



European Commission
Enterprise & Industry Directorate General

The EU policy and regulatory Framework on the Replacement, Reduction, Refinement of Animal Testing and the Development of Alternative Methods

5th Meeting of Chairs and Secretariats of EU Commission and Agency
Scientific Committees and Panels involved in Risk Assessment

Brussels, 18-19 November 2009



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General Outline and Pillars of EU Policy on 3Rs

Cornelis Brekelmans, DG Enterprise and Industry

3R provisions in regulation on chemicals, plant protection products and biocides

Björn Hansen, DG Environment



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Amsterdam Treaty of 2 October 1997

“Protocol on Animal Welfare”

“The European Community and its Member States must, as a principle, pay full regard to the welfare requirements of animals when they formulate and implement the Community's policies on agriculture, transport, internal market and research”



Main components EU 3Rs policy

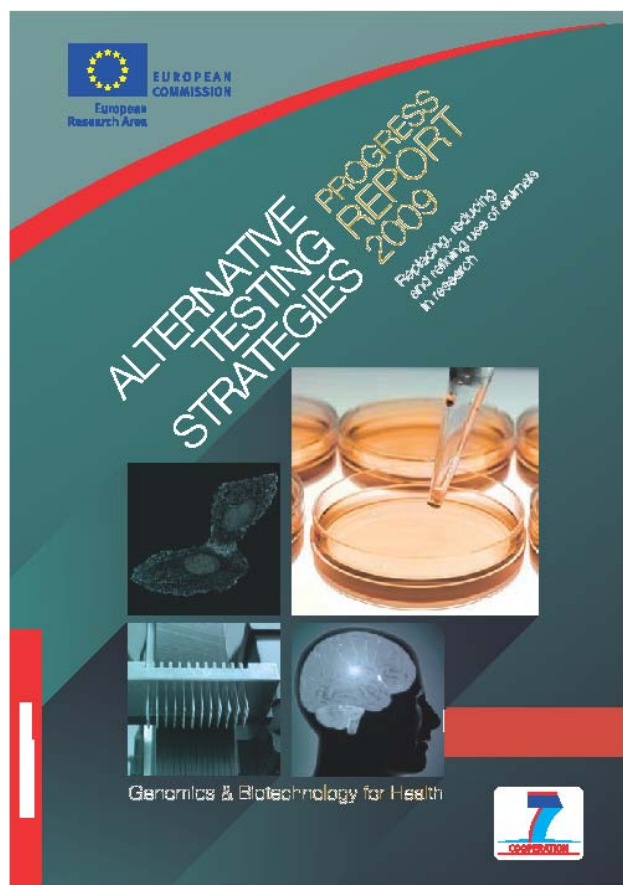
- Research and Development;
- Validation
- Regulatory incentives
- International cooperation
- European Partnership on Alternative Approaches to Animal Testing

Increasingly politically relevant area, both at European and at the international level.



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Research and Development



EU Framework Programmes for Research and Development, more than 200 million € for research on alternative methods,

of which more than 100 million over the last 5 years.

New avenues for cooperation on research: joint 50 mio € EC – Colipa project on replacement in repeated dose systemic toxicity testing



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Validation, ECVAM European Center for the Validation of Alternative Methods



- Coordination of validation of alternative test methods at the European Union level.
- Focal point for the exchange of information on the development of alternative test methods.
- Set up, maintain and manage a data base on alternative procedures
- Promote dialogue between legislators, industries, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation and international recognition of alternative test methods



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Regulatory incentives on 3Rs

Directive 86/609 regarding the **protection of animals used for experimental and other scientific purposes** introduces for the first time the 3Rs principle in EU legislation:

Replacement - Reduction - Refinement

An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.



Increasingly strong regulatory incentives in product legislation

- Directive on **Cosmetic products** introduces a ban on testing and marketing
- **REACH** and other legislation on **chemicals**, e.g. **PPP**, introduce the 3Rs principle, and contain stringent provisions on
 - Prohibition of specific tests on animals
 - Testing and waiving
 - Compulsory data-sharing in order to reduce animal testing



International Regulatory Cooperation on 3Rs

3R policy only effective alternative testing is accepted by trading partners

- OECD (Guidelines for the Testing of Chemicals) main forum
- Standing item on agenda of EU regulatory dialogues
- OECD-WPMN steering group (SG7), on the role of alternative methods for assessing the safety of nanomaterials
- ICCR, the International Cooperation on Cosmetic Regulation
- Framework for International Cooperation on Alternative Test Methods (ICATM) created by various “xVAMs”



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European Partnership on Alternative Approaches to Animal Testing

- A public-private partnership between 5 Commission DGs and industry from 7 sectors, represented by European Trade Federations, and 39 companies
- Voluntary participation
- Consensus driven
- Science based
- Regulatory testing



The European Partnership
for Alternative Approaches to Animal Testing



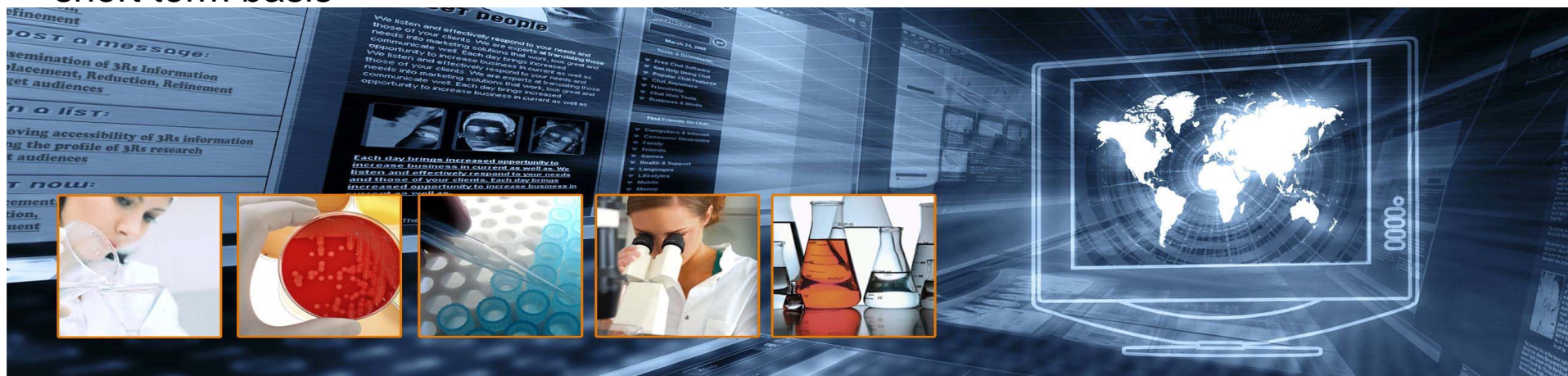
EPAA areas of activity

- Research and Development
- Validation and Acceptance
- Dissemination and communication

Clearly defined deliverables on long and short term basis

EPAA Sectors

Soaps and detergents
Chemicals
Cosmetics
Crop Protection
Pharmaceuticals
Bio-Industries
Animal Health



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