ReProTect

- Operational since July 2004
- Total budget amounts: 13.2 m€
- Project contribution by the EC: 9.1 m€

ReProTect consortium with 32 participating groups

- 7 groups represent industry
- 22 groups represent universities or research institutes
- 3 groups represent organizations

Info

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www.reprotect.eu

Development of new in vitro tests to replace animal experimentation in reproductive toxicology

Development of a novel approach in hazard and risk assessment of reproductive toxicity by combination and application of in vitro, tissue and sensor technologies
Why in vitro?

The identification of reproductive toxicants and their mechanisms is a major scientific challenge of toxicological assessments of chemicals as during the process prioritisation.

Recent demonstrative toxicity chemicals European (REACH) will need more than 70% of experimental animals foreseen for the testing of existing chemicals. In addition, the 7th amendment of the Cosmetics Directive 76/768/EEC foresees the phasing out of testing for reproductive toxicity in 2013.

In certain areas of reproductive toxicity testing, a number of useful and promising in vitro models are already available but they need to be converted into tests with a predictive power for toxicological safety testing.

ReProTect is aiming to optimize these tests in order to ensure their optimal preparation for the following formal validation studies. In vitro tests and test batteries will provide more detailed understanding of the main chemical target tissues and targeted biological mechanisms relevant for mammalian reproduction such as gametogenesis, steroidogenesis, embryogenesis etc.

Why reproductive toxicity testing?

In the late 50s and early 60s the bitter lesson on thalidomide had to be learnt. The thalidomide disaster has far-reaching consequences on the animal numbers used for drug research and the requirements of various regulatory frameworks. The example of thalidomide demonstrates the relevance of a detailed mechanistic understanding of the action of compounds, since for example the isomers of thalidomide have different toxic effects.

In addition, there is strong evidence in wildlife and growing concern for human health that numerous chemicals may adversely affect the endocrine system. Associated consequences may include impaired fertility and other reproductive disorders, as well as increased incidences or progression of some diseases including endometriosis and hormone related cancers.

The overall aim of the ReProTect project is the development and optimization of in vitro tests into testing batteries and strategies that will provide detailed information on the hazard of compounds to the mammalian reproductive cycle.

Bonus of a successful ReProTect outcome?

The potential impact of the project is:

(a) A new approach for regulatory safety assessment in one of the most delicate areas by providing reliable tests that can be used individually or combined in test batteries, which are able to answer specific questions during hazard assessment of potential reproductive toxicants.

(b) The opportunity to make testing more humane and closer to the human species. The use of systems based on human cells can actually increase the predictive value of test results compared to those of animal tests.

(c) Pilot the development of testing strategies for hazard assessment.

(d) Coaching of the development of alternatives from research to validation, integrating the opinions and experiences of relevant stakeholders.