

EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT No.3) REGULATIONS 2009
2009 No. 2562

1. This explanatory memorandum has been prepared by the Department of Business, Innovation & Skills 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 No.3) Regulations 2009 No. 2562 (“the Regulations”) implement Commission Directive 2009/36/EC (O.J. L. 98/31, 17.4.2009) as amended by Corrigendum (O.J. L.103/30, 23.4.2009), and part of Directive 2008/88/EC of 23 September 2008 (O.J. L. 256/12, 24.9.2008) as amended by Corrigendum (O.J. L. 263/26, 2.10.2008) (“the Directives”), which amend 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 restricting the levels of use of substances in hair dyes.
 - 2.3 The provisions of Directive 2009/36/EC must be adopted and published by 15 November 2009 and shall apply from 15 May 2010, after which products which fail to comply with this amendment may not be sold or otherwise disposed of to a final consumer. The one remaining provision of Directive 2008/88/EC should be implemented by 14th 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 Department 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 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 subparagraph 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. The Scientific Committee considered that the evidence provided that these substances were safe for human health, when used in hair dye products up to the limits specified.

- **Consolidation**

7.2 Not Applicable.

8. Consultation outcome

8.1 The Department has discussed this measure with key stakeholders, primarily the Cosmetics Toiletry & Perfumery Association, and it is believed that few companies if any will be using the relevant substances in greater proportions than those proposed in the Regulations

We are notifying industry and stakeholders of the measures by publishing an information exercise and the draft regulations to implement the Directive on the BIS website and publicity is also being disseminated through Business Link. The notification has also been sent directly to the Health & Safety Executive.

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, Innovation and Skills, tel: 020 7215 0360 or e-mail: tony.edenbrown@bis.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS

11 September 2009

Transposition Note for Directive 2009/36/EC of 16 April 2009 (O.J. L. 98/31, 17.4.2009) as amended by Corrigendum, (O.J. L.103/30, 23.4.2009) and for part of Directive 2008/88/EC of 23 September 2008 (O.J. L. 256/12, 24.9.2008), as amended by Corrigendum, (O.J. L263/26, 2.10.2008) which are amending Council Directive 76/768/EEC, on the approximation of the laws of the Member States relating to cosmetic products (O.J. L. 262, 27.9.1976, p 169)

This Transposition Table below shows how the Department has implemented Directive 2009/36/EC and the remaining part of Directive 2008/88/EC (“the Directives”) through the new set of Regulations. The remaining parts of Directive 2008/88/EC were implemented by S.I.2009/796. The deletion of reference number 57 in Part 2 of Schedule 4 was not implemented by S.I. 2009/796. The remaining part of Directive 2008/88/EC must be implemented by 14th October 2009 whilst Directive 2009/36/EC must be implemented by 15th May 2010.

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 Directives 2008/123/EC (O.J. L. 340, 19.12.2008, p.71-72) and 2009/6/EC (O.J. L. 36, 5.2.2009, p.15.17) imposes prohibitions and restrictions on the use of specified substances in cosmetic products (“the Principle Directive”). The 1976 Directive 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 Directives, by amending the Principal Regulations to include consequential changes to ensure coherence in the area to which they apply. The Department for Business, Innovation and Skills has lead responsibility for implementation of the Directives.

| Article | Objective | Implementing regulation | Responsibility (Secretary of State if not specified) |
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