

OSIRIS: Dissemination of Integrated Testing Strategies as Risk Assessment Support Tools Contributing to the 3Rs



A. Richarz¹, M.T.D. Cronin², T.G. Vermeire³, J.J.M. van de Sandt⁴, M. Scheringer⁵ and G. Schüürmann¹

¹ UFZ Department of Ecological Chemistry, Helmholtz Centre for Environmental Research, Leipzig, Germany, ² School of Pharmacy and Chemistry, Liverpool John Moores University, Liverpool, UK, ³ National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands, ⁴ TNO Quality of Life, Zeist, The Netherlands, ⁵ Safety and Environmental Technology Group, Institute for Chemical and Bioengineering, ETH Zürich, Switzerland
andrea.richarz@ufz.de <http://www.osiris-reach.eu>

The OSIRIS Project



According to the new European legislation on chemicals REACH, the (eco-)toxicological effects of all industrial chemicals produced or imported in quantities above 1 tonne/year have to be evaluated, resulting in an **expected significant increase in animal tests**, contrary to the goal of REACH to reduce animal testing. Therefore, other strategies have to be adopted to reduce the number of animal experiments.

OSIRIS (Optimised Strategies for Risk Assessment of Industrial Chemicals through Integration of Non-Test and Test Information) aims to develop **integrated testing strategies (ITS)** for risk assessment of chemicals, considering different information sources, and thus **to contribute to the 3R's**.

ITS shift risk assessment from a "box-ticking" approach with extensive animal testing to a more efficient, context-specific and substance-tailored approach.

The framework envisaged in OSIRIS comprises a Weight-of-Evidence approach based on qualitative and quantitative structure-activity relationships (QSARs), chemical and biological read-across, data from *in vitro* tests, chemoassays and *omics*, as well as thresholds of toxicological concern and exposure-based waiving.

Dissemination of ITS results to **industry, regulatory agencies, NGOs** and **academia** is a vital part of the OSIRIS project.



Stakeholder Communication

- **Stakeholder Workshops** are organised to communicate project results to key stakeholders in order to ensure early input of the OSIRIS outcomes into the REACH process, as well as feedback from practice to further shape ongoing ITS development.
- A **stakeholder communication programme** will be implemented to promote international acceptance and use of the ITS tool and strategies.
- A **survey** will be designed for different stakeholder groups to **evaluate the stakeholders' animal welfare valuation** and **ITS acceptance** and to investigate the conditions for the reduction of animal testing.

Training Courses

- ITS training courses for **professional end-users** address key staff in industry and regulatory agencies involved in the submission and review of chemical risk assessments and aim to introduce advanced ITS methodologies, provide guidance on their use, and training on the practical application of new strategies for risk assessment.
- Courses also target the training of **young scientists** in order to educate the next generation of risk assessors and managers.
- Participant **feedback** helps to further **improve** the OSIRIS ITS tools developed in a way that optimally serves the **users' needs**.

Webtool & Databases

- The **web-tool developed for ITS** will be made **available to end-users**, with ITS frameworks for human and environmental endpoints, decision theory based methodologies for consensus building and decision making, and detailed guidance for their transparent use.
- The **data collated** will also be made available to allow **sharing** of chemical safety data **for a reduction of animal use** and evaluation costs.

Public Dissemination

OSIRIS aims and achievements are

- communicated through the **project website** to the general public
 - actively distributed to stakeholders via an **electronic newsletter**. Subscription is possible through the OSIRIS website.
- Research results are disseminated to the scientific community through **publications** in peer-reviewed journals, scientific **conferences** and **reports** for a scientific discourse on ITS.

Integration with other Projects

OSIRIS aims to integrate different methods and approaches. Accordingly, cooperation with other EU projects such as CAESAR, CASCADE, 2-FUN, NOMIRACLE, ReProTect, and SENS-IT-IV, with the international HESI project, and the ISSCAN database has been established. Through the project partner JRC (the EC Joint Research Centre) additional interaction takes place with key EU stakeholders.

OSIRIS is an EU 6th Framework Integrated Project (contract no. **GOCE-CT-2007-037017**).

