

- 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](http://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:

- Identify the document by docket ID number and other identifying information subject heading, **Federal Register** date and page number.
- 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.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- 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. What Action is the Agency Taking?

EPA is printing a summary of each pesticide petition received under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or amendment of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. EPA has determined that these pesticide petitions contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. Additional data may be needed before EPA rules on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of the petition included in this notice, prepared by the petitioner along with a description of the analytical method available for the detection and measurement of the pesticide chemical residues is available on EPA's Electronic Docket at <http://www.regulations.gov/>. To locate this information on the home page of EPA's Electronic Docket, select "Quick Search" and type the OPP docket ID number. Once the search has located the docket, clicking on the "Docket ID" will bring up a list of all documents in the docket for the pesticide including the petition summary.

## New Tolerances

1. *PP 4F6833.* Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006, proposes to establish a tolerance for residues of the insecticide acetamiprid in or on food commodities cucurbit crop group at 0.5 parts per million (ppm); stone fruit crop group except plum, prune, fresh and dried at 1.2 ppm; plum, prune, fresh and dried at 0.3 ppm; tree nut crop group except almond hulls at 0.1 ppm; almond hulls at 5.0 ppm; and pistachios at 0.1 ppm.

2. *PP 6F7051.* Nippon Soda Co., Ltd. c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006 proposes to establish a tolerance for residues of the insecticide acetamiprid in or on food commodities in bulb vegetables crop group 3 at 3 ppm; edible podded legume vegetables, crop subgroup 6a at 0.5 ppm; succulent shelled pea and beans, crop group 6b, at 0.5 ppm and berries, crop group 13 at 1 ppm.

For both petitions Liquid Chromatography/Mass Spectrometry

(LC/MS/MS) methods is use to measure and evaluate the chemical residue(s).

## List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 12, 2006.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8221-9]

### Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment

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

**ACTION:** Notice of availability.

**SUMMARY:** EPA is announcing the availability of a final report titled, "Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment" (EPA/600/R-05/043F), prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD).

**ADDRESSES:** The document is available electronically through the NCEA Web site at <http://www.epa.gov/ncea>. A limited number of paper copies will be available from the EPAs National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1-800-490-9198 or 513-489-8190; facsimile: 513-489-8695. Please provide your name, your mailing address, the title and the EPA number of the requested publication.

**FOR FURTHER INFORMATION CONTACT:** The Technical Information Staff, National Center for Environmental Assessment/ Washington Office (8623D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone: 202-564-3261; fax: 202-565-0050; e-mail: [nceadc.comment@epa.gov](mailto:nceadc.comment@epa.gov).

**SUPPLEMENTARY INFORMATION:** This final report highlights the benefits of using physiologically based pharmacokinetic (PBPK) modeling and it will be used as a learning tool for EPA scientists and health risk assessors. It describes

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.*

[FR Doc. 06-8053 Filed 9-21-06; 8:45 am]

BILLING CODE 6560-50-P

## 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