

## Workshop on **ASSESSMENT OF RESPIRATORY SENSITIZATION**

28-29 May 2014  
Alexandria, VA



Organized by the  
**ILSI Health and Environmental Sciences Institute**  
**Immunotoxicology Technical Committee**



### **Abstract**

Sensitization of the respiratory tract has significant acute and chronic health implications. While the existence of inducers of respiratory sensitization is widely recognized for some classes of chemicals, validated standard methods or frameworks for identifying and characterizing the hazard are not available. This workshop aims to:

- (1) discuss the current state of science for identification and characterization of respiratory sensitizer hazard,
- (2) identify the near-term and long-term information to facilitate development of validated standard methods and frameworks, and
- (3) consider the regulatory and practical needs regarding risk management.

### **Workshop Location:**

Westin Alexandria – Edison D  
400 Courthouse Sq  
Alexandria, VA 22314

### **Charge Questions:**

- What is current state of science for assessment of respiratory sensitizers?
- What are the most relevant immunological mechanisms with regard to sensitization and respiratory allergy?
- What are the relevant real world exposure conditions in the consumer and occupational realm?
- How do we define the condition for respiratory allergens in terms of elicitation vs. sensitization; what defines or represents the adverse outcome?
- What models are available to assess respiratory sensitizers?
- Are there approaches (e.g., single tests or tiered testing strategies) available for: (A) hazard identification chemical respiratory allergens and (B) their relative potency?
- Are there thresholds for sensitization and elicitation, and if so can they be measured?
- Do chemical respiratory allergens have unique physicochemical/structural characteristics?
- Can repeat dose toxicity studies inform assessment of the potential for respiratory allergy? How can various forms of data of contribute to a weight of evidence for respiratory allergy?

# Program

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## Wednesday, 28 May 2014

8:00am *Continental Breakfast (provided; foyer of Edison D)*

### **Session 1: Introduction, Welcome, and Scene Setting**

8:30am – 8:45am **Welcome & Introductory Remarks;  
Definitions, Remit, and Anticipated Deliverables**  
Colin North (ExxonMobil Biomedical Sciences, Inc.)

8:45am – 9:05am **Overview of Previous HESI Initiatives**  
*Ian Kimber (University of Manchester)*

9:05am – 9:40am **Clinical Aspects of Chemical Respiratory Allergy and Occupational Asthma**  
Susan Tarlo (University of Toronto)

9:40am – 9:50am **Q&A for Session 1**

9:50am – 10:05am *Break*

### **Session 2: State of Science for Respiratory Sensitization**

10:05am – 10:30am **Toxicology Challenges: Mechanisms and Routes of Exposure**  
Ian Kimber (University of Manchester)

10:30am – 10:55am **What differentiates respiratory sensitizers from skin sensitizers? Implications  
for predictive toxicity testing**  
Janine Ezendam (National Institute for Public Health and the Environment  
(RIVM), Netherlands)

10:55am – 11:40am **Dose-Response Models for the OEL-Derivation of Chemicals**  
Jürgen Pauluhn (Bayer Pharma)

11:40am – 12:15pm ***In vivo* and *in vitro* models for Prediction of Respiratory Sensitizers**  
Kohji Aoyama (Kagoshima University)

12:15pm – 12:30pm **Q&A for Session 2**

12:30pm – 1:15pm *Lunch (provided; Edison ABC)*

### **Session 3: Non-Conventional Methods and Models for Respiratory Sensitization**

1:15pm – 1:50pm **Overview of *In Vitro* Models**

Erwin Roggen (3Rs Consulting/Novozymes)

1:50pm – 2:25pm

**Omics Analysis for Identification of Respiratory Sensitizers**

Jon Hotchkiss (The Dow Chemical Company)

2:25pm – 3:00pm

**Grouping and Read-across for the Prediction of Respiratory Sensitization**

Steven Enoch (Liverpool John Moores University)

3:00pm – 3:15pm

**Q&A for Session 3**

3:15pm – 3:30pm

*Break*

**Session 4: Practices for Management of Potential Sensitizers**

3:30pm – 3:55pm

**Current Practices for Risk Management**

Cynthia Graham (Huntsman, LLC)

3:55pm – 4:05pm

**Q&A for Session 4**

4:05pm – 4:40pm

**Committee-directed discussion**

Colin North (ExxonMobil Biomedical Sciences, Inc.)

4:40pm – 4:45pm

**Concluding Thoughts from Day 1**

6:00pm

*Cocktail Reception & Networking (Edison ABC)*

**Thursday, May 29 2014**

8:00am

*Continental Breakfast (provided; foyer of Edison ABC)*

**Session 5: Perspectives and Needs for Identification and Management of Respiratory Sensitizers**

8:30am – 8:40am

**Selected Highlights from Day 2/Agenda and Charge for Day 2**

Colin North (ExxonMobil Biomedical Sciences, Inc.)

8:40am – 9:00am

**WHO Guidance on Assessment for Respiratory Sensitization**

MaryJane Selgrade (ICF International; Retired US EPA – Former Chief of Cardiopulmonary and Immunotoxicology Branch)

9:00am – 9:25am

**EU Regulatory Needs – REACH and CLP**

Antti Karjalainen (European Chemicals Agency)

9:25am – 9:45am

Q&A for Session 5

**Session 6: Identifying the Near- and Long-term Information Needs to Develop Standard Methods & Frameworks**

9:45am – 12:15pm	<b>Breakout for Small Group Discussion</b> <i>*See handout for group assignments and instructions</i>
12:15pm – 1:00pm	<i>Lunch (provided; Edison BC)</i>
1:00pm – 2:15pm	<b>Committee-Directed Discussion – Outcomes from Breakout Groups</b> Rapporteurs
2:15pm – 2:30pm	<b>Concluding Remarks</b> Colin North (ExxonMobil Biomedical Sciences, Inc.)
2:30pm	<i>Adjourn</i>