



*In partnership with*



East African Network for  
Environmental Compliance  
and Enforcement

REPORT OF THE ENVIRONMENTAL TOXICOLOGICAL RISK  
ASSESSMENT WORKSHOP HELD AT THE LAICO REGENCY  
HOTEL, NAIROBI, KENYA ON JUNE 21-23 2016



*Supported by*



## 1.0 Objectives of the Workshop

- i. Introduce East African scientists in the area of toxicology/environmental science to contemporary concepts of risk assessment; and,
- ii. Establish the basis for a regional network, i.e. East African network in toxicology/risk assessment, e.g. East African Society of Toxicology).

## 2.0 Workshop participants

The forum brought together 45 scientists, policy makers, regulatory officials and communication specialists from East Africa. Facilitators and resource persons included scientists with vast experience in toxicology, health and environmental risk assessment from Denmark, South Africa, Italy and USA with diverse backgrounds in academia, government and business.

## 3.0 Organizers

### International Organizers:

International Union of Toxicology (IUTOX): Prof. Herman Autrup (President, IUTOX) and Prof. Mary Gulumian, Vice President and Chair of Developing Countries Subcommittee, IUTOX)

### Local organizer:

Environmental Compliance Institute (ECI – [www.eci-africa.org](http://www.eci-africa.org)) and East African Network for Environmental Compliance & Enforcement (EANECE – [www.eanece.org](http://www.eanece.org)):  
- Gerphas Opondo (Executive Director, ECI and Regional Coordinator, EANECE)

### Funding:

The workshop was funded by a grant from the American Chemistry Council Foundation, with additional support from CropLife Africa Middle East

## 4.0 Faculty



*Herman Autrup, PhD,  
Fellow ATS, Professor  
Emeritus, Denmark*



*Emanuela Testai, PhD,  
ISS, Rome, Italy*



*Mary Gulumian, PhD,  
Professor, National  
Institute of Occupational  
Health (NIOH), and  
University of the  
Witwatersrand, S. Africa*



*Sabitha Papineni, DVM,  
PhD, Senior Toxicologist,  
Dow AgroSciences, USA*

## 5.0 Agenda

The workshop ran for three days. The format of the workshop combined expert presentations, facilitated discussions with Q&A sessions. Day 1 covered a *General Introduction to Risk Assessment*; Day 2 covered *Endocrine Disrupting Chemicals* and Day 3 covered *Risk Assessment Case Studies and Regulation*. The detailed agenda is annexed to this report, and details of the various sessions are summarized below.

## 6.0 Opening Session

### Welcoming Remarks by Gerphas Opondo-ECI/EANCE

The welcoming remarks were delivered by ECI Executive Director/EANECE Regional Coordinator, Mr. Gerphas Opondo. He gave a brief overview of ECI and EANECE and thereafter outlined the background to and objectives of the workshop. He acknowledged the invaluable financial contribution of America Chemistry Council Foundation and support of Crop Life Africa Middle East towards the workshop. He pointed out that the envisaged formation of an East Africa Society of Toxicologists, if actualized, would provide a platform for East African scientist to exchange information and share experiences on the subject of toxicology and risk assessment. He urged participants to seriously consider the idea.

### Prof. Remarks by Mary Gulumian - IUTOX

Prof. Gulumian, Vice President and chair of Developing Countries Subcommittee, IUTOX expressed her happiness and pleasure that the workshop was finally taking place after several years of planning. She acknowledged the invaluable efforts of ECI and EANECE in organizing and lobbying East African scientists, policy makers and institutions of higher learning to attend the workshop. She stressed the importance of forming a regional network of toxicology and risk assessment in East Africa and pointed out that IUTOX was ready and willing to work with the society if formed.

### Remarks by Prof. Herman Autrup- IUTOX

Prof. Herman, President of IUTOX, acknowledged and thanked the various groups of participants represented at the workshop - government officials, NGOs, policy makers, academicians, communicators and scientists. He expressed his happiness to see many people from Africa in the workshop and stated that he is ready to work with them in IUTOX. He proceeded to give a brief overview of IUTOX. He pointed out that West Africa has formed an association of toxicologists and that it is also important for East Africa to form a regional network, e.g. East Africa Toxicological Society. Prof. Autrup expressed optimism that the 3 days of the workshop would yield fruitful deliberations, exchange of ideas and experiences, and that participants would come up with good recommendations for future toxicology and risk assessment work in East Africa.

## 7.0 Presentations

(Note: The full texts of all the presentations in PDF are available separately and will be uploaded on the ECI Website)

### **Day One: General Introduction to Risk Assessment**

#### **i. Living in a Chemical World - by Herman Autrup**

This presentation and discussion covered the following areas:

- Natural vs. Synthetic chemicals
- Challenges of chemicals use and safety
- Chemicals in our daily lives
- Where chemicals are used
- The Janus face chemicals – risk vs. benefits
- Life expectancy and chemical production
- Hazard vs. Risk
- The dose makes the poison
- Different ages – different focus
- WHO/IARC evaluation of carcinogens
- Problems of risk assessment
- Reasons why people fear chemicals
- Chemicals in the blood
- Diseases where chemicals may be involved in the etiology
- Key sources of chemical exposure
- Risk Sources
- Potential mechanism of toxicity
- Epidemics of omics
- Who is at risk?

#### **ii. Introduction to the risk assessment process and Hazard vs. Risk - by Herman Autrup**

The key elements of this presentation and discussion were as follows:

- Risk assessment paradigm
- Brief description of hazard and risk
- Elements of risk assessment (Hazard identification, hazard characterization, hazard assessment and risk characterization)
- Risk assessment steps (problem formulation, hazard identification, exposure assessment, Risk analysis and risk management and classification)
- Compounds of special concern (bioaccumulation, food chain compounds etc.)
- Regulations for chemicals in EU

**iii. Introduction to the IPSC WHO Risk Assessment Toolkit - by Herman Autrup**

The areas covered in the presentation and discussions were:

- IPSC/ WHO Assessment tool kit
- Brief description of SAICEM
- Purpose of the toolkit

**iv. Tools to identify hazards – animal, human and invitro – by Emanuela Testai**

This presentation and discussion covered the following areas:

- Characteristics of experimental and epidemiological studies
- Brief description of OECD and its role in research & guidelines>genetic guidelines, repro-and developmental toxicology
- Good laboratory practice ( GLP)
- Criteria for which evidence is scored ( reliability, relevance and adequacy)

**v. Weight of evidence approach and quality of data – Emanuela Testai**

The key elements covered in this presentation and discussions were:

- Importance of weight relevance approach (used for conflicting results.)
- Threshold of toxicological concern (TTC) ( low, moderate and high toxicity)
- Types of models in toxicology
- Use of invitro studies in risk assessment

**vi. Exposure assessment - by Herman Autrup**

This presentation and discussion covered the following areas:

- Definition and elements of exposure assessment
- Routes of exposure ( Dermal, inhalation, injection and oral ingestion)
- Basic characteristics of exposure (agents, magnitude, frequency and duration)
- Types of exposure scenarios(occupation, consumers and indirect environmental exposures)
- Levels of exposure assessment (environmental monitoring, personal monitoring, biomarkers and modelling)

**vii. The importance of exposure assessment in the risk assessment process- by Mary Gulumian**

The presentation and discussion covered the following areas:

- Overview of Health Risk Assessment (why Health Risk assessment?)
- Elements of hazard identification( Human toxicology, Ecotoxicity to aquatic and avian organisms and environmental hazards)
- Approaches to exposure assessment (Bottom-up and Top-down approaches)
- Challenges of pesticide exposure modelling in Africa (lack of human and technical capacity, lack of local input data e.tc)

## Day Two: Endocrine Disrupting Chemicals (EDC)

### **viii. International definition of endocrine disrupting compounds and monotonic vs. non-monotonic dose response relationship - by Emanuela Testai**

The key elements of this presentation and discussion were:

- General overview of endocrine disrupting compounds (definition of chemical endocrine disruptors, mechanisms with which a chemical interfere with endocrine system)
- Decision tree for MNDR
- Framework for testing and assessing endocrine disrupting chemicals
- Standard guidelines for assessing EDC

### **ix. Sensitive populations: the unborn child - by Herman Autrup**

This presentation covered the following areas:

- General introduction to childhood
- Cases of Global child death
- Why are children more susceptible? (Children have more years of future life, Unaware of the risk and no voice in decision making, Protection of children is the core of sustainability of the human species etc).
- Issues in Children and Health (Asthma, respiratory diseases, allergies, Neurodevelopmental disorder Male genital malformations (hypospadias, cryptorchidism) and Childhood cancer)
- Early exposures of children to chemicals

### **x. Sensitive populations: the inter-individual susceptibility- by Emanuela Testai**

The key issues covered in this presentation and discussion included:

- Objectives of biotransformation
- Susceptibility factors
- Environment-gene interaction
- Gene factors in risk assessment

### **xi. Case study: Risk assessment of DEHP (SCENIHR opinion) - by Emanuela Testai**

This presentation and discussion covered case studies in the assessment of DEHP. Among the issues covered in this case study included:

- Overview of DEHP
- Sources of exposure to DEHP (Food, Transfusion of blood components, premature neonates in intensive care unit etc.)and,

- Toxicokinetics of DEHP

**xii. Case study: Bisphenol – EFSA evaluation - by Emanuela Testai**

This presentation and discussion covered the following areas:

- Description of bisphenol
- Criteria for recognizing relevant toxicological studies and,
- Identification of exposure scenarios for medical devices

**xiii. Risk assessment of endocrine disruptors: US Endocrine Disruptor Screening Program and Implications - by Sabitha Papineni**

The key elements of this presentation and discussion were:

- A Brief History of Endocrine Disruption Issue
- What is Endocrine Disruption?
- US EPA: Endocrine Disruptor Screening Program (EDSP)
- How the EDSP Works?
- Priority List 1 – 2009-2012
- Priority List 2 – Issued in 2013
- Tier 1 assays
- Tier 2 tests
- Weight-of-Evidence (WoE) evaluations
- EU Approach towards Endocrine Disruption.

**xiv. The importance of exposure assessment in the risk assessment process (continued)- by Marry Gulumian**

The presentation and discussion covered the following broad areas:

- Non-carcinogenic chemicals
- Carcinogens
- Risk vs. Exposure
- Dose – Response assessment
- Use of mode of action in assessment of potential carcinogens
- Risk characterization
- Endocrine disruptors

### **Day 3: Risk Assessment Case Studies and Regulation**

**xv. Regulations in Europe ( including Reach) and in the US - by Herman Autrup & Emanuela Testai**

The key areas covered in this this presentation and discussion were as follows:

- Registration of chemicals
- Determinants of exposure (work place, time of activity and substance used, form of substance and location of activity)

- Regulations of chemicals (industrial chemicals, biocides, food additives, food contact materials, toys safety and cosmetics)
- Risk management measures and safety instructions ( user friendly packaging, limited concentration, spill contaminants measures and limitation of market and use)
- Pesticides regulations in Europe (labelling for carcinogenic substances, skin protection etc.)

**xvi. Exposure to complex mixtures- by Herman Autrup**

The key issues covered by this presentation and discussion were:

- Overview of mixtures used in real life (Simple mixtures vs Complex mixtures, Similar mixtures, cumulative exposures etc)
- Effects of mixtures( Synergistic, additive and inhibitory effects)
- Major groupings of mixtures
- Dose response
- WHO/IPCS framework for assessing risk from combined exposures( tiered characterization of exposures, analysis of risk and tiered characterization of responses)

**xvii. Integrated risk assessment – Organotin - by Herman Autrup**

The outline of the presentation and discussion was as follows:

- Historical use of organotin
- Major uses of organotin (as pesticide, biocide, synthesis-food preservative, insole for shoes etc.)
- Effects of organotin ( Bone mineralization, suspected endocrine disruption, inducer of TBT)
- Hazard characterization of organotin
- Sources of organotin (Plastic bags, food, flooring materials, napkins, medical devices etc.)
- Exposure assessment of organotin
- Risk management

**xviii. Uses of toxicokinetic data in toxicology testing for Agrochemicals- by Sabitha Papineni**

The key elements of the presentation were:

- Overview of toxicokinetic data
- Uses of toxicokinetic data ( select dose level, understand species differences and calculation of internal exposures)



**xix. Environmental Issues and Human Health: Cyanotoxins and their relevance for Africa - by Emanuela Testai**

The key elements of this presentation were:

- General introduction to cyanotoxins
- Distribution of cyanotoxins ( deserts, Nile Delta)
- Environmental factors affecting cyanobacterial population toxicity
- Routes of human exposure to cyanotoxins( oral, dermis, inhalation and Hemodialysis)
- Effects of cyanotoxins(topical effects and systematic effects)
- Critical issues in evaluating human risk/exposure

**8.1 Would an East Africa Society of Toxicology and Risk Assessment help us?**

The idea of setting up an East Africa Society of Toxicology and Risk Assessment was welcomed by the participants. Below are some of the benefits outlined by the participants:

- The envisaged Society will:
  - provide a platform for interaction and information sharing by East African scientists;
  - help in building the capacity of scientists from East Africa on toxicology and risk assessment;
  - provide a forum for East African scientists to give opinions on scientific papers published by international institutions such as EPA and IARC on what is relevant to Africa;
  - provide opportunities for East African scientists to participate in international meetings organized by IUTOX; and
  - Provide a platform for East African scientists to share experiences with other scientists from different parts of Africa.

In order to take the idea of the society for toxicology and risk assessment forward, participants proposed a task force to oversee the process of the formation of the society. The specific terms of reference, modalities and procedures of the task force will be worked out in the going forward. ECI coordinate the work of the task-force and help in the process of getting the society registered. The following participants volunteered to be part of the task force:

No.	Name	Email Address
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16.	Tara Barwa	<a href="mailto:tarabarwa@gmail.com">tarabarwa@gmail.com</a>

## **9.0 Participants Evaluation of the Workshop**

The following is a consolidated analysis of the workshop evaluation by participants:

- i. Overall Evaluation:
  - 80% Good
  - 20% Fair
  - 0% Low
- ii. Relevance of the Workshop:
  - 58% Very relevant
  - 42% Relevant
  - 0% Not relevant
- iii. Subjects participants would want covered in the next workshop:
  - Air pollution
  - Investigation of toxicological accidents
  - Current regulatory practice by EU and USA regulatory bodies as well as WHO, UNEP and FAO
  - Exposure Assessment Models for African setting
  - Information sharing among African countries on Epidemiological data
  - Funding for risk assessment in Africa
  - Toxicological effect on wild animals
  - Endocrine disruptors management and monitoring in Africa
  - Analysis of Cyanotoxins
  - Toxicology knowledge management
  - Environmental toxicological risk assessment in relation to chemicals and health
  - Exposure data ( post registration ) as a tool for risk mitigation in African context
- iv. Would you like a practical case study on risk assessment?
  - 100% Yes
  - 0% No

## 10.0 Annexes

### *Annex I: Selected Photos*

















## Annex 2: Agenda

Day 1 - June 21, 2016 General Introduction to Risk Assessment		
TIME	SESSION	FACILITATOR
08.00 – 09.00	Registration	ECI/EANECE
09.00-09.15	Welcome and objectives of the workshop	Gerphas Opondo/Mary Gulumian/Herman Autrup
09.15-10.00	Living in a chemical world	Herman Autrup
10.00-10.30	TEA/COFFEE BREAK	
10.30-11.15	Introduction to the risk assessment process and Hazard vs. Risk	Herman Autrup
12.00-12.45	Introduction to the IPCS WHO Risk Assessment Toolkit	Herman Autrup
13.00-14.00	LUNCH	
14.00-14.30	Tools to identify hazards – animal, human and invitro	Emanuela Testai
14.45-15.15	Weight of evidence approach and quality of data	Emanuela Testai
15.30-16.00	Exposure assessment	Herman Autrup
16.15-1700	The importance of exposure assessment in the risk assessment process	Mary Gulumian
1700	ADJOURN	
Day 2 - June 22, 2016 Endocrine Disrupting Chemicals		
09.00-09.30	International definition of endocrine disrupting compounds and monotonic vs. non- monotonic dose response relationship	Emanuela Testai
09.45-10.15	Mode of actions of EDC- Experimental approaches to identify EDC	Emanuela Testai
10.30-11.00	TEA/COFFEE BREAK	
11.00-11.45	Sensitive populations: the unborn child	Herman Autrup
12.00-12.45	Sensitive populations: the inter-individual susceptibility	Emanuela Testai
13.00-14.00	LUNCH	
14.00 – 14.30	Case study: Risk assessment of DEHP (SCENIHR opinion)	Emanuela Testai
14.45 – 15.15	Case study: Bisphenol – EFSA evaluation	Emanuela Testai
15.30 – 16.00	Risk assessment of endocrine disruptors: US Endocrine Disruptor Screening Program and Implications	Sabitha Papineni
16.15 – 17.00	The importance of exposure assessment in the risk assessment process..... continued	Mary Gulumian
17.00	ADJOURN	
Day 3- June 23, 2016 Risk Assessment Case Studies and Regulation		

09.00-09.30	Regulation in Europe (including Reach) and in the US	Emanuela Testai/ Herman Autrup
0.945 -10.15	Exposure to complex mixtures	Herman Autrup
10.15-10.45	TEA/COFFEE	
10.45 -11.15	Integrated risk assessment – Organotin	Herman Autrup
11.30- 12.00	Use of toxicokinetic data in toxicity testing for Agrochemicals	Sabitha Papineni
12.15-12.45	HESI Risk 2I – risk assessment with limited data	Herman Autrup
13.00-14.00	LUNCH	
14.00-15.00	Environmental Issues and Human health: Cyanotoxins and their relevance for African Countries	Emanuela Testai
15.00	Adjourn	Herman Autrup/Gerphas Opondo
15.15-16.00	Would an East African Society of Toxicology and Risk Assessment help us?	Mary Gulumian
16.00	CLOSING	

### Annex3: List of Participants

NO	NAME	POSITION	INSTITUTION	COUNTRY	EMAIL ADDRESS
<b>GOVERNMENT/REGULATORS</b>					
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		Inspector	Management Authority (NEMA)		
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