



New technology and competitiveness

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Points for discussion

- **EU research policy & competitiveness**
 - Framework programme 7
- **Alternative methods**
 - public perception & competitiveness



EU research policy & competitiveness

Objectives:

- Increase competitiveness of EU industries
- Improve quality of life

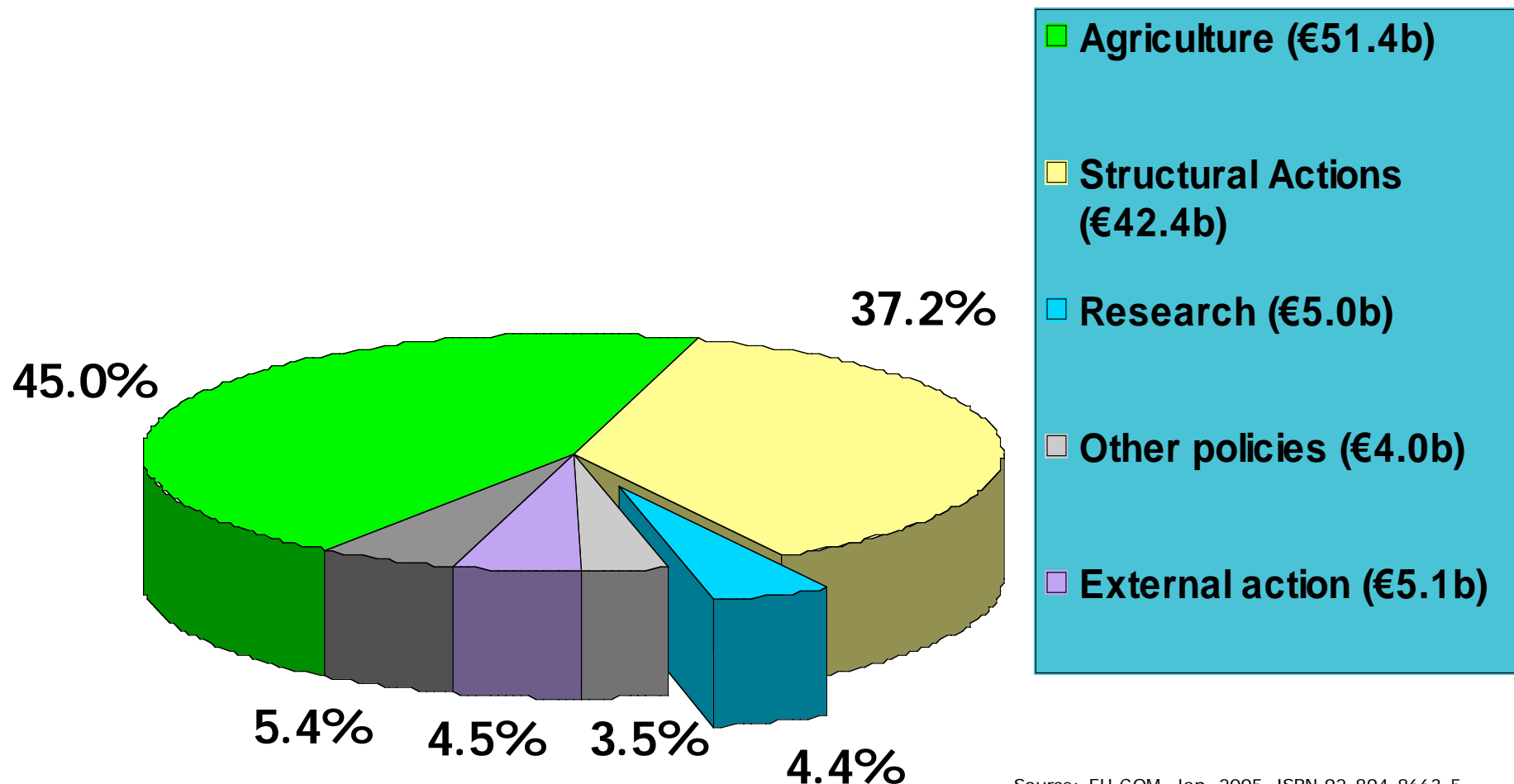


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EU budget for 2005

€119.4 billion expenditure; 1.1% of GNP





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Why do research at European level?

Motivations:

- Pooling and leveraging resources
- Fostering human capacity and excellence in S&T
- Better integration of European R&D



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What's new in FP7?

Main elements of EC proposal compared to FP6:

- **Annual budget doubled (€5 billion ► €10 billion)**
- **Collaborative research**
 - for Health: €600m ► > €1 billion
 - Continuity in themes, instruments and duration
 - Simplification of procedures
- **Basic research: the ERC (~€1.5 billion per year)**
- **Joint Technology Initiatives**

Reminder:

The European Commission currently manages < 5% of total public spending in R&D in the European Union

The European Union currently invests about 1.9% of GDP in research

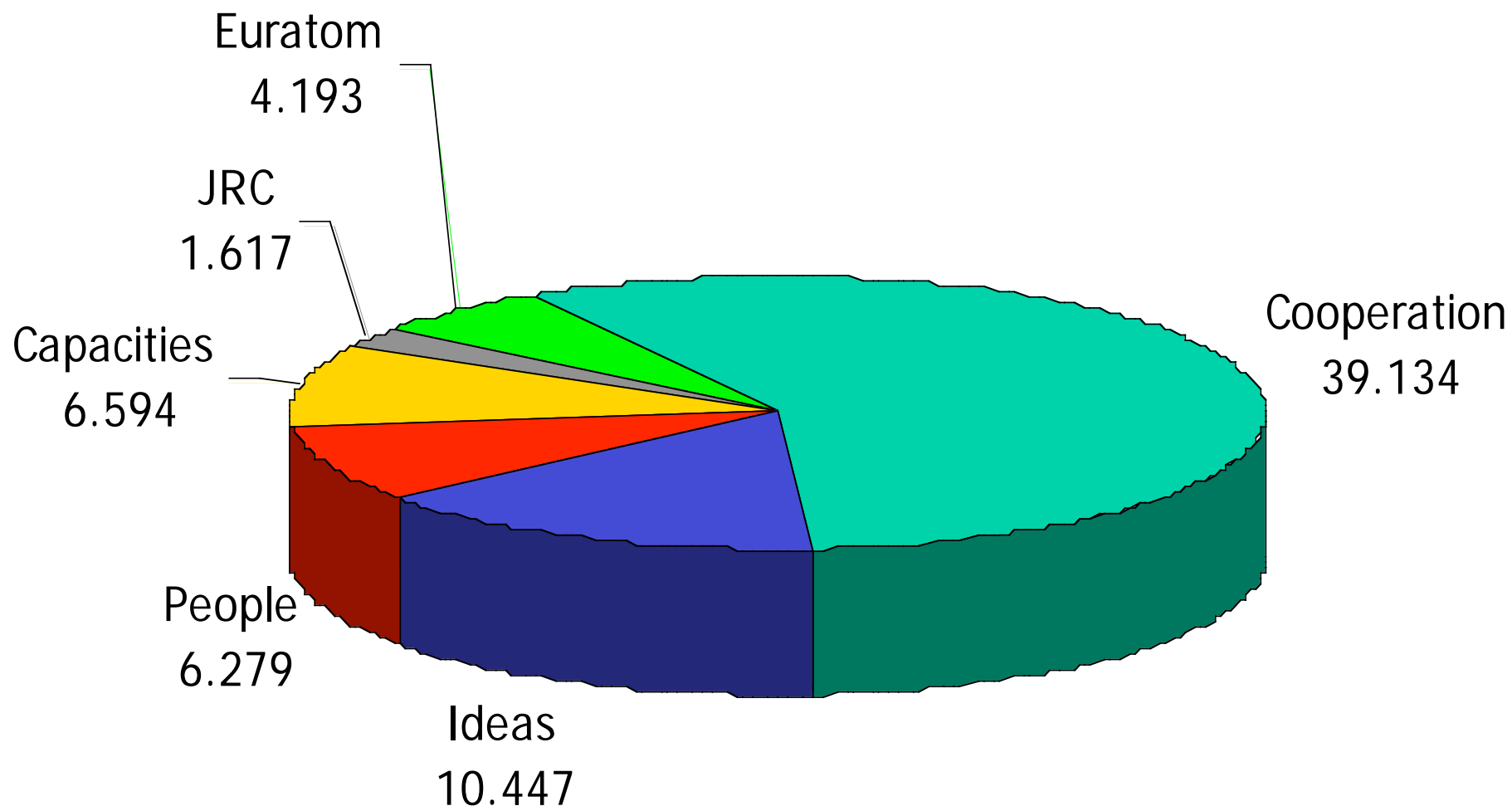


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FP7 – proposed budget

(EUR billion, 2004 constant prices)





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9 thematic priorities in FP7

1. **Health**
 2. Food, agriculture and biotechnology
 3. Information and communication technologies
 4. Nanotechnologies, materials & production technol.
 5. Energy
 6. **Environment** (including climate change)
 7. Transport (including aeronautics)
 8. Socio-economic sciences and the humanities
 9. Security and space
- + Euratom: Fusion energy research, nuclear fission and radiation protection



Health in FP7



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Collaborative research in Health

FP7

Activities in 3 main areas

- Biotechnology, generic tools and technologies for human health
- Translating research for human health
- Optimising the delivery of healthcare to European citizens



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Collaborative research in Health

FP7

1: Biotechnology, generic tools and technologies for human health

- High-throughput research
- Detection, diagnosis and monitoring.
- Innovative therapeutic approaches and interventions
- Predicting suitability, safety and efficacy of therapies
 - incl. alternatives to animal testing (for pharmaceutical uses)

for chemical uses => Environment programme





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Innovative Medicines Initiative

Aim

To remove major bottlenecks in drug development,
acting where research is the key.

Long term objective

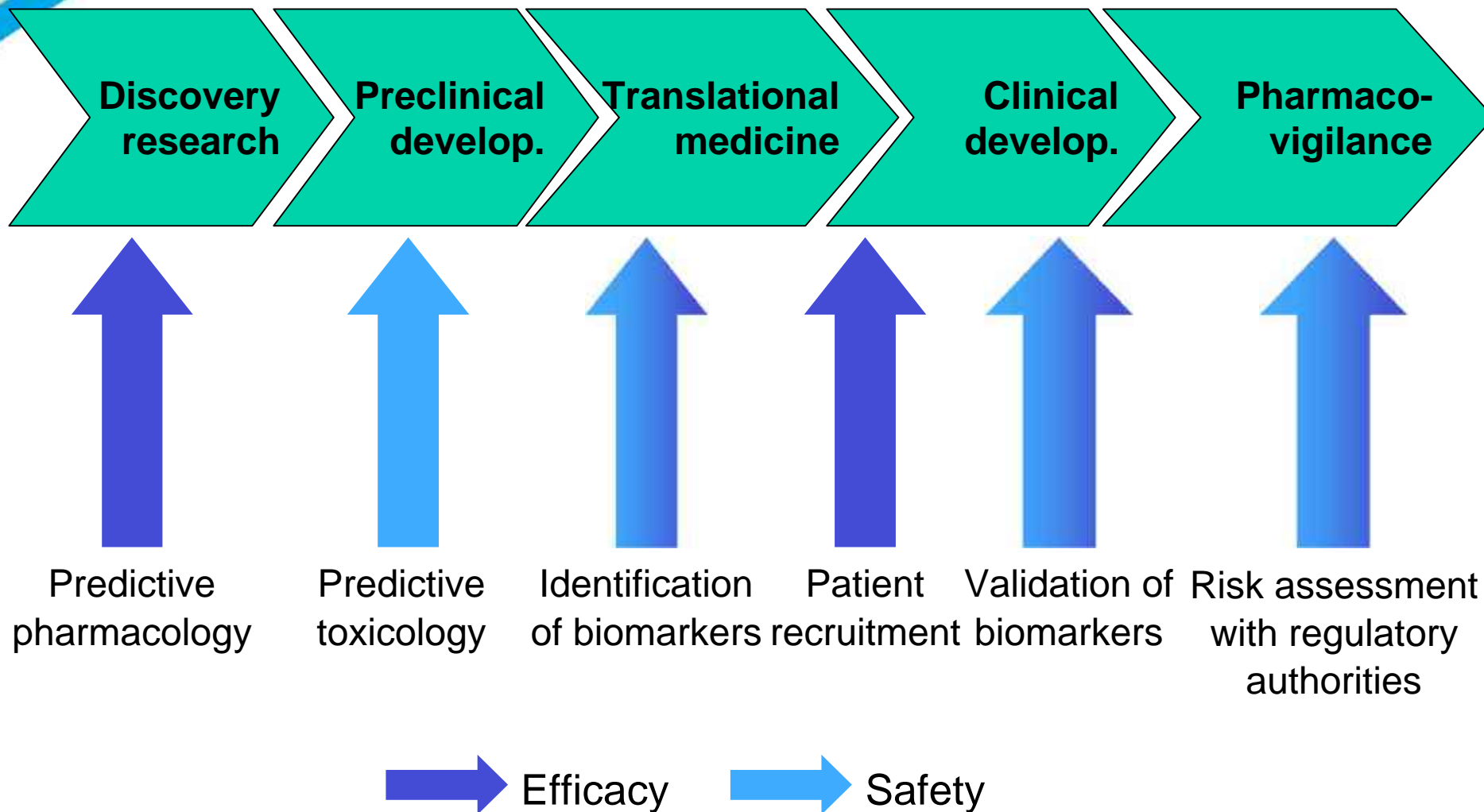
To increase competitiveness of European
pharmaceutical industry and foster Europe as the most
attractive place for pharmaceutical R&D, thereby
enhancing access to innovative medicines for patients.



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R&D bottlenecks identified by stakeholders



Source: EFPIA, 2005



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Innovative Medicines Initiative

Addressing R&D bottlenecks in 4 main areas:

- Improved prediction – for early indications of **safety**
- Improved clinical performance – for early indications of **efficacy** using biomarkers
- Better **knowledge management** through collaboration
- **Education and training**: leverage strengths, bridge gaps (pre-clinical - clinical research), promote interdisciplinarity.



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Innovative Medicines Initiative

Previous stages in development

- **“New Safe Medicines Faster”** (EUFEPS, 1999-2003)
- **Bottlenecks identified under the leadership of industry** (EFPIA) (Nov.'04)
- **Strategic Research Agenda (SRA) developed by experts from key stakeholders** (workshops from Feb.-July '05)
- **Strategic Research Agenda published for consultation** (Aug.'05)
http://europa.eu.int/comm/research/fp6/index_en.cfm?p=1_innomed
- **Pilot project (INNOMED) launched under FP6** (Nov. '05)



Alternative methods

Objectives:

- **Increase competitiveness**
- **Improve quality of life** (for humans and animals)



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EU support for Alternatives motivated by competitiveness

Alternative methods in Framework programmes

- The development of novel alternative *in vitro* tests has been a priority in successive EC research programmes since the 80s.
- In FP5 (1999-2002), EC awarded €65 million to 43 projects.
- In FP6 (2003-2006) research funding on non-animal testing methods is mostly within Thematic Priority 1 (health).
- In FP6 €55.5 million awarded to 12 projects in first 3 years and a further ~€20-30 million foreseen in 4th year.
- However, still oversubscribed: i.e. some very good projects will not be funded due to limited funds: alternatives for alternative ?



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EU-funded projects in FP6 (in “Health”)

ReProTest - Development of a novel approach in hazard and risk assessment for reproductive toxicity by a combination and application of *in vitro*, tissue and sensor technologies – IP

PREDICTOMICS - Short-term *in vitro* assays for predicting long-term toxicity – STREP

CONAM - Consensus networking on alternative methods within Europe – SSA

A-CUTE-TOX - Optimisation and pre-validation of an *in vitro* test strategy for predicting human acute toxicity – IP

TOXDROP - Highly parallel cell culture in nanodrops, a new format for high content cell based toxicity screening on Cell on Chips – STREP

BBMO - Biosensors based on membrane organisation – SSA

NHR DevTox - A prospective analysis of the mechanisms of nuclear hormone receptors and their potential as tools for the assessment of developmental toxicity – SSA

Sens-it-iv - Strategies to replace animal models by *in vitro* assays for identifying skin and respiratory sensitizers – IP

Vitrocellomics - Optimisation and pre-validation of human hepatic *in vitro* models derived from embryonic stem cells for pre-clinical drug testing – STREP

Memtrans - Assessment of drug-transporter interactions, prevalidation of *in vitro* cultured cell predictive screening models, to predict transport across the biological membranes – STREP

Rainbow - (workshop) impact of toxic properties of chemical compounds on the environment – SSA

Rethink - (study) Mini-pigs as models for toxicity testing of new drugs and chemicals – SSA

EU-funded projects in FP6 (in “FOOD”)

Devnertox – Toxic threats to the developing nervous system: in vivo and in vitro studies on the effects of mixture of neurotoxic substances potentially contaminating food – STREP

NOMIRACLE – Novel methods for integrated risk assessment of cumulative stressors in the environment – IP

F&F – Pharmaceutical products in the environment: development and employment of novel methods for assessing their origin, fate and effects on human fecundity – STREP

BIOCOP – New technologies to screen for multiple chemical contaminants in foods. Methods based on transcriptomics, proteomics and biosensors – IP

CAESAR – Computer assisted evaluation of substances according to regulations. Methods - (Q)SAR models for the prediction of the toxicity of chemical substances. Designed to be used for regulatory purposes, especially for REACH – STREP

ATHON – Assessing the toxicity and hazard of non-dioxin-like PCBs present in Food. In vivo and in vitro models for studies of NDL-PCBs; provide toxicokinetic data; toxicity profiles; a new classification strategy for NDL-PCB congeners based on effect biomarker information



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Public perception: impact on competitiveness

Will history repeat itself ?

- **Bovine growth hormone (BSt)**

Public perception, competitiveness, 4th hurdle, trade sanctions !

- **GM plants**

Public perception, “moratorium”, -ve impact on competitiveness !

- **Stem cell**

Public perception, “moratorium”, -ve impact on competitiveness ?

- **Alternative methods** (pharmaceuticals & chemicals)

Public perception, +ve impact on competitiveness for pharma !

Public perception, impact on competitiveness for chemicals ?

+animal welfare lobby pushing for (too) fast transition

Public perception: Alternative methods

- Three Rs in safety and efficacy evaluations under the existing animal protection legislation (Directive 86/609/EEC).
- Alternative tests needed for pharmaceuticals, chemicals, cosmetics, agrochemicals and foods manufacturers. Absence of validated alternative methods, the current legislative paradigm requires animal use
- 7th Amendment to Cosmetics Directive 76/768/EEC, established requirements for the cosmetic industry relating to use of replacement methods for animal-based safety studies by introducing testing and marketing bans.
- REACH - public concerns regarding continued need for animal testing to protect human and animal health and the environment, to better understand risks to humans and the environment from chemicals and to increase assurance in product safety.
- European Partnership to Promote Alternative Approaches to Animal Testing to support development, validation and acceptance of alternative approaches to RRR animal use



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Public perception: impact on competitiveness

Dialogue and communication

- Fora for constructive dialogue
 - ecopa: european consensus-platform for alternatives
 - “Europe goes Alternative” conference (Brussels, 7th Nov. 2005)
 - Follow-up ...
- Communicate
 - success stories
 - explain short-term costs Vs long-term gains



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Thank you

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