and intraspecies variability) and not the additional ten-fold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor. In a final rule (62 FR 63019), EPA concluded that reliable data support use of the standard 100-fold UF for esfenvalerate, and that an additional UF is not needed to protect the safety of infants and children. This decision was based on no evidence of developmental toxicity at doses up to 20 mg/kg/day (ten times the maternal NOAEL) in prenatal developmental toxicity studies in both rats and rabbits; toxicity to offspring only at dietary levels which were also found to be toxic to parental animals in the 2–generation reproduction study; and no evidence of additional sensitivity to young rats or rabbits following prenatal or postnatal exposure to esfenvalerate.

A chronic dietary exposure assessment found the percentages of the RfD utilized by the most sensitive subpopulation to be 4.8% for children 1 to 6 years based on a dietary exposure of 0.000957 mg/kg/day. The percent RfD for children 7 to 12 years was 3.0%. The Agency has no cause for concern if RfDs are below 100%.

The most sensitive subpopulation, children 1 to 6 years, had acute dietary MOEs of 202 and 103 at the 99th and 99.9th percentile of exposure, respectively. Nursing infants had MOEs of 195 and 146 at the 99th and 99.9th percentile of exposure, respectively. Non-nursing infants had MOEs of 304 and 158 at the 99th and 99.9th percentile of exposure, respectively. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger. EPA has concluded that the potential short-term or intermediate-term aggregate exposure of esfenvalerate from chronic dietary food and water plus indoor and outdoor residential exposure to children (1 to 6 years old) is 0.0113 mg/kg/day with an MOE of 177. For infants (less than 1 year old) the exposure is 0.0098 mg/kg/day with an MOE of 204. Thus, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to esfenvalerate residues (62 FR 63019).

F. International Tolerances

Codex maximum residue levels (MRLs) have been established for residues of fenvalerate on a number of crops that also have U.S. tolerances. There are some minimal differences between the section 408 tolerances and certain Codex MRL values. These differences could be caused by differences in methods to establish tolerances, calculate animal feed, dietary exposure, and as a result of different agricultural practices. Therefore, some harmonization of these maximum residue levels will be required.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–1007; FRL–6775–1]

Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1007, must be received on or before April 27, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1007 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, 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; e-mail address: hollis.linda@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'' 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 PF–1007. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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, 1921 Jefferson Davis Highway,

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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1007 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1007. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

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 control 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 pesticide petitions 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 these petitions contain data or information regarding the elements set forth in 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: March 15, 2001.

Janet L. Andersen,

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

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represent the view of the petitioner. The petition summaries announce 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.

1. Valent BioSciences Corporation

PP 6F4632

EPA has received a request from Valent BioSciences Corporation, 870 Technology Way, Suite 100, Libertyville, IL 60048, referencing pesticide petition PP–6F4632 (transferred from Abbott Laboratories), proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.502 by establishing permanent tolerances for residues of the biochemical pesticide aminoethoxyvinylglycine (AVG) in or on the food commodities apples and pears at 0.08 part per million (ppm). 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.

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 February 20, 1997 **Federal Register**, 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

AVG is a plant regulator useful in the management practices of apples and pears. It is applied once during the season at low rates (50 grams active ingredient per acre) using airblast sprayers. The product is recommended to be applied to apples and pears 4 weeks prior to the beginning of normal harvest.

B. Product Identity/Chemistry

1. *Magnitude of residue at the time of harvest and method used to determine the residue.* Residue data previously submitted by Abbott Laboratories and reviewed by EPA indicated that at the proposed use rates, no quantifiable residues were present in or on the food commodities at 21 days after treatment. Additional residue data generated internationally has been provided to EPA by Valent BioSciences Corporation. Trials conducted in New Zealand, Chile, and South Africa in various apple cultivars support the proposed permanent tolerances. Residue levels were below the proposed permanent tolerance at 21 days after application. Decline trials indicate rapid degradation of AVG residues among all the apple varieties and geographies evaluated.

The analytical methods for detection of AVG in apple raw agricultural and processed commodities by high performance liquid chromatography were developed by Abbott Laboratories. A practical analytical method for detecting and measuring levels of AVG in or on commodities with a limit of quantitation (LOQ) that allows for monitoring of food, with the residues at or above the levels set in these tolerances has been submitted to EPA. EPA has provided information on this method to the Food and Drug Administration (FDA). The method is available to anyone interested in pesticide residue enforcement.

C. Mammalian Toxicological Profile

1. *Reproductive toxicity.* AVG was evaluated in a rat 2–generation reproduction study submitted by Abbott Laboratories. Rats were dosed at levels of 0, 0.8, 2.5, 4.0, and 8.0 milligrams active ingredient/kilograms body weight/day (mg ai/kg bwt/day). Based on reductions in body weight, changes in organ weights, and increased incidence of microscopic findings, the parental lowest observed effect level (LOEL) was established at 2.5 mg ai/kg bwt/day. The parental no observed adverse effect level (NOAEL) was established at 0.8 mg ai/kg bwt/day. The NOAEL for reproductive toxicity was established at 4.0 mg ai/kg bwt/day. The NOAEL for neonatal toxicity was established at 2.5 mg ai/kg bwt/day.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Expected dietary exposures from residues of AVG would occur through apples, pears, and processed apples and pears. There are no home and garden uses for AVG. Based on the additional information derived from the rat 2–generation reproduction study, Valent BioSciences Corporation proposes that the NOAEL of 0.8 mg ai/kg bwt/day and a safety factor of 100 be incorporated into the chronic risk assessment. The resulting RfD is 0.008 mg ai/kg bwt/day. The proposed permanent tolerances would utilize approximately 9.1% RfD for non-nursing infants and approximately 0.85% for the general population.

ii. *Drinking water.* Spray drift may potentially lead to exposure to residues in drinking water.

2. *Non-dietary exposure.* The only non-dietary exposure expected is to applicators. Exposure to AVG resulting from its application according to label directions is not expected to present risks of adverse health or environmental effects, based on its toxicology profile and occupational risk assessment. Non-occupational exposures (home/garden uses) are not applicable.

E. Safety Determination

1. *U.S. population.* AVG is an amino acid derived from a naturally occurring soil microorganism. Based on the toxicology profile and the low to no detectable residues in the agricultural commodities, Valent BioSciences Corporation concludes that there is a reasonable certainty of no harm resulting from aggregate exposure of AVG to the general population.

2. *Infants and children.* The effects demonstrated in the developmental and immune toxicity studies are considered secondary to the adverse effects upon body weight gain, food consumption and food efficiency in the treated rats. In the rat reproduction study, decreased neonatal survival, decreased pup body weights, and other effects associated with reduced pup weights were observed only at doses greater than those producing effects on the parental animals. The NOAEL for neonates in the reproduction study, 2.5 mg ai/kg bwt/day, was 3 times greater than the NOAEL for parental animals, 0.8 mg ai/kg bwt/day NOAEL, providing an additional built-in safety factor of 3 for the subpopulation of infants and children. The company concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure.

2. Valent BioSciences Corporation

PP 9G5048

EPA has received a request from Valent BioSciences Corporation, 870 Technology Way, Suite 100, Libertyville, IL 60048, referencing pesticide petition PP 9G5048 (transferred from Abbott Laboratories), proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.502 by extending the temporary tolerance for residues of the biochemical pesticide AVG in or on food commodities of the stone fruit crop group 12, including apricot, cherry (sweet and tart), nectarine, peach, plum, chickasaw plum, damson plum, Japanese plum, plumcot, and prune (fresh) at 0.170 ppm. EPA issued a final rule, published in the **Federal Register** of June 10, 1999 (64 FR 31124) (FRL–6080–4), which announced that it established a temporary tolerance for residues of the plant regulator AVG in or on food commodities of the stone fruit crop group at 0.170 ppm, with an expiration date of April 1, 2001. 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. 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.

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 March 10, 1999 (64 FR 11872) (FRL–6067–5). EPA has not republished the summary of information initially submitted by Abbott Laboratories and published in the March 10, 1999 **Federal Register**, 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 extend the temporary tolerance. 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

AVG is a plant regulator useful in the management practices of stone fruit. It is applied once during the season at low rates (50 grams active ingredient per acre) using airblast sprayers. The product is recommended to be applied to stone fruit 7-14 days prior to the beginning of normal harvest. The proposed, amended, experimental use program will be conducted in Alabama, Arkansas, California, Georgia, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Virginia and Washington. The proposed, amended, experimental program would utilize 146 pounds of active ingredient on 1,325 acres, in each year of the proposed 2–year program.

B. Mammalian Toxicological Profile

1. *Reproductive toxicity*. AVG was evaluated in a rat 2–generation reproduction study submitted by Abbott Laboratories. Rats were dosed at levels of 0, 0.8, 2.5, 4.0, and 8.0 mg ai/kg bwt/day. Based on reductions in body weight, changes in organ weights, and increased incidence of microscopic findings, the parental LOEL was established at 2.5 mg ai/kg bwt/day. The parental NOAEL was established at 0.8 mg ai/kg bwt/day. The NOAEL for reproductive toxicity was established at 4.0 mg ai/kg bwt/day. The NOAEL for neonatal toxicity was established at 2.5 mg ai/kg bwt/day.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Expected dietary exposures from residues of AVG would occur through raw and processed commodities of treated stone fruit. There are no home and garden uses for AVG. Based on the additional information derived from the rat 2–generation reproduction study, Valent BioSciences Corporation proposes that the NOAEL of 0.8 mg ai/kg bwt/day and a safety factor of 100 be incorporated into the chronic risk assessment. The resulting RfD is 0.008 mg ai/kg bwt/day. The proposed temporary tolerance on stone fruit in addition to tolerances on apples and pears would utilize approximately 1.7% RfD for the U.S. population in general, and approximately 12.7% for the non-nursing infants.

ii. *Drinking water*. Spray drift may potentially lead to exposure to residues in drinking water.

2. *Non-dietary exposure*. The only non-dietary exposure expected is to applicators. Exposure to AVG resulting from its application according to label directions is not expected to present risks of adverse health or environmental effects, based on its toxicology profile and occupational risk assessment. Non-occupational exposures (home/garden uses) are not applicable to this experimental use permit.

D. Safety Determination

1. *U.S. population*. AVG is an amino acid derived from a naturally occurring soil microorganism. Based on the toxicology profile and the low to no detectable residues in the agricultural commodities, Valent BioSciences Corporation concludes that there is a reasonable certainty of no harm resulting from aggregate exposure of AVG to the general population.

2. *Infants and children*. The effects demonstrated in the developmental and immune toxicity studies are considered secondary to the adverse effects upon body weight gain, food consumption and food efficiency in the treated rats. In the rat reproduction study, decreased neonatal survival, decreased pup body weights and other effects associated with reduced pup weights were observed only at doses greater than those producing effects on the parental animals. The NOAEL for neonates in the reproduction study, 2.5 mg ai/kg bwt/day, was 3 times greater than the NOAEL for parental animals, 0.8 mg ai/kg bwt/day NOAEL, providing an additional built-in safety factor of 3 for the subpopulation of infants and children. The company concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure.

[FR Doc. 01–7639 Filed 3–27–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1003; FRL–6773–5]

Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1003, must be received on or before April 27, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1003 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION: