

EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) REGULATIONS 2009

2009 No. 796

1. This explanatory memorandum has been prepared by the Department of Business, Enterprise and Regulatory Reform and is laid before Parliament by Command of Her Majesty.
This memorandum contains information for the Joint Committee on Statutory Instruments.
2. **Purpose of the Instrument**
 - 2.1 The Cosmetic Products (Safety) (Amendment) Regulations 2009 No. 796 (“the Regulations”) implement Commission Directive 2008/88/EC (OJ No. L 256/12 of 24.9.2008, as amended by the Corrigenda published in O.J. No.L263/26 of 2.10.2008) (“the Directive”), which amends Council Directive 76/768/EC (OJ L 262, 27.9.1976 p. 169) on the approximation of the laws of the Member States relating to cosmetic products (“the Principal Directive”). The Principal Directive protects public health by prohibiting certain substances in cosmetics and imposing restrictions on the use of others. The Principal Directive was implemented via the Cosmetic Products (Safety) Regulations 2008 (S.I. 2008/1284) (“the Principal Regulations”).
 - 2.2 The Directive amends the Principal Directive by banning the use of 41 substances in hair dyes.
 - 2.3 The provisions of the Directive must be adopted and published by 14 April 2009 and shall apply from 14 October 2009. Products which fail to comply with this amendment may not be sold or otherwise disposed of to a final consumer after 14 October 2009.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 The Regulations are made under section 11 of the Consumer Protection Act 1987 (safety regulations).
 - 4.2 The Principal Directive requires Member States to ban or restrict the use of certain substances in cosmetic products. It also severely limits the use of animal testing of cosmetic products and their ingredients. On 20 June 2005 the DTI submitted a scrutiny

EM (9068/05) on a "Report from the Commission to the Council and the European Parliament on the Development, Validation & Legal Acceptancy of alternative methods to animal tests in the field of Cosmetics (2004)". The Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 1, Sess 05-06). The Lords Select Committee on the EU did not report on it (Progress of Scrutiny, 27/6/05, Sess 05/06).

4.4 The Department of Trade & Industry submitted an Explanatory Memorandum on the Opinion of the Commission relating to Directive 2003/15/EC: Explanatory Memorandum 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".

4.5 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 Sub-Committee D on 29/1/03 (Progress of Scrutiny, 03/02/03, Sess 02/03).

4.6 The Directive is a Commission Directive and has not been subject to Parliamentary Scrutiny.

4.7 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom as consumer safety aspects of goods are a reserved/excepted matter.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 This is part of a strategy on-going since 2001 under which industry is required to submit files containing scientific data on hair dye substances for evaluation by the Scientific Committee allowing an adequate risk assessment to be undertaken. For these 41 hair dye substances there have been no submissions by industry to the Scientific Committee and as there is no evidence that these substances, when used in hair dye products, can be considered safe for human health, they have been added to the list of substances which must not form part of cosmetic products.

- **Consolidation**

7.2 Not Applicable.

8. Consultation outcome

8.1 This strategy has been in place since 2001 and industry and key stakeholders have been engaged are well acquainted with this process. The Department has discussed this measure with key stakeholders, primarily the Cosmetics Toiletry & Perfumery Association, and it is believed that few companies if any would be using the substances and those that have in the past will largely already have re-formulated as they will have been aware that these substances were not being supported for use in hair dyes under the Commission's hair dye strategy.

We have also notified industry and stakeholders of the measures we have taken to implement the Directive by publishing an information exercise and the draft regulations to implement the Directive. This was published from 6 March 2009 on the BERR website at: <http://www.berr.gov.uk/files/file47401.pdf> and publicity has also been disseminated through Business Link. The notification has also been sent directly to the Health & Safety Executive and other interested Government Departments.

9. Guidance

9.1 Not applicable. The Statutory Instrument is self-explanatory.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation applies to small business.

12. Monitoring & review

12.1 The effects of this Directive will be monitored as part of the monitoring of the principle Directive

13. Contact

Tony Eden-Brown at the Consumer and Competition Policy Directorate, Department for Business, Enterprise & Regulatory Reform, tel: 020 7215 0360 or e-mail: tony.edenbrown@berr.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT FOR BUSINESS, ENTERPRISE & REGULATORY REFORM

March 2009

Transposition Note for Directive 2008/88/EC of 23 September 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress (as amended by Corrigendum) (OJ L 093, 4.4.2008, p 13-23) (“the Directive”)

This Transposition Table below shows how the Department has implemented the Directive.

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (O.J. L. 262, 27.9.1976, p.169), as last amended by Commission Directive 2008/42/EC (O.J. L. OJ L186, 15.7.2008, p.42), imposes prohibitions and restrictions on the use of specified substances in cosmetic products (“the Principle Directive”). It is implemented by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the Principal Regulations”).

These new Regulations do what is necessary to implement the Directive, by amending the Principal Regulations to include consequential changes to ensure coherence in the area to which they apply. The Department for Business, Enterprise & Regulatory Reform has lead responsibility for implementation of Directives 76/768/EEC and 2008/42/EC.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	<p>Amends the lists: in Annex II (substances which must not form part of the composition of cosmetic products (unless otherwise specified)) by adding a further 41 substances to the list;</p> <p>and consequentially amends Annex III.</p>	<p>Regulation 2b amends Schedule 3 by adding entries 1329 to 1369 to the Principle Regulations;</p> <p>Regulation 2c amends Part 1 of Schedule 4 to the Principal Regulations by deleting entry 10, amending entry 14, and in Part 2 of Schedule 4 deleting entries 57, 59 and 60.</p>	

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