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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0702; FRL-9339 -7]

Fenamiphos; Data Call-in Order for Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: This order requires the submission of various data to support the continuation of the tolerances for the pesticide fenamiphos. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA). Following publication of this 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. If the Agency does not receive within 90 days after publication of the final order a section 408(f) Response Form identifying a person who agrees to submit the required data, EPA will revoke the fenamiphos tolerances.

DATES: This final order is effective [*insert date of publication in the* **Federal Register**]. A section 408(f) Order Response Form must be received on or before [*insert date* 90 *days after date of publication in the* **Federal Register**].

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0702. 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., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such

as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

Submit your section 408(f) Order Response Form, identified by docket identification (ID) number EPA-HQ-OPP-2011-0702, by one of the following methods:

• *Federal eRulemaking Portal*: 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 section 408(f) Order Response Form to docket ID number EPA-HQ-OPP-2011-0702. EPA's policy is that all information and 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 information or comment includes information claimed to be 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 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 information or comments via an e-mail directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the information or comment that is placed in the docket and made available on the Internet. If you submit information or a comment electronically, EPA recommends that you include your name and other contact information in the body of your information or comment and with any disk or CD-ROM you submit. If EPA cannot read your information or comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your submission. 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: 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. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines," which is listed under "Documents related to our mission."

II. Background

A. What Action is the Agency Taking?

In this document EPA is issuing an order requiring the submission of various data to support the continuation of the fenamiphos tolerances at 40 CFR 180.349 under section 408 of the FFDCA, 21 U.S.C. 346a.

Fenamiphos is not currently registered under FIFRA, 7 U.S.C. 136 *et seq*. The FIFRA registration for fenamiphos was canceled in 2007. However, four FFDCA tolerances remain for residues of fenamiphos on the following commodities: Bananas, grapes, pineapples, and raisins (40 CFR 180.349). Since there are currently no domestic registrations for fenamiphos, these tolerances are referred to as "import tolerances." It is these tolerances that are addressed by the data call-in order.

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

Under section 408(f) of the FFDCA, 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 FIFRA section 3(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A FFDCA section 408 data call-in order may only be issued following publication of notice of the order and a 60-day public comment provision.

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; and

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:

i. A notice identifying the one or more interested persons who commit to submit the data;

ii. The data itself; or

iii. 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)).

C. What Preliminary Steps were Taken by EPA Prior to Issuing this Final Order?

On August 31, 2011, EPA issued a proposed data call-in order for the pesticide fenamiphos in connection with tolerances for that pesticide under section 408 of the FFDCA, 21 U.S.C. 346a. (75 FR 44181). The proposed data call-in order included the following studies:

1. Comparative Cholinesterase Assay (Non-Guideline).
2. Immunotoxicity Study (870.7800).
3. Crop Field Trials (860.1500) – (grapes; foliar use in Mexico).

III. Summary of Public Comments Received and Agency Response to Comments

EPA received one comment in response to the August 31, 2011, **Federal Register** notice announcing the Agency's proposed data call-in order for fenamiphos (76 FR 54185; FRL-8886-2). However, this comment merely argued that there are too many toxic chemicals approved for use in the United States and did not, in any manner, address the Agency's intention to issue a data call-in order for fenamiphos. Therefore, no response to this comment is needed. In addition, the Agency has not received any of the data identified in the proposed order as needed to support the fenamiphos tolerances.

IV. Final Data Call-in Order

Because no comments were submitted on the proposal and the data deficiencies identified in the proposed order remain, EPA is issuing this final data call-in order under FFDCA section 408(f)(1)(C) for fenamiphos in the same form as the proposed order and for the reasons set forth in that proposed order. Specifically, this order:

1. *Requires Notice of Intent to Submit Data*. A notice identifying the person or persons who commit to submit the data and reports in accordance with Unit V.2. must be submitted to EPA if any person wishes to support the fenamiphos tolerances. The notice must be submitted on a section 408(f) Order Response Form which is available in the electronic docket, *http://www.regulations.gov*, under docket ID number EPA-HQ-OPP-2011-0702.

2. *Establishes a Deadline for Submission of Notice Identifying Data Submitters.* The notice described in Unit V.1. identifying data submitters must be submitted to and received by EPA on or before [*insert date 90 days after date of publication in the* **Federal Register**]. Instructions on methods for submitting this notice (referred to in this order as a "section 408(f) Order Response Form") are set out under **ADDRESSES**.

3. *Describes Data and Reports Required to Support Continuation of the Fenamiphos Tolerances, Requires Submission of Those Data and Reports, and Establishes Deadlines for Submission.* The table in this Unit describes the data and reports required to be submitted on fenamiphos under this order and the deadlines for the submission of each study and report. The required submission date is calculated from [*insert date 90 days after date of publication in the* **Federal Register]**. Thus, for example, if EPA generally allows 12 months to complete a study, the required submission date for such a study under this order would be 15 months from the date of publication of the order in the **Federal Register**.

OCSPP Harmonized Guideline Number	Study Title	Timeframe for protocol report submission	Timeframe for data submission
Non-Guideline	Comparative Cholinesterase Assay	*[insert date 9 months after date of*	*[insert date 15 months after date of*

		publication in the **Federal Register]**	*publication in the* **Federal Register].**
870.7800	Immunotoxicity Study	*[insert date 9 months after date of publication in the* **Federal Register].**	*[insert date 15 months after date of publication in the* **Federal Register].**
860.1500	Crop Field Trials (grapes; foliar use in Mexico)	Not Required	*[insert date 27 months after date of publication in the* **Federal Register].**

EPA provided a description of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA in the proposed order and relies on that description in this final order.

V. Failure to Submit Notice of Intent to Submit Data or Data and Reports

If, by [*insert date 90 days after date of publication in the* **Federal Register]** the Agency does not receive a section 408(f) Order Response Form identifying a person who agrees to submit the required data, EPA will revoke the fenamiphos tolerances at 40 CFR 180.349. Such revocation 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 fenamiphos tolerances include, but are not limited to the following:

1. No person submits on the required schedule an acceptable protocol report when such report is required to be submitted to the Agency for review.
2. No person submits on the required schedule acceptable data as required by the final order.

VI. Statutory and Executive Order Reviews

This action, which requires the submission of data in support of tolerances in accordance with FFDCA section 408, is in the form of an order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act (APA), orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

A. Executive Order 12866: *Regulatory Planning and Review and Executive Order 13563*: *Improving Regulation and Regulatory Review*

Because this order is not a "regulatory action" as that term is defined in Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose additional burdens that require approval by OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.). The information collection activities associated with the order requesting data from any party interested in supporting certain tolerances are already approved by OMB under OMB Control No. 2070-0174, and are identified by EPA ICR No. 2288.01. Burden is defined at 5 CFR 1320.3(b). Under the PRA, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after

appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act; Executive Order 13132: Federalism; and Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This order requests data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including States or tribes; nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132 (64 FR 43255, August 10, 1999) and Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538).

E. Executive Order 13045: *Protection of Children from Environmental Health Risks and*

Safety Risks; Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use; and Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

As indicated previously, this action is not a "regulatory action" as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) and Executive Order 13211 (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

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 (NTTAA), (15 U.S.C. 272 note). The Congressional Review Act, 5 U.S.C. 801 *et seq*. does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

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