydrochloride residues and metabolites found in apples under normal field conditions. The only significant incorporation of aminoethoxyvinylglycine hydrochloride in apple tissues, following brush-on application at high rates, resulted from absorption from the peel rather than translocation from the leaves. Aminoethoxyvinylglycine hydrochloride is also metabolized in the tissues to form *N*-acetylaminoethoxyvinylglycine and several other minor metabolites, and is partially degraded on the apple surface