

Colipa's Progress on Alternatives to Animal Testing

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on Alternatives*

Presentation Overview

- Background
- Strategy
- Status of Colipa's activities
- Summary & Conclusions

Background

- Cosmetics deliver important benefits (human health, economy)
- Innovation is essential for cosmetics (aging population, sustainability, European innovation initiative)
- Safety of cosmetics is indispensable
- The cosmetics industry is a pioneer in the development of alternatives

The Cosmetics industry has a strong commitment to end animal testing as soon as it is scientifically / legally possible

Bans of the Cosmetics Directive

7th Amendment



	Testing Ban	Marketing Ban
Finished cosmetic products	11 th Sept. 2004	
Ingredients of cosmetic products	Immediately after validation of alternative methods Final ban 11 th March 2009, Irrespective of availability of alternative methods	11 th March 2009 11 th March 2013 (repeated-dose toxicity, reproductive toxicity, toxicokinetics)
"Member states shall prohibit:..."	...the performance on their territory of animal testing [...] in order to meet the requirements of this Directive	...the marketing of cosmetic products, where the final formulation or ingredients, in order to meet the requirements of this Directive, have been the subject of animal testing after validation of an alternative method..

Future Legal Proceedings

2011

European Commission to report on availability of alternative methods and possibly make legislative proposal to Council and Parliament

➔ *Outcome completely open !*

Status Science Alternatives



Colipa: Mission & Strategy

- Achieve risk assessment without the use of animals as fast as possible
- Develop & propagate accepted replacement methods
- Communicate with regulators
 - legally sound interpretation of the animal testing provisions
 - positive review of the terms of the 2013 ban
- Keep freedom to innovate

Key Developments Since 2009

- New European Commission commenced work on the bans of the 7th Amendment
- Colipa's working groups on alternatives reorganized to further intensify work
- Science portfolio enhanced, continues to deliver
- Joint effort on Systemic Toxicity with the European Commission successfully launched

Legal / Regulatory

- Comprehensive legal package developed to understand the legal situation and to support membership

(→ *Colipa Extranet*)

Stakeholder Dialogue

- Comprehensive strategy and action plan to inform and communicate with all stakeholders (including the regulators)
- Preparation of a cosmetics innovation exhibition at the European Parliament in December 2010

The Science / Policy Interface

Key Steps for Involvement



2010

- **Independent technical review of the state of AAT science**

2010-2011

- **Impact assessment of legislative options**

Autumn 2010:

- **Multi stakeholder workshop to discuss viewpoints**

Autumn 2011

- **Legislative proposal**

THE COLIPA SCIENCE PROGRAMME

AAT Research - Colipa's Main Achievements -

- Validation of 11 methods for 4 endpoints
- *In vitro* method for percutaneous penetration accepted by OECD
- Validation for *in vitro* eye irritation assays running
- Prevalidation underway for 3 skin allergy methods
- Advancing science – Launched up to EUR 50 million Systemic Toxicity programme – joint effort with European Commission

**Total Colipa Research Funding on AAT
for 2007-2014: over *EUR 37 Million***

Latest Science Developments (I)

- Eye Irritation
 - Validation study at ECVAM starting in summer

- Skin Sensitisation
 - Substantially enlarged research portfolio
 - Pre-validation of 3 assays at ECVAM on-going

Latest Science Developments (II)

- Genotoxicity
 - Encouraging progress in the reduction of false-positive results of current regulatory assays
 - Development of follow-up assay using 3D skin models

- Safety Assessment (SA)
 - Tiered approaches for 2009 endpoints (publications for skin & eye irritation, genotoxicity)
 - Analysis of alternative SA approaches for skin sensitisation
 - Meta-analysis SA methods for other 2013 endpoints

Systemic Toxicity Colipa/EU Project

Status

- Successful call under FP7 rules completed in 2/2010
- Funding: up to EUR 25 million each by E.C. & Colipa
- 7 proposals pre-selected by Commission
 - 6 science projects addressing systemic toxicity
 - 1 coordination action
- Timing: 2010-2016

Summary & Conclusions

- The bans of the 7th Amendment are a big challenge for the European Cosmetics industry
- (Industry) scientists alone cannot solve the challenge
 - cross-disciplinary cooperation is necessary
- The Cosmetics industry is a key force for the establishment of alternative methods, the Colipa programme continues to deliver

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SPT AAT

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**The European Cosmetic Industry
- a leader in AAT research -**

**Thank you for listening -
Comments and questions,
please...**