

**EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) (No.4)
REGULATIONS 2009**

2009 No. 3367

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 specific information for the Joint Committee on Statutory Instruments.

2. **Purpose of the Instrument**

- 2.1 The Regulations implement Commission Directive 2009/159/EC (OJ No. L336, 18.12. 2009, p.29) (“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.

- 2.2 The Directive amends the Principal Directive by extending the date until which 31 hair dye substances on the list of substances in Part 2 of Annex III are allowed to be used. The extension allows these substances to be used in hair dyes for an additional year, which will allow time for safety dossiers submitted by industry to be examined by the Scientific Committee to see whether these substances are safe for continued use. If the amending Directive did not extend the dates for use, the substances would be banned as from 1 January 2010.

- 2.3 The provisions of the Directive apply from 1 January 2010.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

- 3.1 The Committee will note that these Regulations come into force less than 21 days after being laid. The reason for this is because the Directive was not published in the Official Journal until 18 December 2009. Details of the publication in the Official Journal are inserted in these Regulations for the purposes of Schedule 2 to the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284), which are being amended. As we have said, the provisions implementing the Directive must be in force from 1 January 2010. The Regulations could not be finalised until after publication and accordingly there is insufficient time to ensure that the Regulations are made and laid 21 days in advance of the coming into force date.

4. Legislative Background

4.1 These Regulations are made under section 11 of the Consumer Protection Act 1987 to implement the Principal Directive.

4.2 As stated above, the Directive requires Member States to ban the use of certain substances in cosmetic products. 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 Ctte on the EU did not report on it (Progress of Scrutiny, 27/6/05, Sess 05/06).

4.3 On 30 September 2002 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 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 January 2003 (Progress of Scrutiny, 03/02/03, Sess 02/03).

4.5 Directive 2009/159 /EC 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 Consumer safety of goods is a reserved/excepted matter and therefore the Regulations apply to the whole of the United Kingdom.

6. European Convention on Human Rights

6.1 As the Regulations are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 This is part of the European Commission's on-going strategy to make cosmetics safer in the light of new scientific evidence. Data is examined by the Commission's Scientific Committee on Consumer Safety (SCCS), (previously 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 has had insufficient time to assess the data submitted for these substances.

- **Consolidation**

7.2 Not Applicable.

8. Consultation outcome

8.1 Industry Europe-wide are already fully aware of these proposals, through discussions that have taken place at the Commission, and support them. The proposals will not have any practical effect as they preserve the status quo.

8.2 We are notifying industry and stakeholders of these Regulations by undertaking an information exercise. The regulations are being publicised on the BIS web-site and through Business Link. The notification will also be sent directly to the Health & Safety Executive and other interested Government Departments.

9. Guidance

9.1 The Statutory Instrument is self-explanatory and we have therefore decided not to issue guidance.

10. Impact

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

10.2 The impact on the public sector is nil.

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 and in particular the considerations of the SCCS will be examined by the Commission and Member States during 2010.

13. Contact:

Tony Eden-Brown at the Consumer and Competition Policy Directorate, Department for Business, Innovation & 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

18 December 2009

The Cosmetic Products (Safety)(Amendment No 4) Regulations 2009

Transposition Table

This Transposition Table shows how the Department has implemented Commission Directive **2009/159/EC** of 16 December 2009 (OJ L336 of 18.12.2009, p. 29) (“the Directive”), amending Council Directive 76/768/EEC, (O.J. L. 262, 27.9.1976, p.169) concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress.

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, as last amended by Commission 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 by 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, imposes prohibitions and restrictions on the use of specified substances in cosmetic products. It is implemented by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the Principal Regulations”) as last amended by the Cosmetic Products (Safety) (Amendment)(No.3) Regulations 2009 SI 2007/2562.

These Regulations do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply. The Department for Business, Innovation & Skills has lead responsibility for implementation of Directives 76/768/EEC and 2009/ 159/EC. The table below shows how the Directive has been implemented.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	Amends the list in Part 2 of Annex III of Directive 76/768/EEC (substances that are provisionally allowed in cosmetic products) by extending the date until which 31 items on the list are provisionally allowed from 31.12. 2009 to 31.12.2010.	Regulation 2 amends Part 2 of Schedule 4 to the Principal Regulations to implement the amendment in the Directive.	