

ADDRESSES: The draft is available via the Internet at <http://cfpub2.epa.gov/ncea/raf/recordisplay.cfm?deid=55887>.

Comments may be submitted electronically, by mail, or in person, as described in the instructions under Supplementary Information.

FOR FURTHER INFORMATION CONTACT:

Marilyn Brower, Risk Assessment Forum Staff (8601D), 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone: 202-564-3363; fax: 202-565-0061; e-mail: brower.marilyn@epa.gov

SUPPLEMENTARY INFORMATION:

I. Submission of Comments

Electronic comments are preferred and may be sent by e-mail to: risk_forum@epa.gov. Alternatively, comments may be mailed to the Technical Information Staff (8623D), NCEA-W, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, or delivered to the Technical Information Staff at 808 17th Street, N.W., 5th Floor, Washington, DC 20006; telephone: 202-564-3261; facsimile: 202-565-0050. In the case of paper comments, 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.

Please note that all comments received in response to this notice will be placed in a public record. For that reason, comments should not contain personal information (such as medical data or home address), Confidential Business Information, or information protected by copyright.

II. Background

EPA has been investigating ways to improve Agency risk assessments for children in response to recent reports and regulatory initiatives including the 1993 National Academy of Sciences (NAS) report "Pesticides in the Diets of Infants and Children", the Food Quality Protection Act of 1996 (FQPA) and Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risk". One effort undertaken by a Risk Assessment Forum workgroup has been exploring children's exposure assessment issues. Children's behavior changes over time in ways that can have an important impact on exposure and potential dose. Further, children's physiology changes over time in ways that can affect potential dose, internal dose, and susceptibility to certain health effects.

The workgroup has concluded that a major issue facing the Agency is how to consistently consider age-related changes in behavior and physiology when assessing early life stage exposure and potential dose. A key issue is how to capture these changes in an assessment of risks from exposure to environmental contaminants. This issue is critical for scientists involved in preparing exposure assessments applicable to children and for use in evaluating integrated lifetime exposures.

The workgroup's draft guidance provides a recommended set of childhood age groups to promote cross-program consistency in Agency risk assessments for children. In addition, these age groups will guide future analyses of exposure factors data as well as new research and data collection efforts. The recommendations presented are based on discussions held during a July 2000 technical workshop on considering developmental changes when assessing exposures to children and a subsequent expert analysis of existing exposure factors data.

The document is undergoing peer review concurrent with the public comment period described in this notice. This guidance is not a regulation nor is it intended to substitute for federal regulations. It does not establish any substantive "rules" under the Administrative Procedure Act or any other law and will have no binding effect on EPA or any regulated entity.

Dated: September 10, 2003.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 03-24122 Filed 9-18-03; 12:01 pm]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0302; FRL-7327-2]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 2-day consultation meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review issues concerned with ensuring data quality for *in vitro* tests used as alternatives to animal studies for regulatory purposes.

DATES: The meeting will be held on October 28-29, 2003, from 8:30 a.m. to approximately 5 p.m.

Comments. For the deadline for the submission of requests to present oral comments and the submission of written comments, see Unit I.E. of the **SUPPLEMENTARY INFORMATION.**

Nominations. Nominations of scientific experts to serve as ad hoc members of the FIFRA SAP for this meeting should be provided on or before October 2, 2003.

Special seating. Requests for special seating arrangements should be made at least 5 business days prior to the meeting.

ADDRESSES: The meeting will be held at the Holiday Inn Hotel, 1900 North Fort Myer Drive, Arlington, VA. The telephone number for the Holiday Inn Hotel is (703) 807-2000.

Comments. Written comments may be submitted electronically or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

Nominations, requests to present oral comments, and special seating: To submit nominations to serve as an ad hoc member of the FIFRA SAP for this meeting, or requests for special seating arrangements, or requests to present oral comments, notify the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT.** To ensure proper receipt by EPA, your request must identify docket ID number OPP-2003-0302 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Myrta R. Christian, Designated Federal Official, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-8450; fax number: (202) 564-8382; e-mail addresses: christian.myrta@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), FIFRA, and the Food Quality Protection Act of 1996 (FQPA). Since other entities may also 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 DFO listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0302. 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 Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

EPA's position paper, charge/questions to the FIFRA SAP, FIFRA SAP composition (i.e., members and consultants for this meeting) and the meeting agenda will be available as soon as possible, but no later than early October, 2003. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, from the FIFRA SAP Internet Home Page at <http://www.epa.gov/scipoly/sap>.

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 ID 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. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

Public commenters should 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 delivered to the docket will be transferred to EPA's electronic public docket. Public comments in hard copy that are 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.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID 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." EPA is not required to consider these late comments. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, 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.

i. *EPA Dockets.* 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. Once in the system, select "search," and then key in docket ID number OPP-2003-0302. 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.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP-2003-0302. 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.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you deliver as described in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By hand delivery or courier.* Deliver your comments to: Public Information

and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0302. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1. For questions about delivery options, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. Provide specific examples to illustrate your concerns.
5. Make sure to submit your comments by the deadline in this document.
6. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

E. How May I Participate in this Meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2003-0302 in the subject line on the first page of your request.

1. *Oral comments.* Oral comments presented at the meetings should not be repetitive of previously submitted oral or written comments. Each individual or group wishing to make brief oral comments to the FIFRA SAP is strongly advised to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, eastern standard time, October 21, 2003, in order to be included on the meeting agenda. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before the FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. To the extent that time permits, interested persons may be permitted by

the Chair of the FIFRA SAP to present oral comments at the meeting. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

2. *Written comments.* Although submission of written comments are accepted until the date of the meeting (unless otherwise stated), the Agency encourages that written comments be submitted, using the instructions in Unit I.C., no later than noon, eastern time, October 21, 2003, to provide the FIFRA SAP the time necessary to consider and review the written comments. There is no limit on the extent of written comments for consideration by the FIFRA SAP. Persons wishing to submit written comments at the meeting should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** and submit 30 copies.

3. *Seating at the meeting.* Seating at the meeting will be on a first-come basis. Individuals requiring special accommodations at this meeting, including wheelchair access, should contact the DFO at least 5 business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT** so that appropriate arrangements can be made.

4. *Request for nominations to serve as ad hoc members of the FIFRA SAP for this meeting.* The FIFRA SAP staff routinely solicit the stakeholder community for nominations to serve as ad hoc members of the FIFRA SAP for each meeting. Any interested person or organization may nominate qualified individuals to serve on the FIFRA SAP for a specific meeting. No interested person shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency (except EPA). Individuals nominated should have expertise in one or more of the following areas: toxicology, *in vitro* test methods, and biostatistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before October 2, 2003.

The criteria for selecting scientists to serve on the FIFRA SAP are that these persons be recognized scientists—experts in their fields; that they be as

impartial and objective as possible; that they represent an array of backgrounds and perspectives (within their disciplines); have no financial conflict of interest; have not previously been involved with the scientific peer review of the issue(s) presented; and that they be available to participate fully in the review, which will be conducted over a relatively short-time frame. Nominees will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. Finally, they will be asked to review and to help finalize the meeting minutes.

If a FIFRA SAP nominee is considered to assist in a review by the FIFRA SAP for a particular session, the nominee is subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. As such, the FIFRA SAP nominee is required to submit a Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency (EPA Form 3110-48 [5-02]) which shall fully disclose, among other financial interests, the nominee's employment, stocks, and bonds, and where applicable, sources of research support. The EPA will evaluate the nominee's financial disclosure form to assess that there are no formal conflicts of interest before the nominee is considered to serve on the FIFRA SAP. Selected FIFRA SAP members will be hired as a Special Government Employee. The Agency will review all nominations. FIFRA SAP members participating at this meeting 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.

II. Background

A. Purpose of the FIFRA SAP

Amendments to FIFRA enacted November 28, 1975 (7 U.S.C. 136w(d)), include a requirement under section 25(d) that notices of intent to cancel or reclassify pesticide regulations pursuant to section 6(b)(2) of FIFRA, as well as proposed and final forms of rulemaking pursuant to section 25(a) of FIFRA, be submitted to a SAP prior to being made public or issued to a registrant. In accordance with section 25(d) of FIFRA, the FIFRA SAP is to have an opportunity to comment on the health and environmental impact of such actions. The FIFRA SAP also shall make comments, evaluations, and recommendations for operating guidelines to improve the effectiveness

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.

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