

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.

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### 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.

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### 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