Commenters may use PRC Form 61, which is available on the Commission’s Web site, http://www.prc.gov.

§ 3025.20 The record on review.
(a) The record on review includes:
(1) The final determination;
(2) The notices to persons served by the post office to be closed or consolidated;
(3) The administrative record;
(4) All documents submitted in the appeal proceeding; and
(5) Facts of which the Commission can properly take official notice.
(b) However, a petitioner or commenter may dispute factual matters or conclusions drawn in the administrative record.

§ 3025.21 Filing of the administrative record.
The Postal Service shall file the administrative record within 10 days of the date of posting of a Petition for Review on the Commission’s Web site. The Commission may alter this time for good cause. The Postal Service shall notify participants who do not file electronically of the filing of the administrative record. Such notification shall be made by First-Class Mail.

§ 3025.22 Making documents available for inspection by the public.
Copies of all filings (including the administrative record) related to an appeal shall be available for public inspection at the post office whose closure or consolidation is under review. If that post office has been suspended or closed, the filings shall be available at the nearest open post office. The Postal Service must notify all petitioners and commenters of the location(s) (other than the Commission offices) where the filings may be inspected. Such notification shall be made by First-Class Mail.

§ 3025.30 Suspension pending review.
A final determination to close or consolidate a post office is suspended until final disposition by the Commission when a person files a timely Petition for Review.

§ 3025.40 Participant statement.
(a) When a timely Petition for Review of a decision to close or consolidate a post office is filed, the Secretary shall furnish petitioner with a copy of PRC Form 61. This form is designed to inform petitioners on how to make a statement of his/her arguments in support of the petition.
(b) The instructions for Form 61 shall provide:
(1) A concise explanation of the purpose of the form;
(2) A copy of section 404(d)(2)(A) of title 39, U.S. Code; and
(3) Notification that, if petitioner prefers, he or she may file a brief in lieu of or in addition to completing PRC Form 61.

§ 3025.41 Due date for participant statement.
The statement or brief of petitioner and of any other participant supporting petitioner shall be filed not more than 20 days after the filing of the administrative record.

§ 3025.42 Due date for Postal Service response.
The statement or brief of the Postal Service and of any other participant supporting the Postal Service shall be filed not more than 14 days after the date for filing of petitioner’s statement.

§ 3025.43 Due date for replies to the Postal Service.
Petitioner and any other participant supporting petitioner may file a reply to the Postal Service response not more than 7 days after the date of the Postal Service response. Replies are limited to issues discussed in the Postal Service’s response.

[FR Doc. 2011–22009 Filed 8–30–11; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
Fenamiphos: 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 fenamiphos. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before October 31, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0702, by one of the following methods:

• 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–2011–0702. 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 regulations.gov or e-mail. The regulations.gov Web site 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 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.
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: Eric Miederhoff, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 347–8028; e-mail address: miederhoff.eric@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 fenamiphos tolerances at 40 CFR 180.349. Under section 408(f) of 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:

• A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit(s) to submit the data required in the order;

• A description of the required data and the required reports connected to such data;

• An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA;

• 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 the one or more interested persons who commit to submit the data;

• The date of FIFRA itself; or

• 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 Fenamiphos

Fenamiphos is an organophosphate nematicide/insecticide. It is not currently registered under FIFRA. Fenamiphos’ last FIFRA registration was canceled in 2007. However, four FFDCA tolerances remain for residues of fenamiphos on the following commodities: Pineapples, grapes, raisins, and bananas (40 CFR 180.349). Since there are currently no domestic registrations for fenamiphos, these tolerances are referred to as “import tolerances.”

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

In February 2002, EPA issued an Interim Reregistration Eligibility Decision (IRED) for fenamiphos. The IRED evaluated the potential human health and ecological risks associated with all registered uses of fenamiphos. In connection with its obligation under the Food Quality Protection Act of 1996 (FQPA), the Agency also evaluated whether all fenamiphos 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 IRED, EPA concluded that the risks of fenamiphos when evaluated in isolation from other organophosphates met the revised safety standard in FFDCA section 408.
The Immunotoxicity Test Guideline (OPPTS 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. An immunotoxicity study for fenamiphos has not been submitted.  

### 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 import tolerances for fenamiphos which are codified at 40 CFR 180.349. These data cannot be obtained under FIFRA section 3(c)(2)(B) because fenamiphos is not registered under FIFRA, and the data call-in authority under that section only extends to registered pesticides. These data cannot be obtained under TSCA because pesticides are excluded from coverage under that statute. 15 U.S.C. 2602(2)(B)(ii).

Accordingly, EPA proposes to issue a final order requiring the submission of the following data:

1. **Comparative Cholinesterase Assay (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 Data Call-In 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. 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 fenamiphos 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 fenamiphos is not required at this time.

2. **Immunotoxicity study (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) and for establishment of a tolerance.

The Immunotoxicity Test Guideline (OPPTS 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. An immunotoxicity study for fenamiphos has not been submitted.

3. **Crop field trials—grapes (860.1500).** A final report is required.

### Rationale:

Field trials are required for each commodity/commodity group under 40 CFR part 158. These data are used to establish the legal maximum residue that may remain on food and to assess the risk posed by the pesticide residue. While residue data for fenamiphos use on grape is adequate to support several application methods, the Agency has not received data to support the current foliar use of fenamiphos on grape in Mexico.

EPA guidelines recommend that crop field trials be designed to 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 a 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 the number and location of field trials.

#### B. Persons Who Commit To Submit the Required Data

After the 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 fenamiphos in the Federal Register. If EPA issues such an order, persons who are interested in the continuation of the fenamiphos tolerances must notify the Agency by completing and submitting the required “Section 408(f) Order Response” form (available in the docket) within 90 days after publication of the final Order in the Federal Register.

The “Section 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:

1. Develop new data.
2. Submit an existing study—submit existing data not submitted previously to the Agency by anyone.
3. Upgrade a study—submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradable.
4. 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 following table 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.

<table>
<thead>
<tr>
<th>Guideline requirement No.</th>
<th>Study title</th>
<th>Timeframe for protocol submission</th>
<th>Timeframe for data submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>870.6300</td>
<td>Comparative Cholinesterase Assay</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>870.7800</td>
<td>Immunotoxicity Study</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>860.1500</td>
<td>Crop Field Trials (grapes)</td>
<td>Not Required</td>
<td>24 months</td>
</tr>
</tbody>
</table>

D. Failure To Submit

If the Agency does not receive a Section 408(f) Response Form identifying a person who agrees to submit the required data within 90 days after publication of the final order in the Federal Register, EPA will proceed to revoke the fenamiphos tolerances at 40 CFR 180.349. Such revocation order is subject to the objection and hearing procedures 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 fenamiphos 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.