



# Complex environments – Approaches for improving human and environmental exposure assessment

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# Outline

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- **Relevance of exposure assessment**
- **Human exposure assessment**
  - **LRI research approaches on**
    - **Human biomonitoring**
    - **Consumer exposure assessment**
  - **Outlook – Human exposure assessment needs**
- **Environmental exposure assessment**
- **Conclusions**

# Complex environments – Relevance of exposure assessment

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- **Discussion on environment focuses on potential public health effects**
  - **Environment and Health Action Plans for Europe: EU Commission and WHO Europe**
  - **Focus on neurodevelopmental disorders, asthma, transgenerational effects, cancer**
- **New and emerging environmental contaminants may pose further health risks**
- **Environmental health aspects are complex, often multi-causal**
- **Uncertainties lead to increasing use of precautionary approaches in risk management**
- **Tools for assessing complex environmental health problems needed**
  - **Accurate assessment of environmental human exposures essential for risk assessment, but least known**



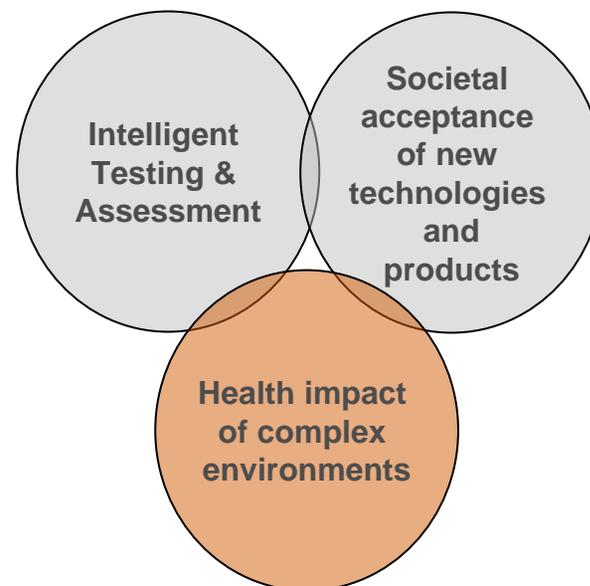
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# Human and environmental exposure assessment

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- **Industry recognises shortcomings in accurate exposure assessment**
- **CEFIC LRI projects**
  - **to advance process of human exposure assessment**
  - **on modeling approaches for more accurate environmental exposure assessment**

## LRI Strategic Themes





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# Human biomonitoring (HBM) as a tool for exposure assessment

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- **HBM reveals information about exposure from all sources and routes – overall exposure**
- **Tool for identification of substances of very high concern (REACH legislation)**
- **Will augment, sometimes replace exposure estimates in assessment of health risks**
- **CEFIC LRI program on HBM**
  - **Provide good HBM data and knowledge on their interpretation**
  - **Enable better risk assessment of chemicals and better public health programs**

# HBM-related LRI projects – Areas covered



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## completed

- **Basic understanding**
  - Methods, interpretation, baseline levels
- **Biomarkers of exposure**
  - Inter- and intraindividual variations among general population and occupational groups

## ongoing

- **Biomonitoring guidance values (BGVs)**
  - Framework for development and application of BGVs
  - Computational tools for derivation of BGVs
- **PBPK\* modeling approaches for interpretation of HBM data**

\*PBPK : Physiologically-based pharmacokinetic

# Political and regulatory impact of HBM-related LRI research

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## Support coherent approach to HBM as indicated by EU Environment & Health Action Plan

- **Communication and networking between stakeholders improved (ICCA LRI HBM Workshops)**
- **CEFIC LRI contributed to advancement of HBM techniques and interpretation of HBM data (What is normal?, variabilities)**
- **More accurate human exposure assessments – optimized risk assessment of chemicals**
- **Enable better public health programs**

# Communication and networking between stakeholders on HBM



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## At ICCA Global Workshops

- **Paris 2005** Common understanding on HBM
- **Minneapolis 2006** Coordination of research programs
- **RTP 2007** Public health applications of HBM
- **Amsterdam 2008** 21st century approaches to toxicity testing, BM and risk assessment
- **Charleston 2009** Connecting innovations in biological, exposure and risk sciences

- **High participation of members of European Commission, U.S. EPA and academia, besides industry**
- **Forum for scientific engagement and exchange between different stakeholders**

**TWENTY-FIRST CENTURY APPROACHES TO TOXICITY TESTING, BIOMONITORING, AND RISK ASSESSMENT**

Renaissance Amsterdam Hotel

16th – 17th June, 2008

CONNECTING INNOVATIONS IN BIOLOGICAL, EXPOSURE AND RISK SCIENCES:  
Better Information for Better Decisions

Charleston Place Hotel, Charleston, South Carolina, United States

June 16–17, 2009

REGISTER ONLINE

An exciting new generation of scientific tools is emerging that can rapidly measure the effects of chemicals on cells, tissues and organisms. The International Council of Chemical Associations' Long-Range Research Initiative (ICCA-LRI) is sponsoring a workshop to stimulate discussions on approaches to translate the data from these new technologies into information that is effective and useful for risk-based decision making.

### Harnessing the New Data: Better Information for Better Decisions

This workshop will assess the growing gap between advancements in the new technologies and the science to interpret and understand the emerging data. Key questions include what research is needed to bridge this knowledge gap; how to harness the data to better inform decisions about public health; and how best to communicate research outcomes as they evolve.



The City of Charleston, South Carolina, is known for its southern hospitality, historical charm, and stunningly beautiful location along the South Carolina coastline. Settled in the early 17th century, it is known as "The Holy City" due to the prominence of historical churches on the city skyline. Charleston is home to tree-canopied streets, historic alleys, award-winning restaurants, majestic homes, and famous events.

### Highlighted Workshop Themes:

1. **Technology** – Effective interpretation of the new biological tools for revolutionizing risk-based decision-making.
  2. **Exposures** – Innovative tools to characterize biologically relevant environmental exposures and their implications for health risks.
  3. **Communication** – Frameworks for appropriately communicating research outcomes.
- Understanding genetic influences and gene-environment interactions for improved assessments of susceptible populations will be a cross-cutting theme.

Posters will be presented from relevant current research conducted in Europe, the United States, and Canada. For more information contact:

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## LRI research on consumer exposure assessment

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- **Consumer exposure data are a necessary tool for the chemical risk assessment for humans**
- **LRI research is aiming at a better understanding of the nature of human exposures to chemicals and implied risks**
- **LRI projects designed to**
  - **improve understanding of sources and magnitudes of exposure**
  - **foster collaboration, exchange and access to exposure data (REACH)**
  - **encourage transparency in exposure assessment**



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## Consumer exposure-related LRI projects

### - Areas covered

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- **Biomarker related research**
- **Approaches for centralization of data and development of new resources for availability of current exposure information**
  - **Handbook and databases on determinants of exposure relevant to European population**
  - **Databases on exposure factors**
  - **Inventories of ongoing exposure research on indoor environment and workplace environment**

# Political and regulatory impact of LRI-related research on consumer exposure assessment

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- **Support of EU Environment & Health Action Plan**
- **Support of WHO Regional Priority Goal IV - reduce risk of disease from exposure to hazardous chemicals**
- **Tools to comply with REACH regulations**
  - **Advancement of HBM improves risk assessment of chemicals for all exposure scenarios**
  - **Databases facilitate exchange of exposure data**
  - **Tools for risk-based management of exposure to environmental chemicals**

# Outlook – Human exposure assessment needs defined at major workshops



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- **IHCP\*/ECETOC workshop on ‘Exposure and risk assessment of chemical mixtures in consumer products’, January 2009:**
  - **Strategies for assessment of aggregate exposure to chemicals in consumers**
  - **Tiered approaches to define when (enhanced) exposure assessment might be useful for risk assessment**
  - **Reliable characterization of exposure/risk across population and within subgroups**
- **ICCA LRI WS, June 2009, Charleston, U.S.:**
  - **Accurate assessment of real-world environmental exposures – an outstanding and a largely unmet challenge**
  - **Traditional chemical risk assessment addressing singular relationships between chemical agents and health effects not sufficient for complex health risks**
    - **Cumulative and integrated exposure assessments for chemicals emerging as new norm**

# Future of LRI-related human exposure research has started

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- **RfP\* on 'Realistic estimation of exposure to substances from multiple sources', 24 months, €400,000**
  - **Development of methodologies to estimate human exposure to substances present in numerous sources**
  - **Development of guidance when aggregate assessment may be required**
  - **Recommendations on type and quality of data required**
  - **Identification of parameters likely to have most influence on exposure estimation outcomes**

\*RfP: Request for Proposal



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# Regulatory impact of LRI research on environmental exposure assessment

- Improved understanding of factors that influence concentrations of chemicals in environment
- Access to more accurate information
- **Development of exposure models** enabling better estimations of predicted environmental concentrations (PECs) of chemicals in different environmental media (e.g. GREAT-ER\*, GEMCO\*\*, TERRACE\*\*\*)
- **Environmental exposure assessment advanced**
- **REACH compliance supported**



\*GREAT-ER: Geography-referenced Regional Exposure Assessment Tools for European Rivers

\*\*GEMCO: Generic Estuary Model for Contaminants

\*\*\*TERRACE: TERrestrial Runoff modelling for Risk Assessment of Chemical Exposures

# Conclusions

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- **Exposure assessment-related LRI research**
  - **delivers on regulatory requirements, societal concerns and political processes**
  - **enables engagement as constructive, competent partner and solution provider**
    - **CEFIC invited as official partner in the EU HBM Pilot Project, kick-off meeting December 1st, 2009 (COPHES\*)**
    - **CEFIC contributing via WBCSD to Children's Environment and Health Action Plan at WHO Ministerial Conference in March 2010**

\*COPHES: COnsortium to Perform Human biomonitoring on a European Scale