

20th COMMISSION DIRECTIVE 97/1/EC

of 10 January 1997

adapting to technical progress Annexes II, III, VI and VII of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽¹⁾, as last amended by Commission Directive 96/41/EC⁽²⁾, and in particular Article 12,

After consultation of the Scientific Committee on Cosmetology,

Whereas the French Government has informed the Commission, pursuant to Article 12 of Directive 76/768/EEC, that it has suspended for a period of one year the placing on the market, whether free of charge or for consideration, of cosmetic products and personal hygiene products containing extracts from the encephalon, the spinal cord or the eyeballs of bovine animals aged over six months and of ovine or caprine animals aged over 12 months;

Whereas Commission Decision 96/362/EC⁽³⁾ amending Commission Decision 96/239/EC⁽⁴⁾ on emergency measures to protect against bovine spongiform encephalopathy stipulates that the United Kingdom shall not export from its territory to the other Member States or third countries products obtained from bovine animals slaughtered in the United Kingdom destined, *inter alia*, for use in cosmetic products, with the exception of those listed in the Annex to this Decision, and that the United Kingdom shall authorize the production of products mentioned therein only in establishments under official veterinary control which have been shown to be operating in accordance with the conditions set out in the Annex;

Whereas the bovine spongiform encephalopathy (BSE) epizootic has developed in the United Kingdom; whereas, however, its geographic distribution is not fully known at present;

Whereas it is not currently possible to detect the disease during the incubation period;

Whereas scientific knowledge on spongiform encephalopathies is constantly developing; whereas various scientific publications and reports from recognised international bodies such as the World Health Organization may provide new information;

Whereas the emergence of a variant of the Creutzfeldt-Jakob disease (CJD-V) suggests the possible transmissibility of BSE to humans; whereas, however, the causal link between CJD-V and population exposure to the BSE contaminating agent has not yet been demonstrated;

Whereas, according to currently available data, it has been possible to detect infectivity in the encephalon, the spinal cord and the eyes of bovine animals with BSE;

Whereas it is recognised that the recommended inactivation methods cannot be used in the cosmetics sector for brain, spinal cord and eye extracts;

Whereas the cosmetics industry has for several years been implementing the recommendations of governmental and international agencies concerning BSE; whereas on 22 April 1996 the European Federation of the Perfume, Cosmetics and Toiletries Industries (COLIPA) advised its members against using bovine tissues or extracts of bovine tissues derived from the encephalon, the spinal cord and the eyes; whereas ovine and caprine tissues and fluids from the encephalon, spinal cord and the eyes and ingredients derived therefrom are practically not used in cosmetic products;

Whereas on 21 October 1994, 29 March, 11 April and 18 July 1996 the Scientific Committee on Cosmetology delivered opinions on the risk of using products of bovine origin liable to transmit the BSE contaminating agent;

Whereas on 2 October 1996 the Scientific Committee on Cosmetology delivered an opinion to the effect that risks linked to the utilization in cosmetic products of bovine, ovine or caprine tissues and fluids from the encephalon, spinal cord or eyes and ingredients derived therefrom cannot be excluded;

Whereas experience has shown that sheep scrapie does not present a hazard for humans; whereas, however, recent data have shown that the BSE agent can be transmitted to sheep; whereas it is therefore necessary to take into account the fact that the transmissibility spectrum of the BSE agent is greater than that of sheep scrapie;

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 198, 8. 8. 1996, p. 36.

⁽³⁾ OJ No L 139, 12. 6. 1996, p. 17.

⁽⁴⁾ OJ No L 78, 28. 3. 1996, p. 47.

Whereas it is necessary to take measures to ensure the health and safety of consumers without awaiting irrefutable scientific proof of the causal link between BSE and CJD or its variant;

Whereas, therefore, it is prudent to ban provisionally the marketing of certain ingredients of bovine, ovine and caprine origin in cosmetic products;

Whereas this Directive must be reviewed when all the above-mentioned elements have been examined, at the latest two years after implementation of the measures listed in the Annex;

Whereas the measures provided for in this Directive are in conformity with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the removal of technical barriers to trade in the cosmetic products sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/786/EEC is hereby amended as shown in the Annex hereto.

Article 2

Member States shall take all the necessary measures to ensure that as from 30 June 1997 cosmetic products containing the substances set out in the Annex shall not be placed on the market.

Article 3

At the latest two years after the date of entry into force of the Directive the Commission shall propose a possible amendment to this Directive in the light of the development of scientific knowledge.

Article 4

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 1997. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such references shall be adopted by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 10 January 1997.

For the Commission

Emma BONINO

Member of the Commission

ANNEX

The following number is added to Annex II to Directive 76/768/EEC:

'419. Bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom.'
