EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (SAFETY) AMENDMENT REGULATIONS 2010

2010 No. 1150

1. This explanatory memorandum has been prepared by the Department of Business, Innovation and 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. The Cosmetic Products (Safety) Amendment Regulations 2010 No. xxxx ("the Regulations") implement Commission Directive 2009/129/EC (O.J. L.267/18, 10.10.2009), Commission Directive 2009/130/EC (O.J. L.268/5, 13.10.2009), Commission Directive 2009/134/EC (O.J. L.282/15, 29.10.2009), Commission Directive 2009/164/EU (O.J. L.344/41, 23.12.2009) as amended by Corrigendum (O.J. L.3/30, 7.1.2010) Commission Directive 2010/3/EU (O.J. L.29/5, 2.2.2010) and Commission Directive 2010/4/EU (O.J. L.36/21, 9.2.2010) ("the Directives"), which amend Council Directive 76/768/EEC (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"). 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 2009/129/EC amends the Principal Directive by requiring new labelling on toothpastes containing any of the 20 "fluorine" compounds listed in Part 1 of Annex III.

2.3. The provisions of Directive 2009/129/EC must be adopted and published by 15 April 2010 and shall apply from 15 October 2010, Member States shall not prevent the marketing of toothpaste which complies with the new labelling requirements before 15 October 2010.

2.4. Directive 2009/130/EC amends the Principal Directive by creating two separate entries for hair dyes "p-Phenylenediamine (PPD)" and "Toulene-2-5-diamine (PTD)" with decreased maximum authorised concentrations in Part 1 of Annex III.

2.5. The provisions of Directive 2009/130/EC must be adopted and published by 15 April 2010 and shall apply from 15 July 2010.

2.6. Directive 2009/134/EC amends the Principal Directive by requiring all oxidative and certain non-oxidative hair dyes products listed in Part 1 of Annex II to carry additional warnings for consumers.

2.7. The provisions of Directive 2009/134/EC must be adopted and published 1 May 2010. Member States must ensure that non-complaint products are not placed on the market after 1 November 2011 and that after 1 November 2012 no non-complaint products are sold or disposed of to consumers.

2.8. Directive 2009/164/EU amends the Principal Directive by amending the reference to Verbena in Part 1 of Annex III so that "Verbena Absolute" is split from "Allyl phenethyl ether" and a trade name is removed from the entry for "Terpene".

2.9. The provisions of Directive 2009/164/EU must be adopted and published by 15 August 2010. Member States must ensure that no non-compliant products are placed on the market after 15 February 2011 and that after 15 August 2011 no non-compliant products are sold or disposed of to consumers.

2.10. Directive 2010/3/EU amends the Principal Directive by setting a maximum authorised concentration in Part 1 of Annex III for "Ethyl Lauroyl Arginate" when used in soap, anti dandruff shampoos and non-spray deodorants. In Part 1 of Annex VI the use of the substance as a preservative in lip, oral products and sprays is also prohibited.

2.11. The provisions of Directive 2010/3/EU must be adopted and published by 1 September 2010 and shall apply from 1 March 2011.

2.12. Directive 2010/4/EU amends the Principal Directive by moving hair dyes "HC Orange No2" and "2-Hydroxyethylamino-5-nitroanisole" from Part 2 of Annex III into Part 1 of Annex II with maximum authorised concentrations.

2.13. The provisions of Directive 2010/4/EU must be adopted and published by 1 September 2010 and shall apply from 1 December 2010 except the labelling provisions in column (f) of entry 208. Member States must ensure that no hair dyes containing "HC Orange No2" not complying with the labelling requirements in column (f) of entry 208 are placed on the market after 1 November 2011 and that from 1 November 2010 no hair dyes containing "HC Orange No2" not complying with the labelling requirements in column (f) of entry 208 are sold or disposed of to consumers.

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 Department submitted a scrutiny EM (9068/05) on a “Report from the Commission to the Council and the European Parliament on the Development, Validation & Legal Acceptance 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 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 Directives are Commission Directives and have 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

6.1. As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1. The hair dye substances are being regulated as part of a strategy on-going since 2001 under which industry is required to submit files containing

scientific data on hair dye substances for evaluation by the Scientific Committee allowing an adequate risk assessment to be undertaken. The Scientific Committee considered that the evidence provided that these substances were safe for human health, when used in hair dye products up to the maximum limited specified was acceptable and the hair dyes regulated in the Directives reflect that.

7.2. The other 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 Scientific Committee using both risk assessment and risk management processes.

8. Consultation outcome

8.1. The Department has discussed this measure with the key stakeholders, primarily the Cosmetics Toiletry Perfumery Association, and it is believed that few companies, if any, will be using the relevant substances in greater proportions than proposed in the Regulations. Most of main stakeholders have been aware of the proposed control of these substances throughout the promulgation and negotiation of the amending Directives.

8.2. We are notifying industry and other stakeholders of the measures by an information exercise and the draft regulations to implement the Directives on the BIS website and publicity is also disseminated through Business Link. The notification has also been sent directly to stakeholders with a known interest and to the Health and Safety Executive.

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 and 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 and review

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

13. Contact

David Southerland at the Consumer & Competition Policy Directorate, Department for Business, Innovation and Skills. Tel 020 7215 0371 Or e-mail david.southerland@bis.gsi.gov.uk can answer queries regarding this instrument.

DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS

26 March 2010

Transposition Note for Commission Directive 2009/129/EC (O.J. L.267/18, 10.10.2009), Commission Directive 2009/130/EC (O.J. L.268/5, 13.10.2009), Commission Directive 2009/134/EC (O.J. L.282/15, 29.10.2009), Commission Directive 2009/164/EU (O.J. L.344/41, 23.12.2009) as amended by Corrigendum (O.J. L.3/30, 7.1.2010) Commission Directive 2010/3/EU (O.J. L.29/5, 2.2.2010) and Commission Directive 2010/4/EU (O.J. L.36/21, 9.2.2010), which are amending Council Directive 76/768/EEC (O.J. L.262, 27.9.1976 p.169) on the approximation of the laws of the Member States relating to cosmetic products.

This Transposition Tables below shows how the Department has implemented Directives 2009/129/EC, 2009/130/EC, 2009/134/EC, 2009/164/EU and its corrigendum, 2010/3/EU and 2010/4/EU through the new set of Regulations. 2009/129 and 2009/134 must be implemented by 15 April 2010, 2009/134 must be implemented by 1 May 2010. 2009/164 must be implemented by 15 August 2010 and 2010/3 and 2010/4 must be implemented by 1 September 2010.

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 2009/159/EU (O.J. L. 336, 18.12.2009, implemented by the Cosmetic Products (Safety) (Amendment No.4) Regulations 2009 (S.I. 2009/3367), imposes prohibitions and restrictions on the use of specified substances in cosmetic products ("the Principle Directive"). The 1976 Directive is implemented by the Cosmetic Products (Safety) Regulations 2008 (SI 2008/1284) ("the Principal Regulations").

These new Regulations do what is necessary to implement the Directives, by amending the Principal Regulations to include consequential changes to ensure coherence in the area to which they apply. The Department for Business, Innovation and Skills has lead responsibility for implementation of the Directives.

Directive 2009/129/EC

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annex III part 1 by requiring additional labelling for certain entries	Regulation 2(d)(viii)	
2	Implementing measure to be adopted and	Regulation 1(3) and Regulations to be made and	

	published by 15 April 2010 and applied from 15 October 2010	laid before Parliament before 15 April 2010	
3	Member States shall not prohibit the marketing of toothpaste labelled in accordance with Directive 2009/129/EC before 15 October 2010	No need to implement – no such prohibitions in place	
4-5	Administrative provisions	No need to implement	

Directive 2009/130/EC

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified
1	Amends Annex III part 1 by amending certain entries	Regulation 2(d)(i), 2(d)(v) and Schedule 1	
2	Implementing measures to be adopted and published by 15 April 2010 and applied from 15 July 2010	Regulation 1(2) and Regulations to be made and laid before 15 April 2010.	
3-4	Administrative provisions	No need to implement	

Directive 2009/134/EC

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annex III, Part 1 and Annex III Part 2 by requiring additional labelling for	Regulations 2(d)(ii) to 2(d)(iv), 2(d)(vi), 2(d)(vii), 2(d)(xi) and Regulations 2(e)(i) to 2(d)(vi)	

	certain entries	and Schedules 2, 3, & 4.	
2	Implementing measures to be adopted and published by 1 May 2010	Regulations to be made and laid before 1 May 2010.	
3	Prohibits the placing on the market of non-compliant cosmetic products from 1 November 2011 and sale or disposal to the final consumer of these cosmetic products after 1 November 2012	Regulation 1(9) and 1(6).	
4-5	Administrative provisions	No need to implement	

Directive 2009/164/EU and Corrigenda

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Annexes II and Part 1 of Annex III by adding and amending entries	Regulation 2(c), 2(d)(ix) 2(d)(x), 2(d)(xii) and Schedule 1	
2	Prohibits the placing on the market of non-compliant cosmetic products from 15 February 2011 and sale or disposal to the final consumer of these cosmetic products after 15 August 2011	Regulation 1(2) and 1(7)	
3	Implementing measures to be adopted and	Regulation 1(7) and to be made and laid before	

	published by 15 August 2010 and applied from 15 February 2011	Parliament in advance of 1 September 2011.	
4-5	Administrative provisions	No need to implement	

Directive 2010/3/EU

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Part 1 of Annex III and Part 1 of Annex VI by adding certain entries	Regulation 2(d)(xiii), 2(d) (xv) and 2(f) and Schedules 1 and 5	
2	Implementing measures to be adopted and published by 1 September 2010 and applied from 1 March 2011	Regulation 1(8) and to be made and laid before Parliament in advance of 1 September 2010.	
3-4	Administrative provisions	No need to implement	

Directive 2010/4/EU

Article	**Objective**	**Regulation**	**Responsibility** (Secretary of State if not specified
1	Amends Annex III by adding and deleting entries in Parts 1 and 2	Regulation 2(d)(xiv) and 2(e)(vii) and Schedule 1	
2	Implementing measures to be adopted and published by 1 September 2010 and applied the obligations from 1 November 2010 except those concerning the labelling relating to entry 208	Regulations to be made and laid in advance of 1 September 2010. Regulation 1(4) and (5).	

3	Prohibits the placing on the market of cosmetic products failing to comply with the labelling set out in column (f) in entry 208 from 1 November 2011 and sale or disposal to the final consumer of these cosmetic products after 1 November 2012	Regulation 1(2) and 1(5)	
4-5	Administrative provisions	No need to implement	