The Seventh Amendment to the Cosmetics Directive: what does DG Enterprise want from ECVAM?

Regina Schumann

Enterprise Directorate General, European Commission, 1049 Brussels, Belgium

Summary: A short overview is given of the current situation regarding the draft seventh amendment to the EU cosmetics directive, *Council Directive 76/768/EEC*. Future perspectives are discussed.

Key words: *alternative methods, animal testing*, *Cosmetics Directive, cosmetic products, legislation*.

In spite of the relatively low number of animals used for the testing of cosmetic products and their ingredients (30,000–35,000, representing less than 0.3% of the total number of animals used in the EU for safety testing each year), the prohibition of animal testing for this purpose is of keen interest to the European Parliament and the general public.

For some testing purposes, alternative *in vitro* methods to animal testing have already been developed, and validated by ECVAM. To date, four alternative tests have been validated, three corrosivity tests and one phototoxicity test. Another two tests have been accepted by the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP), as being equivalent to a formally validated test, the murine local lymph node assay, and the percutaneous absorption test *in vitro* employing Franz cells.

Alternatives for endpoints of great importance (eye irritation, skin sensitisation) are still missing. Alternative methods for evaluating long-term toxic effects (carcinogenicity, reproductive toxicity) may take many years to develop and validate.

Some EU Member States have already banned the performance of animal tests for cosmetic products on their territory, either by law (Austria, Germany and The Netherlands), or on a voluntary basis (United Kingdom). At the international level, some countries still require safety tests conducted on animals.

The current text of the Cosmetics Directive (1) foresees, in Article 4(1), following the sixth amendment (2), that "Member States shall prohibit the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals after 30 June 2002". The date of entry into force of this marketing ban had already been postponed once from its original deadline of 1 January 1998 by *Directive 97/18/EC*. According to Article 2, the Commission should have, by 1 January 2000, submitted draft measures to postpone the date beyond 30 June 2000, if insufficient progress in developing alternatives to animal testing had been made.

This marketing ban did not comply with World Trade Organization (WTO) requirements and might have led to a trade dispute. Therefore, *Directive 76/768/EEC* had to be amended to make the prohibition WTO-compliant, with the aim of settling definitively the question of animal testing in the cosmetic sector. Furthermore, the marketing ban was postponed a second time until 30 June 2002 (*Directive 2000/41/EC* of 19 June 2000), to allow a seventh amendment to be adopted.

On 5 April 2000, a proposal for a seventh amendment to *Directive 76/768/EEC* (COM [2000] 189 final) was adopted by the Commission. The European Parliament adopted its opinion at first reading in April 2001. In October 2002, the Belgian Presidency proposed a compromise that integrated the idea of the global approach, with the aim of achieving high animal protection while safeguarding public health. The purpose is to render immediately effective all progress regarding alternative methods in the cosmetic sector. It included a marketing ban as soon as alternative methods are accepted at the OECD level, and an EU testing ban as soon as alternative methods are judged to have been validated at the EU level, either by ECVAM or by the SCCNFP, while deleting the idea of any cut-off date. A political agreement on the Belgian compromise was reached, and a Common Position was adopted by the Council of Ministers on 14 February 2002. On 22 February 2002, the Communication from the Commission to the European Parliament on the Common Position was adopted. The European Parliament voted on the second reading in June 2002. Because the opinions of the European Parliament and of the Council of Ministers diverged substantially, a conciliation procedure was then launched by the Danish Presidency.

At present, we do not know what the seventh amendment will look like, but it is clear that, regardless of the outcome of the seventh amendment, the issue of alternative methods will be high on the political agenda of the Commission. All stakeholders (public and private) should therefore make efforts to increase the number of scientifically validated alternative methods available. A second need is to improve the international cooperation in this field, especially with the OECD.

References

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