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

Final OSIRIS Meeting

The Final OSIRIS Stakeholder Meeting will be held on 29 September 2011 at the Helmholtz Centre for Environmental Research – UFZ in Leipzig, Germany.

Details on the agenda and registration will be announced on the OSIRIS website www.osiris-reach.eu.

For information and pre-registration contact osiris@ufz.de.

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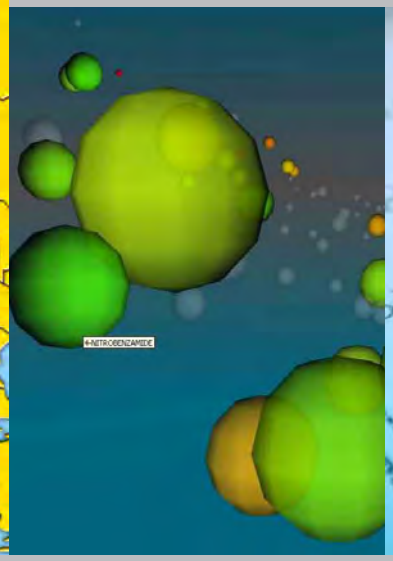
EU Integrated Research Project

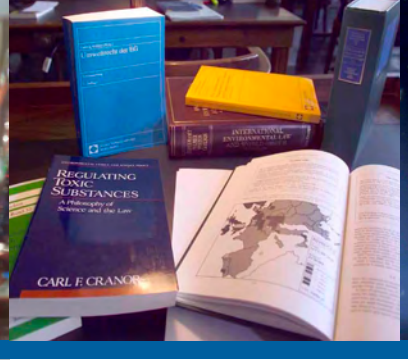
SIXTH FRAMEWORK PROGRAMME

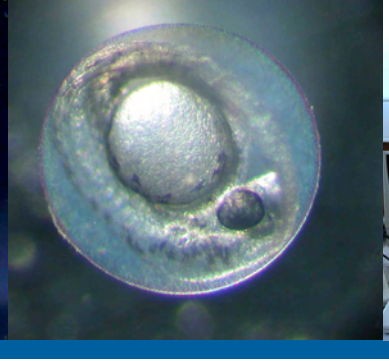
Contract no. GOCE-CT-2007-037017

OSIRIS

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



Optimised Strategies for the Risk Assessment of Chemicals

According to REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), the 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
- *In vivo* information (existing)
- 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 web-based OSIRIS Tool, which will be made freely available 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 (BCF).

Two uncertainty reasoning schemes are implemented in the ITS: Bayesian Networks and Dempster-Shafer theory of evidence. A Chemical Space Navigation Tool has been integrated as a visual aid for pre-screening of substances.

The Webtool also includes interfaces to locally installed QSAR software for generating *in silico* predictions including information about respective applicability domains (e.g. from ChemProp, TIMES etc).

The OSIRIS Webtool indicates what tests (if any) should be performed in order to satisfy REACH data requirements.

OSIRIS Methods and Models

OSIRIS developments include:

Screening methods:

- Cut-off criteria for substance-specific waiving of BCF studies
- Screening method for persistent transformation products
- PBT (persistent, bioaccumulative, toxic) index model
- CMR (carcinogenic, mutagenic, reprotoxic) screening tool

Waiving opportunities:

- Exposure-based waiving (environment, workers, consumers)
- TTC approach for inhalation and dermal exposure
- TTC values for drinking water

Models for toxicity prediction:

- Experimental and computational determination of toxicity-related electrophilicity of chemicals (chemoassays, bioassays, quantum chemistry)
- Prediction of physico-chemical properties and toxicity from structure (ChemProp OSIRIS edition)
- Category formation and read-across approaches
- Prediction of internal exposure
- Prediction of aquatic hazard distribution (NOEC95)

Models for environmental exposure assessment:

- Bioaccumulation of polar and non-polar compounds
- Fate of neutral and ionisable chemicals
- Fate of parent chemicals and their transformation products
- QSAR predictions of fate-related properties
- Probabilistic exposure assessment

Data collation:

- OSIRIS-wide database system, implemented in ChemProp
- E-SovTox: online database on Russian (eco)toxicity data
- Toxicogenomics data

Data and model analysis:

- Data quality assessment strategies
- Determination of the applicability domain

Optimisation possibilities of *in vitro* tests:

- Passive dosing to control exposure concentrations

Optimisation possibilities of *in vivo* tests:

- Guidance on the optimisation of *in vivo* tests
- Acute-chronic ratios to prioritise chemicals for chronic aquatic toxicity testing
- Data quality-related optimisation of testing protocols, *in vitro* and *in silico* approaches for ecotoxicity testing

Decision models:

- Cost-effectiveness analysis model
- Value-of-Information (VOI) model for sequential testing

ITS acceptance:

- Survey on ITS implementation and acceptance