EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT No.2) REGULATIONS 2009

2009 No. 1346

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 No.2) Regulations 2009 No.1346 ("the Regulations") implement Commission Directives 2008/123/EC (OJ No. L 340/71 of 19.12.2008 and 2009/6/EC (OJ No. L 36/15 of 5.2.2009) ("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 Directive amends the Principal Directive by banning the use of 4-amino-benzoic acid (PABA) previously allowed in sunscreens, and Directive 2009/6 bans the use of diethylene glycol and phytoadione, sets levels of restriction for toluene and various glycol ethers in all cosmetics.

2.3 The provisions of the Directive must be adopted and published by 9 July in the case of Directive 2008/123 and by 5 August in the case of Directive 2009/6. The provisions take effect from 8 July (though this is just to remove some unnecessary wording, that does not affect the legal meaning), 8 October 2009 in respect of Directive 2008/123 and 5 November 2009 and 5 February 2010 in respect of Directive 2009/6.

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).

4.3 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".

4.4 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).

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

4.6 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 the on-going strategy to make cosmetics safer in the light of new scientific evidence. Data is examined by the Scientific Committee on Consumer Products who undertake a risk assessment in the case of suspected dangerous or allergenic substances. In the case of these particular substances the Scientific Committee recommended a complete ban for use in all cosmetics, or restrictions on their use, and Member States agreed.

- **Consolidation**

7.2 Not Applicable.

8. Consultation outcome

8.1 Industry Europe-wide has not objected to these measures and informal consultation indicates that these particular substances are not used, not widely used or used in percentages which will not be affected by these measures.

8.2 We are also notifying 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 on the BERR web-site and 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

May 2009

Transposition Notes for Commission Directive 2008/123/EC of 18 December 2008 (O.J. L340/71, 19.12.2008) and Commission Directive 2009/6/EC of 4 February 2009 (O.J. L36/15, 5.2.2009) amending Council Directive 76/768/EEC, concerning cosmetic products.

This Transposition Table below shows how the Department has implemented Directive 2008/123/EC and Directive 2009/6/EC.

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 2008/88/EC (O.J. L. 256/12 of 24.9.2008), 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").

The Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2009 implement Directive 2008/123/EC and Directive 2009/6/EC, 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 the Principle Directive and Directives 2008/123EC and 2009/6EC.

In respect of Directive 2008/123:

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	**Amends the lists: in Annex II (list of substances which must not form part of the composition of cosmetic products) by amending the name of a substance in the list;** **and consequentially amends Annex VII by deleting entry 1.** **In Annex VII entry 28 is amended.**	**Regulation 2b (i) amends Schedule 2 to the Principle Regulations by amending entry 167;** **Regulation 2d consequentially amends Part 1 of Schedule 7 to the Principal Regulations by deleting entry 1, and amending entry 28.**	

In respect of Directive 2009/6:

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	**The Directive amends Annexes II and III of the Principle Directive. In Annex II (list of substances which must not form part of the composition of cosmetic products) it adds two new substances, listed at reference numbers 1370 and 1371.** **In Part 1 of Annex III, (list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down) it adds four new substances, listed at reference numbers 185 to 188.**	**Regulation 2 (b) (ii) amends Schedule 3 to the Principle Regulations by adding entries 1370 and 1371;** **Regulation 2 (c) amends Part 1 of Schedule 4 by adding four new entries, listed at reference numbers 185 to 188.**	

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