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European Society for Alternatives to Animal Testing



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Meeting the Deadline 2013 – the Animal Welfare Perspective

Irmela Ruhdel

Akademie für Tierschutz / Deutscher Tierschutzbund
Animal Welfare Academy / German Animal Welfare Federation



Cosmetics, animal testing and ethics

- Toxicity testing causes pain, suffering and distress to sentient animals
- There are already thousands of cosmetic products and ingredients on the market

Animal testing for cosmetic purposes is ethically not acceptable!



Legal development

The long way to end animal testing for cosmetics

1990 European animal welfare organisations start campaigning



1993 6th Amendment of the EU Cosmetics Directive
marketing ban for cosmetic products containing ingredients
tested on animals after **1998**

**1997/
2000** Two postponements of the marketing ban

2003 7th Amendment of the EU Cosmetics Directive

Contents of the 7th Amendment of the Cosmetics Directive

Deadlines for phasing out animal testing

2004 Ban on **animal testing** of finished cosmetic products within EU

2009 Ban on **animal testing** of cosmetic ingredients independent of the availability of non-animal test methods

For animal experiments conducted outside EU:

- **marketing ban** for animal tested finished cosmetic products
- **marketing ban** for cosmetics containing animal tested ingredients

Exemptions: Tests for toxicokinetics, repeated dose toxicity, reproductive toxicity

2013 Complete **marketing ban** for cosmetics containing animal tested ingredients – could be further postponed

Last step

Implementation of the marketing ban by 2013

Option in the Directive to postpone the marketing ban for technical reasons - if non-animal tests are not available for the listed toxicological endpoints

7th Amendment of the Cosmetics Directive 2003/15/EC

*(2.1) In relation to the tests concerning **repeated-dose toxicity, reproductive toxicity and toxicokinetics**, for which there are no alternatives yet under consideration, the period for implementation ... (marketing ban) shall be limited to the maximum of 10 years after the entry into force of Directive 2003/15/EC.*

(2.3) ... If the studies conclude, at the latest two years prior to the end of the maximum period referred to in paragraph 2.1, that for technical reasons one or more tests referred to in paragraph 2.1 will not be developed and validated ... shall inform ...

Last step Implementation of the marketing ban by 2013



The EU Commission scientific report on the availability of alternative methods concluded in 2010

- that full replacement of animal tests for the five endpoints cannot be achieved by 2013
- at least further 10 years or even an unforeseeable timeline are necessary for the establishment of non-animal testing strategies

The implementation of the marketing ban is in danger!

Meeting the deadline 2013

European Commission proposal

End of 2011

Maintain 2013 deadline, however, introduce derogations to the marketing ban

- Derogations possible if manufacturer demonstrates that ingredient brings considerable technical progress and a significant added value for health and / or well-being of consumers / society or for the environment

EU Commission may forward a legislative proposal for derogations or even a further postponement in the 3rd or 4th quarter of 2012

Co-decision procedure: agreement of EP and Council of Ministers necessary

Meeting the deadline 2013

Comment on European Commission proposal

From the point of view of animal welfare neither a postponement of the date nor derogations of the marketing ban are acceptable

Additionally the current formulation of the derogations are very vague (no definitions for „considerable technical process“ or „well-being of consumers“ ...)

What consequences could a strict marketing ban have?

What issues are of concern?

- Availability of non-animal tests
- Consumer safety
- Innovation
- Impact on animal welfare

Meeting the deadline 2013

Availability of non-animal tests

Claim that full replacement of the animal tests for five endpoints can not be achieved by 2013

Supported by the results of the report on behalf of the Commission

But

This scientific report is flawed

- It is just an inventory of alternative methods – no focus on cosmetic purposes
- Overall non-animal testing strategies are missing
- No statements on the way forward

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REVIEW ARTICLE

Alternative (non-animal) methods for cosmetics testing: current status and future prospects—2010

Sarah Adler · David Basketter · Stuart Creton · Olavi Pelkonen · Jan van Benthem · Valérie Zuang · Klaus Ejner Andersen · Alexandre Angers-Loustau · Aynur Aptula · Anna Bal-Price · Emilio Benfenati · Ulrike Bernauer · Jos Bessems · Frederic Y. Bois · Alan Boobis · Esther Brandon · Susanne Bremer · Thomas Broschard · Silvia Casati · Sandra Coecke · Raffaella Corvi · Mark Cronin · George Daston · Wolfgang Dekant · Susan Felter · Elise Grignard · Ursula Gundert-Remy · Tuula Heinonen · Ian Kimber · Jos Kleinjans · Hannu Komulainen · Reinhard Kreiling · Joachim Kreysa · Sofia Batista Leite · George Loizou · Gavin Maxwell · Paolo Mazzatorta · Sharon Munn · Stefan Pfuhler · Pascal Phrakonkham · Aldert Piersma · Albrecht Poth · Pilar Prieto · Guillermo Repetto · Vera Rogiers · Greet Schoeters · Michael Schwarz · Rositsa Serafimova · Hanna Tähti · Emanuela Testai · Joost van Delft · Henk van Loveren · Mathieu Vinken · Andrew Worth · José-Manuel Zaldivar

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Abstract The 7th amendment to the EU Cosmetics Directive invited stakeholder bodies (industry, research, academia, animal welfare, environmental organizations, EU Member States, and

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Availability of non-animal tests

According to the Directive, the expanded deadline of the marketing ban of 2013 is only applicable for the endpoints **repeated-dose toxicity, reproductive toxicity and toxicokinetics**

However, the Directive has been misinterpreted

In addition to toxicokinetics, repeated dose toxicity and reproductive toxicity the Commission added **skin sensitisation** and **carcinogenicity**, explaining that these are also „repeated dose“ endpoints

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Availability of non-animal tests

But

- Skin sensitisation and carcinogenicity are always listed in EU legislation as discrete endpoints (as in REACH, Pesticides Directive or Biocides Directive)
- In the co-decision procedure of the adoption of the Directive: No written evidence that EU Parliament or Council of Ministers intended that the term „repeated dose“ be used to cover additional tests

Meeting the deadline 2013

Availability of non-animal tests

For sensitisation and carcinogenicity the marketing ban should have been in place since 2009

⇒ **Incomplete scientific report and incorrect approach**

The report provides no scientific basis for a further postponement or derogations of the marketing ban

What is in fact needed?

Non-animal testing strategies for **cosmetic** ingredients that have a **predictive value for humans**, e.g. especially for hair dyes, UV filters, preservatives

Meeting the deadline 2013

What about consumer safety?

Claims that the marketing ban could jeopardize consumer safety

But

The Directive does not allow the use of ingredients that are carcinogenic, mutagenic or toxic for reproduction -
(exceptions after assessment by the Scientific Committee on Consumer Safety of the EU Commission)

Ideally no ingredients that could cause e.g. cancer, would harm offspring should be used in cosmetics, so tests on these endpoints are not necessary

Meeting the deadline 2013

What about consumer safety?

Myth: Animal tests are essential for the protection of consumers

But

- More and more studies show that animal experiments are not reliable, reproducible or have a predictive value for humans
- Current international consensus that integrated non-animal testing strategies are more suitable to protect consumers against health risks

Additionally

- Under the Cosmetics Directive cosmetic products and their ingredients have to be safe for consumers to use – industry may only bring safe products onto the market
- In exceptional circumstances where serious concerns arise as regards to safety of an existing cosmetic ingredient Member States may grant a derogation from the animal testing ban

Meeting the deadline 2013

What about consumer safety?

⇒ **Consumers are not in danger**

Consumer protection will be improved by using innovative non-animal testing strategies

Meeting the deadline 2013

What about innovation?

Claims that the ban will prevent innovations

Agreement that for cosmetics, carcinogenicity, reproductive toxicity and toxicokinetics are not considered the core data requirements (SCCS Notes of Guidance)

For cosmetic ingredients, unlike chemicals in general, the whole data set on toxicology is not necessary – so also after 2013 new ingredients could be developed and assessed without testing for the mentioned endpoints

Meeting the deadline 2013

What about innovation?

Additionally

- Only a few new cosmetic ingredients are put on the market every year
- New non-animal tests will be available in the near future, so that testing of all ingredients will again be possible

Even now, there are some 15 000 ingredients available – this should allow production of innovative cosmetics during the coming years

In a few years non-animal test methods will be available and all ingredients will be usable

Meeting the deadline 2013

What about the impact on animal welfare?

Claims that the marketing ban will have little impact on animal welfare

But

- It would reduce animal testing; 7.892 animals for tests for EU Cosmetics outside EU by EU companies in 2010 (COLIPA)
- It would be a significant incentive on the further development and adoption of non-animal testing strategies, which will be useful for other areas of toxicity testing
- A postponement or derogations could be understood to mean that legislative EU-bans do not have to be met
- It will influence the global market - ethical attitudes have to be respected and not everything should be subject to economic interests

Meeting the deadline 2013 – What about the impact on animal welfare?

The marketing ban will have an impact on animal welfare beyond the cosmetics sector and on the reliability of EU political decisions

EU would lead the world in considering the ethical sensibilities of the public and putting them above economic greed

Meeting the deadline 2013

No serious arguments for a further postponement or derogations of the marketing ban of cosmetics containing animal tested ingredients

20 years after its first announcement the marketing ban must be implemented independent of the availability of non-animal test methods by 2013!

EU animal welfare organisations will continue campaigning

January 2011: Start of EU-wide campaign of the European Coalition to End Animal Experiments – *No Cruel Cosmetics*

Activities

- Raise public awareness
- Participation in public consultations
- Contribute to scientific workshops
- Petition
- Lobbying the Commission and European Parliament



Thank you for your attention!

Irmela Ruhdel

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