Basic information

1997/2093(COS) COS - Procedure on a strategy paper (historic)	Procedure completed
Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1996 report **Subject** 3.40.12 Luxury products industry, cosmetics 4.20.02.06 Clinical practice and experiments	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Public Health and Consumer Protection	ROTH-BEHRENDT Dagmar (PSE)	02/07/1997
Council of the European Union			

Key events

Date	Event	Reference	Summary
05/05/1997	Non-legislative basic document published	COM(1997)0182	Summary
18/07/1997	Committee referral announced in Parliament		
24/09/1997	Vote in committee		Summary
24/09/1997	Committee report tabled for plenary	A4-0277/1997	
22/10/1997	End of procedure in Parliament		
10/11/1997	Final act published in Official Journal		

Technical information

Procedure reference	1997/2093(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 148
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/08919

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, single reading		A4-0277/1997 OJ C 325 27.10.1997, p. 0003	24/09/1997	
Text adopted by Parliament, single reading		T4-0495/1997 OJ C 339 10.11.1997, p. 0047-0061	22/10/1997	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(1997)0182	05/05/1997	Summary

Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1996 report

1997/2093(COS) - 05/05/1997 - Non-legislative basic document

OBJECTIVE: this third annual Commission report (1996) on the development, validation and legal acceptance of alternative methods to animal experiments in the field of cosmetics reviews the situation on the eve of the date by which the Commission has to present draft measures postponing the date for the ban on animal testing if alternative methods have not been scientifically validated (1 January 1998). SUBSTANCE: the report comprises two parts. The first describes the objectives and anticipated constraints concerning legal acceptance on the eve of the date (1 January 1998) from which the ban on cosmetic products containing ingredients or combinations of ingredients tested on animals is due to be introduced. The second part is more scientific and describes the initiatives taken with a view to the development, validation and legal acceptance of alternative methods. (1) Objectives and constraints: two principal objectives are pursued: - the safety of cosmetic products with regard to human health: in this connection the basic 'Cosmetics' Directive (93/35/EEC) requires manufacturers, as from 1 January 1995, to keep certain information on product safety readily accessible to the competent authorities. It also establishes a system of lists of prohibited products, products subject to certain limitations and authorized products. These lists are regularly adapted to technical progress. The Commission believes that a blanket ban on the use of new substances would not obviate the need for tests. Furthermore, putting a stop to innovation in this area would spell ruin for many SMEs; - reduction /elimination of animal suffering: the Commission recognizes the fact that it is a question of ethical imperatives, even though tests of this type account for a mere 0.03% of all animal tests. However, it feels that the use of human volunteers cannot in itself replace animal tests across the board. The constraints which have to be taken into account concerning acceptance of alternative methods fall into two categories: - compatibility with the rules of international trade (especially WTO rules): any measure that leads to banning products from third countries because they have been tested on animals is likely to prove incompatible with these rules. The Commission is therefore proposing to review the basic 'Cosmetics' Directive in order to resolve this problem; - the interests of SMEs must be safeguarded, particularly with regard to jobs created in this sector. (2) Existing and expected results: a distinction must be made between ingredients (and/or combinations of ingredients) and finished cosmetic products: - ingredients/combinations of ingredients: the report notes that no alternative method offering an equivalent degree of protection are available as yet, nor are they expected to become available by 1 January 1998. However, alternative methods should progressively become available in the domains pertaining to percutaneous absorption and local risks to the eye and skin: photoirritation, eye irritation and skin irritation (same conclusions as the 1995 report - see COS0505). By contrast, in the case of tests relating to systemic effects, there is no hope of replacing animal testing in the foreseeable future, although the reduction in the number of animals used for tests should continue; - finished cosmetic products: after 1 January 1998 it will be possible to evaluate these products without animal testing as a result of available knowledge on the safety of their ingredients. However, the report notes that there are grounds to fear toxic effects as a result of interaction between ingredients or where skin penetration by ingredients is facilitated by the vehicle used. In such cases animal testing is likely to remain necessary. (3) Conclusions: while research has made progress, no alternative test methods have yet been scientifically validated and accepted. The situation is unlikely to change before 1 January 1998. The Commission is therefore proposing: - postponement of the ban on products tested on animals until 30 June 2000, - presentation of draft measures before 1 January 2000, taking account of progress made by that date, - promotion of research into and validation of alternative methods, - dissemination among SMEs of testing methods for finished products which do not involve the use of animals, - presentation of a proposal banning animal testing for finished cosmetic products as of 1 January 1998 (to be adopted by the Codecision Procedure with the European Parliament; also covers aspects relating to products from third countries).

Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1996 report

1997/2093(COS) - 22/10/1997 - Text adopted by Parliament, single reading

The European Parliament approved without debate the report by Mrs Dagmar Roth-Behrendt (PSE, D) on the Commission Communication on animal experiments in the field of cosmetics. In its resolution, Parliament deeply regrets the acceptance by the Council of the Commission proposal to postpone the date of implementation of the ban on the marketing of cosmetics containing ingredients tested on animals until 1 June 2000. Furthermore, more than four years after adoption of Directive 93/35/EEC, the Commission is still not able to provide detailed statistics on animal experiments. Little progress has been made in adopting alternative methods. Questioning the effectiveness of the measures taken since 1993 to develop and validate alternative methods, Parliament calls on the Commission to: - bring forward without delay a Parliament/Council proposal to ban animal testing of finished cosmetic products with effect from 1 January 1998; Parliament believes that this is the only way to force the sector to develop and validate alternative methods; - at the very least, include in this proposal a full ban on animal testing of finished products and fix the year 2000 as the deadline for implementation of the ban with regard to ingredients; - take positive and urgent measures to give new momentum to the development of alternative methods (for example through the Community's framework R & D programme); - avoid further delays to both the implementation of the ban and the acceptance of alternative methods resulting from efforts aimed at acquiring the widest possible international acceptance (such acceptance is not required by Directive 93/35/EEC). With regard to compliance with WTO rules, the EU should adopt a position without delay and press for GATT guidelines reconciling trade, environmental and animal welfare concerns; - draw up a comprehensive strategy in order to speed up the development of alternative methods, with appropriate division of responsibilities among the parties concerned and forcing the sector to do more to achieve the objective; Parliament suggests in this connection, as in the case of previous resolutions, that companies and institutions undertaking animal tests be required to participate in the development of alternative validation methods or to pay a levy/duty to fund such work.