

Authority: 21 U.S.C. 321(q), 346a and 371.
 ■ 2. The table in paragraph (a) of § 180.495 is amended by:
 ■ i. Alphabetically adding amaranth, grain, stover; cattle, liver; goat, liver;

hop, dried cones; horse, liver; and sheep, liver.
 ■ ii. Revising the remainder of the entries listed.

The additions and revisions to the table in paragraph (a) read as follows:
§ 180.495 Spinosad; tolerances for residues.
 (a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Amaranth, grain, stover	10	None
Cattle, fat	50	None
Cattle, liver	10	None
Cattle, meat	2.0	None
Cattle, meat byproducts, except liver	5.0	None
Egg	0.30	None
Goat, fat	50	None
Goat, liver	10	None
Goat, meat	2.0	None
Goat, meat byproducts, except liver	5.0	None
Hop, dried cones	22	None
Horse, fat	50	None
Horse, liver	10	None
Horse, meat	2.0	None
Horse, meat byproducts, except liver	5.0	None
Milk	7.0	None
Milk, fat	85	None
Poultry, fat	1.3	None
Poultry, meat	0.10	None
Poultry, meat byproducts	0.10	None
Sheep, fat	50	None
Sheep, liver	10	None
Sheep, meat	2.0	None
Sheep, meat byproducts, except liver	5.0	None

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 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0325; FRL-8117-9]

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 pear when applied/used as a plant regulator. Valent BioSciences Corporation (Valent) 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-benzyladenine.

DATES: This regulation is effective March 21, 2007. Objections and requests for hearings must be received on or before May 21, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0325. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as

copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The 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.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), 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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCFA, 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0325 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 May 21, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0325, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 19, 2006 (71 FR 20100) (FRL-8058-1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F7035) by Valent BioSciences Corporation (Valent), 870 Technology Way, Libertyville, IL 60048-6316. The petition requested that 40 CFR part 180 (specifically, § 180.1150) be amended by establishing an exemption from the requirement of a tolerance for residues of 6-benzyladenine (6-BA) in or on pear when applied at a rate of ≤182 grams of active ingredient per acre per season. The electronic docket (EPA-HQ-OPP-2006-0325) for this notice includes a summary of the petition prepared by the petitioner, Valent. Previously, on April 2, 2004 (69 FR 17304; FRL-7347-6), EPA issued a final rule granting a permanent exemption from the requirement of a tolerance for residues of 6-BA in or on pistachio when applied at a rate of ≤60 grams of active ingredient per acre per season, and the existing permanent tolerance exemption for apple was amended to expand the uses (by adding a post-bloom-applied stand-alone fruitlet thinner use) and increase the permissible application rate to ≤182 grams of active ingredient per

acre per season. Both apple and the subject new crop, pear, are pome fruit and, therefore, botanically similar. The two crops are grown in the same climatic/geographic regions, and are similarly cultivated. For both crops, 6-BA is applied for the same purpose, on the same schedule, at the same application rate and with the same 86-day pre-harvest interval restriction. Based on these similarities, the Agency has determined for the purpose of establishing the requested tolerance exemption that previously-submitted and reviewed information and data supporting the current tolerance exemption for apple will apply equally to the new crop, pear. In submitting this petition, therefore, Valent is relying on information previously submitted in connection with seeking and obtaining the tolerance exemption for the expanded use of 6-BA on apple, which was summarized in the April 2, 2004, final rule, and also on new data summarized in the cited petition summary (i.e., PP 6F7035). New data submitted to the Agency by Valent on October 20, 2004 and summarized by the company in the current petition are a two-generation rat reproduction study, which is data not required for U.S. registration of this biochemical active ingredient, but rather was conducted to satisfy the registration requirements of other countries and submitted by the petitioner to augment the Agency's 6-BA data base.

In response to EPA's April 19, 2006 notice, no comments were submitted in accordance with the instructions for submitting comments set forth in the notice. However, one informal comment was received from a private citizen who opposed issuance of a final rule. The commenter expressed concern regarding the hazard associated with plant regulator use in general, stated the unsupported belief that more testing needs to be done, and was generally opposed to the establishment of an exemption from the requirement of a tolerance as proposed in the subject pesticide tolerance petition for 6-BA. The Agency understands and recognizes that some individuals believe that pesticides, which include plant regulators, should be banned completely. Notwithstanding such beliefs, pursuant to its authority under the FFDCFA, EPA has conducted a comprehensive assessment of 6-BA and has concluded that there is a reasonable certainty that no harm will result from dietary exposure to this chemical when its use is limited by the specified maximum application rates.

Section 408(c)(2)(A)(i) of the FFDCFA 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 exemption 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) of the FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of the FFDCA, 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 was published by the Agency in the June 1994 N6-Benzyladenine (synonymous with the subject active ingredient, 6-benzyladenine) Reregistration Eligibility Decision (RED) document (http://www.epa.gov/oppsrrd1/REDs/old_reds/n6benzyladenine.pdf). The summarized values and categories for the various,

previously reviewed 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 to 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 section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 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.

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.

In addition to the previously reviewed studies discussed above, a two-generation rat reproduction study was relied upon by Valent to support the current petition to establish an exemption from the requirement of a tolerance for residues of 6-BA in or on pear. The lowest-LOAEL for parental systemic toxicity of technical 6-BA is 750 ppm (58.6–70.4 mg/kg bwt/day) and is based on reduced body weight and weight gain in F₀ and F₁ male rats¹. The NOAEL is 400 ppm (31.5–37.5 mg/kg bwt/day)¹. This systemic adult endpoint was used in the dietary risk assessment. Although the systemic endpoint is similar to that used in previous occupational risk assessments, the previous toxicological endpoint (40

mg/kg bwt/day) has been modified to more precisely reflect the composition of test diets, rat body weights, and food consumption estimates¹.

Because only systemic and no reproductive effects were observed, the LOAEL for reproductive toxicity of technical 6-BA in rats could not be determined. The NOAEL, therefore, is >1,500 ppm (115.7–144.2 mg/kg bwt/day for males and 133.0–139.2 mg/kg bwt/day for females), the highest dose tested¹.

The LOAEL for offspring toxicity of technical 6-BA in rats is 750 ppm (66.7–68.1 mg/kg bwt/day) and is based on decreased body weight and weight gain in F₁ and F₂ male and female pups. The NOAEL is 400 ppm (35.8–36.0 mg/kg bwt/day)¹.

Uncertainty factors for inter- and intra-species variation (10X each) and subchronic to chronic extrapolation (3X) were used to modify the toxicity NOAEL.

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 field trials yielded acceptable magnitude of the residue data. In apples, residues of 6-BA were consistently near the limit of quantitation (LOQ). However, the residue levels for processed commodities did not increase relative to those on the raw commodity, and were below the LOQ. The apple field data are adequate to support the tolerance exemption for pear, limited by a maximum application rate of ≤182 grams of active ingredient per acre per season, because of the shared physical, compositional and cultural characteristics of the two botanically similar pome fruits, which also are grown in the same climatic/geographic regions. The proposed use pattern; low application rate, frequency and timing; and 86-day pre-harvest interval are identical for apple and pear. Because application precedes harvest by approximately 2.5 months for apple and pear, 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 VI.), and the

¹ USEPA. N6-Benzyladenine: Review of Information for an Exemption from the Requirement of a Tolerance. K. R. Carlson to D. Greenway; December 5, 2006.

fact that actual exposure will probably be considerably less because the dietary exposure analysis was based on worst-case assumptions (such as conservatively assuming: That 100% of the crop is treated, that non-detected or <LOQ residue concentrations are present, and that chronic exposure from the few seasonal applications made 60–86 days before harvest could occur), it is highly unlikely that the proposed new use of 6–BA on pear will result in adverse effects to human health.

2. *Drinking water exposure.* The proposed use on pear is not expected to add potential exposure to residues of 6–BA in drinking water. Soil leaching studies have suggested that 6–BA is relatively immobile, adsorbing to sediment, and is degraded in the soil. Migration to potable water resources, therefore, is highly improbable. However, any residues that do reach surface waters from field runoff should quickly adsorb 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, non-occupational exposure to 6–BA residues for the general population, including infants and children, is unlikely because the uses, both those currently allowed and the one currently being established, are limited to applications in certain tree fruit and nut tree orchards. Additionally, because 6–BA is a naturally-occurring cytokinin plant regulator (having been detected in all higher plants tested for its presence), it is a normal part of the human diet. Moreover, the proposed use rates are well below the toxicity NOAELs (see Unit III.), and the residues resulting from applications made in accordance with the proposed use rates indicate dietary exposures that are <1.0% of the chronic and acute population adjusted doses. Therefore, not only is there a great likelihood of prior exposure for most, if not all, individuals to 6–BA, due to its natural presence in food crops, the data submitted also demonstrate that any incremental increased exposure due to the proposed use 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 FFDCFA 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

A. U.S. Population

When assessing the contributions of apple and pistachio, the Agency’s analysis estimated that the chronic exposures for the overall U.S. population was 0.00002 mg/kg/day (<1.0% of the chronic population adjusted dose (cPAD))¹. Similarly, the acute dietary estimated exposure was 0.000069 mg/kg/day (<1.0% 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. Dietary exposure to 6–BA residues in or on pear did not add significantly to the current dietary exposure to 6–BA from its use in or on apple or pistachio. 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 (such as conservatively assuming: That 100%

of the crop is treated, that non-detected or <LOQ residue concentrations are present, and that chronic exposure from the few seasonal applications made 60–86 days before harvest could occur), the Agency is reasonably certain that no dietary harm will result from aggregate exposure to 6–BA residues, including all anticipated dietary exposures (including the proposed new use of 6–BA on pear) and all other exposures for which there is reliable information.

B. Infants and Children

Section 408(b)(2)(C) of the FFDCFA 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. In the case of 6–BA, the safety factor was reduced from 10X to 3X based on adequate data from a new 2-generation rat reproduction study, and from a rat developmental toxicity study, neither of which demonstrated unique fetal susceptibility (i.e., fetal or neonatal effects occurred only at maternally toxic doses)¹. Additionally, genotoxicity and mutagenicity tests were negative. EPA did not reduce the uncertainty factor any further, however, because of the lack of a developmental toxicity study in a second species, and the resulting residual uncertainties for 6–BA-induced pre-/post-natal toxicity. The analysis estimated that the chronic exposures for the most highly exposed subgroup, non-nursing infants, was 0.000012 mg/kg/day (<1.0% of the cPAD). The acute dietary estimated exposure was 0.000361 mg/kg/day (<1.0% 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 (such as conservatively assuming: that 100% of the crop is treated, that non-detected or <LOQ residue concentrations are present, and that chronic exposure from the few seasonal applications made 60–86 days before harvest could occur), it is reasonably certain that no dietary harm will result to infants and children from aggregate exposure to residues of 6–BA

resulting from all currently-registered uses, as well as from the proposed new use of 6-BA on pear.

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 any possible 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 Methods

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 (a pome fruit botanically similar to the new crop, pear), both raw agricultural and processed commodities, and for pistachio have been developed and submitted by the registrant. The analytical method for apple is expected to be fully applicable (have the same

sensitivity) to pear because the two pome fruits are physically and compositionally comparable, and therefore should present similar sequestration and matrix interference characteristics.

C. Codex Maximum Residue Level

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

VIII. Conclusions

Based on the toxicology information submitted and reviewed previously and summarized in the June 1994 N6-Benzyladenine RED, in combination with the newly submitted two generation rat reproduction study and other information available to the Agency, there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 6-BA under reasonably foreseeable circumstances, when 6-BA is used as a biochemical pesticide in accordance with its label and 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 is establishing an exemption (albeit, limited by a maximum application rate) from the tolerance requirements pursuant to section 408(c) and (d) of the FFDCA for residues of 6-BA in or on pear.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance 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 from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of 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.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 25, 2007.

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(g), 346a and 371.

■ 2. Section 180.1150 is revised to read as follows:

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

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

[FR Doc. 07-1386 Filed 3-20-07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0208; FRL-8117-1]

Thifensulfuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thifensulfuron methyl in or on rice, grain; rice, straw; sorghum, grain, forage; sorghum, grain, grain; and sorghum, grain, stover. E. I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 21, 2007. Objections and requests for hearings must be received on or before May 21, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0208. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the

index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5704; e-mail address: walters.vickie@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 code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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