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.