

**EXPLANATORY MEMORANDUM TO
THE COSMETICS PRODUCT (SAFETY) (AMENDMENT) REGULATIONS
2011**

2011 NO. 3037

1. This explanatory memorandum has been prepared by the Department for Business, Innovation and Skills and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The main purpose of the instrument is to amend the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the Principal Regulations”) to give effect to Commission Directive 2011/59/EU (OJ No L 125, 14.5.2011, p 17). The Commission Directive amends Council Directive 76/768/EEC of 27 July 1976 (OJ No L 262, 27.9.1976, p 169) on the approximation of the laws of the Member States on cosmetic products (“the Cosmetics Directive”). The Cosmetics Directive (as previously amended) protects public health by prohibiting certain substances in cosmetics products, either for consumer or professional use, and imposing restrictions on the use of others and has been implemented by the Principal Regulations.

2.2 The Commission Directive makes technical amendments to the Cosmetics Directive based on the latest conclusions of the Scientific Committee on Consumer Safety which has been assessing the safety of hair dye substances. The Regulations amend Schedule 4 to the Principal Regulations by including in the list of substances which cosmetic products may include subject to specified restrictions and conditions certain substances used in hair dye products the use of which was previously only provisionally allowed.

2.3 Additionally, to protect consumer health the Regulations prohibit one substance, o-aminophenol, from use in cosmetics products and the provisional use of two further substances is extended until 31st December 2011.

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

3.1 These Regulations implement a European Directive which requires Member States to bring the laws into force by 3rd January 2012. We apologise that in order to comply with our EU obligations the Committee has not been given the 21 days to scrutinise the instrument before it comes into force.

4. Legislative Context

4.1 This instrument is being made to implement Commission Directive 2011/59/EU which amends the Cosmetics Directive.

4.2 BIS submitted an EM on Council Doc No. 12123/11 on 13th July 2011 relating to a "Proposal for a Council Directive amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress". The Commons European Scrutiny Committee cleared it (Report 38, Session 10/12). The Lords Select Committee on the EU cleared it (Progress of Scrutiny, 11th October 2011, Session 10/12).

4.3 BERR submitted an EM on Council Doc No. 6725/08 on 7th March 2008 relating to a "Proposal for a Regulation on the European Parliament and of the Council on Cosmetic products". The Commons European Scrutiny Committee considered it politically important and cleared it (Report 12, Session 08/09). The Lords Select Committee on the EU cleared it (Progress of Scrutiny 4th April 2008, Session 07/08).

4.4 Directive 2001/1/59 /EU is a Commission Directive and has not been subject to Parliamentary Scrutiny.

4.5 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom and does not cover issues that are devolved in Scotland, Wales or Northern Ireland.

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 It is important that EU consumers are protected from cosmetic products which pose a potential risk to their health. The Cosmetics Directives ensures that cosmetic products in the EU are safe by specifying which chemical ingredients for use in cosmetic products are allowed, prohibited or permitted subject to particular restrictions.

7.2 Over time, technical amendments to the Directive may be required. This may be due to further innovation in the industry which has resulted in the development and commercialisation of new or reformulated cosmetic products or a better understanding of the health risks associated with the use of certain substances.

7.3 Serious human health concerns were raised over the use of certain chemical substances in hair dye products. In light of these concerns, the cosmetics industry and the European Commission launched a strategy in 2001 to regulate the use of hair dye substances within the EU. Together with the Scientific Committee on Consumer Safety (SCCS), they have been assessing the safety of these specific

substances on the basis of data submitted by the industry whilst provisionally permitting the use of the chemicals.

7.4 The new Directive makes technical amendments to the Cosmetic Directive based on the SCCS's latest conclusions. The SCCS considered that evidence provided that certain substances were safe for human health, when used in hair dye products up to the maximum limits specified was acceptable. The new Directive (2011/59/EU) therefore amends the Cosmetics Directive by adding a number of substances that were previously only provisionally authorised to Part 1 of Annex III to the Directive (i.e. to the list of substances that cosmetic products can contain subject to specified conditions and restrictions).

7.5 However, the SCCS found no conclusive evidence that one substance used in the manufacture of cosmetic products - o-aminophenol - could be considered safe. Accordingly, to protect consumer health, the Directive adds this substance to Annex II and prohibits it from use in cosmetic products.

7.6 In the case of two other substances the SCCS had had insufficient time to assess the data submitted for these substances and as a result, their provisional use was extended until 31 December 2011.

7.7 The substances regulated in this instrument are regulated as part of the Commission and Member States on-going commitment to ensure that consumers have access to cosmetic products that will be safe if used as intended. The work is carried out with the SCCS using both risk assessment and risk management processes.

7.8. The UK is required by EU law to implement the amending Directive by 3 January 2012. The UK runs the risk of infraction proceedings if it does not do so.

7.9 The policy objective is to ensure that only safe substances can be used in cosmetics thereby protecting consumers whilst allowing businesses to continue using a wide range of substances to bring innovative products to market thereby supporting growth in the UK industry. The amending Directive makes permanent almost all of the provisional allowances which would otherwise have ended on 31 December 2010 and is welcomed by the UK industry.

Consolidation

7.10 It is not intended to consolidate the Principal Regulations. This is because with effect from July 2013 the Cosmetic Directive, which the Principal Regulations implement, has been repealed and replaced by the new Cosmetic Products Regulation, Regulation 1223/2009/EU. As a result, the Principal Regulations will in any event have been revoked by July 2013 and replaced by regulations required to implement the new EU Cosmetic Products Regulation.

8. Consultation outcome

8.1 The industry Europe-wide are already fully aware of these proposals, through discussions that have taken place at the Commission, and support them. The

Cosmetics, Toiletry and Perfumery Association, who represents the industry, support the amending Directive, which is based on scientific opinion and has been supported by Member States.

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 negligible.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating small business

11.1 The legislation applies to small business. The Government considers that the legislation is not expected to impose a disproportionate cost to small firms.

12. Monitoring & review

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

13. Contact

13.1 Carol Wheeler at the Department for Business, Innovation and Skills Tel: 020-7215 5993 or email: carol.wheeler@bis.gsi.gov.uk can answer any queries regarding the instrument.

Transposition note for Commission Directive 2011/59/EU amending, for the purpose of adapting to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products (OJ No L 125, 14.5.2011, p 17) (“the Directive”)

Directive 76/768/EEC relating to cosmetic products (O.J. L. 262, 27.9.1976, p.169) (as amended) is intended to ensure the free circulation of cosmetic products in the internal market and to ensure the safety of cosmetic products placed on it, including by imposing prohibitions and restrictions on the use of specified substances in cosmetic products. Directive 76/768/EEC is implemented into UK law by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) (“the Principal Regulations”).

The Directive amends Directive 76/768/EEC by making some changes to the Annexes of that Directive relating to the regulation of substances used in hair dye products.

The relevant provisions of the Directive will be transposed into UK law by the Cosmetic Products (Safety) (Amendment) Regulations 2011 (“the Regulations”) which amend the Principal Regulations as set out in the table below. The Department for Business, Innovation and Skills has lead responsibility for implementation of the Directive.

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility (Secretary of State if not specified)
Article 1	Provides for Annexes II and III to Council Directive 76/768/EEC to be amended in accordance with the Annex to the Directive (which adds and amends entries in the Annexes to Directive 76/768/EEC relating to substances used in hair dye products)	Regulation 2(3)-(5) and the Schedule to the Regulations	
Article 2	Duty on Member States to adopt and publish implementing legislation before	Regulation 1(2) and the Regulations to be made and laid before 3 rd January	

	3rd January 2012 and apply the provisions from that date.	2012	
Article 3	Fixes entry into force date of Directive.	No transposition required	
Article 4	Directive is addressed to Member States.	No transposition required	