

<http://www.epa.gov/fedrgstr/>. Please note that the draft proposed rule is not currently publicly available. It will only become publicly available when the proposed rule is signed, at which time it will be published in the **Federal Register**.

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. What Action Is EPA Taking?

Section 25(a)(2) of FIFRA requires the Administrator to provide the Secretary of Agriculture with a copy of any proposed regulation at least 60 days before signing it for publication in the **Federal Register**. The draft proposed rule is not available to the public until after it has been signed by EPA. If the Secretary comments in writing regarding the draft proposed rule within 30 days after receiving it, the Administrator shall include the comments of the Secretary and the Administrator's response to those comments in the proposed rule when published in the **Federal Register**. If the Secretary does not comment in writing within 30 days after receiving the draft proposed rule, the Administrator may sign the proposed regulation for publication in the **Federal Register** anytime after the 30-day period.

III. Do Any Statutory and Executive Order Reviews Apply to This Notification?

No. This document is not a proposed rule, it is merely a notification of submission to the Secretary of Agriculture. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in 40 CFR Part 166

Environmental protection, Administrative practice and procedure, Emergency exemptions, Intergovernmental relations, Pesticides and pests, Reporting and recordkeeping requirements

Dated: March 13, 2004.

James Jones,

Director, Office of Pesticide Programs.

[FR Doc. 04-7474 Filed 4-1-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0013; FRL-7347-6]

6-Benzyladenine; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide, 6-benzyladenine (6-BA), in or on pistachio, and amends the existing exemption for apple to expand the uses and increase the application rate. Valent BioSciences Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 6-BA.

DATES: This regulation is effective April 2, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0013, must be received on or before June 1, 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 IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), 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-2004-0013. 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

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. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of July 30, 2003 (68 FR 44777) (FRL-7315-7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6586) by Valent BioSciences Corporation, 870 Technology Way, Suite 100, Libertyville, IL 60048. This notice included a summary of the petition prepared by the petitioner Valent BioSciences Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1150 be amended by establishing an exemption from the requirement of a tolerance for residues of 6-BA in or on pistachio, and by amending the existing exemption under § 180.1150 for apple to expand the uses and increase the application rate.

Previously, temporary exemptions from the requirement of a tolerance, set to expire on January 31, 2005, were established by EPA for residues of 6-BA in or on apple and pistachio (February 5, 2003, 68 FR 5835) (FRL-7287-2) for the same uses as proposed above, when applied in accordance with the Experimental Use Permit (73049-EUP-2) issued on January 22, 2003 (February 26, 2003, 68 FR 8900) (FRL-7293-4).

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(2)(A)(ii) of the 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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factor set forth in section 408(b)(2)(C), which require 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. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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 toxicological profile for 6-BA has been previously published by the Agency in the N6-Benzyladenine (synonymous with the subject active ingredient, 6-benzyladenine) Reregistration Eligibility Decision (RED) document of June 1994 (http://www.epa.gov/oppsrrd1/REDS/old_reds/n6benzyladenine.pdf.) The summarized values and categories for the various studies for the technical active ingredient are presented here.

1. *Acute toxicity.* Toxicity Category III was assigned to the acute oral toxicity study in the rat (lethal dose (LD)₅₀ = 1.3 grams/kilogram (g/kg)), and in the eye irritation study in the rabbit (moderate irritant). Toxicity Category IV (the least toxic category) was assigned to the acute dermal toxicity study in the rabbit (LD₅₀ >5 g/kg), the acute inhalation toxicity study in the rat (lethal concentration (LC)₅₀ = 5.2 milligrams/liter (mg/L)), and in the dermal irritation study in the rabbit (slight irritant). Additionally, from a dermal sensitization study in the guinea pig, it was determined that 6-BA is not a dermal sensitizer. There have been no reported incidents of hypersensitivity directly linked to 6-BA. Nevertheless, to comply with the Agency's requirement under FIFRA section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

2. *Genotoxicity.* From three mutagenicity studies (Ames test, mouse micronucleus assay, and unscheduled DNA synthesis assay in the rat), it was determined that 6-BA is not mutagenic.

3. *Developmental toxicity.* The no observed adverse effect levels (NOAEL)

and the lowest observed adverse effect levels (LOAEL) for maternal and developmental toxicity in rats, respectively, were found to be 50 and 175 milligrams/kilogram body weight/day (mg/kg bwt/day), respectively. Based on these results and the Agency's assessment of dietary risk (see Units IV. and VI.) there is a reasonable certainty that no harm will be associated with this proposed pesticide use of 6-BA.

4. *Subchronic toxicity.* For rats of both sexes, the NOAEL was approximately 111 mg/kg bwt/day and the LOAEL was approximately 304 mg/kg bwt/day. Based on these results and the Agency's assessment of dietary risk (see Units IV. and VI.) there is a reasonable certainty that no harm will be associated with the proposed pesticide use of 6-BA.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* Apple and pistachio field trials yielded acceptable magnitude of the residue data. Residues were below the limit of quantitation (LOQ) for pistachios treated with a total of 60 g of active ingredient (a.i.) per acre. In apples, residues of 6-BA were consistently near the LOQ. However, residues did not increase in processed commodities (relative to the levels on the raw commodity), and were below the LOQ. Thus, the apple field data are adequate to support the tolerance exemption, limited by maximum application rates ≤182 grams of active ingredient per acre per season. Also, because application precedes harvest by 2 months for pistachio and by approximately 2.5 months for apple, the potential for dietary exposure is reduced. Due to the low anticipated dietary intake of 6-BA residues relative to the chronic and acute population adjusted doses (see Unit VII.), and the fact that actual exposure will probably be considerably less because the dietary exposure analysis was based on worst-case assumptions, it is highly unlikely that the proposed new uses of 6-BA on apple and pistachio will result in adverse effects to human health.

2. *Drinking water exposure.* The proposed uses on apple and pistachio are not expected to add potential

exposure to drinking water. Soil leaching studies have suggested that 6-BA is relatively immobile, absorbing to sediment. Residues reaching surface waters from field runoff should quickly absorb to sediment particles and be partitioned from the water column. 6-Benzyladenine also has low solubility in water, 76 ± 2 mg/L at 20 °C, and detections in ground water are not expected. Together, these data indicate that residues are not expected in drinking water.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to 6-BA residues for the general population, including infants and children, is unlikely because the uses are limited to applications in apple and pistachio orchards. Because 6-BA is a naturally occurring cytokinin plant regulator, it is a normal part of the human diet. The proposed use rates are well below the toxicity NOAELs (see Unit III.). The residues indicate dietary exposures that are 0.03% and 0.01% of the chronic and acute population adjusted doses, respectively. Therefore, while there exists a great likelihood of prior exposure for most, if not all, individuals to 6-BA, any increased exposure due to the proposed uses would be negligible due to the lack of residue in comparison with the toxicity NOAELs.

V. Cumulative Effects

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." These considerations include the possible cumulative effects of such residues on infants and children.

EPA does not have, at this time, available data to suggest whether 6-BA 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 6-BA and any other substances and 6-BA 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 6-BA 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 Office of Pesticide Programs 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/>.

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* The analysis estimated that the chronic exposures for the overall U.S. population was 0.000014 mg/kg/day (0.03% of the chronic population adjusted dose (cPAD)). The acute dietary estimated exposure was 0.000069 mg/kg/day (0.01% of the acute population adjusted dose (aPAD)) for the overall U.S. population. Critical exposure commodity analysis showed that apple juice contributed the most to dietary exposure for the overall population. Due to the low anticipated dietary intake of 6-BA residues relative to the chronic and acute population adjusted doses, and the fact that actual exposure will probably be considerably less because the dietary exposure analysis was made based on worst-case assumptions, it is reasonably certain that the proposed new uses of 6-BA on apple and pistachio will not result in adverse effects to human health.

2. *Infants and children.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal 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. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. Here, the analysis estimated that the chronic exposures for the most highly exposed subgroup, non-nursing infants, was 0.000085 mg/kg/day (0.2% of the cPAD). The acute dietary estimated exposure was 0.000361 mg/kg/day (0.07% of aPAD) for the most highly exposed subgroup, non-nursing infants. Critical exposure commodity analysis showed that apple juice contributed the most to dietary exposure for all infants. Due to the low anticipated dietary intake of 6-BA residues relative to the chronic and acute PAD, and the fact that actual exposure will probably be considerably less because the dietary exposure analysis was made based on worst-case assumptions, it is reasonably certain that the proposed new uses of 6-BA on

apple and pistachio will not result in adverse effects to human health.

Accordingly, the Agency believes the data indicate there are no threshold effects of concern to infants, children, and adults when 6-BA is used as labeled, and that the provision requiring an additional margin of safety is not necessary to protect infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of 6-BA.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, 6-BA may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on available data, no endocrine system-related effects have been identified with consumption of 6-BA. To date, there is no evidence to suggest that 6-BA affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance for the reasons stated above. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes

for 6-BA. Nonetheless, analytical methods for apple raw agricultural and processed commodities, and pistachio, have been developed, and submitted by the registrant.

C. Codex Maximum Residue Level

Currently, there are no Codex, Canadian or Mexican maximum residue levels for residues of 6-BA in/on apple or pistachio.

VIII. Conclusions

Based on the toxicology information submitted and reviewed previously, and summarized in the June 1994 N6-Benzyladenine RED, there is a reasonable certainty that no harm will result from aggregate exposure of residues of 6-BA to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the data submitted previously and summarized in the RED, as well as that data submitted to support this tolerance exemption, demonstrating negligible dietary exposure in comparison with the toxicity NOAELs. As a result, EPA establishes an exemption (albeit, limited by maximum application rates) from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of 6-BA in or on apple and pistachio.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the FFDCA, as was provided in the old sections 408 and 409 of the 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-2004-0013 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 June 1, 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 IX.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-2004-0013, 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).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance

requirement under section 408(d) of the 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 the FFDCA, such as the exemption 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 the 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.

XI. 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: March 23, 2004.

Janet L. Andersen,

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

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1150 is amended by revising paragraph (a) to read as follows:

§ 180.1150 6-Benzyladenine; exemption from the requirement of a tolerance.

(a) The biochemical plant regulator 6-benzyladenine (6-BA) is exempt from the requirement of a tolerance in or on apple at an application rate of ≤182 grams of active ingredient per acre per season, and in or on pistachio at an application rate of ≤60 grams of active ingredient per acre per season.

(b) * * *

[FR Doc. 04-7475 Filed 4-1-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[FRL-7642-8]

Delaware and Maryland: Adequacy of State Solid Waste Landfill Permit Programs Under RCRA Subtitle D

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Under section 4005(c)(1)(C) of the Resource Conservation and Recovery Act (RCRA), EPA can approve state permit programs for solid waste disposal facilities that receive hazardous waste from conditionally exempt small quantity generators (CESQGs). A CESQG is a generator that generates less than 100 kilograms of hazardous waste per month. CESQGs are subject to minimal recordkeeping and reporting requirements under RCRA, but must satisfy three basic regulatory requirements to remain exempt from the full scope of hazardous waste regulations that apply to other