

## Intelligent Testing Strategies for REACH:

# Endpoints BCF and Skin Sensitization

### INTEGRATED TESTING STRATEGIES FOR REACH – ENDPOINTS BCF AND SKIN SENSITIZATION

OSIRIS and the BfR invite you to its 3rd Stakeholder Workshop to be held 1 and 2 March 2010 at the Federal Institute for Risk Assessment (BfR), Berlin, Germany. This workshop will give you an overview about integrated testing strategies in relation to REACH and in-depth knowledge of the two endpoints BCF and Skin Sensitization. Experts from industry, academia and government will present new insights, demonstrate hands-on experience about BCF and Skin sensitization and will explain how they can be used in REACH.



The workshop will help you to get the scientific background behind the integrated testing strategies and match the REACH requirements.

- **Method and Procedure of BCF and Skin Sensitization:**  
compatibility with REACH?
- **Coping with uncertainty:**  
which are the 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?

#### YOU SHOULD ATTEND, WHEN YOU WANT TO

- Discuss new approaches of integrated testing strategies and their potential for REACH, such in vitro testing, QSAR's, and read across.
- Gain new insights and hand on experience of two endpoints BFC and Skin Sensitization
- Ask and discuss your REACH requirements with experts from industry, academia and government.

#### TARGET AUDIENCE: BFC AND SKIN SENSITIZATION EXPERTS

The target audiences are REACH multipliers, stakeholders from industry, scientists, end-users in industry and regulatory authorities (EU-Stakeholders) working on REACH related testing strategies.

**THIRD STAKEHOLDER WORKSHOP,  
1 AND 2 MARCH 2010,  
in cooperation with the Federal Institute  
for Risk Assessment (BfR), Berlin, Germany**

Check the programme and register at [www.osiris-reach.eu](http://www.osiris-reach.eu)



#### PLEASE NOTE

Travel and accommodation: Participants are expected to organize and cover the cost of their own travel and accommodation themselves. We will not be able to offer any reimbursement for travel expenses or accommodation. In cases of special need we can finance parts of travel expenses. Please contact us.

#### VENUE

Federal Institute for Risk Assessment (BfR)  
Location Marienfelde  
Diedersdorfer Weg 1  
D – 12277 Berlin  
Tel.: + 49-30-84-12-0

#### DOWNLOAD OF A MAP

- > [www.bfr.bund.de/cd/5533](http://www.bfr.bund.de/cd/5533)
- > [www.bfr.bund.de/cm/255/arrival\\_marienfelde.pdf](http://www.bfr.bund.de/cm/255/arrival_marienfelde.pdf)

**Registration is open now  
until the 22 February 2010  
deadline.**

#### FOR MORE INFORMATION OF THE WORKSHOP PLEASE CONTACT

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The project is funded by the European Commission within in the 6th Framework Programme under the theme „Global Change and Ecosystems“, coordinated by Prof. Dr. Gerrit Schüürmann at the Helmholtz Centre for Environmental Research-UFZ, Permoserstr. 15, 04318 Leipzig, 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. Dr. hc. Ortwin Renn, University of Stuttgart, Germany
- 14.20 In silico Models: Risk Assessment with non-testing methods in OSIRIS – opportunities and limitations**  
Dr. Mark Cronin, Pharmacy & Biomolecular Sciences, Liverpool John Moores University, UK
- 14.45 OSIRIS webtool: An integrated Framework for non-testing methods**  
Dr. Dinant Kroese, TNO Quality of Life, Zeist, The Netherlands
- 15.15 Validation of testing strategies**  
Dr. Manfred Liebsch, Centre for Alternative Methods to Animal Experiments – ZEBET, BfR, Berlin, Germany
- 15.30 Coffee break**

### BCF: DEMONSTRATION AND HAND-ON USE OF ITS

- 16.00 Endpoint „Bioconcentration Factor“ (BCF)**
- Requirements of the end-point within REACH
  - Non-testing tool development in OSIRIS
  - Weight of Evidence (WoE) and ITS
- Dr. Monika Nendza, Analytisches Laboratorium, Luhnstedt, Germany  
Dr. Alessandra Roncaglioni, Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy
- 17.00 BCF hands on experience: break-out groups**
- 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

### NEW INSIGHTS FROM THE CASES AND THE DEMONSTRATIONS

- 18.45 Results of the World Cafe: panel discussion**  
Prof. Dr. Dr. hc. Ortwin Renn, University of 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

## 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

### EXAMPLE FOR A SCIENTIFIC VALIDATED NON-TESTING SYSTEM

**9.15 BfR Decision Support System (DSS) for local effects**  
Dr. Matthias Herzler, BfR, Berlin, Germany

### SKIN SENSITIZATION: DEMONSTRATION AND HAND-ON USE OF ITS

- 9.30 Endpoint „Skin Sensitization“**
- Sensitization testing in the frame of REACH: Any reliable in vitro alternatives in sight
  - Requirements of the end-point within REACH
  - Non-testing tool development in OSIRIS
  - Weight of Evidence (WoE) and ITS
- PD Dr. Dr. Andreas Luch, BfR, Berlin, Germany  
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
- 11.00 Skin Sensitization hands on experience: break-out groups**
- 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

### NEW INSIGHTS FROM THE CASES AND THE DEMONSTRATIONS

- 12.45 Results of the World Cafe: panel discussion**  
Christina Benighaus, DIALOGIK Stuttgart, Germany
- 13.30 Conclusion and Farewell**  
Dr. Mark Cronin, Pharmacy & Biomolecular Sciences, Liverpool John Moores University, UK
- 13.45 Adjourn and lunch**

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