

427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed approval action does not include a federal mandate that may result in estimated annual costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 21, 1999.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 00–151 Filed 1–4–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300951; FRL–6393–1]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to revise the tolerances for residues of

azoxystrobin (methyl(*E*)-2–(2–(6–(2-cyanophenoxy)pyrimidin-4-yl)oxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(*Z*)-2–(2–(6–(2-cyanophenoxy)pyrimidin-4-yl)oxy)phenyl)-3-methoxyacrylate) in or on pistachios at 0.02 part per million (ppm) and tree nuts at 0.02 ppm. A final rule establishing tolerances for residues of azoxystrobin and its Z isomer in or on pistachios at 0.01 ppm and tree nuts at 0.01 ppm was published in the **Federal Register** of March 17, 1999 (64 FR 13106). These were the tolerances that Zeneca Ag Products had originally proposed, in pesticide petition (PP) 7F4864. Immediately following completion of this final rule, EPA received telephone comments from two parties indicating that they believed the pistachio and tree nuts tolerances were too low, considering the data submitted in support of the tolerances and the use directions on the label, and might lead to adulterated commodities even when the label use directions were accurately followed. EPA agreed to revisit the tolerances assigned to these commodities, has concluded that the commentors are correct in their concerns, and here proposes to increase the tolerances for residues of azoxystrobin and its Z isomer in or on pistachios to 0.02 ppm and in or on tree nuts to 0.02 ppm.

DATES: Comments, identified by docket control number OPP–300951, must be received by EPA on or before March 6, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the “SUPPLEMENTARY INFORMATION.”

To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–300951 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia L. Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–7740; and e-mail address: giles-parker.cynthia@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 categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under “FOR FURTHER INFORMATION CONTACT.”

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “**Federal Register**–Environmental Documents.” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300951. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday

through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-300951 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-300951. Electronic comments may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential

will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under "FOR FURTHER INFORMATION CONTACT."

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

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

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the proposed rule or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background and Statutory Findings

A. What Action is the Agency Taking?

In the **Federal Register** of March 17, 1999 (64 FR 13106) (FRL-6064-6), EPA issued a final rule pursuant to section 408(b)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), announcing the establishment of tolerances for residues of azoxystrobin and its Z isomer on several commodities, including pistachio nuts at 0.01 ppm and tree nuts at 0.01 ppm, as had been proposed by Zeneca Ag Products in tolerance petition number (PP) 7F4864. This final rule included a detailed discussion of the risk assessment and of residue and other considerations that lay behind EPA's decision to establish the tolerances. Telephone comments were received from two parties in California immediately after completion of the rule. In both cases the parties believed that the pistachios and tree nuts tolerances were too low, considering the data submitted in support of the tolerances and the use directions on the label, and might lead to adulterated

commodities even when the use directions on the label were accurately followed. EPA agreed to revisit the tolerances assigned to these commodities. If the commentor's comments were substantiated, a reassessment of the risk from the use of azoxystrobin would also be necessary. The Agency has concluded that the commentors' concerns are justified and that the appropriate tolerances for these commodities are 0.02 ppm in or on pistachios and 0.02 ppm in or on tree nuts.

This document proposes to amend 40 CFR 180.507 by increasing the tolerances for combined residues of the fungicide azoxystrobin and its Z isomer, in or on pistachios at 0.02 ppm and tree nuts at 0.02 ppm.

B. What is the Agency's Authority for Taking this Action?

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish 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(b)(2)(A)(ii) 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. Section 408(b)(2)(C) requires 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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

C. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for

combined residues of azoxystrobin and its Z isomer in or on pistachios at 0.02 ppm and in or on tree nuts at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances were published in 64 FR 13106 (March 17, 1999), the final rule that established the initial tolerances for residues of azoxystrobin in or on pistachios at 0.01 ppm and in or on tree nuts at 0.01 ppm. In that rule the Agency concluded that there was a reasonable certainty that no harm would result from the establishment of azoxystrobin tolerances for several other commodities. A reassessment of the risk associated with increasing the azoxystrobin tolerances for pistachios and tree nuts to 0.02 ppm demonstrated that the calculated risk increases were so small (generally at the fourth decimal place) that the risk assessment values (rounded) reported in 64 FR 13106 (March 17, 1999) were not changed. That is, the risk increase resulting from this proposed rule will be negligible. Accordingly, EPA concludes that modifying these tolerances as described will be safe for the general population, including infants and children. EPA reaffirms its specific risk findings set forth in the March 1999 azoxystrobin tolerance action.

D. International Residue Limits

There are no Codex, Canadian or Mexican Maximum Residue Limits (MRL) established for azoxystrobin for pistachios or tree nuts. Thus, harmonization is not an issue.

III. Regulatory Assessment Requirements

This proposed rule seeks to establish a tolerance under FFDCA section 408(e). 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). This action 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income*

Populations (59 FR 7629, February 16, 1994); or require 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). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. 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 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 FFDCA section 408(n)(4).

List of Subjects in 40 CFR Part 180

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

Dated: December 16, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I shall be 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. In § 180.507, the table to paragraph (a)(1), by revising the entries for pistachios and tree nuts to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Pistachios	0.02
Tree nuts	0.02

[FR Doc. 00-75 Filed 1-4-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

[RIN 0991-AB08]

Standards for Privacy of Individually Identifiable Health Information

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, DHHS.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the preamble and proposed regulatory text published in the **Federal Register** of November 3, 1999, regarding the Standards for Privacy of Individually Identifiable Health Information.

FOR FURTHER INFORMATION CONTACT: Roxanne Gibson, (202) 260-5083.

SUPPLEMENTARY INFORMATION:

Corrections

In the proposed rule 45 CFR Parts 190 through 164, beginning on page 59918