

8.00 – 9.00	Registration and check of the software implementation on participants' laptops	
INTRODUCTION		
9.00 – 9.30	Welcome Introduction on OSIRIS and ITS	Gerrit Schüürmann, UFZ
9.30 – 9.45	Demo of the OSIRIS Webtool	Eduard Pauné, SIMPPLE
SKIN SENSITISATION		
9.45 – 10.30	Background REACH requirements, ITS Introduction skin sensitisation ITS webtool	Emiel Rorije, RIVM Tom Aldenberg, RIVM
10.30 – 11.00	Coffee Break	
11.00 – 12.45	Demo of skin sensitisation ITS webtool with concrete examples Practical application including exercises by participants	Emiel Rorije, RIVM Tom Aldenberg, RIVM
12.45 – 13.15	Feedback: skin sensitisation ITS (questionnaire distributed in addition)	Emiel Rorije, RIVM Tom Aldenberg, RIVM
13.15 – 14.15	Lunch Break	
REPEATED DOSE TOXICITY		
14.15 – 15.00	Background REACH requirements, ITS Introduction repeated dose toxicity webtool	Sylvia Escher, FhG Inga Tluczkiwicz, FhG
15.00 – 16.00	Demo of repeated dose toxicity ITS webtool with concrete examples Practical application including exercises by participants	Sylvia Escher, FhG Inga Tluczkiwicz, FhG
16.00 – 16.30	Coffee Break	
16.30 – 17.15	Demo of repeated dose toxicity ITS webtool with concrete examples Practical application including exercises by participants (continued)	Sylvia Escher, FhG Inga Tluczkiwicz, FhG
17.15 – 17.45	Feedback: repeated dose toxicity ITS (questionnaire distributed in addition)	Sylvia Escher, FhG Inga Tluczkiwicz, FhG
19:00	Dinner	

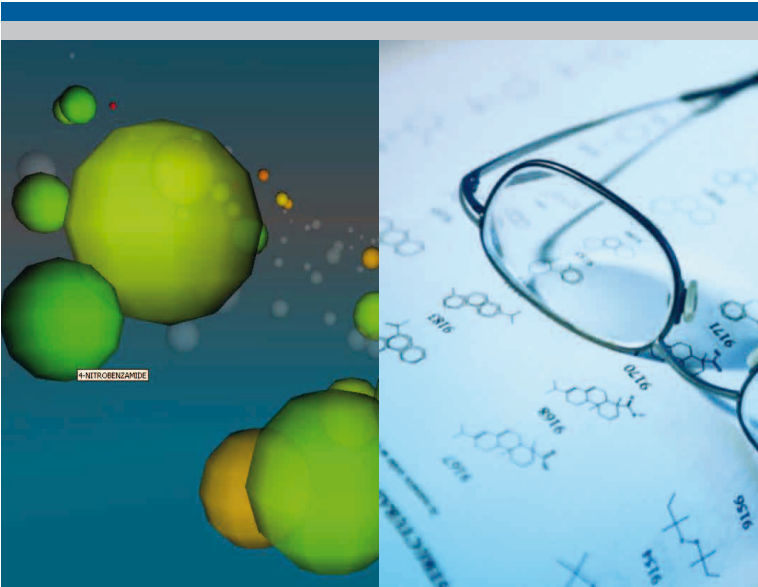
8.00 – 9.00	Registration and check of the software implementation on participants' laptops	
BIOCONCENTRATION FACTOR		
9.00 – 9.45	Background REACH requirements, ITS Introduction BCF webtool	Monika Nendza, AL Alessandra Roncaglioni, IRFMN
9.45 – 10.30	Demo of BCF ITS webtool with concrete examples Practical application including exercises by participants	Anna Lombardo, IRFMN, Alessandra Roncaglioni, IRFMN
10.30 – 11.00	Coffee Break	
11.00 – 12.00	Demo of BCF ITS webtool with concrete examples Practical application including exercises by participants (continued)	Anna Lombardo, IRFMN, Alessandra Roncaglioni, IRFMN
12.00 – 12.30	Feedback: BCF ITS (questionnaire distributed in addition)	Anna Lombardo, IRFMN, Alessandra Roncaglioni, IRFMN
12.30 – 13.30	Lunch Break	
AQUATIC TOXICITY		
13.30 – 14.00	Background REACH requirements, ITS	Alessandra Roncaglioni, IRFMN, Anna Lombardo, IRFMN
14.00 – 15.00	Introduction aquatic toxicity webtool and associated ITS workflow	Anna Lombardo, IRFMN Alessandra Roncaglioni, IRFMN
15.00 – 15.15	Feedback: aquatic toxicity ITS (questionnaire distributed in addition)	Alessandra Roncaglioni, IRFMN, Anna Lombardo, IRFMN
15.15 – 15.45	Coffee Break	
MUTAGENICITY & CARCINOGENICITY		
15.45 – 16.15	Background REACH requirements, ITS	Dinant Kroese, TNO Emiel Rorije, RIVM
16.15 – 17.15	Introduction mutagenicity & carcinogenicity webtool and associated ITS workflow	Dinant Kroese, TNO Emiel Rorije, RIVM
17.15 – 17.30	Feedback: mutagenicity & carcinogenicity ITS (questionnaire distributed in addition)	Dinant Kroese, TNO Emiel Rorije, RIVM

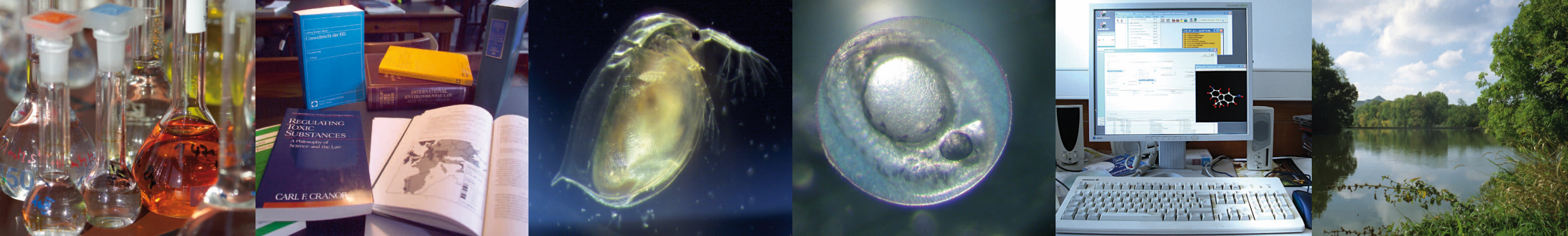


Stakeholder Workshop

Integrated Testing Strategies

8 - 9 March 2011, Leipzig





Optimised strategies for the risk assessment of chemicals

According to [REACH](#) (Registration, Evaluation, Authorisation and Restriction of Chemicals), the new European legislation on chemicals and their safe use, all [industrial chemicals](#) produced or imported in quantities above 1 t/y have to be evaluated regarding their [toxicological and ecotoxicological effects](#). Considering the currently used testing schemes, this procedure is expected to result in a significant increase in animal tests. However, REACH also aims at [reducing animal testing](#) where possible.

OSIRIS is developing [Integrated Testing Strategies \(ITS\)](#) considering both non-test and test information and thus combining different approaches for the hazard and risk evaluation of chemicals. ITS shift risk assessment from a "box-ticking" approach with extensive animal testing to a more efficient, context-specific and substance-tailored approach. The underlying principle is to take advantage of existing information, to group information about similar substances, and to integrate exposure considerations in the decision making.

The [complementary alternative approaches](#) considered include:

- chemical and biological read-across
- qualitative/quantitative structure-activity relationships (QSAR)
- in vitro testing
- (existing) in vivo information
- chemoassays
- omics
- thresholds of toxicological concern (TTC)
- exposure analysis and exposure-based waiving.

The different information is weighted and the respective uncertainties taken into account in a [Weight of Evidence](#) approach.

OSIRIS Webtool

The methods and ITS developed are implemented in the [webbased OSIRIS Tool](#), which will be made available to the public for end-users from industry, regulatory authorities and academia.

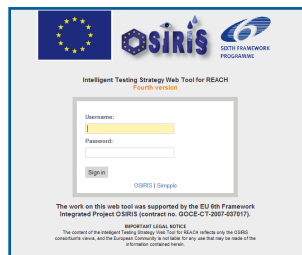
The following [endpoints](#) are included in the Webtool:

- skin sensitisation
- mutagenicity & carcinogenicity
- repeated dose toxicity
- aquatic toxicity
- bioconcentration factor.

Two [uncertainty reasoning schemes](#) are implemented with the OSIRIS Consensus Tool: Bayesian Networks and Dempster-Shafer theory of evidence. A [Chemical Space Navigation Tool](#) has been integrated as visual aid for pre-screening tasks.

The Webtool also includes [interfaces to locally installed QSAR software](#) for generating in silico predictions including information about respective application domains (ChemProp, OECD (Q)SAR Application Toolbox, ...).

The OSIRIS Webtool indicates what tests (if any) should be performed in order to satisfy REACH data requirements. Data used and decisions taken are documented.



OSIRIS Stakeholder Workshop

The OSIRIS ITS Stakeholder Workshop will be held on [Tuesday 8 March – Wednesday 9 March 2011](#) at the [Helmholtz Centre for Environmental Research - UFZ](#) in Leipzig, Germany.

Key stakeholders and experts from regulatory authorities, industry and academia are invited to test the methods and Integrated Testing Strategies developed within OSIRIS. The [feedback](#) for the final phase of the project will be highly appreciated.

The Workshop addresses the five ITS implemented in the OSIRIS Webtool. The ITS presentation and discussion will include:

- Background information on the ITS
- Demonstration of the ITS Webtool with concrete examples
- Practical application and exercises
- Feedback.

Registration:

You may register for the whole workshop or for specific endpoint sessions. Please register via email to osiris-workshop@ufz.de until [28 February 2011](#). Please specify upon registration the endpoints the sessions of which you plan to attend.

A laptop will be required for the practical application exercises. There is no conference fee.

Venue:

Leipziger KUBUS
Helmholtz Centre for Environmental Research – UFZ
Permoserstraße 15
04318 Leipzig
Germany

More information on the workshop and the venue as well as contact details are available at www.osiris-reach.eu.