

**Red Española para el Desarrollo de  
Métodos Alternativos a la  
experimentación animal**

**10 años**



**1999-2009**

***Los métodos alternativos a la experimentación  
animal ante las nuevas normativas  
internacionales***

**IV Jornada de REMA, X Aniversario  
Colegio Oficial de Veterinarios de Madrid  
1 de diciembre de 2009**

**Documentos disponibles en <http://www.remanet.net/>**



## ***Los métodos alternativos a la experimentación animal ante las nuevas normativas internacionales. Desde la perspectiva de la Industria***

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Tutela de Producto e Invocación

Punto de contacto: Long Range Research Initiative (LRI)

FEIQUE

[www.feique.org](http://www.feique.org)    [www.cefic-lri.org](http://www.cefic-lri.org)

**feiQue**

Federación Empresarial de la Industria Química Española

Madrid, 1 de diciembre de 2010



## Los principios 3R

**FEIQUE está comprometida con los principios de:**

- Refinar
- Reducir
- Reemplazar

**los ensayos con animales**

## Los principios 6R (según la legislación europea)



**FEIQUE está comprometida con los principios de:**

- Refinar
- Reducir
- Reemplazar
- Reliability  
(Fiabilidad)
- Relevancia
- Regulatory  
acceptance  
(aceptación legal)

**los ensayos con animales**

## Long-range Research Initiative (LRI)

- **Misión**
  - Identificar y cubrir los vacíos en la comprensión de los peligros que tienen las sustancias químicas
  - Mejorar los métodos disponibles para valorar sus riesgos asociados
- **Investigación estratégica**
  - “Intelligent testing”
  - “Complex environments”
  - Aceptación de tecnologías
- **Valor de la iniciativa**
  - Red de expertos
  - Compromiso de la comunidad científica
  - Ciencia aplicada de gran calidad

[www.cefic-lri.org](http://www.cefic-lri.org)

## Long-range Research Initiative (LRI)

- Proceso de Investigación:
  - Publicación de las convocatorias (Request for Proposals (RfPs) – abiertas para cualquier entidad público y/o privada
  - Requisito los resultados se publicarán en “peer-reviewed journals”
  - Evaluados por una Panel Científico Externo
- Annual LRI Innovative Science Award para jóvenes investigadores:
  - Desde 2004
  - En cooperación con SETAC y EUROTOX, Chemical Week (100.000 euros y varias presentaciones en Foros reconocidos)



Tuesday 01-December-09,



About Cefic LRI

Strategic Research

Projects

Request for Proposals

Events

Awards

Selection Criteria

Selection Committee

2004 Award Winner

2005 Award winner

2006 Award winner

2007 Award winner

2008 Award Winner

2009 Award winner

Frequently asked questions

Press corner

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## LRI Innovative Science Award

### Do you have a good idea? Make it come alive!

The European Chemical Industry Council (Cefic), in conjunction with the Association of European Toxicologists and European Societies of Toxicology (EUROTOX), the Society of Environmental Toxicology and Chemistry (SETAC), the International Society of Exposure Sciences (ISES) and Chemical Week, is offering a €100,000 award to support promising new research in the field of exposure sciences.

The award will be presented to an early career scientist with a concept for creative interdisciplinary research. This could for example include exposure assessment methods using novel approaches and/or tools; innovative concepts for interpreting exposure data; or strengthening the aspects of exposure in risk assessment.

The research should be complementary to the Long-range Research Initiative's (LRI) objectives, a chemical industry funded programme that aims at enhancing scientific knowledge to help protect health and the environment.

The award is intended for a European-based scientist with less than ten years post-doctoral experience. Active involvement in interdisciplinary research and access to appropriate networks will be considered in the selection.

The LRI Innovative Science Award will be officially presented at the LRI Annual Workshop in November 2010. The 2010 Awardee will be expected to present the results of his/her research supported by the Award at the LRI Annual Workshop in November 2011.

The competition covers the broad field of exposure sciences directed at the impacts for humans with particular focus on:

- **Evaluating exposures to mixtures** (both from preparations and in multi-component environments);
- **Characterising the nature of exposures from combined exposures** (chemical, biological or physical stressors);
- **Consumer exposures in indoor environments;**
- **Predictive exposure and computational exposure sciences.**

Other aspects include but are not limited to:

- Improved strategies for the interpretation of monitoring data;
- Exposure analysis of environmental contaminants;
- Determining the contribution of different exposure routes;
- Real life exposure scenarios;
- Indirect exposures to humans from environmental sources.

**Closing date for applications: 19 MARCH 2010**

**Presentation of the winner: JUNE 2010**

For more information feel free to send an e-mail to [lri@cefic.be](mailto:lri@cefic.be)

*"Since I won the Award only a year ago I have been busy putting the project into action. It has been great having the freedom to, and experience of, setting up my own project, and managing both the science and financial aspects of the project. Whilst it was initially planned that the award would provide me with an extra years salary (I was originally employed as a Researcher with the MRC), winning the award enabled me to apply and be successfully recruited to an Investigator*

**Compromiso**

- **Cefic es miembro fundador de EPAA y tesorero (European Partnership for Alternative Approaches to Animal Testing)**
  - **Expertos de las compañías participan en los Grupos de Trabajo**
  - **Aporta aspectos científicos y políticas**



## Marco legislativo (REACH)

- **Objetivo: la protección de la salud y el medio ambiente**
  - **Duty of care (Deber de diligencia)**
  - **Requisitos legales para ensayos**
- **Promover el desarrollo de métodos alternativos**
  - **Muy pocos métodos alternativos que cumplan con los requisitos legales y los criterios 3Rs**
  - **Se necesita “Integrated testing strategies”**

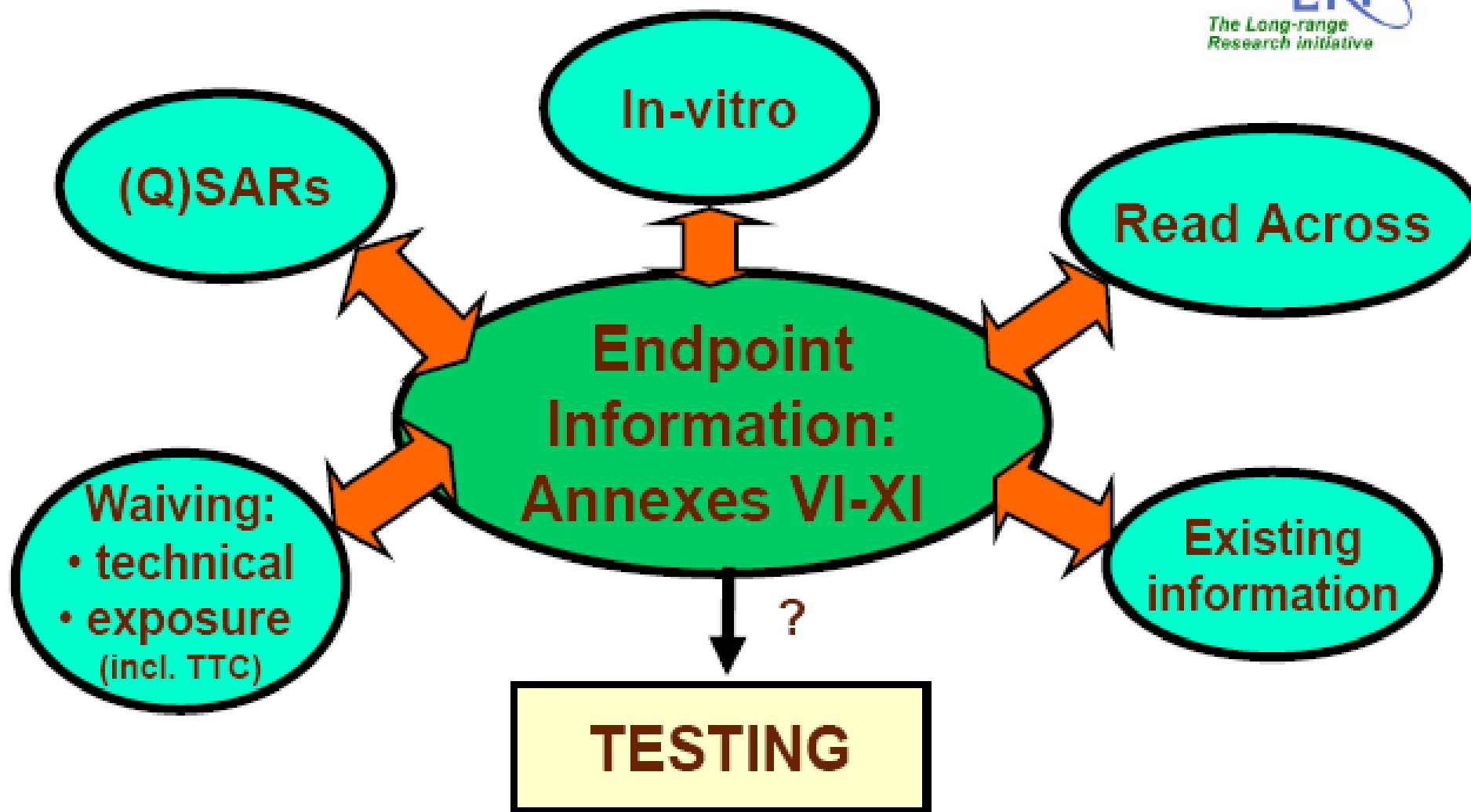
## Proyectos LRI

- **Refino/Reducción**
  - Estrategia de Ensayos
  - Estudios Reprotóxicos
  - Bases de datos
- **Reemplazo**
  - Herramientas informáticas
  - Métodos *In vitro*
  - Toxicogenómicos

# Integrated testing strategies



LRI  
The Long-range  
Research initiative



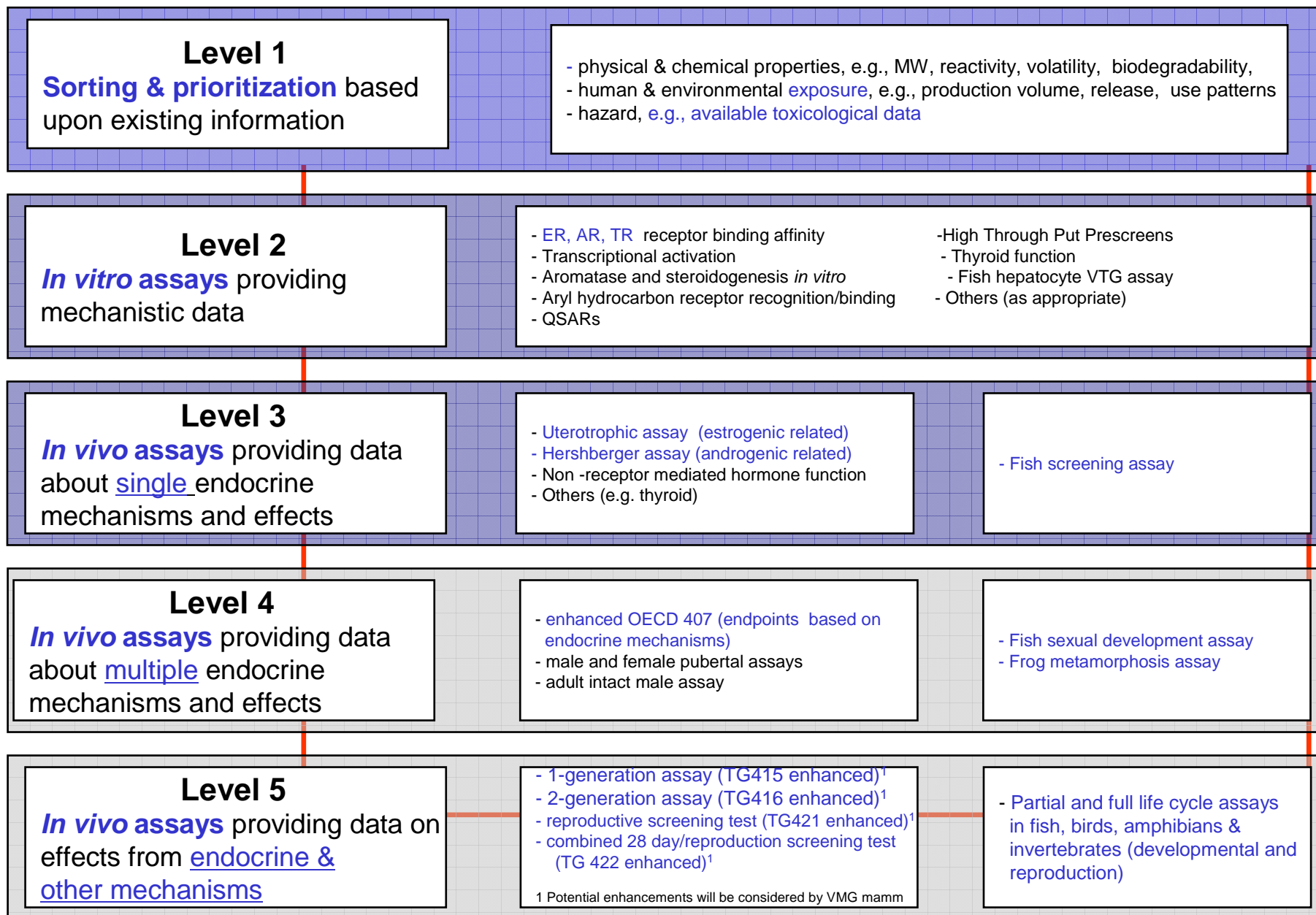
## Testing strategies

### Endocrine disruptors

- Validation of test methods (e.g. TG407, 21-day fish, Hershberger assay, non-castrated Hershberger assay, Uterotropic assay)
- Development of Testing and Assessment Framework within OECD EDTA task force
- Development of strategies for toxicology and ecotoxicology testing
- Incorporation of categorisation and read-across
- Promotion of ITS
  - European Technology Platform for Sustainable Chemistry (SusChem)
  - REACH Implementation Projects (RIPs)

# OECD Conceptual Framework\* for the Testing and Assessment of Endocrine Disrupting Chemicals

## Industry-sponsored development and validation activities



\* Framework based on 6th meeting of OECD EDTA Task Force, see [www.oecd.org](http://www.oecd.org)

## Estudios Reprotoxicos

- Requisito de REACH para grandes tonelajes
- New design of mammalian reprotoxicity studies (1-generational vs 2-generational)
  - Cooperation with EPAA, OECD and government bodies
  - Development of triggers/waivers by ECETOC Task Force
  - Co-sponsoring of expert workshop
  - Potentially saving 1200 animals per study
- Research to develop genetically modified model organisms (signal transduction pathways) to increase predictivity

## Bases de datos

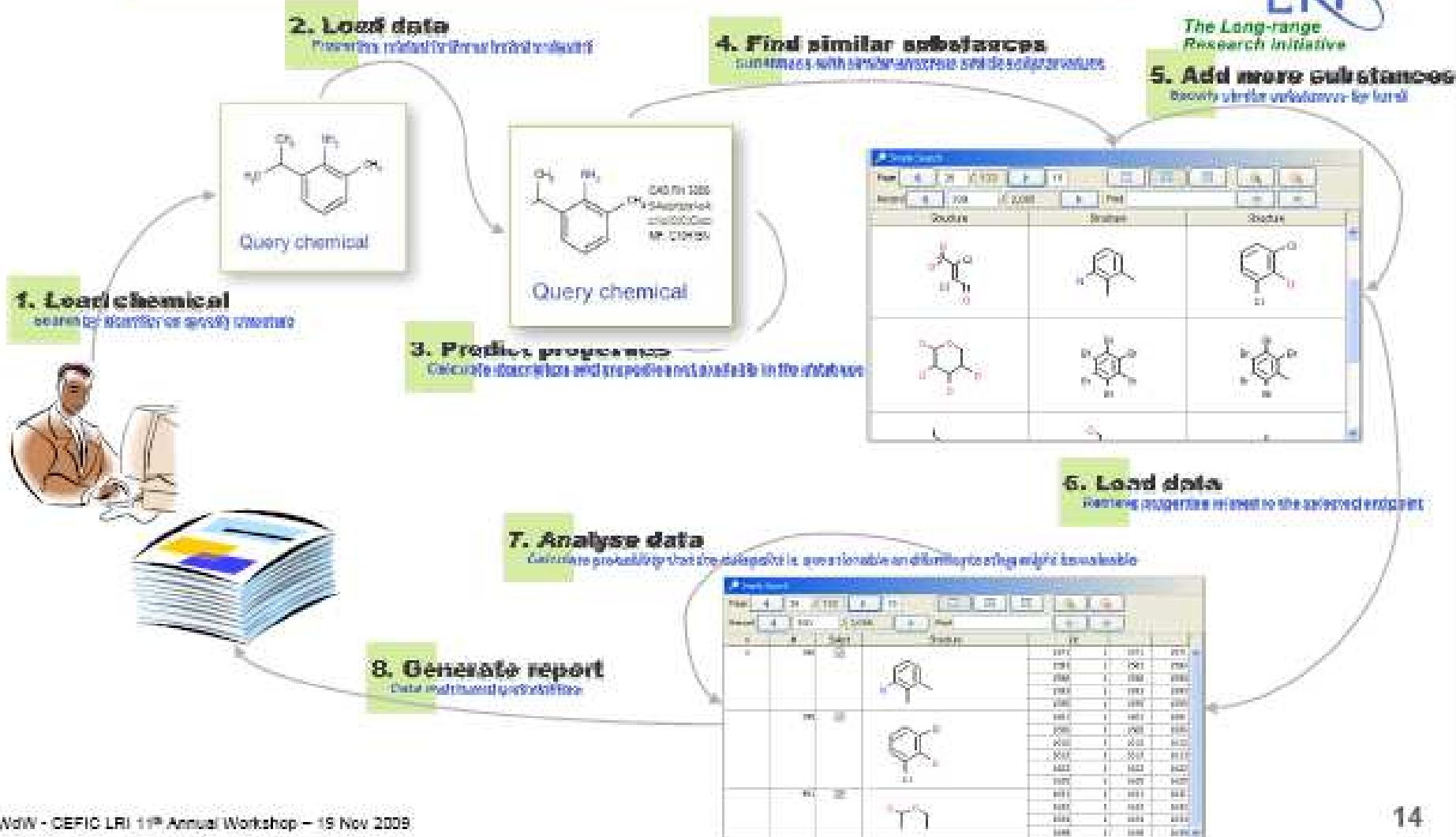


- **BCF gold standard database**
  - **Quality-controlled compilation of bioconcentration factors**
  - **Available under [www.euras.be/bcf](http://www.euras.be/bcf) and [ambit.acad.bg](http://ambit.acad.bg)**
- **RepDose**
  - **Quality-controlled compilation of data from repeat-dose studies**
  - **Data-mining to study TTC concept**

# Datapoint evaluation workflow



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## Herramientas IT

- **Categorisation and read-across can fill data gaps**
- **Development of tools**
  - **OECD (Q)SAR Application Toolbox**
  - **AMBIT tool**
  - **PBPK database and model equation generator (HSL MEGen)**

## ***In vitro* methods**

- **Development of *in vitro* methods**
  - **Cell systems for DNT**  
**(LRI Innovative Science Award 2006)**
  - **Cell lines and fish embryos for acute and chronic toxicity**
- **Co-sponsoring of workshops**
  - **TestSmart DNT-III Symposium, 2010**

## Conclusiones



- La Industria Química esta comprometida con el concepto de 3Rs
- El progreso con 3Rs, no puede ser sobre 1R sola porque retrasa
  - Para “complex endpoints”, el reemplazo es un objetivo a largo plazo.
  - A cortoplazo, refino y reducción tendrán un gran impacto en el número de animales
- La Industria Química está involucrada en varios proyectos de investigación.
- Para el desarrollo y la aceptación de los métodos alternativos con éxito, es necesario:
  - Involucración temprana de los legisladores
  - Tener en cuenta la legislación importante
  - Integración del método en una estrategia de ensayos
- Encontrar el balance entre el Bienestar Animal y la Seguridad es la clave

**Muchas  
gracias**