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[FR Doc. 97–11910 Filed 5–6–97; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 Part CFR 180

[OPP–300480; FRL–5713–5]

RIN 2070–AB78

Aminoethoxyvinylglycine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This document establishes time-limited tolerances for residues of the plant regulator aminoethoxyvinylglycine in or on the food commodities apples and pears. The tolerances expire on and will be revoked by EPA on April 1, 2001. Abbott Laboratories submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerances. This regulation sets the permissible levels of this plant regulator on apples and pears.

EFFECTIVE DATE: This regulation becomes effective May 7, 1997. Objections and hearing requests must be filed by July 7, 1997.

ADDRESSES: Written objections and hearing requests, identified by the document control number [OPP–300480], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburg, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in Wordperfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300480]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VII of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5–W57, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8263; e-mail: greenway.denise@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 20, 1997 (62 FR 7778), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Abbott Laboratories, 1401 Sheridan Road, North Chicago, IL 60064–4000. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by adding tolerances for residues of aminoethoxyvinylglycine, in or on the following food commodities: apples at 0.08 part per million (ppm), and pears at 0.08 ppm.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of these tolerances.

I. Toxicological Profile

1. A battery of acute toxicity studies placing technical aminoethoxyvinylglycine in Toxicity Categories III and IV.

2. A 13–week feeding study in rats at dietary intakes of 0, 0.45, 1.9 and 9.2 milligrams per kilogram per day (mg/kg/day) (males) and 0, 0.55, 2.2, and 9.4 mg/kg/day (females) with a no-observed-effect-level (NOEL) of 9.2 mg/kg/day for male rats and 2.2 mg/kg/day for female rats. The lowest-observed-effect-level (LOEL) was established at 9.4 mg/kg/day (the highest dose tested in 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.

3. A developmental toxicity study in rats at 0, 0.4, 1.77, and 8.06 mg/kg/day. The maternal LOEL is 8.06 mg/kg/day (the highest dose tested) based on decreased defecation, body weight gain, and food consumption; and the presence of red material around the nose. The developmental LOEL is also 8.06 mg/kg/day based on decreased mean fetal body weight and increases (within historical ranges) in two developmental skeletal variants (reduced ossification of the sternebrae and vertebral arches). The NOEL for maternal and developmental toxicity was established at 1.77 mg/kg/day.

4. A 21–day repeated dose dermal toxicity study in rats at 0, 100, 500, and 1,000 mg/kg/day. The NOEL is 1,000 mg/kg/day; a LOEL was not determined.

5. An immunotoxicity study in rats at 0, 1.25, 2.5, 5 and 15 mg/kg/day with a NOEL of 5 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. The LOEL is 15 mg/kg/day. The study did not fully meet the requirements outlined in the Pesticide Assessment Guidelines Subdivision M OPPTS Series 152–18. However, because a NOEL and LOEL were determined, and found to be consistent with those from other repeat-dose studies, the study need not be repeated.

6. An acceptable Ames study for inducing reverse mutation in *Salmonella* strains of bacteria exposed with or without activation at doses up to 5,000 micrograms per plate. The study showed negative results.

7. An acceptable study for inducing micronuclei in bone marrow cells of rats treated up to the maximum dose tested of 6,200 mg/kg. The study showed negative results.

8. A mutagenicity study with mouse lymphoma cells with or without activation to doses up to 5,000 micrograms/mL. Aminoethoxyvinylglycine is not mutagenic or cytotoxic when tested against mouse lymphoma cells strain L5178Y at a concentration of 5,000 micrograms/mL.

9. Additional data (a two-generation reproduction study in the rat) is being required by the Agency.

II. Aggregate Exposures

1. *From food and feed uses.* The primary source for human exposure to aminoethoxyvinylglycine will be from ingestion of both raw and processed food commodities as proposed in the February 20, 1997 Notice of Filing cited above. Based on tolerances of 0.08 ppm in or on apples and pears, the Theoretical Maximum Residue Contributions (TMRC) for the U.S. adult population and for U.S. children (1 to 6 years of age) were determined. In deriving the dietary exposure to aminoethoxyvinylglycine, EPA assumed that 100% of the apple and pear crops were cultured with the aid of this plant regulator. A subchronic exposure was used to estimate the TMRC. The TMRC for the U.S. population was estimated to be 0.000069 mg/kg/day. The TMRC for non-nursing infants less than 1 year old was 0.000722 mg/kg/day. The TMRC for nursing infants less than 1 year old was 0.000552 mg/kg/day. The TMRC for children 1 to 6 years old was 0.000224 mg/kg/day. The TMRC for children 7 to 12 years old was 0.000092 mg/kg/day.

2. *From potable water.* In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (Reference Doses (RfDs) or acute dietary NOELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause aminoethoxyvinylglycine to exceed the RfD if the time-limited tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with aminoethoxyvinylglycine in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the time-limited tolerances are granted.

3. *From non-dietary uses.* There is a proposed non-dietary use for aminoethoxyvinylglycine as a commercial plant regulator to be applied to certain ornamentals. There are no proposed home and garden uses. The exposure from this commercial use is expected to be dermal in nature. An acute dermal toxicity study yielded an LD_{50} of > 2 g/kg. A 21–day repeated dose dermal toxicity study resulted in no significant treatment-related effects at 1,000 mg/kg/day, the highest dose tested.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether aminoethoxyvinylglycine has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, aminoethoxyvinylglycine 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 aminoethoxyvinylglycine has a common mechanism of toxicity with other substances.

III. Determination of Safety for U.S. Population and Non-nursing Infants

1. *The U.S. population.* Based on a NOEL of 2.2 milligrams per kilogram of bodyweight per day (mg/kg bwt/day) from a subchronic toxicity study that demonstrated reduced body weight gain, food consumption, and food efficiency; increased severity and incidence of reversible kidney and liver effects; and discoloration of the liver; and using an uncertainty factor of 1,000 the Agency has set a RfD of 0.0002 mg/kg bwt/day for this assessment of risk. Based on the available toxicity data and the available exposure data identified above, the proposed tolerances will utilize 3.4% of the RfD for the U.S. population.

2. *Non-nursing infants.* Exposure to non-nursing infants as a result of the use of aminoethoxyvinylglycine in the culture of apples and pears will result in the use of 36.1% of the RfD.

3. *From nonfood uses.* Exposure from nonfood uses of aminoethoxyvinylglycine and from

contaminated potable water sources have not been precisely addressed in this assessment. However, the EPA does not foresee that these exposures will result in a cumulative level that exceeds the RfD. EPA concludes that there is reasonable certainty that no harm will result from the aggregate exposures to residues of aminoethoxyvinylglycine.

IV. Determination of Safety for Infants and Children

Risk to infants and children was determined by the use of a developmental study in rats that had a NOEL for developmental toxicity of 1.77 mg/kg/day, based on decreased mean fetal body weight and increases (within historical ranges) in two developmental skeletal variants (reduced ossification of the sternebrae and vertebral arches), and a maternal NOEL of 1.77 mg/kg/day based on decreased defecation, body weight gain, and food consumption; and the presence of red material around the nose.

FFDCA section 408 provides that EPA may apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children.

Available data indicate that maternal and developmental toxicity were observed in the developmental toxicity study in rats at the highest dose tested (8.06 mg/kg/day). Maternal toxicity was observed in the rat in the 8.06 mg/kg/day dose group as decreased defecation, body weight gain, and food consumption; and the presence of red material around the nose. Developmental toxicity was observed in the high dose group (8.06 mg/kg/day) as decreased mean fetal body weight and increases (within historical ranges) in two developmental skeletal variants (reduced ossification of the sternebrae and vertebral arches). Due to the incompleteness of the data, the Agency used a thousandfold uncertainty factor in the RfD calculations, and has imposed a requirement for a two-generation reproduction study in rats. The thousandfold uncertainty factor includes an additional uncertainty factor of 10 to protect infants and children.

The percent of the RfD that will be utilized by the aggregate exposure to aminoethoxyvinylglycine will range from 4.6% for children 7 to 12 years old, up to 36.1% for non-nursing infants less than 1 year old. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure.

V. Other Considerations

A. Endocrine Effects

Currently, EPA does not have any data indicating that aminoethoxyvinylglycine has endocrine effects. The Agency is not requiring information on the endocrine effects of this biochemical plant regulator at this time; Congress has allowed 3 years after FQPA was signed into law on August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Metabolism in Plants and Animals

The metabolism of aminoethoxyvinylglycine in plants and animals is adequately understood for the purposes of these time-limited tolerances. A study designed to determine whether uptake, translocation and metabolism of aminoethoxyvinylglycine occurs in apples identified seven minor metabolites in addition to the primary metabolite, *N*-acetyl aminoethoxyvinylglycine. The study was not meant as a measure of the amount of aminoethoxyvinylglycine residues and metabolites found in apples under normal field conditions. The only significant incorporation of aminoethoxyvinylglycine in apple tissues, following brush-on application at high rates, resulted from absorption from the peel rather than translocation from the leaves. Aminoethoxyvinylglycine is also metabolized in the tissues to form *N*-acetyl aminoethoxyvinylglycine and several other minor metabolites, and is partially degraded on the apple surface to water-soluble products that may be formed due to microbial and/or photodegradative action.

C. Analytical Method

There is a practical method for detecting and measuring levels of aminoethoxyvinylglycine in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these time-limited tolerances. The proposed analytical method for determining residues is high-pressure liquid chromatography (HPLC). The HPLC/fluorescence detector analytical method used by the registrant has been validated by an independent laboratory (ABC Laboratories), as required by PR Notice 88–5, and is sufficient for these time-limited tolerances. Validation by an EPA laboratory is a condition of registration for aminoethoxyvinylglycine, and upon such validation information on this method will be provided to FDA. In the interim, the registrant-submitted method is available to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Branch. Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202 (703) 305–5937.

D. International Tolerances

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

E. Data Gaps

A data gap currently exists for a rat two-generation reproduction study. All tolerances are time-limited because of this data gap. The time limitation allows for development and review of the data. The study, imposed by EPA to augment the results of the developmental toxicity study, is expected to be submitted and reviewed prior to the expiration date of these tolerances. Based on the available toxicological data, the thousandfold uncertainty factor, and the levels of exposure, the EPA has determined that the proposed time-limited tolerances have a reasonable certainty of no harm from aggregate exposure to the pesticide and its residues.

F. Summary of Findings

The analysis for aminoethoxyvinylglycine using tolerance level residues shows that the proposed uses in the culture of apples and pears will not cause exposure to exceed the levels at which the Agency believes there is an appreciable risk. All population subgroups examined by EPA are exposed to aminoethoxyvinylglycine residues at levels below 100 percent of the RfD for chronic effects.

Based on the information cited above, the Agency has determined that the establishment of the time-limited tolerances by adding a new section to 40 CFR part 180 will be safe; therefore the time-limited tolerances are established as set forth below.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) as was provided in the old section 408 and in

section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 7, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP–300480] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), this action is not a ''significant regulatory action'' and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995. (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, Oct. 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact (46 FR 24950, May 4, 1981).

Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This 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: April 24, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.502 to read as follows:

§ 180.502 Aminoethoxyvinylglycine; tolerances for residues.

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

Commodity	Parts per million	Revocation/Expiration Date
Apples	0.08	April 1, 2001
Pears	0.08	4April 1, 2001

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–11901 Filed 5–6–97; 8:45 am]

BILLING CODE 6560–50–F