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

OSIRIS Objective

OSIRIS aims for intelligent testing strategies in the context of REACH, integrating non-test and test information.

Contact OSIRIS

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EU Integrated Research Project

SIXTH FRAMEWORK PROGRAMME

Contract no. GOCE-CT-2007-037017

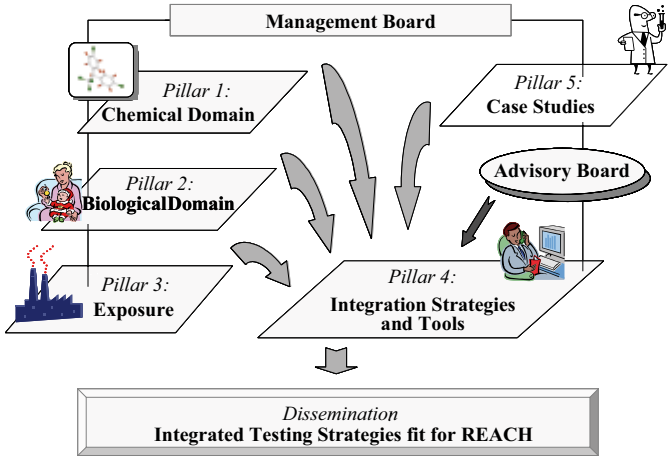
Optimised Strategies for Risk Assessment of Industrial Chemicals through Integration of Non-Test and Test Information

Intelligent Testing Strategies

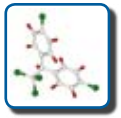
The new European law on chemicals and their safe use, **REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)** entered into force on 1 June 2007. While it is based on the precautionary principle, it includes also the aim to **reduce animal testing** where possible.

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.



5 interlinked Research Pillars



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

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

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.

ITS Components

The envisaged decision theory framework includes alternative methods such as:

- **exposure-based waiving**
- chemical and biological **read-across**
- **QSARs:** qualitative and quantitative structure-activity relationships
- **thresholds of toxicological concern**
- ***in vitro*** tests,
- **optimised *in vivo*** tests.

A major scientific challenge is to identify, reduce and manage the level of uncertainty.

Stakeholder Involvement

To ensure optimal uptake of the results obtained, end-users are closely involved in monitoring and in providing specific technical contributions.

→ **Advisory Board:** platform for interaction with external experts, stakeholders and end-users
→ **OSIRIS Stakeholder Workshops:** feedback on the ITS methodology development

Training Courses

→ Background on chemicals risk assessment
→ Practical application of the new ITS methodologies

Target groups: **professional end-users** in industry and regulatory agencies, **young scientists**