

principles of and the kind of data needed for PBPK modeling, and discusses some approaches for the evaluation and use of PBPK models in the health assessment of environmental agents. PBPK models represent an important class of dosimetry models that are useful for predicting internal doses to target organs. To predict internal dose level, PBPK models use physiological, biochemical, and physicochemical data to construct mathematical representations of processes associated with the absorption, distribution, metabolism, and elimination of compounds. With the appropriate data, these models can be used to extrapolate across species and exposure scenarios, and address various sources of uncertainty in health assessments.

This report addresses the following questions: (1) Why do risk assessors need PBPK models; (2) How can these models be used in risk assessments; and (3) What are the considerations for evaluating whether a PBPK model can be used in a given health assessment of an environmental agent?

The report is not intended to be used as Agency guidance on the use of PBPK modeling and does not specify when to use a PBPK model in health assessments of environmental agents.

Dated: September 14, 2006.

**George W. Alapas,**

*Acting Director, National Center for Environmental Assessment.*

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8221-8; Docket ID No. EPA-HQ-ORD-2006-0756]

### Evaluation of the Carcinogenicity of Ethylene Oxide

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

**ACTION:** Notice of public comment period.

**SUMMARY:** EPA is announcing a 30-day public comment period for the draft document titled, "Evaluation of the Carcinogenicity of Ethylene Oxide" (EPA/635/R-06/003). The document was prepared by the National Center for Environmental Assessment within EPA's Office of Research and Development.

EPA is releasing this draft document solely for the purpose of seeking public comment and for review by the EPA Science Advisory Board (SAB) via a

meeting to be held later in 2006 (time and place to be specified in a separate **Federal Register** notice). This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination. EPA will consider any public comments submitted in accordance with this notice when revising the document.

**DATES:** The 30-day public comment period begins September 22, 2006, and ends October 23, 2006. Technical comments should be in writing and must be received by EPA by October 23, 2006.

**ADDRESSES:** The draft "Evaluation of the Carcinogenicity of Ethylene Oxide" is available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and the Data and Publications menus at <http://www.epa.gov/ncea>. A limited number of paper copies are available from the Technical Information Staff, NCEA-W; telephone: 202-564-3261; facsimile: 202-565-0050. If you are requesting a paper copy, please provide your name, your mailing address, and the document title, "Evaluation of the Carcinogenicity of Ethylene Oxide." Please provide your name, your mailing address, the title, and the EPA number of the requested publication.

Comments may be submitted electronically via [www.regulations.gov](http://www.regulations.gov), by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** For information on the public comment period, contact the Office of Environmental Information Docket; telephone: 202-566-1752; facsimile: 202-566-1753; or e-mail: [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov).

For technical information, contact Henry D. Kahn, D.Sc., NCEA; telephone: 202-564-3269; facsimile: 202-565-0079; or e-mail: [kahn.henry@epa.gov](mailto:kahn.henry@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Information About the Project/ Document**

Ethylene oxide (EtO) is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and as a fumigating agent for spices. The largest sources of human exposure are in occupations involving contact with the gas in production facilities and in hospitals that sterilize

medical equipment. EtO can also be inhaled by residents living near production or sterilizing/fumigating facilities.

This draft assessment document characterizes the potential for a carcinogenic health hazard from human inhalation exposure to EtO. This is accomplished by a weight-of-evidence evaluation as to how likely EtO is to be a human carcinogen, as well as an evaluation of related dose-response information which leads to the development of lifetime cancer risk estimates per unit of exposure. This assessment, when finalized, will be posted to EPA's Integrated Risk Information System (IRIS) database. The document was prepared by EPA's National Center for Environmental Assessment (NCEA). EPA last published a health assessment of the potential carcinogenicity of EtO in 1985 (U.S. EPA, 1985).

The current assessment reviews the more recently developed database on the carcinogenicity of EtO, pertinent data from the 1985 assessment, and several reviews and assessments issued by other organizations (IARC, 1994; Health Canada, 2001; CalEPA, 1999; EOIC, 2001).

#### **II. How To Submit Technical Comments to the Docket at [www.regulations.gov](http://www.regulations.gov)**

Submit your comments, identified by Docket ID No. EPA-HQ-ORD 2006-0756 by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- *E-mail:* [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov).
- *Fax:* 202-566-1753
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The phone number is 202-566-1752.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

If you submit comments by mail or hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an

index, number pages consecutively with the comments, and submit an unbound original and three copies.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-ORD-2006-0756. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless a 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](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.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 [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm).

**Docket:** Documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) 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 materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: September 15, 2006.

**George W. Alapas,**

*Acting Director, National Center for Environmental Assessment.*

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**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2006-0351; FRL-8076-3]

### Pesticides; Draft Guidance for Pesticide Registrants on Use of Antimicrobial Pesticide Products in Heating, Ventilation, Air Conditioning, and Refrigeration Systems

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

**ACTION:** Notice of availability.

**SUMMARY:** The Agency is announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) entitled "Use of Antimicrobial Pesticide Products in Heating, Ventilation, Air Conditioning and Refrigeration Systems." PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular draft PR Notice would, once final, provide guidance to the registrants concerning EPA-registered sanitizer, disinfectant and other antimicrobial products whose labels bear general directions for use on or incorporation within hard, non-porous or porous surfaces, but which are not specifically registered for treatment of Heating, Ventilation, Air Conditioning and Refrigeration Systems (HVAC&R).

**DATES:** Comments must be received on or before November 21, 2006.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0351, 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-2006-0351. 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](http://www.regulations.gov) or e-mail. The Federal [www.regulations.gov](http://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](http://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. 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.