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*TECHNICAL COMMITTEE ON INTEGRATION OF  
BIOMONITORING EXPOSURE DATA INTO THE  
RISK ASSESSMENT PROCESS*

HESI Assembly of Members Session

January 19, 2009

*BIOMONITORING TECHNICAL COMMITTEE:  
Leadership*



Co-Chairs:

**Dr. Steven H. Robison**  
(The Procter & Gamble Company)

**Dr. Peter Boogaard**  
(Shell Health)

**Dr. Christina Cowan-Ellsberry**  
(presenting)

# BIOMONITORING TECHNICAL COMMITTEE



## 2008 Industry Members

- Arkema, Inc.
- BASF Corporation
- Bayer CropScience
- Biogen Idec MA Inc.
- The Dow Chemical Company
- E.I. DuPont de Nemours & Co.
- ExxonMobil Biomedical Sciences, Inc.
- The Procter & Gamble Company
- Shell Health

## Public Participation

- Agency for Toxic Substances and Disease Registry
- CDC National Center for Environmental Health
- Institute of Occupational, Social and Environmental Medicine, University of Erlangen (Berlin)
- Johns Hopkins University Bloomberg School of Public Health
- Mississippi State University
- Ohio State University School of Public Health
- University of Leicester
- University of Vermont College of Medicine
- University of Washington
- US Environmental Protection Agency
- US Food and Drug Administration

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# *BIOMONITORING TECHNICAL COMMITTEE*



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## *Mission Statement*

- ❖ To delineate the appropriate scientific use(s) of biomonitoring tools and/or biomonitoring data needed to characterize exposure to chemicals
- ❖ To explore mechanisms for integrating biomonitoring data and toxicology data into a robust risk assessment process.

# *Biomonitoring Projects - Completed*



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- International Biomonitoring Workshop (2004)
- Outlined “common criteria” for biomonitoring
- Presented HESI biomonitoring work to NAS Biomonitoring Committee
- Scientific Session at the 2006 HESI Annual Meeting
- Publication of the *Environmental Health Perspectives* mini-monograph
- Publication of Forum paper in *Toxicological Sciences*

# *Biomonitoring: Common Criteria*



- ❖ Analytical Methods for Biomarkers of Exposure
- ❖ Toxicology/Toxicokinetics
- ❖ Exposure
- ❖ Epidemiology
- ❖ Risk Assessment
- ❖ Risk Management

# 2008: Two Work Groups



- Generic Criteria

- Mission: to formulate criteria for the use and interpretation of biomonitoring exposure data by comparing biological monitoring methodologies in occupational and environmental settings

- Strawman Interpretive Framework

- Mission: to develop a practical method for determining the appropriateness of a biomarker for specific exposures through the use of interpretive criteria

# Environmental Public Health Paradigm



**RISK CHARACTERIZATION**

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**ADVERSE OUTCOME**

**ALTERED STRUCTURE FUNCTION**

**EARLY BIOLOGICAL EFFECT**

**Workshop Focus Area**

**HAZARD IDENTIFICATION**

Modifications to population or toxicology study design

**EXPOSURE**

**DOSE**

- Individual
- Community
- Population

**ENVIRONMENTAL CHARACTERIZATION**

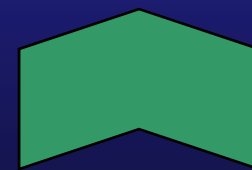
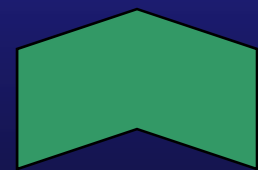
**TRANSPORT/ TRANSFORMATION**

**SOURCE / STRESSOR FORMATION**

**EXPOSURE CHARACTERIZATION**

Benzene case study phase I

Benzene case study phase II



## **Common Criteria**

- Analytical Methods/Biomarkers of Exposure
- Exposure
- Toxicology/Toxicokinetics

## **Common Criteria**

- Epidemiology
- Risk Assessment
- Risk Management



# *Generic Criteria Work Group:*

## *Benzene Case Study*



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Objective: Determine the relationship between benzene exposure and risk

- Develop an understanding of sources of benzene exposure
- Develop an understanding of background sources of benzene metabolites and “typical” ranges
- Develop an understanding of formation and distribution of benzene metabolites in the body
- Integrate CDC/NHANES biomonitoring data on benzene into the case-study
- Develop perspective on biomonitoring data for occupational versus general population exposure
- Develop PBPK models to help put biomonitoring data for benzene into a risk-based context
- Integrate epidemiology data

# *Generic Criteria Work Group: 2009*



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## *Benzene Case Study*

- The final work product of the Work Group will be one or more manuscripts submitted to peer-reviewed scientific journals
  - Manuscript is near completion and anticipated for submission in the first half of 2009
- Continue biomonitoring outreach efforts by presenting work at Society meetings and other venues

# Status of SIF Work Group Activities



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- Completed

- Organized smaller working group
- Agreed upon appropriate framework to fulfill Work Group mission
- Identified and defined key interpretive criteria
- Developed prototype tool for evaluating biomarkers of exposure for specific biomonitoring questions
- Developed beta tool, called *Biomonitoring Weight of Evidence Calculator*, for evaluating biomarkers of exposure for specific exposure questions.
- Conducted 2 independent tests for a benzene example
- Conducted second case study

# SIF Work Group Activities 2009



- Ongoing

- Additional case studies with other examples in progress
- Manuscript is in preparation; anticipated for submission by the close of 2009

- Future

- Convert framework format from Excel to visual program
- Make the framework program publicly available (website)

# *BIOMONITORING TECHNICAL COMMITTEE*

## *2008 & 2009 Planned Outreach*



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### 2008

- Joint Annual Conference of the International Society for Epidemiology/International Society of Exposure Analysis, Pasadena, CA, October 2008 (poster)
- Society for Risk Analysis Annual Meeting, Boston, MA, December 2008 (presentation within platform session)

### 2009

- Plan to submit an abstract for the Annual Conference for the International Society of Exposure Science (ISES), Minneapolis, MN, November 2009

# *Biomonitoring Technical Committee*

## *Future Projects*



### ❖ Generic Criteria Work Group

- ❑ Preparation of a second case study: parabens (part of the CDC-NHANES biomonitoring program)
  - Will allow comparison of benzene case study to a compounds with a different primary route of exposure
  - Expected Outcome: a manuscript to be submitted to the peer-reviewed literature

### ❖ New project proposals solicited from the Committee

- ❑ A request for proposals was issued in November 2008
  - Proposals will be reviewed by the Committee for prioritization in January 2009

# For more information:



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