Thursday, 9th October 2014

10:00–10:30 a.m. Registration

10:30–11:00 a.m.
Welcome and introduction
Alfonso Lampen, BfR, Germany

Session 1: Use of Omics Techniques in Toxicology – Overview

Chair: Thomas Noll, CeBiTec, Germany and Jean-Lou Dorne, EFSA, Italy

11:00–11:25 a.m.
Recent advances in toxicotranscriptomics
Richard Paules, NIEHS, USA

11:25–11:50 a.m.
Recent advances in toxicometabolomics
Bennard van Ravenzwaay, BASF, Germany

11:50–12:15 a.m.
Toxicogenomics and systems toxicology-practical implications for risk assessment
Jan Hengstler, IfADo, Germany

12:15 a.m.–1:30 p.m. Lunch Break

Session 2: Use of Omics Techniques in Experimental and Regulatory Toxicology - Examples

Chair: Marianne Dybdahl and Hendrik Frandsen DTU, Denmark

1:30–1:55 p.m.
Impact of toxicoproteomics on the risk assessment of 3-MCPD-Esters
Alfonso Lampen, BfR, Germany

1:55–2:20 p.m.
***Omics* data to evaluate a mode of action**
Remi Bars, Bayer, France

2:20–2:45 p.m.
***Omics* data to evaluate low dose and combination effects**
Rudolf Pfeil, BfR, Germany

2:45–3:15 p.m. *Coffee Break*

Session 3: Use of Omics Techniques in Regulatory Toxicology – Perspectives

Chair: Thierry Mercier, ANSES, France
Brigitte Landesmann, JRC, Italy

3:15–3:40 p.m.
Combination of omics and in vitro methods – application and validation
Thomas Hartung, JHSPH, USA

3:40–4:05 p.m.
Is there a need for new uses of *omics* data in regulatory toxicology?
Jos Kleinjans, UM, Netherlands

4:05–4:30 p.m.
Considerations about the application of *omics* techniques in chemical risk assessment
David Bell, EChA, Finnland

4:30–4:45 p.m.
Introduction to break out groups

Break Out Group 1: Combination of *omics* and *in vivo* methods – a way forward to get more information from toxicity studies?

Chairs: Vera Rogiers, VUB, Belgium and Richard Currie, Syngenta, UK; Rapporteurs: Lars Niemann and Flavia Schmidt, BfR, Germany

Break Out Group 2: Combination of *omics* and *in vitro* methods – a way forward to reduce animal testing?

Chairs: Thomas Hartung, JHSPH, USA and Fozia Noor, US, Germany; Rapporteurs: Michael Oelgeschlaeger and Svenja Rieke, BfR, Germany

4:45–6:30 p.m.
Break out group session 1

8:00 p.m. Joint Dinner

Friday, 10th October 2014

09:00 – 10:30 a.m.
Break out group session 2

10:30 – 11:00 a.m. Coffee Break

11:00 – 12:15 a.m.
Presentation of results

12:15 a.m.–1:15 p.m. Lunch Break

Session 4: Regulatory application of *omics* and in vitro methods – a way forward to improve risk assessment?

Chair: Alfonso Lampen and Roland Solecki, BfR, Germany; Rapporteur: Philip Marx-Stoelting, BfR, Germany

1:15 – 1:40 p.m.
Regulatory toxicology in the 21st century
Tewes Tralau, BfR, Germany

1:40 – 3:15 p.m.
Final discussion

3:15–3:30 p.m.
Concluding remarks and outlook
Rudolf Pfeil, BfR, Germany

3:30–3:45 p.m.
Closure of the workshop
Professor Dr. Dr. Andreas Hensel
President of the BfR

Workshop on Application of *Omics* Data in Regulatory Toxicology

International Expert Workshop on Application of *Omics* Data in Regulatory Toxicology

Omics methods have been applied in experimental toxicology for more than a decade. They have successfully been used for mechanistic analysis of toxic effects, inter-species- or *in vivo*- / *in vitro*-comparison.
Several authorities have already started to implement the use of *omics* methods for purposes such as the identification of adverse outcome pathways or mode of action analysis. *Omics* methods may contribute to the grouping of toxic substances and identification of sensitive subgroups, and may also be used for priorization for further testing within an integrated testing strategy.

Prior to a general utilization of *omics* data in regulatory toxicology several issues need to be clarified, including 1) requirements on data quality and analysis, 2) biological relevance of effects detected by *omics* methods and 3) identification of areas of regulatory toxicology for which these methods might be used.

First of all, quality criteria for *omics* data need to be discussed taking into account recommendations of already existing initiatives. This includes but is not limited to an appropriate documentation of the experiment, appropriate statistics and standardization of experimental settings and bioinformatics tools used for the interpretation of respective data sets. To be used in regulatory toxicology, data would have to elaborated, stored and made available to relevant authorities in an appropriate manner. Additionally, *omics* experiments, statistics and bioinformatics analysis of data would have to be performed in accordance with standardized procedures to ensure reproducibility of results and respective interpretations.

Second, biological relevance of effects observed at molecular level needs to be assessed. This should take into account correlation between adversity observed on a tissue, organ or whole-organism level and respective findings by *omics* methods. Furthermore, one focus should be on the identification of signalling pathways that lead to adverse outcomes and to confirm findings on altered signalling pathways by multi-level *omics* and approaches from systems biology.

Third, areas of regulatory toxicology where *omics* methods are intended and foreseen to be applied are the identification of a mode of action or of molecular initiating events and respective signalling pathways. In this context it should be noted that several initiatives and research projects exist to take *omics* methods further and to use such data for the identification of adverse effects as well as for quantitative aspects in regulatory toxicology like the derivation of no adverse effect levels and respective thresholds, especially for substance classes where animal testing has been prohibited. Additionally *omics* methods may facilitate grouping of chemicals. Within integrated testing strategies they may also help to prioritize substances for further toxicity testing.

Announcement

We are delighted to announce an International Expert Workshop on the Application of *Omics* Data in Regulatory Toxicology in Berlin on 09-10 October 2014.
The workshop will be organised by the Federal Institute for Risk Assessment (BfR).

The forthcoming workshop brings together experts from academia, regulatory bodies and industry, to discuss these issues and find recommendations for a way forward to implement *omics* techniques in the regulatory decision process.

Correspondence

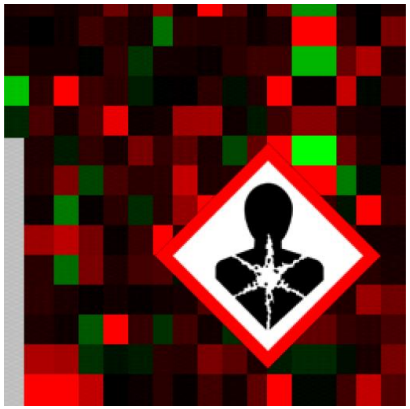
Dr. Philip Marx-Stoelting
Federal Institute for Risk Assessment
Max-Dohrn-Straße 8–10, 10589 Berlin, Germany
E-Mail: omicsworkshop@bfr.bund.de ; www.bfr.bund.de

Location

Federal Institute for Risk Assessment; Lecture Room
Diedersdorfer Weg 112277 Berlin (Marienfelde)
For directions, please click here:
www.bfr.bund.de/de/standort_marienfelde-5409.htm

FEDERAL INSTITUTE FOR RISK ASSESSMENT

Application of *Omics* Data in Regulatory Toxicology



International Expert Workshop

9th and 10th October 2014, Berlin

BfR
Bundesinstitut für Risikobewertung