

# Europe as the pacemaker for alternative methods



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**<http://ecvam.jrc.it>**



- **Can I be sure that nothing harmful is in my cosmetics?**
- **How to test this animal-free?**

- **Average spending on cosmetics (EU/US): 200\$ per year**
- **The average European leaving home has used already 7 cosmetic products**

## *Cosmetics industry*



- **EU: 2.000 companies, 65 billion € turnover, (world > 230 billion \$)**
- **EU: 5.000 new products per year (world 22.000)**
- **EU: 5 billion units sold per year**
- **EU: 150.000 directly and 350.000 indirectly employed**
- **25% turnover with products released within last 6 months**

## *The 7<sup>th</sup> amendment of the Cosmetics Directive 2003*



- **Marketing ban if testing finished products or not using ECVAM-validated methods since 2003**
- **Phasing out ingredient testing with test and marketing bans in 2009 and 2013**
- **Critical need for alternatives**

**Often forgotten:  
there was good reason  
to introduce animal  
experiments,  
e.g. Draize  
eye test**

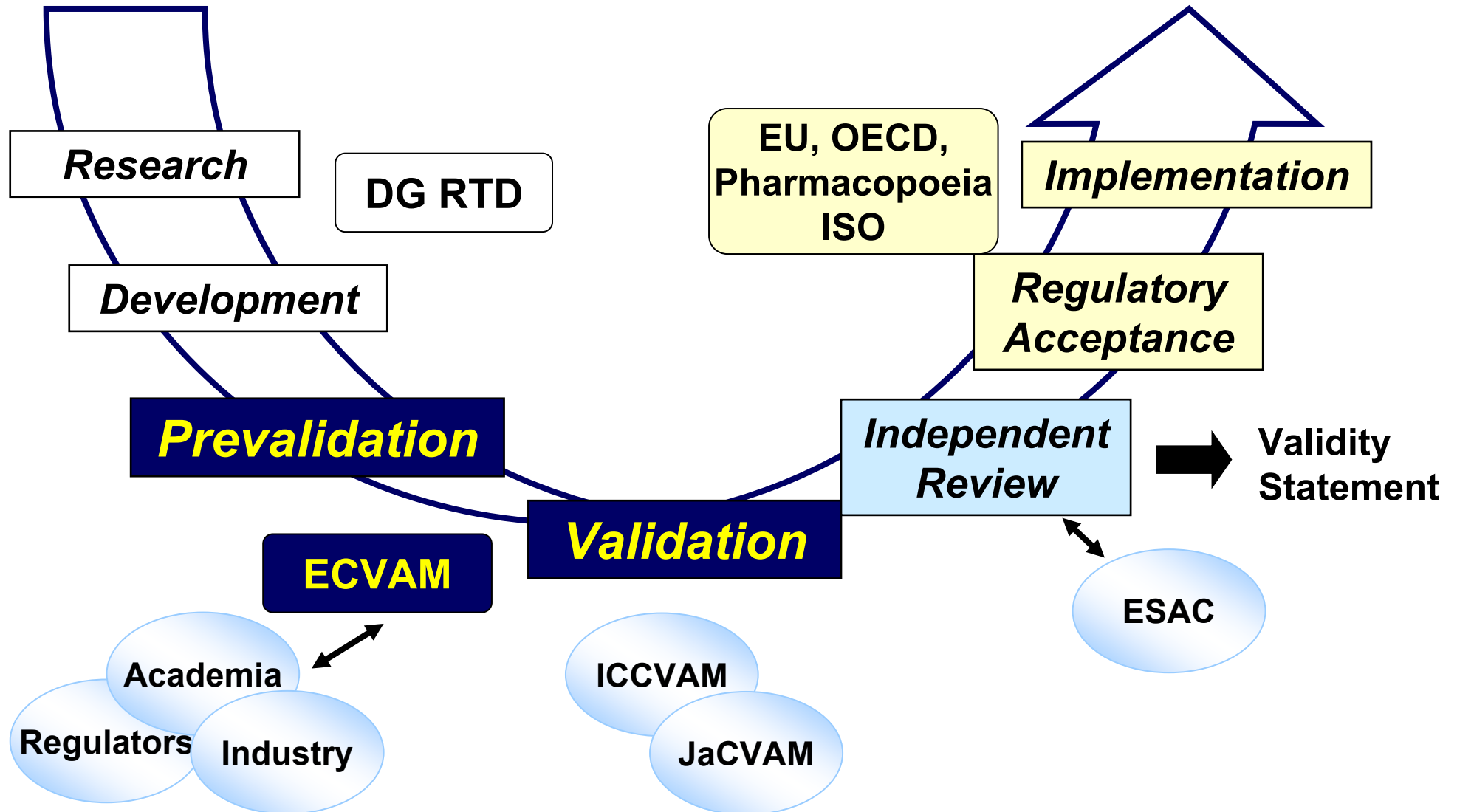


## **ECVAM**

- **Animal welfare directive 1986 (86/609/EEC)**
- **Established 1991, 60 staff**
- **Business plan and reorganization 2003 responding to 7<sup>th</sup> amendment of the cosmetic directive 2003 and emerging REACH legislation 2007**
- **Focus FP7 (2007-2013): more drug, vaccine, food**
- **ECVAM website and database**  
<http://ecvam.jrc.it>  
<http://ecvam-dbalm.jrc.it>



# Stages in the evolution of regulatory tests



## *2003: An unprecedented program to make alternative methods for chemical and cosmetic safety available*

- **17 research projects with >300 partner organisations (110 million €)**
- **COLIPA collaboration**
- **171 methods under validation; 37 of these in ring trials**
- **18 methods validated in 2006/2007**
- **Expected 40 methods validated until 2009**





Source: ECEAE

Toxicological Endpoints	Status
Skin Corrosion	OECD accepted
Acute Phototoxicity	OECD accepted
Skin Absorption / Penetration	OECD accepted
Skin Irritation	Validated 2008
Genotoxicity	OECD accepted
Photogenotoxicity	Expected 2010
Acute toxicity	Expected 2010
Eye Irritation	Expected 2010

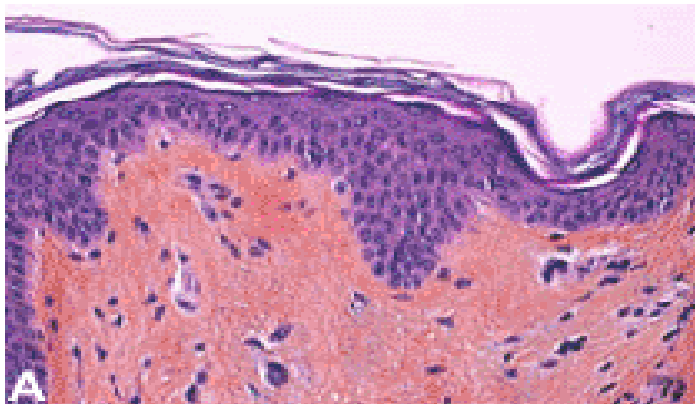
## *Validated 2007: Skin irritation*



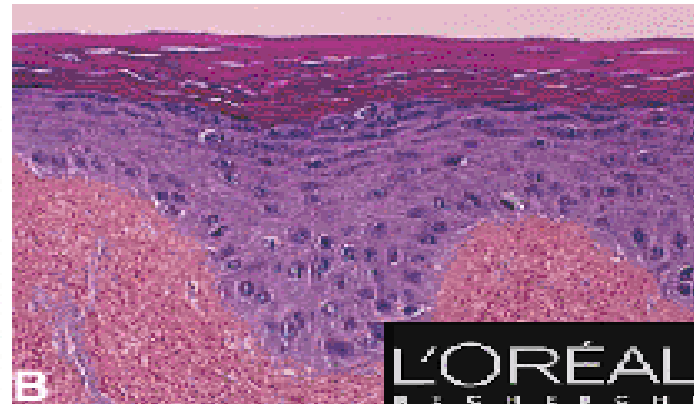
- Rabbit test for drugs, chemicals and cosmetics introduced 60 years ago
- Validation study 2003-2006 of three models with 9 labs (2 U.S.), 58 test chemicals
- Best model (Episkin), optimized in an EU project, **represents a full replacement**

## *Artificial human skin*

- **Biotechnology product originally to treat burn patients**
- **5 European and 1 American producer**
- **Forerunner Episkin opens the avenue for others to follow**
- **2009 deadline of cosmetics directive, 10.000 REACH substances**



Skin



Reconstructed epidermis EPISKIN

## *Validated 2007: Eye irritation*



- Retrospective evaluation with U.S. ICCVAM
- 4 tests analyzed, 2 qualify for the detection of severe eye irritants confirming an ECVAM analysis of 2003
- 8 other assays and the suitability for mild irritants currently under evaluation
- Intense collaboration with COLIPA
- REACH 10.000 substances; critical for cosmetics 2009

## Success so far



- **Full replacement:**  
six out of ten in time, all possible until 2011
- **Animal reduction:**  
six standard tests “six-pack” from 73 to 18 animals per substance
- **Animal suffering:**  
refinement for skin allergy and eye irritation
- **Relevant validity statements completed:**  
1997: 1  
2007: 17

1997: **1**

1998: **4**

2000: **6**

2006: **9**

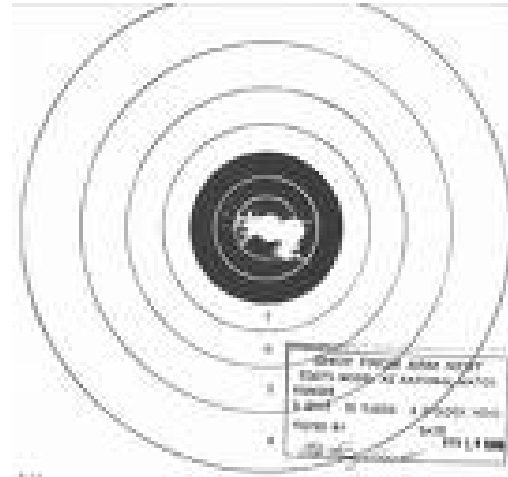
2007: **17**

2008: **up to 32**

(expected up to 15 additional, i.e. 1 skin corrosion, 3 skin irritation, 1 refinement eye irritation, 3 carcinogenicity, 2 skin absorption, 2 reduction mutagenicity, 3 acute toxicity)

2009-2010: **up to 68**

(expected up to 36, i.e. 12 eye irritation, 3 acute toxicity, 12 endocrine disrupter, 3 sensitization refinement, 3 sensitization, 1 phototoxicity, 2 mutagenicity)



## *The expansion of the 3R*

**3R** → EU → US → Japan → OECD → ICH → Korea, China, Brazil

Cosmetics



Chemicals



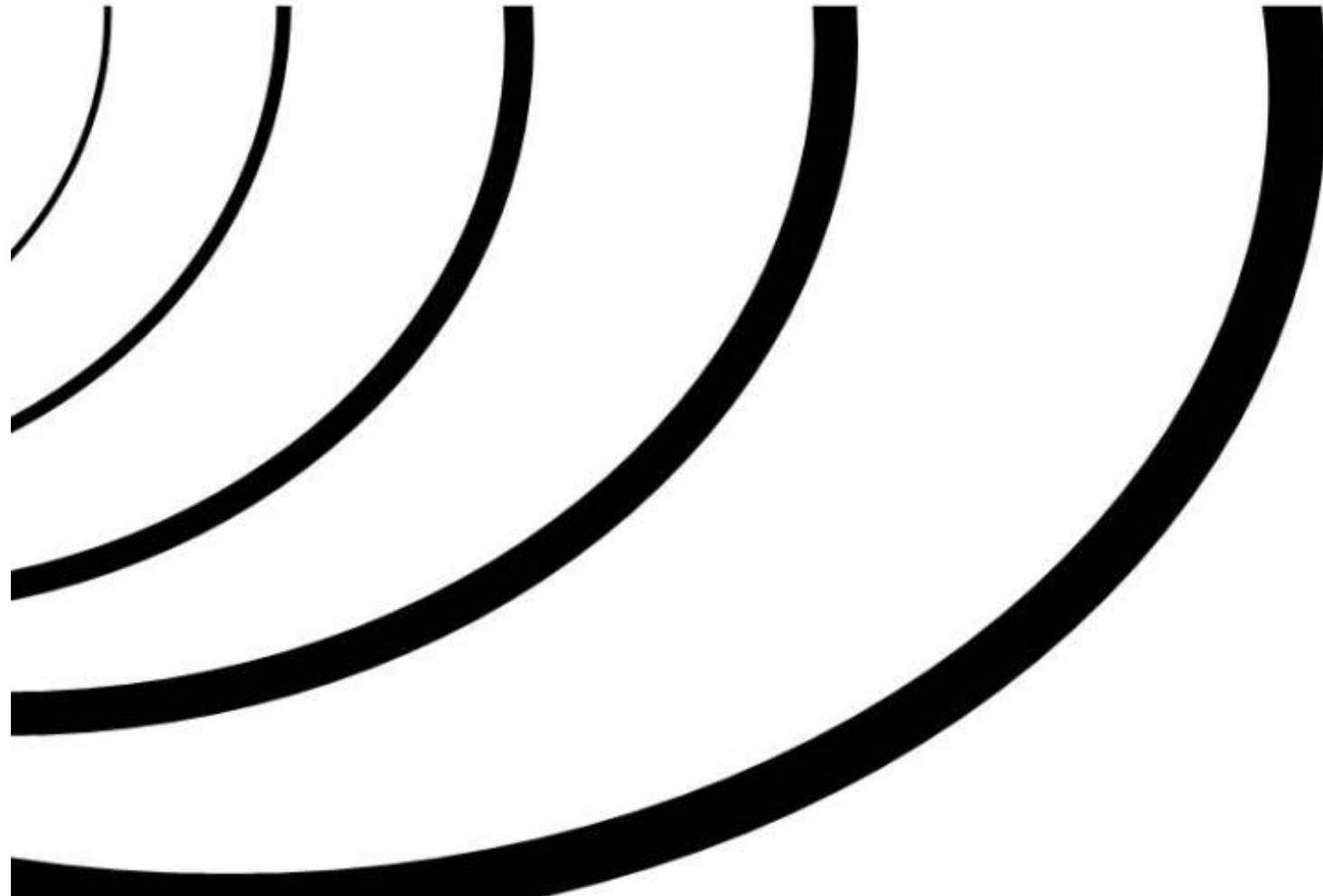
Vaccines



Pesticides



Drugs



## Globalisation of 3R



***Nothing is as strong as an idea  
whose time has come.***

**Victor Hugo**

***rephrased 2008:***

***There is no alternative to alternatives***

