

**EXPLANATORY MEMORANDUM TO**  
**THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT No.2)**  
**REGULATIONS 2010**

**2010 No. 1927**

1. This explanatory memorandum has been prepared by the Department for 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 This instrument amends the Cosmetic Products (Safety) Regulations 2008 in order to implement Article 1 of Council Directive 2008/112/EC (O.J. L 345, 23.12.2008, p 68) (“the Directive”) which amends Council Directive 76/768 (O.J. L.262, 27.9.1976 p 169) on the approximation of the laws of the Member States relating to cosmetic products (“the Principal Directive”).

2.2 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”). The purpose of Article 1 of Directive 2008/112/EC is to adapt the reference to classification criteria in the Principal Directive to the new system introduced by Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (O.J. L.353, 31.12.2008 p 1). That Regulation incorporates the criteria for classification and labelling of substances and mixtures provided for by the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

2.3 From 27 August 2010 the words “preparation” or “preparations” in the Principle Regulations will be replaced with “mixture” or “mixtures” respectively, and from 1 December 2010 the essential safety requirements and the warnings and indications of precautions to be taken when using cosmetics will also make reference to stated hazard classes or categories in Annex I of Regulation (EC) No 1272/2008.

### **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 This instrument is being made to transpose amendments made to the Principal Directive by Directive 2008/112/EC. These amendments adapt provisions of the Principal Directive to the new terminology resulting from the new classification rules for substances and mixtures set out in Regulation (EC) No 1272/2008.

4.3 The Department for Work & Pensions submitted an EM on Council Doc No 14110/07 on 1st November 2007 relating to " Draft Decision amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC in order to adapt them to Regulation (EC) ... on Classification, Labelling and Packaging of Substances and Mixtures, and amending Directive 67/548/EEC and Regulation (EC) No.1907/2006. ". The Commons European Scrutiny Committee cleared it, (Report 2, Session 07/08). The Lords Select Committee on the EU cleared it. (P.O.S. 23rd November 2007 session 07/08).

4.4 A Transposition note is attached to this memorandum.

### **5. Territorial Extent and Application**

5.1 This instrument applies to all of the United Kingdom.

### **6. European Convention on Human Rights**

6.1 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 Regulation (EC) No 1272/2008 of 16 December 2008 provides for the harmonisation of the classification and labelling of substances and mixtures by aligning existing EU legislation with the United Nations Globally Harmonised System (GHS) and contributes to the GHS aim that the same hazards will be described and labelled in the same way all around the world. It substantively changes hazard descriptions and classes from the previous EU legislation

covering dangerous substances: Council Directive 67/548/EEC (OJ No 196, 16.8.67, p 1).

7.2 Directive 2008/112 reflects these changes in the nomenclature of particular classes of substances as set out in the EC Regulation. It amends the Principal Directive so as to prevent undesired changes in its scope or in the obligations it imposes.

7.3 Regulations implementing the Directive should have been published by 1 April 2010 and implemented by 1 June and 1 December 2010. We have not yet done this but action now should prevent further infraction action by the Commission.

Consolidation

7.4 Not applicable.

## **8. Consultation outcome**

8.1 The Department has consulted on this measure through discussions with key stakeholders, primarily the Cosmetics Toiletry & Perfumery Association. Those approached were aware of EU Regulation 1272/2008 and content with our proposals. We are also 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 will also be sent directly to the Health & Safety Executive who are aware of this Directive.

## **9. Guidance**

9.1 No specific guidance is required as the Statutory Instrument is self-explanatory and the changes are of terminology only.

## **10. Impact**

10.1 There is no impact on business, charities or voluntary bodies.

10.2 There is no impact on the public sector.

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

## **11. Regulating small business**

11.1 The legislation applies to small business in the cosmetic sector but does not impose any burdens on them.

## **12. Monitoring & review**

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

## **13. Contact**

13.1 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](mailto:tony.edenbrown@bis.gsi.gov.uk) can answer any queries regarding the instrument.

**Transposition Note for Article 1 of Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 (OJ No L 345, 23.12.2008, p.68) amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures**

Directive 2008/112/EC (“the Amending Directive”) amends provisions of the Directives specified in its title in order to adapt them to the new system introduced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p.1). That Regulation provides for the harmonisation of the classification and labelling of substances and mixtures by aligning existing EU legislation with the United Nations Globally Harmonised System (GHS) and contributes to the GHS aim that the same hazards will be described and labelled in the same way all around the world.

Article 1 of the Amending Directive amends provisions of 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)<sup>1</sup> (“the Cosmetics Directive”). The Cosmetics Directive imposes prohibitions and restrictions on the use of specified substances in cosmetic products and is implemented by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the CPS Regulations”).

The Cosmetic Products (Safety) (Amendment No.2) Regulations 2010 implement Article 1(1) and (4) of the Amending Directive. Article 1(2) and (5) of the Amending Directive are already transposed by the CPS Regulations (as noted below).

Article 1(3) of the Amending Directive has been superseded by Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ No L 342, 22.12.2009, p 59) (“the Cosmetics Regulation”). Article 1(3) of the Amending Directive amends Article 4b of the Cosmetics Directive with effect from 1st December 2010 but the Cosmetics Regulation repeals Article 4b as from the same date and accordingly Article 1(3) will not be transposed by this instrument.

The Department for Business, Innovation and Skills has lead responsibility for implementation of the Cosmetics Directive.

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<sup>1</sup> as last amended by Commission Directive 2009/129/EC (OJ No L 267/18, 10.10.2009), Commission Directive 2009/130/EC (OJ L 268/5, 13.10.2009), Commission Directive 2009/134/EC (OJ No L 282/15, 29.10.2009), Commission Directive 2009/164/EU (OJ No L 344/41, 23.12.2009) as amended by Corrigendum (OJ No L 3/30, 7.1.2010) Commission Directive 2010/3/EU (OJ No L 29/5, 2.2.2010) and Commission Directive 2010/4/EU (OJ No L 36/21, 9.2.2010) implemented by the Cosmetic Products (Safety) (Amendment) Regulations 2010 (S.I. 2010/1150).

| Article 1 of the Directive | Objectives   | Implementation in the Regulations  |
|----------------------------|--|--|
| Article 1(1)               | Replacement of the words “preparation” and “preparations” with “mixture” or “mixtures” throughout the text of the Cosmetics Directive  | Regulation 2(2)  |
| Article 1(2)               | Replaces Article 4a(1), point (d) of the Cosmetics Directive to take account of the adoption of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) <sup>2</sup> and Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down alternative test methods (to replace animal testing) pursuant to Article 13(2) of REACH <sup>3</sup> | Already transposed by regulation 10 of the CPS Regulations   |
| Article 1(3)               | Replaces Article 4b of the Cosmetics Directive with effect from 1 <sup>st</sup> December 2010  | Article 1(3) of the Amending Directive has been superseded by the Cosmetics Regulation. The Cosmetics Regulation repeals Article 4b of the Cosmetics Directive with effect from 1 <sup>st</sup> December 2010 and accordingly Article 1(3) will not be transposed. |

<sup>2</sup> OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3.

<sup>3</sup> OJ L 353, 31.12.2008, p. 1.

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|--------------|--|--|
| Article 1(4) | Replaces part of Article 7a(1)(h) of the Cosmetics Directive so that the information required is limited to quantitative information relating to any substance which fulfils the criteria for certain stated hazard classes or categories in Annex I of Regulation (EC) No 1272/2008 (OJ No L 353, 31.12.2008, p 1) instead of quantitative information relating to any dangerous substances covered by Council Directive 67/548/EEC (OJ No 196, 16.8.67, p 1) | Regulation 2(3)  |
| Article 1(5) | Amends the first sentence of Annex IX of the Cosmetics Directive so that it refers to alternative test method not listed in Commission Regulation (EC) No 440/2008 of 30 May 2008  | Already transposed by regulation 10 of the CPS Regulations |