

**List of Subjects**

Environmental protection, Pesticides and pests.

Dated: August 3, 2004.

**Arnold E. Layne,**

*Director, Information Resources Services  
Division, Office of Pesticide Programs.*

[FR Doc. 04-18768 Filed 8-17-04; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-2004-0137; FRL-7361-1]

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

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket ID number OPP-2004-0137, must be received on or before September 17, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@rps.gov](mailto:jackson.sidney@rps.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 Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2004-0137. 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/>.

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.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not

included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. 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. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be

marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2004-0137. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2004-0137. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that

you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2004-0137.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2004-0137. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also, provide the name, date, and **Federal Register** citation.

## **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### **List of Subjects**

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

Dated: August 6, 2004.

**Donald R. Stubbs,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

### **Summary of Petitions**

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by Interregional Research Number 4 (IR-4) and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and

measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### Interregional Research Number 4 (IR-4)

PP 3E6768, PP 3E6784, PP 3E6790, PP 3E6796, and PP 3E6801

EPA has received pesticide petitions (PP 3E6768, PP 3E6784, PP 3E6790, PP 3E6796, and PP 3E6801) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.544, by establishing tolerances for residues of the insecticide methoxyfenozide, benzoic acid, 3-methoxy-2-methyl, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the following raw agricultural commodities:

1. PP 3E6768 proposes the establishment of tolerances for spearmint, tops at 7.0 parts per million (ppm); peppermint, tops at 7.0 ppm; and dill at 7.0 ppm.

2. PP 3E6784 proposes the establishment of a tolerance for strawberry at 1.5 ppm.

3. PP 3E6790 proposes the establishment of tolerances for vegetable, root, subgroup 1A at 0.5 ppm, and vegetable, leaves of root and tuber, Group 2 at 30 ppm.

4. PP 3E6796 proposes the establishment of tolerances for papaya; star apple; sapote, black; mango; sapodilla; canistel; and sapote, mamey at 0.5 ppm. PP 3E6796 also proposes the establishment of a tolerance for coriander, leaves at 30 ppm.

5. PP 3E6801 proposes the establishment of tolerances for vegetable, legume, edible podded, subgroup 6A at 1.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.2 ppm; and vegetable, foliage of legume, except soybean, subgroup 7A at 35 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes summary of the petition prepared by the registrant, Dow AgroScience, 9330 Zionsville Road, Indianapolis, IN 46268.

#### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of methoxyfenozide residues in plants and animals is adequately understood and was previously

published in the **Federal Register** of July 5, 2000 (65 FR 41355) (FRL-6497-5).

2. *Analytical method.* Adequate enforcement methods are available for determination of methoxyfenozide residues in plant commodities. The available Analytical Enforcement Methodology was previously reviewed in the **Federal Register** of September 20, 2002 (67 FR 59193) (FRL-7198-5).

3. *Magnitude of residues.* Residue data for methoxyfenozide on commodities listed within this notice has been submitted.

#### B. Toxicological Profile.

The toxicological profile and endpoints for methoxyfenozide which supports this petition to establish tolerances were previously published in the **Federal Register** of September 20, 2002 (67 FR 59193).

#### C. Aggregate Exposure

1. *Dietary exposure.* Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U.S. population subgroups to residues of methoxyfenozide. These analysis cover all registered crops, as well as, uses pending with the Agency, active and proposed section 18 uses, and proposed IR-4 minor uses. There are no registered residential nonfat uses of methoxyfenozide.

i. *Food—a. Acute.* No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide including the acute neurotoxicity study in rats, the developmental toxicity study in rats and the developmental toxicity study in rabbits. Since no acute toxicological endpoints were established, Dow AgroSciences considers acute aggregate risk to be negligible.

b. *Chronic.* Chronic assessments were conducted to evaluate potential risks due to chronic dietary exposure of the U.S. population and selected population subgroups to residues of methoxyfenozide. Dow AgroSciences used the Dietary Exposure Evaluation Model (DEEM™, Novigen Sciences, Washington, DC) software for conducting a chronic dietary (food) risk analysis. Dow AgroSciences assumed 100% of crops would be treated and contain methoxyfenozide residues at the tolerance level.

ii. *Drinking water—a. Acute exposure.* Because no acute dietary endpoint was determined, Dow AgroSciences concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

b. *Chronic exposure.* Tier II screening-level assessments can be conducted using the simulation models screening concentration in Groundwater (SCI-GROW) and Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to generate estimated environmental concentrations (EECs) for ground water and surface water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for methoxyfenozide (1.0 lb a.i./acre/season). PRZM/EXAMS was used to generate the surface water EECs because it can factor the persistent nature of the chemical into the estimates.

2. *Non-dietary exposure.* Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short-term or intermediate-term exposure.

#### D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, it is assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population.* Using the DEEM™ exposure assumptions, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 22.2% of the chronic population adjusted dose (cPAD) for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1–2 years old at 50.9% of the cPAD. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a

lifetime will not pose appreciable risks to human health.

2. *Infants and children.* The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2-generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide an exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 50.9% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Drinking water.* The EECs for assessing chronic aggregate dietary risk used by the Agency are 3.5 parts per billion (ppb) (in ground water, based on SCI-GROW) and 30 ppb (in surface water, based on the PRZM/EXAMS, long-term mean). The back-calculated drinking water levels of concern (DWLOCs) for assessing chronic aggregate dietary risk range from 501 ppb for the most highly exposed population subgroup (children 1–2 years old) to 2,778 ppb for the U.S. population (total).

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for methoxyfenozide residues in drinking water as a contribution to chronic aggregate exposure. Dow AgroSciences thus concludes with reasonable certainty that residues of methoxyfenozide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from methoxyfenozide residues in food and drinking water will not exceed the Agency's level of concern (100% of the cPAD) for chronic dietary aggregate exposure by any population subgroup.

EPA generally has no concern for exposures below 100% of the cPAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

#### F. International Tolerances

There are no Codex or Canadian maximum residue levels (MRLs) established for residues of methoxyfenozide. Mexican MRLs are established for residues of methoxyfenozide in cottonseed (0.05 ppm) and maize (0.01 ppm). The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels cannot be reduced to harmonize with the Mexican MRLs, so incompatibility will exist.

[FR Doc. 04–18769 Filed 8–17–04; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0160; FRL–7364–6]

### Glyphosate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket identification (ID) number OPP–2004–0160, must be received on or before September 17, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

#### FOR FURTHER INFORMATION CONTACT:

James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: [tompkins.jim@epa.gov](mailto:tompkins.jim@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?

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