

Intelligent Testing Strategies for REACH: Endpoints BCF and Skin Sensitization

Third Stakeholder Workshop, 1 and 2 March 2010,
Federal Institute for Risk Assessment (BfR), Berlin, Germany

Program 1st of March 2010

13.00 On-site Registration, Coffee and Communication

BASIC REQUIREMENTS FOR TEST AND NON-TEST PROCEDURES WITHIN REACH

14.00 **Welcome and Introduction**
Prof. Dr. Dr. Andreas Hensel, Head of BfR, Berlin

14.15 **Agenda**
Prof. Dr. Ortwin Renn, DIALOGIK and University of Stuttgart, Germany

14.20 ***In silico* Models: Risk Assessment with non-testing methods in OSIRIS – opportunities and limitations**
Prof. Dr. Gerrit Schüürmann, Helmholtz Centre for Environmental Research – UFZ, Germany

15.00 **OSIRIS webtool: An integrated Framework for non-testing methods – conditions and requirements of using ITS in the REACH process**
Dr. Dinant Kroese, TNO Quality of Life, Zeist, The Netherlands

15.30 Coffee break

Bioconcentration factor and skin sensitization in the OSIRIS web tool: Demonstration and hand-on use of ITS

16.00 **Endpoint “Bioconcentration Factor” (BCF)**

- Non-testing tool development in OSIRIS
- Requirements of the end-point within REACH
- Weight of Evidence (WoE) and ITS

Dr. Monika Nendza, Analytisches Laboratorium, Luhnstedt, Germany
Dr. Alessandra Roncaglino, Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy



17.00 **BCF hands on experience: break-out groups**

- Brief case study introduction for the break-out groups
- Break-out groups

Dr. Alessandra Roncaglino, Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy

Dr. Monika Nendza, Analytisches Laboratorium, Luhnstedt, Germany

18.00 **World Café BCF: Coffee and Communication**

- Method and Procedure of BCF: compatibility with REACH?
- Coping with uncertainty: methods of characterization and their impacts for regulation
- Regulatory conditions and requirements: How can they be integrated in the testing procedures and the scientific protocol?

New Insights from the cases and the demonstrations

18.45 **Results of the World Cafe: panel discussion with the chairs/hosts of the tables**

Prof. Dr. Ortwin Renn, University of Stuttgart and DIALOGIK Stuttgart, Germany

19.30 End of the first day

19.45 Dinner

20.30 **After Dinner Speech:
Toxicity Testing in the 21st Century: Challenges and Opportunities**

Prof. Dr. Daniel Krewski, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, Canada (requested)



Program 2nd of March 2010

8.30 Morning Coffee and Communication

9.00 **Summing up the first day – agenda for the second day**

Dr. Mark Cronin, Pharmacy & Biomolecular Sciences, Liverpool John Moores University, UK

9.15 **Titel**

Dr. Manfred Liebsch, Centre for Alternative Methods to Animal Experiments – ZEBET, BfR, Berlin, Germany

9.45 **Endpoint “Skin Sensitization”**

- Non-testing tool development in OSIRIS
- Requirements of the end-point within REACH
- Weight of Evidence (WoE) and ITS

Dr. Mark Cronin, Pharmacy & Biomolecular Sciences, Liverpool John Moores University, UK

Dr. Joanna Jaworska, Procter & Gamble, Brussels, Belgium

Emiel Rorije, National Institute for Public Health & the Environment (RIVM), Bilthoven, The Netherlands

N.N., BfR, Berlin, Germany (requested)

11.00 **Skin Sensitization hands on experience: break-out groups**

- Brief case study introduction for the break-out groups
- Break-out groups

Dr. Mark Cronin, Pharmacy & Biomolecular Sciences, Liverpool John Moores University, UK

Dr. Joanna Jaworska, Procter & Gamble, Brussels, Belgium

Emiel Rorije, National Institute for Public Health & the Environment (RIVM), Bilthoven, The Netherlands

N.N., BfR, Berlin, Germany (requested)

12.00 **World Café “Skin Sensitization”: Coffee and Communication**

- Method and Procedure of Skin Sensitization: compatibility with REACH?
- Coping with uncertainty: methods of characterization and their impacts for regulation
- Regulatory conditions and requirements: How can they be integrated in the testing procedures and the scientific protocol?



New Insights from the cases and the demonstrations

12.45 **Results of the World Cafe: panel discussion with the chairs/hosts of the tables**

Christina Benighaus, DIALOGIK Stuttgart, Germany

13.30 **Conclusion and Farewell**

Prof. Dr. Gerrit Schüürmann, Helmholtz Centre for Environmental Research – UFZ, Germany

13.45 Adjourn and lunch