

OSIRIS: Integrated Testing Strategies for Risk Assessment of Chemicals under REACH



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REACH

REACH, the new European legislation on chemicals and their safe use (**Registration, Evaluation, Authorisation and Restriction of Chemicals**), aims at greater responsibility on industry to manage the risks that chemicals, manufactured and used in the EU, may pose to health and the environment.

By 2018, all industrial chemicals produced or imported in quantities above 1 tonne/year have to be **evaluated and**

classified with respect to their toxicological and ecotoxicological effects.

Although data sharing is mandatory, this procedure will result in a significant increase in animal tests in the next 10 years, if the conventional testing schemes are followed. However, another important aim of REACH is the **reduction of animal testing where possible.**

Therefore, other strategies have to be adopted to reduce the number of animal experiments.



The Project

The Integrated Project 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 REACH, **considering both non-test and test information.**

OSIRIS is an **international collaborative project**: 31 partners from 14 European countries work together on the **development of a web tool** which will be made available to end-users from industry and regulatory authorities for the risk assessment of chemicals.

OSIRIS integrates a large **variety of scientific disciplines** such as biology, chemistry, toxicology, ecotoxicology, toxicogenomics, statistics, information science, decision theory, as well as social sciences and economy.



The 5 OSIRIS Domains

- Chemical Domain:** Chemistry-driven information.
- Biological Domain:** Exploitation of all types of biological information on toxic effects of chemicals in ITS.
- Exposure:** Criteria for exposure informed testing, refinement of relevant exposure assessment methods.
- Integration Strategies and Tools:** Weight-of-evidence approaches for ITS, optimising the use of existing data and non-test information, minimising the need for new testing.
- Case Studies:** Feasibility and effectiveness of the new ITS methodologies covering major human and environmental endpoints.

Impact of OSIRIS for Animal Welfare and the 3 R's

The OSIRIS project contributes to all the **3 R's: Replacement, Reduction and Refinement.**

Integrated testing strategies (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 before experimental testing, to group information from similar substances and to integrate considerations about the likelihood of exposure to the chemicals.

The framework envisaged in OSIRIS comprises complementary approaches including **alternative methods** such as

- qualitative and quantitative structure-activity relationships (QSARs),
- chemical and biological read-across and
- data from *in vitro* tests,

as well as

- thresholds of toxicological concern and
- exposure-based **waiving** of testing.

• Deductions from the structure of a chemical on its potential hazard (QSARs) can also be used for screening in order to prioritise chemicals and to focus subsequent testing.

• Alternatives to animal tests will be reviewed in the course of the project.

• Information from existing tests is collected from a variety of sources in databases, and the quality of these data assessed.

• Based on the collated data, **optimisation** of existing *in vivo* and *in vitro* testing procedures will be proposed.

• A major challenge is to identify, reduce and manage the level of uncertainty in hazard assessment.

Integration with other Projects

In order to synchronise collection efforts of biological data, integration with other ongoing EU-funded and national projects has been established, e.g. CAESAR, ReProTect, SENS-IT-IV, CASCADE and ISSCAN database on chemical mutagens and carcinogens project. Through the project partner JRC (Joint Research Centre of the European Commission) additional interaction takes place with key EU stakeholders.

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