

EXPLANATORY MEMORANDUM

THE COSMETICS (SAFETY) REGULATIONS 2004 No. 2152

1. This explanatory memorandum has been prepared by the Department of Trade & Industry and is laid before Parliament by Command of Her Majesty.

The memorandum contains information for the House of Lords Merits of Statutory Instruments Committee.

2. DESCRIPTION

- 2.1 These Regulations implement European Parliament and Council Directives 2003/15/EC (OJ L 66, 11.3.2003 p 26) 2003/83/EC (OJ L 238 25.9.2003 p23) & 2003/80/EC (OJ L 224, 6.9.2003 p 27) which amend, for the 7th, 30th and 31st time respectively, the Council Directive 76/768/EC (OJ L 262, 27.7.1976 p. 169) on the approximation of the laws of the Member States relating to protect public health by requiring cosmetic products to meet the provisions of the Directive.
- 2.2 Directive 2003/15/EC seeks to ban the marketing of finished cosmetic products which have been tested on animals and the marketing of cosmetic products containing ingredients or combination of ingredients have been tested on animals where a suitable alternative method exists. The regulations also introduce an immediate prohibition on the testing of finished cosmetic products on animals and they prohibit the testing on animals of ingredients intended for use in cosmetic products where a suitable alternative testing method exists. .
- 2.3 Irrespective of whether a suitable alternative method exists, the prohibitions on marketing and testing will become outright prohibitions after a period of 6 or 9 years (depending on the nature of the relevant test).
- 2.4 Directive 2003/83/EC seeks to protect public health by requiring cosmetic products to meet the provisions of the Directive including restricting the use of certain cosmetic ingredients.
- 2.5 Directive 2003/80/EC seeks to improve information available to consumers regarding the durability of cosmetic products.

3. MATTERS OF SPECIAL INTEREST TO THE JOINT COMMITTEE ON STATUTORY INSTRUMENTS

- 3.1 Directives 2003/15/EC and 2003/80/EC require Member States to bring into force implementing legislation by 11th September 2004. However, Directive 2003/15/EC requires Member States to take implementing measure in respect of 2 particular provisions (parts of

1.3 and 1.4) by 11th March 2005 rather than 11th September 2004. Accordingly, the relevant regulations (7(2)(c) and 7(9)(b)) will come into force on 11th March 2005.

- 3.2 Directive 2003/15 contains one article with retrospective effect (which applies from 1st July 2002). We have not included a retrospective provision in the implementing regulations as this would risk breaching the European Communities Act 1972 (Schedule 2, 1(1)(b)). However, it should be noted that animal testing of either cosmetic ingredients or finished cosmetic products has not been possible in the UK since 1997 when the Home Office, in voluntary agreement with test houses, removed licences which allowed animal testing for cosmetic purposes.
- 3.3 Directive 2003/83/EC inserts, deletes and amends various entries in the Annexes to Directive 76/768/EEC. The implementation date for Directive 2003/83/EC is 24th September 2004 at the latest. However, the Directive specifies later dates for giving effect to the directive's provisions. In particular, it requires Member States to take measures to ensure that products contravening the Directive are not placed on the market after 24th March 2005 and that such products shall not be sold or disposed of to the final consumer after 24th September 2005.
- 3.4. The effect of this is that marketing ban under the Directive will not operate in relation to the new or amended substances inserted or amended by 2003/83 until 24th March 2005. In view of this, regulations 1(3) and 1(4) provide that newly inserted entries in the schedules to the regulations shall not have effect until 24th March 2005. Equally, these regulations provide that certain entries, which are amended or deleted by 2003/83, shall continue to operate in their existing form (i.e. as they appear in the Cosmetic Products (Safety) Regulations 2003) until 24th March 2005.
- 3.5 Directive 2003/83 also requires Member States to ensure that products containing these new or amended substances shall not be sold to the final consumer after 24th September 2005. Regulation 16(3) provides that no enforcement action shall be taken in respect of products contravening the provisions inserted or amended by 2003/83/EC where the goods were placed on the market before 24th March 2005 and supplied before 24th September 2005.

4. LEGISLATIVE BACKGROUND

- 4.1 These Regulations are made under section 11 of the Consumer Protection Act 1987 and section 2(2) of the European Communities Act 1972.
- 4.2 The DTI submitted EM 11451/02 on 30/9/02 relating to an "Opinion of the Commission pursuant to Article 251 (2), third sub-paragraph point (c) of the EC Treaty on the European Parliament's amendments to the Council's Common Position regarding the proposal for a Directive of

the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to Cosmetic Products".

- 4.3 The Commons European Scrutiny Committee considered it legally and politically important and cleared it (Report 38, Item 23741, Sess 01/02). The Lords Select Committee on the EU cleared it in Subcommittee D on 29/1/03 (Progress of Scrutiny, 03/02/03, Sess 02/03).
- 4.4 Directive 2003/83/EC and Directive 2003/80/EC are Co-Decisions and have not been subject to Parliamentary Scrutiny.
- 4.5 A Transposition Note is attached to this Memorandum.

5. EXTENT

- 5.1 Consumer safety is a reserved matter and therefore the instrument will apply to the whole of the United Kingdom.

6. EUROPEAN CONVENTION OF HUMAN RIGHTS

- 6.1 In the Department's view, these Regulations are compatible with the European Convention on Human Rights.

7. POLICY BACKGROUND

- 7.1 A consultation exercise for the Amendments was conducted in April-July 2004 prior to the adoption of the Directive. This involved over 200 manufacturers, trade associations, consumer groups, individuals and other interested parties.
- 7.2 The results indicated that the Directive would not have any major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products or ingredients of cosmetic products. Ten responses were received which were all broadly supportive of the proposal. Some minor changes have been made to the proposed regulations as a result of the consultation exercise.

8. REGULATORY IMPACT

- 8.1 The primary objectives of the Regulations are to protect public health by restricting the use of certain ingredients in cosmetic products and introduce prohibitions, with specified timescales, on the uses of animals in testing of cosmetics and their ingredients.
- 8.2 A Regulatory Impact Assessment (RIA) and Transposition Note have been prepared and are attached to this memorandum.

9. COSTS TO THE PUBLIC

9.1 There will be no additional costs imposed on the public.

10. COSTS TO THE EXCHEQUER

10.1 No additional costs will fall to the Exchequer.

11. CONTACT

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DEPARTMENT OF TRADE AND INDUSTRY

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