

and quality of analyses made by Agency scientists. Members are scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments as to the impact on health and the environment of regulatory actions under sections 6(b) and 25(a) of FIFRA. The Deputy Administrator appoints seven individuals to serve on the FIFRA SAP for staggered terms of 4 years, based on recommendations from the National Institutes of Health and the National Science Foundation.

Section 104 of FQPA (Public Law 104-170) established the FQPA Science Review Board (SRB). These scientists shall be available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP.

#### B. Public Meeting

The FIFRA Scientific Advisory Panel will meet to consider and review issues concerned with processes for regulatory acceptance of and ensuring the quality of data from *in vitro* tests used as alternatives to animal studies for regulatory purposes. A number of such *in vitro* methods have been developed or are under development that use *ex vivo* tissues, cell cultures, or biological constructs as target tissues. Some *in vitro* methods are being developed and marketed as proprietary test methods. Consistent with its goal of obtaining scientifically sound test data for hazard and risk assessment of pesticides and toxic chemicals, EPA is exploring what changes in current policies and procedures may be needed to facilitate the acceptance of data developed using *in vitro* alternatives.

*In vitro* alternatives to animal testing pose some new issues regarding assurance of the reliability and quality of test data. To ensure their ability to detect the adverse effect of concern, new *in vitro* methods typically undergo substantial validation testing before being accepted for regulatory use. However, subsequent changes in the ingredients or processes used to prepare the test system or shifts in the methods or criteria used to interpret the test outcome could lead to failure of the test to perform as it did during the validation. Therefore, a process is needed to ensure consistency and reliability of test performance. In addition, EPA wishes to establish a process and criteria under which additional methods that are mechanistically and functionally similar to an already validated method can seek to qualify for regulatory acceptance without repeating the full range of

validation studies initially conducted to qualify that testing approach.

EPA will consult with the Panel regarding these issues, including performance standards, essential test method components, and quality control of test methods, in the context of three new *in vitro* assays for dermal corrosivity which will be incorporated into its OPPTS 870.2500 test guideline for Acute Dermal Irritation. These assays are: Corrositex®, the rat skin Transcutaneous Electrical Resistance (TER) assay, and EpiDerm™/EPISKIN™.

#### C. FIFRA SAP Meeting Minutes

The FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency in approximately 60 days. The meeting minutes serve as the Panel's report and is the formal summary of its findings. The meeting minutes will be posted on the FIFRA SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

#### List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 16, 2003.

#### J. Thomas McClintock,

Acting Director, Office of Science Coordination and Policy.

[FR Doc. 03-24124 Filed 9-18-03; 12:01 p.m.]

BILLING CODE 6560-50-S

---

#### Environmental Protection Agency

[FRL-7562-2]

#### CSFII Analysis of Food Intake Distributions

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability of final document.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) announces the availability of a final document, *CSFII Analysis of Food Intake Distributions* (EPA/600/R-03/029, March 2003), prepared by the National Center for Environmental Assessment-Washington (NCEA-W), within EPA's Office of Research and Development. The report was compiled by the Exposure Assessment Division of Versar, Inc., in Springfield, Virginia under an EPA contract. NCEA published the *Exposure Factors Handbook* (EFH) in 1997 (EPA/600/P-95/002Fa-c). The handbook provides a summary of the available statistical data on various factors used

in assessing human exposure. The primary source of information on consumption rates of food presented in the handbook is the U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intakes by Individuals (CSFII). It was recommended by the Science Advisory Board that the EFH be kept up-to-date and that food consumption from USDA's most recent national survey be analyzed for an update to the Handbook. The purpose of this report is to present the analysis of the CSFII 1994-96 data for food consumption and to update chapters 9, 11, and 12 of the EFH data.

**ADDRESSES:** The document is available electronically from the NCEA Web site (<http://www.epa.gov/ncea>). A limited number of copies will be available from EPA's National Service Center for Environmental Publications (NSCEP) in Cincinnati, Ohio (telephone: 1-800-490-9198, or 513-489-8190; facsimile 513-489-8695). Please provide the title and EPA number when ordering from NSCEP. Documents also may be ordered via the internet at <http://www.epa.gov/NCEP/home/orderpub.html>. Paper copies may be purchased from the National Technical Information Service (NTIS) in Springfield, VA (1-800-553-NTIS[6847] or 703-605-6000; facsimile 703-321-8547). Please provide the number, PB2003-103268, for this document when ordering from NTIS.

**FOR FURTHER INFORMATION CONTACT:** For further information, please contact Jacqueline Moya (202-564-3245); mailing address: National Center for Environmental Assessment, (8623D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; facsimile: 202-565-0076; e-mail: [moya.jackie@epa.gov](mailto:moya.jackie@epa.gov).

Dated: September 10, 2003.

#### Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 03-24007 Filed 9-18-03; 12:01 pm]

BILLING CODE 6560-50-P

---

#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-7562-4; OAR-2003-0192]

#### Papers Addressing Scientific Issues in the Risk Assessment of Metals

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Availability and Public Comment Period.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is announcing a public comment period ending

November 7, 2003 for the draft documents titled: Issue Paper on the Environmental Chemistry of Metals; Issue Paper on Metal Exposure Assessment; Issue Paper on the Ecological Effects of Metals; Issue Paper on the Human Health Effects of Metals; and Issue Paper on the Bioavailability and Bioaccumulation of Metals. These draft papers are being made available for public comment consistent with EPA's commitment to provide opportunities for external input. Scientific comments received on these papers will be made available to authors for final disposition. The material contained in these papers may be used in total, or in part, as source material for the Agency's framework for metals risk assessment and EPA's evaluation of this material will therefore include consideration of the Assessment Factors recently published by EPA for use in evaluating the quality of scientific and technical information. In addition to written comments, a public meeting will be held during the public comment period for stakeholders to provide additional input to EPA. Meeting logistics, to include registration information, will be announced in a subsequent **Federal Register** Notice. The meeting will be held in the Washington D.C. area.

**DATES:** The public comment period begins September 22, 2003, and ends November 7, 2003. Technical comments should be in writing and must be postmarked by November 7, 2003.

**ADDRESSES:** The draft issue papers are available primarily via the Internet on the Risk Assessment Forum's web page at <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=59052>. A limited number of paper copies are available from EDOCKET. The EPA Office of Environmental Information (OEI) Docket (Docket I.D. No. OAR-2003-0192); telephone: (202) 566-1742; facsimile: (202) 566-1741; e-mail: [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov). Comments may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** For information on the public comment period, contact the Office of Environmental Information Docket; telephone: (202) 566-1742; facsimile: (202) 566-1741; e-mail: [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov).

For technical information, contact Dr. William P. Wood, Executive Director, Risk Assessment Forum, National Center for Environmental Assessment, Office of Research and Development; telephone: (202) 564-3361; facsimile:

(202) 565-0062; or e-mail: [risk.forum@epa.gov](mailto:risk.forum@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA has established an official public docket for this action under Docket ID No. OAR-2003-0192. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Office of Environmental Information (OEI) Docket in the Headquarters EPA Docket Center, (EPA/DC) 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, and the telephone number for the OEI Docket is (202) 566-1742.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide

a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

You may submit comments electronically, by mail, by facsimile, or by hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." Late comments may be considered if time permits.

If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources,"

“Dockets,” and “EPA Dockets.” Once in the system, select “search,” and then key in Docket ID Number. The system is an “anonymous access” system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

Comments may be sent by electronic mail (e-mail) to *a-and-r-Docket@epa.gov*, Attention Docket ID No. OAR-2003-0192. In contrast to EPA’s electronic public docket, EPA’s e-mail system is not an “anonymous access” system. If you send an e-mail comment directly to the Docket without going through EPA’s electronic public docket, EPA’s e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA’s e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA’s electronic public docket.

You may submit comments on a disk or CD ROM that you mail to the OEI Docket mailing address. These electronic submissions will be accepted in WordPerfect, Word, or ASCII file format. Avoid the use of special characters and any form of encryption.

If you provide comments in writing, 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.

### Background

Many EPA programs are faced with deciding whether and how to regulate metals. These decisions range from site-specific assessments performed to determine, for example, whether a site needs remediation and, if so, to what degree; to national-scale assessments where, for example, national air and water quality standards are being developed; to national hazard or risk ranking conducted for purposes of setting priorities for future analysis, action, or information gathering. In recognition of the unique assessment issues raised by metals and the complexity of addressing these issues consistently across the Agency’s various programs, an Agency workgroup, under the auspices of the Science Policy Council, is working to develop an integrated framework for metals risk assessment that will (1) foster consistent application of scientific principles for assessing the hazard and risk for metals, (2) reflect state-of-the-science application of methods and data, (3) incorporate a transparent process (*i.e.*

articulating assumptions and uncertainties), and (4) provide the flexibility to address program-specific issues. Issues discussed in these papers are focused on the inorganic species of metals and metal compounds.

### Role of the Issue Papers

In September 2002, EPA discussed plans for the development of the metals assessment framework and associated guidance with the Agency’s Science Advisory Board (SAB). That discussion included the context and key issues the Agency believed should be addressed in a metals assessment guidance and also identified the anticipated process for development of such guidance. In their review, the SAB expanded and condensed key technical areas into those represented by the five issue papers identified above. The SAB also emphasized the importance of engaging the outside community so as to contribute to the knowledge base the Agency would draw from in developing the subsequent guidance. As part of the effort to engage stakeholders and the scientific community and to build on existing experience, the Agency has commissioned external experts to lead the development of scientific papers on issues and state-of-the-art approaches to metals risk assessment. (Some individual EPA experts contributed specific discussions on topic(s) for which he or she has scientific expertise or knowledge of current Agency practice). Although Agency technical staff, as well as representatives from other Federal agencies reviewed and commented on previous drafts, the comments were addressed at the discretion of each respective author or group of authors. Therefore, the views expressed are those of the authors and do not necessarily reflect the views or policies of the EPA and should not be construed as implying EPA consent or endorsement. Comments of a technical nature received during the public comment period will be provided to Eastern Research Group for disposition by the authors.

### Organizing Questions

For the purpose of organizing comments on the issue papers, the Agency suggests that commenters address the following questions:

1. For the purpose of deriving general principles that can be applied in the assessment of metals, do the issue papers provide an appropriate level of detail?
2. Are there additional chemical, biological and physical processes that should be considered for metals

assessment? If so, please describe and provide references.

3. Are you aware of any models, approaches or methods not considered in the reports that if implemented, would substantially reduce uncertainty in the Agency’s metal assessments? If so, which ones are ready for application now (or in the next few years), and which types of assessments would benefit most from their application (*e.g.*, hazard ranking/characterization, national, or site-specific assessments)?

4. What other suggestions do you have to improve the utility of these papers as the Agency develops a metals assessment framework?

Dated: September 12, 2003.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

[FR Doc. 03-24006 Filed 9-18-03; 12:01 pm]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7562-3]

### Notice of Extension of Public Comment Period on the Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment (External Review Draft)

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

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

**SUMMARY:** This notice extends the comment period for the Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment (External Review Draft). The availability of this document was originally announced in the **Federal Register** on July 30, 2003 (68 FR 44784).

**DATES:** Comments must be received by Wednesday, October 29, 2003.

**ADDRESSES:** The document is available via the Internet from <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55669>.

Instructions for submitting comments are provided in the July 30, 2003 **Federal Register** notice, which is accessible from this Web site.

**FOR FURTHER INFORMATION CONTACT:** Dr. William P. Wood, Risk Assessment Forum (mail code 8601D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, telephone 202-