EXPLANATORY MEMORANDUM TO

THE

COSMETIC PRODUCTS (SAFETY) (AMENDMENT) REGULATIONS 2012

2012 No. 2263

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") in order to implement Commission Directive 2011/84/EU which amends Council Directive 76/768/EEC on cosmetic products ("the Cosmetics Directive").

2.2 The Cosmetics Directive (as previously amended) ensures the free circulation of cosmetic products in the internal market and ensures the safety of cosmetic products placed on it, including by imposing prohibitions and restrictions on the use of specified substances in cosmetics. The Directive has been implemented by the Principal Regulations.

2.3 The Commission Directive 2011/84/EU makes a technical amendment to the Cosmetics Directive based on the latest conclusions of the EU's Scientific Committee on Consumer Safety which has been assessing the safe level of hydrogen peroxide in tooth whitening products. Hydrogen peroxide is the most widely used substance to whiten teeth. The maximum hydrogen peroxide level is currently set at 0.1 %. The scientific dental and medical consensus is that this is not sufficiently strong to whiten teeth.

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

3.1 None.

4. Legislative Context

4.1 This instrument is being made to implement Commission Directive 2011/84/EU which amends Council Directive 76/768/EEC on cosmetic products (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 DTI submitted an EM on Council Doc No. 11451/02 on 30th September 2002 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". The Commons European Scrutiny Committee considered it politically and legally important and cleared it (Report 38, Session 01/02). The Lords Select Committee on the EU cleared it (Progress of Scrutiny, 3rd March 2003, Session 02/03).

4.5 DTI submitted an EM on Council Doc No. 8586/92 on 16th October 1992 relating to an "Amended proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of laws of Member States relating to cosmetic products". The Commons European Scrutiny Committee considered it politically important and recommended it for debate (Report 7, Session 91/92). The debate was held on 25/11/92 in European Standing Committee "B". The Lords Select Committee on the EU cleared it {Sift 753 Session 91/92).

4.6 A transposition note on the implementation of the provisions of the Directive has been prepared and is annexed 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

7.1 The changes clarify regulation of tooth whitening in the Directive by permitting the supply of tooth whitening or bleaching products containing up to 6% of hydrogen peroxide.

7.2 Changes were needed as there has been some confusion and concern about the regulation and enforcement of tooth whitening products under the Cosmetics Directive. This is because the current level of 0.1 % of hydrogen peroxide was considered too low to have any effect and there were fears that the absence of a safe limit could cause problems. The new limit has been set following scientific research.

8. Consultation outcome

8.1 The changes to the legislation did not merit the usual 12 week consultation mainly because there is no impact on business and they are for the purpose of adaption to technical progress. However, BIS has had substantive discussions with the Department of Health, Trading Standards (who enforce the Cosmetics Directive), the British Dental Association and the Cosmetics, Toiletries, Perfume Association (CTPA). All parties have agreed with the BIS approach. The CTPA advised that the amending Directive does not pose costs to business. Member States are required to transpose the Directive by 31 October 2012.

9. Guidance

9.1 Guidance on the Principle Regulations is available at http://www.bis.gov.uk/assets/biscore/corporate/docs/c/10-761-guide-to-cosmetic-safety-regulations-2008.pdf

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 No impact assessment has been prepared because these Regulations are deregulatory and have no effect on the costs of business and the voluntary sector.

11. Regulating small business

As this is Union harmonised safety legislation it would not be appropriate to allow SMEs to manufacture under separate conditions.

12. Monitoring & review

12.1 It is not proposed to use the draft Regulations to include a statutory duty to review in the Principal Regulations. This is because with effect from 11 July 2013 the Cosmetics Directive, which the Principal Regulations implement, will have been repealed and replaced by the new EU Regulation on cosmetic products (Regulation 1223/2009/EU) which will have direct effect across the EU. As a result, the Principal Regulations which includes this amendment will in any event have to be revoked in 2013 and replaced by new regulations enforcing the new EU Regulation.

13. Contact

13.1 Tony Eden Brown at the Department for Business, Innovation and Skills. Tel: 020-7215 0360 or email: tony.edenbrown@bis.gsi.gov.uk who can answer any queries regarding the instrument.

Transposition note for Council Directive 2011/84/EU amending Council Directive 76/768/EEC concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (OJ No L 283. 29.10.2012, p 36) ("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 Annex III of that Directive relating to the regulation of hydrogen peroxide for tooth whitening products.

The relevant provisions of the Directive will be transposed into UK law by The Cosmetic Products (Safety) (Amendment) Regulations 2012 ("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 Annex III to Council Directive 76/768/EEC to be amended in accordance with the Annex to the Directive	Regulation 2(b) and the Schedule to the Regulations	
Article 2	Duty on Member States to adopt and publish implementing legislation before 31 October 2012 and apply the provisions from that date.	Regulation 1(2) and the Regulations to be made and laid before 31 October 2012	
Article 3	Fixes entry into force date of Directive.	No transposition required	
Article 4	Directive is addressed to Member States.	No transposition required	