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Notices

ENVIRONMENTAL PROTECTION AGENCY (EPA)

[EPA-HQ-OPP-2006-0618; FRL-8082-5]

Organophosphate Cumulative Risk Assessment; Notice of Availability

71 FR 43740

DATE: Wednesday, August 2, 2006**ACTION:** Notice.

SUMMARY: This notice announces the availability of EPA's cumulative risk assessment for the organophosphate group of pesticides and opens a public comment period on this document and other support documents. As required by the Food Quality Protection Act (FQPA), a cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate the risk from food, drinking water, residential, and other non-occupational exposures resulting from registered uses of organophosphate pesticides. The organophosphate group includes over 30 pesticides including acephate, azinphos-methyl (AZM), bensulide, chlorethoxyfos, chlorpyrifos, chlorpyrifos-methyl, diazinon, dichlorvos (DDVP), dicrotophos, dimethoate, disulfoton, ethoprop, fenamiphos, fenthion, fosthiazate, malathion, methamidophos, methidathion, methyl-parathion, mevinphos, naled, omethoate, oxydemeton-methyl, phorate, phosalone, phosmet, phostebupirim, pirimiphos-methyl, profenofos, terbufos, tetrachlorvinphos, tribufos, and trichlorfon. Several organophosphate pesticides, however, were not incorporated into the cumulative risk assessment because no dietary, drinking water, or residential human exposure to these pesticides is anticipated from any of the currently registered uses .

DATES: Comments must be received on or before October 2, 2006.**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0618, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2006-0618. 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 Federal 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 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. 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805. [*43741]

FOR FURTHER INFORMATION CONTACT: Kelly Sherman, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-8401; fax number: (703) 308-8005; e-mail address: sherman.kelly@epa.gov; or Kendra Tyler, Special Review and Reregistration Division (7508P); telephone number: (703) 308-0125; e-mail address: tyler.kendra@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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. Background

A. *What Action is the Agency Taking?*

EPA is making available the completed cumulative risk assessment for the organophosphate pesticides. The Agency developed this risk assessment as part of its ongoing process for making pesticide reregistration eligibility and tolerance reassessment decisions. Through these programs, EPA is ensuring that pesticides meet current standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the FQPA.

Section 408(b)(2)(D)(v) of the FFDCA directs the Agency to consider available information on the cumulative risk from substances sharing a common mechanism of toxicity. The Agency determined in 1999 that the organophosphate pesticides share a common mechanism of toxicity, cholinesterase inhibition. The organophosphates have been among EPA's highest priority pesticides for review under FQPA.

In developing the organophosphate cumulative risk assessment and underlying methodologies, EPA consulted with the FIFRA Scientific Advisory Panel numerous times, seeking expert review, advice, and recommendations at each major step of the process. The Agency also met with several of its advisory committees to obtain input from a broad spectrum of stakeholders representing the pesticide industry, environmental and public interest groups, growers, academia, and others, including other federal and state regulatory agencies. EPA issued the Preliminary Organophosphate Cumulative Risk Assessment for public comment in December 2001, and presented the cumulative assessment at a Technical Briefing for the public in January 2002. The Agency released the Revised Organophosphate Cumulative Risk Assessment for public comment in June 2002. The Organophosphate Cumulative Risk Assessment (2006 update) is considered an addendum to the June 2002 assessment, and includes improvements and refinements in assessing the cumulative risks of the organophosphate pesticides. The previous versions of the Organophosphate Cumulative Assessment may be accessed on the EPA website at <http://www.epa.gov/pesticides/cumulative>.

EPA has concluded that the cumulative risks associated with the remaining uses of the organophosphate pesticides are below the Agency's level of concern. While completing reregistration eligibility and tolerance reassessment decisions for individual organophosphates, the Agency also evaluated the cumulative risk posed by this group. Although individual risk assessments were conducted for each of the organophosphate pesticides, several were not incorporated into the cumulative risk assessment because no dietary, drinking water, or residential human exposure is anticipated from any of the currently registered uses of these pesticides.

The Interim Reregistration Eligibility Decisions (IREDs) previously issued for a number of organophosphate pesticides are now considered final; the tolerance reassessment and reregistration eligibility process for these pesticides is complete. EPA has determined that the remaining/reassessed tolerances for these pesticides meet the FFDCA safety standard and that no further risk mitigation is necessary as a result of the organophosphate cumulative risk assessment.

EPA is providing an opportunity, through this notice, for interested parties to provide comments and input on the Agency's completed cumulative risk assessment for the organophosphates. Such comments and input could address the Agency's risk assessment methodologies and assumptions as applied to this cumulative assessment. The Agency will consider all comments received, and make changes, if appropriate, to the organophosphate cumulative risk assessment.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and [*43742] policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to organophosphate pesticides, compared to the general population.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004, (69 FR 26819) (FRL-7357-9) explains that in conducting these programs, EPA is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. The organophosphate pesticides have had extensive opportunities for public comment as part of their reregistration and tolerance reassessment process.

Comments should be limited to issues raised within the organophosphate cumulative risk assessment and associated documents. Failure to comment on any such issues as part of this opportunity will not limit a commenter's opportunity to participate in any later notice and comment processes on this matter. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. Comments will become part of the Agency Docket for the organophosphate cumulative risk assessment. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

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

Section 4(g)(2)(A) of FIFRA, as amended, requires the Administrator to make "a determination as to the eligibility for reregistration (i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a((q)(1)(C))..."

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) of (c)(2) of FFDCA. This review is to be completed by August 3, 2006. A tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2), respectively, if "the Administrator determines the pesticide chemical residue is safe," i.e., "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. 346a(b)(2)(A), and (c)(2)(A). In making this safety finding, FFDCA requires the Administrator to consider, among other factors, "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity..." 21 U.S.C. 346a(b)(2)(D)(v), and (c)(2)(B).

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 20, 2006.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

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