

BRIEFING

THE EU COSMETICS DIRECTIVE (2003/15/EC)

January 2005

After a legislative review of three years under the co-decision procedure, the 7th Amendment to the Cosmetics Directive was adopted by the European Parliament and the Council of Ministers in January 2003. The Directive came into force on 11 March 2003 and Member States had to transpose it into national legislation by 11 September 2004, which not all have done so far.

The new Directive's main points in relation to animal testing include:

- An immediate marketing ban on new cosmetics tested on animals where alternative test methods have been validated and adopted in the EU, *ie* from 11 September 2004.
- A marketing ban on new animal-tested cosmetics six years after the Directive comes into force, *ie* from 11 March 2009. This date applies to the use of the majority of animal tests and cannot be extended.
- A marketing ban on new animal-tested cosmetics in relation to tests for repeated-dose toxicity, reproductive toxicity and toxicokinetics ten years after the Directive comes into force, *ie* from 11 March 2013. If for technical reasons alternatives to one or several of these tests will not be validated by that date, the Commission shall put forward a legislative proposal to extend the date.
- An immediate ban on animal testing of finished cosmetic products, *ie* from 11 September 2004.
- An immediate ban on animal testing of ingredients where alternative test methods have been validated and adopted in the EU, *ie* from 11 September 2004.
- A complete ban on all animal testing for cosmetics in the EU six years after the Directive comes into force, *ie* from 11 March 2009 (including the three test areas).

Any extension of the marketing ban beyond 2013 for the three animal (toxicity) test areas will have to be agreed by the European Parliament and the Council through a full legislative review under co-decision. Under the 6th Amendment, the Commission and Council twice postponed the date of the marketing ban without involvement of the Parliament.

In June 2003, two legal actions were brought against the test and marketing bans in the 7th Amendment: one by the European Federation for Cosmetic Ingredients (EFfCI) and one by France. In December 2004, the case by EFfCI was rejected as being inadmissible by the European Court of First Instance, on the grounds that the applicants couldn't show that they were 'directly and individually concerned' as required by the Treaty. In the French case there will be a public hearing of the European Court of Justice on 18 January 2005.

After the adoption of the Directive, the Commission and the European Centre for the Validation of Alternative Methods (ECVAM) organised a number of stakeholder meetings with the Scientific Committee on Cosmetic and Non-Food Products (SCCNFP), the Organisation for Economic Cooperation and Development (OECD), industry and animal welfare organisations. The stakeholders produced a report on the current status of alternative test methods, with timetables for the replacement of animal tests. The report also identifies gaps and needs for the development and validation of alternatives. The Commission presented its own report on timetables for the phasing-out of animal testing to the Parliament and the Council in October 2004. The Commission will also have to produce a yearly report about progress and compliance with the deadlines, including provisional and final results in the development and validation of alternative test methods.

Another stakeholder working group produced draft guidelines for the labelling of cosmetic products that have not been tested on animals. The Commission is currently in the process of adopting a Recommendation establishing such guidelines.

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