

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 239 final - SYN 307

Brussels, 28 May 1993

Re-examined proposal for a

Council Directive

amending for the sixth time Directive 76/768/EEC  
on the approximation of the laws of the Member States  
relating to cosmetic products

(presented by the Commission pursuant to Article 149.2(d)  
of the EEC treaty)

Explanatory memorandum

On 20 and 21 April 1993, the European Parliament completed the second reading of the proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

The European Parliament approved two amendments (Nos 1 and 2) to the common position adopted by the Council of Ministers on 17 December 1992.

The Commission accepted amendment 1 introducing an explicit ban on tests on animals for purposes other than compliance with the requirements of the Directive.

Amendment 2 was rejected by the Commission.

This amendment would have allowed the European Parliament to take part in the decision-making process concerning the deferment of the date of 1 January 1998 for the imposition of the ban on animal testing. The Commission was unable to accept such a proposal because, in view of the technical nature of the question of developing alternative methods, it had agreed at the first reading by the Council of Ministers that where alternative methods had not been scientifically validated, any deferment of the date of 1 January 1998 would be based on the procedure set out in Article 10 of Directive 76/768/EEC rather than Article 100a of the Treaty.

A further aim of amendment 2 was to take into account the work carried out by the European Centre for the Validation of Alternative Methods (ECVAM).

When the vote in plenary session was taken, the Commission acknowledged that, with regard to the latter point, there were grounds for supplementing the reference to OECD toxicity test directives already included in the common position with a reference to the fact that ECVAM's results would be taken into account.

The European Parliament also wished an element of transparency to be introduced in the decision-making process relating to deferment of the date for imposition of the ban on animal testing.

This was unacceptable to the Commission because it went too far. The Commission, however, pointed out that it was prepared to seek a little more transparency through a formula which, without prejudice to the protection of trade secrecy, would give the public access to the available scientific and technical information prior to the meeting of the Committee referred to in Article 10 to discuss deferment of the date of 1 January 1998.

The Commission proposed a compromise text along these lines. Despite the fact that the European Parliament did not accept this compromise, the Commission declared that it was still prepared to ask the Council to incorporate both these points.

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(submitted by the Commission  
under the terms of Article 149(2)(d) of the EEC Treaty)

Council's common position

Re-examined proposal

Recitals unchanged

Article 1, points 1 and 2 unchanged

Article 1, point 3, first subparagraph

3) The following point is added to  
Article 4(1):

"(i) ingredients or combinations of  
ingredients tested on animals  
after 1 January 1998 in order to  
meet the requirements of this  
Directive.

3) The following point is added to  
Article 4(1):

"(i) ingredients or combinations of  
ingredients tested on animals  
after 1 January 1998 in order  
to assess their safety or  
efficacy for use in cosmetic  
products or to comply with the  
requirements of this Directive.

Article 1, point 3, second and third subparagraphs unchanged.

Article 1, points 4 - 14 unchanged.

Articles 2, 3 and 4 unchanged.

Annex unchanged.

Amendments by the European Parliament rejected by the Commission

(Amendment 2)

Article 1, point 3, second subparagraph

If there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a sufficient period, and in any case for no less than two years, in accordance with the procedure laid down in Article 10. Before submitting such measures, the Commission will consult the Scientific Committee on Cosmetology.

If there has been insufficient progress in developing satisfactory methods to replace animal testing, the Commission may, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a period not exceeding two years. Such postponement shall be limited to specific types of test. Any proposal for a postponement shall be made to the Council, pursuant to Article 100a of the EEC Treaty. Before submitting such measures, the Commission shall consult the Scientific Committee on Cosmetology and the European Centre for the Validation of Alternative Methods. It shall take particular account of standards of validation and non-animal test methods acceptable to EC authorities and Member States.

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ISSN 0254-1475

COM(93) 239 final

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Catalogue number : CB-CO-93-270-EN-C

ISBN 92-77-56188-2

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Office for Official Publications of the European Communities  
L-2985 Luxembourg