Procedure file

Basic information

COS - Procedure on a strategy paper (historic)	1994/2225(COS)	Procedure completed
Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1994 Report Subject 3.40.12 Luxury products industry, cosmetics 4.20.02.06 Clinical practice and experiments		

Key players

	Committee responsible	Rapporteur	Appointed
European Parliament	ENVI Environment, Public Health and Consumer Protection	PSE ROTH-BEHRENDT Dagmar	11/04/1995
Council of the European Union			

Key events

15/12/1994	Non-legislative basic document published	COM(1994)0606	Summary
03/04/1995	Committee referral announced in Parliament		
27/06/1995	Vote in committee		Summary
27/06/1995	Committee report tabled for plenary	A4-0165/1995	
14/07/1995	Decision by Parliament	T4-0373/1995	Summary
14/07/1995	End of procedure in Parliament		
25/09/1995	Final act published in Official Journal		

Technical information

Procedure reference	1994/2225(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/06326

Documentation gateway

Non-legislative basic document		COM(1994)0606	15/12/1994	EC	Summary
Committee report tabled for plenary, single reading		A4-0165/1995 OJ C 249 25.09.1995, p. 0004	27/06/1995	EP	
Text adopted by Parliament, single reading		T4-0373/1995 OJ C 249 25.09.1995, p. 0198-0207	14/07/1995	EP	Summary

Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1994 Report

In its 1994 annual report on the development, validation and legal acceptance of alternative methods to animal experiments, the Commission reviews the main objectives and future action by the Community in this area, the aim being to replace animal experiments by alternative methods which guarantee consumers an equivalent level of protection. The report points out that a great deal of work has been done since Directive 93/35/EEC on cosmetic products was adopted by the whole industry and the Commission, mainly thanks to intense collaboration with the USA and Japan. However, the only interesting results to emerge from studies carried out in 1993 demonstrated that, although it was possible to reduce the number of animals used in experiments on the finished product, it was still not possible to replace animal tests by alternative methods of testing the ingredients. Only finished products could be tested in vitro on the basis of data on the toxicity of the ingredients. As far as the prospects are concerned, the Commission points out that there is reason to hope that alternative in vitro methods could replace animal experiments in the near future, while offering consumers the same level of protection as that achieved with animal tests in areas such as eye irritation, cutaneous absorption, mutagenicity, phototoxicity/photoirritation. Finished products could soon all be tested in vitro on the basis of prior knowledge of the toxicity of the ingredients. However, the Commission foresees a number of difficulties, the main problem being the fact that, with current levels of scientific knowledge, it is unlikely that all animal experiments will be replaced in a series of studies (acute lethal toxicity, sub-chronic and chronic toxicity, carcinogenesis, teratogenesis etc.). The Commission considers that it will be important in the future, when implementing Directive 93/35/EEC (banning the introduction of toxic substances when formulating finished cosmetic products and setting limits on the use of certain ingredients which could be hazardous to human health) to: - check if development and validation studies under way might apply to a larger number of different substances, especially the ingredients regulated by the directive, - select from cosmetic ingredients which have been safety-assessed a group of substances with in-vivo toxicity data which are relevant to correlated in vitro/in vivo tests, - optimise the use of test databases and introduce an information system by organizing a database specifically for cosmetics. The Commission also considers that research into alternative methods designed to replace animal tests will continue to progress in parallel to methods to reduce the suffering of the animal or help reduce the number of animals tested. The European Centre for the Validation of Alternative Methods (ECVAM), a unit of the European Research Centre, could speed up the process of legal adoption of methods validated by the OECD.?

Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1994 Report

The Committee adopted the report of Mrs. Dagmar ROTH-BEHRENDT (D, PES) on the 1994 annual report of the Commission on the development, validation and legal acceptance of alternative methods to animal experiments (COM(94)0606)). According to the provisions of Council Directive 93/35/EEC relating to cosmetic products, the Commissions presented an annual report on progress in the field of alternative methods to animal experiments. The rapporteur had not noticed much progress at all, she said this morning. This calls into question the deadline 1 January 1998 set for the banning on animals. The Committee adopted almost unanimously 2 amendments tabled by Mrs. Udine BLOCH VON BLOTTNITZ (D, GREEN), condemning the fact that little progress has been made in replacing experiments on animals with alternative methods, which calls into question the deadline mentioned above and pointing out the Parliament insists on 1 January 1998 as the deadline for the banning of experiments on animals. The rapporteur vehemently criticized the Commission for not being able to provide a detailed analysis of the scale and purpose of animal testing for cosmetic in the EU, even two years after the adoption of the Directive. She called on the Commission to produce such a detailed analysis in all Member States in the period 1991-1993 and to confirm, according to Article 4 of the Directive, that finished product test are within the scope of the Directive. The Commission should discuss urgently with the national competent authorities means of greater scrutiny of cosmetic tests prior to authorization, including a critical review of their necessity and severity and the number of animals used. And the Commission should also establish means whereby all companies and institutions undertaking animals tests within the EU are actively required to participate in developmental and validation studies; conduct parallel in vitro work where animal tests are performed and supply relevant data for use in EU data facilities. The report may be on the agenda of the July plenary session (without debate)?

Cosmetics: development, validation and legal acceptance of alternative methods to animal experiments. 1994 Report

Adopting the report by Mrs ROTH-BEHRENDT (PSE, D), the European Parliament deplored the fact that, two years after the adoption of the directive on cosmetic products, the Commission was unable to provide a detailed analysis of the scale and purpose of animal testing of cosmetic products in the Union. It was particularly scathing about the lack of progress in replacing animal tests, as this called the deadline of 1 January 1998 set in Directive 93/35 on cosmetic products for banning these tests into question, and reaffirmed its wish to ban these tests by that date. It called on the Commission to: - present a detailed analysis of animal experiments carried out in the Union between 1991 et 1993; - re-evaluate its interpretation of Article 4 of Directive 93/35/EEC in order to include finished products; - instigate a debate on controls of animal experiments prior to authorization (including the need for the experiment and the numbers of animals used); - take measures calling on companies conducting these experiments to take part in studies into in vitro methods and launch a debate on the acceptance of alternative

methods; - implement studies allowing progress to be made in alternative methods, especially for tests on skin sensitization and acute/sub-chronic/chronic sensitization, to be financed by the Commission, the Member States and the industries concerned.?