

OSIRIS Newsletter

No. 1

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- The OSIRIS Project: Goal, Partners, Structure
- OSIRIS Meetings
- OSIRIS Workshops



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OSIRIS in the World Wide Web

<http://www.osiris-reach.eu>



- Objectives
- Partners
- Project Structure
- REACH
- Events and Activities
- OSIRIS Training
- Useful Links
- Open Positions at OSIRIS Partner-Institutes

OSIRIS Goal

The new European law on chemicals and their safe use **REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)** entered into force on 1 June 2007. While it is based on the precautionary principle, it includes also the aim to **reduce animal testing** where possible.

The goal of OSIRIS is to develop **integrated testing strategies (ITS)** fit for REACH that enable to significantly increase the use of non-testing information for regulatory decision making, and thus to minimise the need for animal testing.

To this end, operational procedures are developed, tested and disseminated that guide a transparent and scientifically sound evaluation of chemical substances in a **risk-driven, context-specific and substance-tailored** manner.



OSIRIS Partners

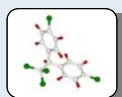
OSIRIS has **31 Partners** from **14 European countries**.



24 Research institutes / universities
 5 Small and medium-sized enterprises
 2 Manufacturers of chemicals and chemical products

Participant Name	Short name	Country
Helmholtz Centre for Environmental Research	UFZ	DE
Universitat Rovira i Virgili	URV	ES
Liverpool John Moores University	LJMU	UK
University of Bern (UB)	UB	CH
National Institute of Public Health and the Environment	RIVM	NL
Technical University of Denmark	DTU	DK
TNO Quality of Life	TNO	NL
Istituto Di Ricerche Farma-cologiche "Mario Negri"	IRFMN	IT
Procter & Gamble, Company	P&G	BE
Eidgenössische Technische Hochschule Zürich	ETHZ	CH
Istituto Superiore de Sanità	ISS	IT
Universiteit Antwerpen	UA	BE
Vrije Universiteit Amsterdam	VU	NL
Enginieria de Sistemas, SME	SIMPPLE	ES
Kiwa Water Research	KIWA	NL
Institute of Public Health of the Republic of Slovenia	IVZ RS	SI
National Institute of Chemical Physics and Biophysics	NICPB	EE
ECT Oektoxicologie GmbH, SME	ECT	DE
Fraunhofer-Institut für Toxikologie und Experimentelle Medizin	FhG	DE
Aarhus Universitet	AU	DK
Stockholm University	SU	SE
Bourgas "Prof. As. Zlatarov" University	LMC	BG
Merck KGaA, Company	Merck	DE
Environmental Microbial Genomics Group - UMR CNRS 5005	CNRS	FR
Nofer Institute of Occupational Medicin	NIOM	PL
Joint Research Centre	JRC	IT
University of Exeter	UNEXE	UK
Analytisches Laboratorium, SME	AL	DE
DIALOGIK, SME	DIA	DE
Cyprotex PLC, SME	CYPROTEX	UK
University of Wageningen	WUR	NL

The 5 interlinked OSIRIS Research Pillars



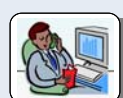
Pillar 1: Chemical Domain
Develops methods and guidance for transparent and scientifically sound use of chemistry-driven information in ITS.



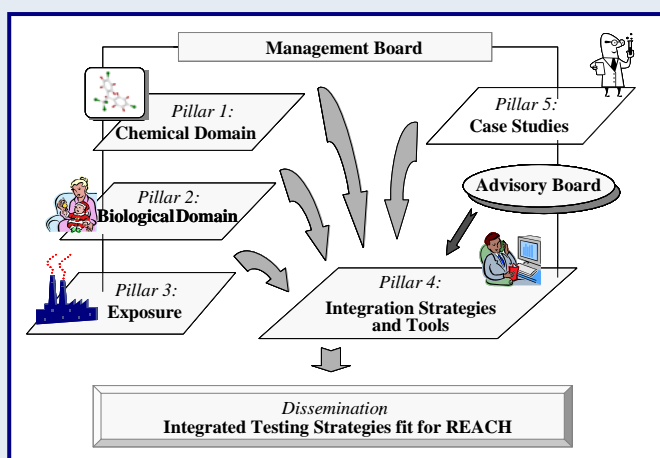
Pillar 3: Exposure
Develops criteria for exposure informed testing as foreseen in the REACH regulation, and refines relevant exposure assessment methods accordingly.



Pillar 2: Biological Domain
Provides efficient strategies and guidance for exploitation of all types of biological information on toxic effects of chemicals in ITS, focusing on reduced animal use and informed extrapolation across human and environmental toxicology, species, endpoints and time scales.



Pillar 4: Integration Strategies and Tools
Develops weight-of-evidence approaches for ITS based on a computerised decision theory framework ready for web access, optimising the use of existing data and non-test information, and minimising the need for new testing in risk assessment procedures.



Pillar 5: Case Studies
Evaluates the feasibility and effectiveness of the new ITS methodologies and provides guidance for their use in concrete form, covering major human and environmental endpoints.

OSIRIS Co-ordinator:

Prof. Dr. Gerrit Schüürmann

OSIRIS Project manager:

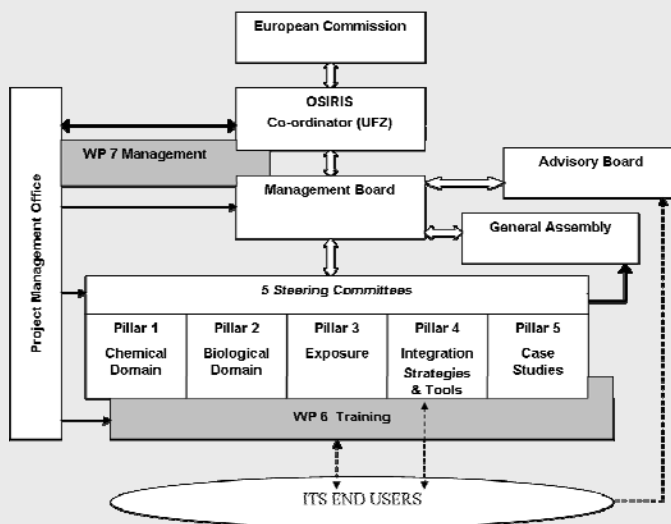
Dr. Andrea Richarz

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Helmholtz Centre for
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04318 Leipzig
Germany

OSIRIS Management Structure

- Project Co-ordinator:**
 responsible for general scientific and administrative management, intermediary to the **European Commission**
- Project Management Office**
 (at the UFZ)
- Management Board:**
 supports the Co-ordinator
- Advisory Board:**
 platform for targeted communication and interaction with external experts, stakeholders and end-users
- General Assembly** of all Partners
- Steering Committees:**
 managing the activities of the 5 research Pillars, each headed by a **Pillar Co-ordinator**
- Workpackage Leaders:**
 responsible for managing activities at the workpackage level



OSIRIS Management Board

Function	Member	Deputy
Project Co-ordinator	Gerrit Schüürmann, UFZ	Andrea Richarz, UFZ
Pillar 1 Co-ordinator		Francesc Giralt, URV
Pillar 2 Co-ordinator	Mark Cronin, LJMU	Helmut Segner, UB
Pillar 3 Co-ordinator	Theo Vermeire, RIVM	Stefan Trapp, DTU
Pillar 4 Co-ordinator	Han van de Sandt, TNO	Emilio Benfenati, IRFMN
Pillar 5 Co-ordinator	Martin Scheringer, ETHZ	Joanna Jaworska, P&G
Cross-cutting Co-ordinator of Modelling Work	Francesc Giralt, URV	Ovanes Mekenyan, LMC
Cross-cutting Co-ordinator of Experimental Work	Helmut Segner, UB	Ronny Blust, UA
Cross-cutting Co-ordinator of Training Activities (WP 6)	Andrew Worth, JRC	Emilio Benfenati, IRFMN

1st OSIRIS Stakeholder Workshop

DIA organised the First Stakeholder Workshop on **28-29 November 2007** in **Stuttgart, Germany** to enable early communication with and input from outside experts.

The main objective was to receive feedback from the participants on the overall scientific approach and the further shaping of the project work. To this end, representatives of Pillar 4, coordinated by Han van de Sandt, **presented the project status**, highlighting major issues of discussion such as the selection of priority endpoints, respective selection criteria (animal use, costs, time, scope for alternative approaches and non-test methods).

The discussion with the stakeholders was organised in the form of a **Group Delphi** (group discussions and justification of results in the plenum). 24 scientific experts from industry, academia, and regulatory agencies attended the workshop; 21 experts took part in the Group Delphi itself. The advantage of Delphi is to find the common ground among the experts, and the reasons and arguments that cause differences in assessments.



The **stakeholders provided suggestions for setting priorities** with respect to endpoints and software for *in silico* work, and **expressed preferences and needs** to guide further work on the integrated testing strategies as addressed in Pillar 4.

Overall, the stakeholder workshop was very successful, providing both valuable input and positive feedback on the OSIRIS plans for developing ITS.

SETAC Europe Special Science Symposium (SESSS)

Integrated Testing Strategies for REACH: from Science to practical implementation

OSIRIS will actively participate in the SETAC Europe Special Science Symposium on REACH that will take place on **23-24 October 2008 in Brussels** as first of a new series of conferences organised by SETAC.

The symposium will serve as major international platform for presenting the ITS methodology as a means to provide REACH-relevant hazard and risk information about chemical substances, and to support respective regulatory decision making.

The OSIRIS Co-ordinator is member of the Steering Committee and there will be several **presentations from OSIRIS Partners** at the symposium.

Accordingly, OSIRIS will have opportunity to present major achievements of the project to an international audience of stakeholders covering industry, governmental authorities and academia, and to get feedback on the ITS methodology developed by that time.

OSIRIS First Annual Meeting in Milan

The OSIRIS First Annual Meeting was held on **11–13 March 2008** at the Istituto di Ricerche Farmacologiche Mario Negri (**IRFMN**) in **Milan, Italy**.

On the first day, the five Research Pillars and Workpackage 6 summarised the **first year results** as well as ongoing activities and presented highlights from the different workpackages.

The second and third day focused on the preparation of the **annual report** and the next 18-month planning.

Furthermore, the **feedback** received so far **from Stakeholders** – at the First OSIRIS Stakeholder Workshop and from the Advisory Board – was reported.

During all three meeting days, Pillars and workpackages had the opportunity for **discussion** in several Pillar break-out meetings.



On the third day, all Pillars including Workpackage 6 presented their planned objectives, deliverables and milestones for the **next 18 months** in the plenum. Pillar and workpackage interactions were discussed.



2nd OSIRIS Stakeholder Workshop

The Second OSIRIS Stakeholder Workshop will be held on **Monday, 17 November 2008** in **Brussels, Belgium**, organised by DIALOGIK.

It is scheduled to start on 9:30 and to end on 17:00 to make arrival and departure on the same day possible.

More detailed information on the programme and venue will follow.

OSIRIS Training Course for PhD Students and Young Researchers

The first training course for PhD students and young researchers took place on **10 March 2008** at the **IRFMN** in **Milan, Italy**.

37 students, young researchers and guests from 10 countries participated in this training course organised by IRFMN.

The aim was to give the **theoretical basis for Intelligent Testing Strategies (ITS)** components envisaged for REACH, based on the respective work performed in OSIRIS.

9 speakers (from OSIRIS Partners involved in WP 6) gave lectures on the following **5 main topics**:



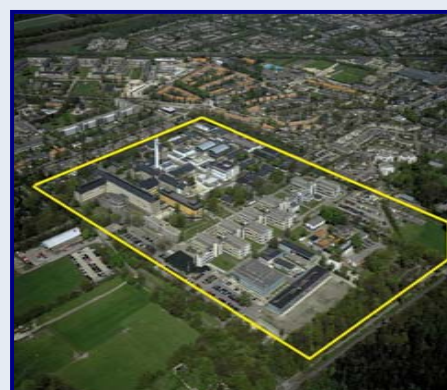
- Introduction on risk assessment
- Ecotoxicological hazard / risk assessment
- *In silico* hazard assessment
- Exposure assessment
- Decision making in risk assessment.

A **webspaces** dedicated to the training course has been created in the OSIRIS intranet, with the aim of giving the training course participants a place for discussion.

Forthcoming OSIRIS Meetings

The next Annual meetings are scheduled as follows:

- **16-18 March 2009**, **RIVM**, Bilthoven, The Netherlands
- March 2010, **LJMU**, Liverpool, UK
- March 2011, **URV**, Tarragona/Barcelona, Spain.
- The final meeting will take place at the **UFZ**, Leipzig, Germany in September 2011.



RIVM, Bilthoven



Liverpool



URV, Tarragona



UFZ, Leipzig

Conference Calendar: OSIRIS-related Events

5th SETAC World Congress

Society of Environmental Toxicology and Chemistry

3-7 August 2008, Sydney, Australia

<http://www.setac2008.com>

2nd EuCheMS Chemistry Congress

European Association for Chemical and Molecular Sciences

16-20 September 2008, Torino, Italy

<http://www.euchems-torino2008.it/site/home.asp>

3rd Joint Meeting of the SETAC-GLB and GDCh

Society of Environmental Toxicology and Chemistry (SETAC GLB), German Chemical Society (GDCh)

23-26 September 2008, Frankfurt/Main, Germany

<http://www.setac-glb.org>

ESTIV2008 - 15th International Congress on In Vitro Toxicology

Organised by European Society of Toxicology In Vitro (ESTIV), Scandinavian Society for Cell Toxicology (SSCT) and Expertrådet

25-28 September 2008, Stockholm, Sweden

<http://www.estiv2008.org>

EUROTOX 2008 - 45th Congress of the European Societies of Toxicology

From Toxins to Omics: Health, Safety and Well-being

5-8 October 2008, Rhodes, Greece

<http://www.eurotox2008.org>

SETAC Europe Special Science Symposium

Integrated Testing Strategies for REACH: from Science to practical implementation

23-24 October 2008, Brussels, Belgium

<http://reach.setac.eu>

EPAA Annual Conference 2008

European Partnership for Alternative Approaches to Animal Testing

Annual conference 2008: « 3 Rs Research »

3 November 2008, Brussels, Belgium

http://ec.europa.eu/enterprise/epaa/index_en.htm

SETAC North America 29th Annual Meeting

Society of Environmental Toxicology and Chemistry

16-20 November 2008, Tampa, Florida, USA

<http://tampa.setac.org>

EMEC9 - 9th European Meeting on Environmental Chemistry

Association of Chemistry and the Environment

3-6 December 2008, Girona, Catalonia, Spain

<http://www.udg.edu/tabid/10391/Default.aspx/Welcome/tabid/10391/language/ca-ES/Default.aspx>

SETAC Europe 19th Annual Meeting

31 May-4 June 2009, Göteborg, Sweden

<http://www.setaceumeeting.org>

ICCE 2009 - 12th EuCheMS International Conference on Chemistry and the Environment

European Association for Chemical and Molecular Sciences

14-17 June 2009, Stockholm, Sweden

<http://www.chemsoc.se/sidor/KK/icce2009.htm>

EUROTOX 2009 - 46th Congress of the European Societies of Toxicology

13-17 September 2009, Dresden, Germany

<http://www.eurotox2009.org/home.asp>

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OSIRIS is a EU 6th Framework Integrated Project,
contract no. GOCE-CT-2007-037017.

