

- Are not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);

- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Are not subject to the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: July 15, 2010.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2010-18553 Filed 7-27-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0423; FRL-8835-7]

Mevinphos; Proposed Data Call-in Order for Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed order.

SUMMARY: This document proposes to require the submission of various data required to support the continuation of the tolerances for the pesticide mevinphos. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0423, 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 Facility'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 Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2010-0423. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment.

If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., 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 either 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 hours of operation of this Docket Facility are 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: K. Avivah Jakob, Pesticide Re-evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 305-1328; e-mail address: jakob.kathryn@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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. FFDCA Data Call-In Authority

In this document, EPA proposes to issue an order requiring the submission of various data to support the continuation of the mevinphos tolerances at 40 CFR 180.157. Under section 408(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(f), EPA is authorized to require, by order, submission of data “reasonably required to support the continuation of a tolerance” when such data cannot be obtained under the Data Call-In authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A section 408(f) Data Call-In order may only be issued following notice and a comment period of not less than 60 days.

A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit to submit the data required in the order.
2. A description of the required data and the required reports connected to such data.
3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA.
4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order. (21 U.S.C. 346a(f)(1)(C)).

EPA may by order modify or revoke the affected tolerances if any one of the following submissions is not made in a timely manner:

- A notice identifying one or more interested persons who commit to submit the data.
- The data itself.
- The reports required under a section 408(f) order are not submitted by the date specified in the order. (21 U.S.C. 346a(f)(2)).

III. Regulatory Background for Mevinphos

Mevinphos is a contact/systemic insecticide-acaricide. It is not currently registered under FIFRA and may not be sold, distributed, or used in the United States. Mevinphos’ FIFRA registration was canceled in 1994. However, 15 FFDCA tolerances remain for residues of mevinphos on the following commodities: Broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach,

strawberries, summer squash, tomatoes, and watermelon (40 CFR 180.157). Since there are currently no domestic registrations for mevinphos, these tolerances are referred to as “import tolerances.”

Mevinphos is a member of a family of pesticides known as the organophosphates. EPA has concluded mevinphos and other organophosphate pesticides share a common mechanism of toxicity. As with other organophosphates, the principal toxic effects induced by mevinphos are related to its cholinesterase-inhibiting activity. It produces the associated clinical signs such as tremors, unsteady gait, decreased activity, salivation, disturbed balance in rats and rabbits, and decreased cholinesterase activity (plasma, brain) in rats and rabbits following acute, subchronic, and chronic oral exposure.

In September 2000, EPA issued an Interim Tolerance Reassessment Eligibility Decision (ITRED) for mevinphos in connection with its obligation under the Food Quality Protection Act of 1996 (FQPA), to evaluate whether all tolerances in existence at the time of the passage of FQPA met the revised safety standard that the FQPA adopted for FFDCA section 408. In the ITRED, EPA concluded that the risks of mevinphos when evaluated in isolation from other organophosphates met the revised safety standard in FFDCA section 408. This conclusion was labeled “interim,” however, because EPA had not yet completed a cumulative risk assessment for the organophosphates. In July 2006, EPA completed its cumulative risk assessment for the organophosphate pesticides finding that these tolerances met the revised safety standard.

The ITRED called attention to several data gaps for mevinphos including:

1. A developmental neurotoxicity (DNT) study in rats (with expanded protocol to extend the postnatal treatment period and to measure cholinesterase inhibition in offspring) as was required for all organophosphate pesticides.

2. Various studies evaluating mevinphos residue levels on treated crops. EPA noted that it would be taking steps to require the submission of this data. Subsequently, the manufacturer of mevinphos submitted residue data for grapes and frozen storage stability data for broccoli, cucumbers, lettuce, tomatoes, and strawberries. However, the registrant has not submitted a DNT study or residue data for the remaining imported commodities.

Under section 3(g) of FIFRA and implementing regulations, EPA has

established a review program for pesticides registered under FIFRA. The goal of that program is a periodic review of pesticide registrations every 15 years to ensure that the registrations satisfy FIFRA standards and are based on "current scientific and other knowledge regarding the pesticide." (40 CFR 155.40(a)). EPA is in the preliminary stages of the registration review process for organophosphate pesticides. Although mevinphos is not registered under FIFRA, EPA will be re-examining mevinphos with the other registered organophosphates because of the organophosphates shared mechanism of toxicity.

In re-examining mevinphos, EPA has identified several studies noted in the ITRED as data gaps for which data have not been submitted and one new regulatory data requirement for which a study is needed. These data are necessary to support the continuation of mevinphos tolerances and are listed below.

IV. Data Requirements

A. Required Data and Reports

Pursuant to FFDCA section 408(f), EPA has determined that additional data are reasonably required to support the continuation of the tolerances for mevinphos which are codified at 40 CFR 180.157. Accordingly, EPA proposes to issue a final order requiring the submission of the following data:

1. Comparative Cholinesterase Assay (Test Guideline 870.6300). A protocol and a final report are required.

Rationale. As an organophosphate pesticide (OP), inhibition of acetylcholinesterase (AChE) is the critical effect for use in human health risk assessment. Many OPs were subject to a Data-Call-In for the developmental neurotoxicity study (DNT). This DCI also included the requirement for AChE inhibition data to evaluate comparative sensitivity in juvenile and adult rats. These data are most often collected in a study called the comparative cholinesterase assay (CCA). Since that time, CCA studies for more than 20 OPs have been submitted to OPP. Although for some OPs no difference in sensitivity has been observed in juvenile and adult animals, for many of the OPs, juveniles have been shown to be more sensitive. At this time, OPP has determined that

a CCA is required for mevinphos to evaluate the potential for increased sensitivity in juvenile animals compared with that of adult animals. Given that the AChE data provided in the CCAs have provided more sensitive results than DNT studies for the OPs, a DNT study for mevinphos is not required at this time.

2. Immunotoxicity Study (Test Guideline 870.7800). A final report and protocol are required.

Rationale. This is a new data requirement under 40 CFR part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).

The Immunotoxicity Test Guideline (Harmonized Guideline 870.7800) prescribes functional immunotoxicity testing and is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), severe acquired respiratory syndrome (SARS), or neoplasia.

3. Directions for Use (Test Guideline 860.1200)

Rationale. The Agency needs use directions, which appear on the Mexico label(s).

4. Crop Field Trials (Test Guideline 860.1500) – (broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, strawberries, summer squash, and tomatoes.)

Rationale. Field trials are required for each commodity/commodity group according to guidelines that take into account where the crop is grown and how much of the crop is grown. Field trials are required for each type of formulation because the formulation can have significant effect on the magnitude of the pesticide residue left on the crop. Residue trials also need to represent the maximum application rate on the label and have a geographic distribution representative of the commodity/commodity group. On June 1, 2000 (65 FR 35069) (FRL-6559-3), EPA published in the **Federal Register**, a Notice which provided detailed guidance on applying current U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods. A

copy of that Notice is available in the docket of this proposed order. That Notice contains instructions for determining number and location of field trials.

5. Processing Study (tomatoes) (Test Guideline 860.1520)

Rationale. Processing studies are required to determine whether residues in raw commodities may be expected to degrade or concentrate during food processing. If residues concentrate in a processed commodity, a food or feed additive tolerance must be established. If residues do not concentrate in a processed commodity, the tolerance for the raw agricultural commodity applies to all processed food or feed derived from it.

B. Persons who Commit to Submit the Required Data

After this 60-day comment period closes, the Agency will respond to comments, if appropriate, and may issue a final order requiring the submission of various data for mevinphos in the **Federal Register**. If EPA issues such an order, persons who are interested in the continuation of the mevinphos tolerances must notify the Agency by completing and submitting the required "\$408(f) Order Response" form (available in the docket) within 90 days after publication of the final order in the **Federal Register**.

The "\$408(f) Order Response Form" requires the identification of persons who will submit the required data and lists the options available to support the required data:

- i. Develop new data.
- ii. Submit an Existing Study — submit existing data not submitted previously to the Agency by anyone.
- iii. Upgrade a Study — submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradable.
- iv. Cite an Existing Study — cite an existing study that EPA classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.

C. Required Dates for Submission of Data/Reports

The table below lists the time allocated for both the completion and submission of each study. The required submission date is calculated from the date of publication in the **Federal Register** of the final order.

Guideline Requirement Number	Study Title	Timeframe for protocol submission	Timeframe for data submission
860.1200	Directions for use	Not required	12 months

Guideline Requirement Number	Study Title	Timeframe for protocol submission	Timeframe for data submission
860.1500	Crop Field Trials (broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, strawberries, summer squash, and tomatoes)	Not Required	24 months
860.1520	Processing studies (tomatoes)	Not Required	24 months
870.6300	Comparative Cholinesterase Assay	6 months	12 months
870.7800	Immunotoxicity Study	6 months	12 months

D. Failure to Submit

If the Agency does not receive a §408(f) Response Form identifying a person who agrees to submit the required data within 90 days after publication of the final order, EPA will proceed to revoke the mevinphos tolerances at 40 CFR 180.157. Such revocation order is subject to the objection and hearing procedure in FFDCA section 408(g)(2) but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of mevinphos tolerances include, but are not limited to the following:

1. No person submits on the required schedule an acceptable proposal or final protocol when such is required to be submitted to the Agency for review.

2. No person submits on the required schedule an adequate progress report on a study as required by the order.

3. No person submits on the required schedule acceptable data as required by the final order.

4. No person submits supportable certifications as to the conditions of submitted data, where required by order and where no other cited or submitted study meets the data requirements the study was intended to fulfill.

V. Statutory and Executive Order Reviews

As required by statute, this proposal to require submission of data in support of tolerances is in the form of an order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act, orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: July 22, 2010.

Richard P. Keigwin, Jr.,
Director, Pesticide Re-evaluation Division,
Office of Pesticide Programs.

[FR Doc. 2010-18541 Filed 7-27-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0490; FRL-8834-1]

Aluminum tris(O-ethylphosphonate), Butylate, Chlorethoxyfos, Clethodim, et al.; Proposed Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with current Agency practice to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing minor revisions to tolerance expressions for a number of pesticide active ingredients, including the insecticides chlorethoxyfos, clofentezine, cyromazine, etofenprox, fenbutatin-oxide, fosthiazate, propetamphos, and tebufenozide; the fungicides aluminum tris(O-ethylphosphonate) and fenarimol; the herbicides butylate, clethodim, clomazone, fenoxaprop-ethyl, flumetsulam, flumiclorac pentyl, fluridone, fomesafen, glufosinate ammonium, lactofen, propanil, quinclorac, and pyridate; and the fungicide/bactericide oxytetracycline. Also, EPA is proposing to revoke the tolerances for aluminum tris(O-ethylphosphonate) on pineapple fodder and forage because they are not considered to be significant livestock feed items, and revise specific tolerance nomenclatures for aluminum tris(O-ethylphosphonate), clethodim, flumetsulam, and fluridone. In addition,

EPA will be removing several expired tolerances for aluminum tris(O-ethylphosphonate), etofenprox, propanil, and tebufenozide.

DATES: Comments must be received on or before September 27, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0490, 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 Facility'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 Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2010-0490. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly