



European Commission

Enterprise Directorate General

Cosmetics and Alternative Methods - Achievements and Prospects in the framework of the Directive 76/768

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Cosmetics and Alternative Methods Challenges

ANIMAL TESTING

- The need to reconcile different political objectives.
- To protect the health of consumers while reducing animal suffering.
- Realism : promoting research does not mean that science can always deliver !
- Promoting the discussions with different stakeholders : consumers, industry representatives and animal welfare groups.

Cosmetics and Alternative Methods

Animals are used for testing of cosmetic ingredients

- 0.4 % of the total amount of animals used for safety testing purposes
- animal test ban in some member states

Cosmetics and Alternative Methods

6th Amendment

- Member States shall **prohibit the marketing** of cosmetic products containing ingredients or combinations of ingredients **tested on animals after 30 June 2002**
- If there has been insufficient progress in developing satisfactory methods to replace animal testing, **the Commission shall submit draft measures to postpone the date of implementation** of this provision, for those test methods in respect of which there has been insufficient progress

Cosmetics and Alternative Methods Achievements

Acute toxicity: 3 reduction and refinement methods accepted by OECD and EU

Percutaneous absorption: 1 replacement method accepted by OECD and EU

Skin corrosivity: 3 replacement methods accepted by OECD and EU

Skin Sensitisation: 1 refinement method accepted by OECD and EU

Mutagenicity/Genotoxicity: various replacement tests for genotoxicity accepted by OECD and EU

Phototoxicity: 1 replacement method accepted by OECD and EU

Teratogenicity: 3 in vitro embryotoxicity tests accepted by ESAC



Cosmetics and Alternative Methods Failures

Skin Irritation

Eye Irritation

Subchronic and Long-term Toxicity

Toxicokinetics and Metabolism Data

Reproduction Toxicity

Carcinogenicity

Cosmetics and Alternative Methods

7th Amendment

Adoption of the Council Common Position supported by the Commission (14 February 2002)

→ a marketing ban

- with no cut-off date
- linked to the validation of alternative methods at OECD and accepted at EU level
- aim to reduce the risk of a challenge at WTO, even if not totally WTO secured

→ a testing ban

- linked to the validation of alternative methods by ECVAM
- with no cut-off date

→ based on the 3 Rs principle

Cosmetics and Alternative Methods

7th Amendment

EUROPEAN PARLIAMENT

2nd READING (11 June 2002)

- Adopted by absolute majority of its members -

- Marketing ban as soon as alternative methods exist - but no later than 5 years after adoption of the Directive
- Exception for 3 tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics with a final cut-off date no later than 10 years adoption of the Directive
- No reference to OECD validation
- Full EU testing ban for ingredients as from 31.12.2004

Cosmetics and Alternative Methods Prospects

WORK AHEAD/CHALLENGES

- Proceed with scientific development
- Set priorities in research
- Increase the Research efforts to produce alternative methods
- Speed up process of validation
- Accelerate the process at OECD level
- Ensure a maximum consistency between ECVAM and OECD

Cosmetics and Alternative Methods Prospects

WORK AHEAD/CHALLENGES

- Set up a **timetable**
- Accountability: set up a **monitoring** system
- Trust-building
- Achievement of our objectives:
this implies **responsibility** by
 - **industry** and animal **welfare groups**
 - **research institutions**
 - **validation bodies**
 - **member states**