EXPLANATORY MEMORANDUM TO

THE COSMETICS (SAFETY) (AMENDMENT) REGULATIONS 2006
2006 No. 1198

1. This explanatory memorandum has been prepared by the Department of Trade & Industry and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 The Regulations implement Commission Directive 2005/80/EC (OJ L L303, 22.11.2005, p.32), 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. Directive 2005/80/EC contains the latest amendments to the Principal Regulations adding 75 carcinogenic, mutagenic or repro-toxic substances (CMRs) substances to the list of those prohibited or restricted. The Directive also makes some minor amendments to the list of prohibited substances and to those which may only be used subject to restrictions.

2.2 The prohibition in respect of the CMRs applies to products placed on the market after 21 July 2006 or supplied after 22 November 2006; the other amendments come into force on 22 May 2006.

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

3.1 None.

4. Legislative Background

4.1 These Regulations are made under section 11 of the Consumer Protection Act 1987 to implement Directive 2005/80/EC.

4.2 As stated above, Directive 2005/80/EC requires Member States to ban the use of certain substances in Cosmetics. Previously the DTI submitted a scrutiny EM (9068/05) on 20 June 2005 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 The DTI also 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 Directive 2005/80 is a Commission Directive and has not been subject to Parliamentary Scrutiny

4.6 A Transposition Note is attached to this Memorandum.

5. Extent

5.1 Consumer safety is a reserved matter and therefore the Regulations will 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

7.1 A consultation exercise on draft regulations to implement the Directive was conducted from 24 January – 14 April 2006. The consultation document was sent to manufacturers, trade associations, consumer groups, individuals and other interested parties. The consultation document was also published on the DTI website at: http://dti.gov.uk/ccp/consultpdf/cosregcondoc.pdf

7.2 The results of the consultation indicated that the Directive would not have any major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products of ingredients of cosmetic products. Only two responses were received, and these were supportive of the proposal. A Report on the consultation exercise will be published on the DTI website in June2006.

8. Regulatory Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

9.1 Ian Parsons at the Consumer and Competition Policy Directorate, Department of Trade and Industry, tel 020 7215 0360 or e-mail: ian.parsons@dti.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT OF TRADE AND INDUSTRY
…..April 2006

Amendment to The Cosmetic Products (Safety) Regulations 2006

Proposal

To transpose Commission Directive 2005/80/EC into UK Law.

Purpose and intended effect of measure

Objective

The primary aim of the Cosmetic Products (Safety) Regulations is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients.

The Directive adds 75 substances that are classified carcinogenic, mutagenic or toxic to reproduction (CMRs) to the list of banned ingredients in Annexe II – prohibited from use in all cosmetic products.

The Regulation also makes a number of changes to the naming of entries in Schedule 4 Part I.

Rationale for Government Intervention

The Cosmetics Directive (76/768/EEC) prohibits the use in cosmetic products of substances classified as CMRs of category 1, 2 and 3, under Annexe I of Council Directive 67/548/EEC on the approximations of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Certain substances classed as category 3 have been allowed in cosmetic products, subject to approval by the Scientific Committee on Cosmetic and Non-food Products and the Scientific Committee on Consumer Products.

The implementation of the Directive is an update of the lists and classification of CMRs. Of these 75 substances only 1 is currently used in cosmetic products. It is used by a small number of manufacturers in hair dyes. However, its continued use is not being supported by the cosmetics industry, which have chosen not to submit a dossier to the Scientific Committee. Other CMRs classed as category 1 or 2 are not yet listed in Annexe II of the Cosmetics Directive.

Options

Option (i): to fully implement the provisions of the proposed Directive, if adopted.

Option (ii): to request industry to adopt voluntary measures.

Option (iii): to do nothing.

Option (i) is the recommended option. The proposed Directive is consistent with UK policy and practice on these issues. It guarantees a high level of consumer safety, restricting the use of ingredients identified as CMRs.

Option (ii) under the Cosmetics Directive, substances used as ingredients in cosmetic products are subject to approval by the Scientific Committee. Those not allowed or allowed with restrictions are in a positive schedule. Voluntary measures would not guarantee knowledge of the restrictions on use of the ingredients.

Option (iii) would not make the information available. This could possibly mislead manufacturers and consumers as to the safety of these particular ingredients.

Benefits

Economic

The Directive bans the use of certain substances as ingredients in cosmetic products, which may incur costs in the reformulation of certain finished products.

Environmental

No specific benefits to the environment have been identified.

Social

The Directive, if adopted, will improve consumer protection. The restriction on substances identified as being CMRs is in the interests of improving consumer safety.

Costs

The choice of manufacturers to use allowed ingredients is discretionary. The restriction and prohibition on certain ingredients may incur cost on manufacturers. Only one of the substances listed is used in cosmetic products – as an ingredient in hair dyes. It is not widely used, but will require a small

number of manufacturers to reformulate their product to take account of the new Regulations. It is unlikely that there will be any additional costs for consumers.

Equity & Fairness

The overriding consideration of the Directive is the safety of consumers. The Directive will impact equally across the particular sectors of industry affected and will be implemented in all Member States.

Consultation with small business: the Small Firms Impact Test

On the advice of the Small Business Service, stage one of the Small Firms Impact Test was carried out by contacting small businesses and the industry trade association. We were unable to identify any disproportionate impact on small firms as a result of this proposal.

Competition Assessment

Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment filter, the results indicated that, as the proposed Directive would not introduce any restrictions and is unlikely to have the effect of distorting or removing competition in the market. 74 of the 75 substances banned by the Regulation are not used in cosmetic products and the one currently used in hair dyes is in the process of being phased out. The Directive, if adopted, would not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others.

Enforcement & Sanctions

The Cosmetic Products (Safety) Regulations 2004, which are amended by these Regulations, are enforced by local authorities trading standards departments. It is the responsibility of the manufacturers of cosmetic products made in the EU or importers of finished cosmetic products to ensure that products comply with the Regulations.

Consultation

Within Government

The relevant interested department; the Department of Health was consulted about these proposals during the consultation exercise.

Public Consultation

DTI conducted a full consultation for the implementation of the Cosmetic Product (Safety) (Amendment) Regulations 2006.

Summary & Recommendation

Our recommendation is that the option chosen offers the best level of public health protection by extending the restrictions on the use of specific substances in finished cosmetic products.

Our legal obligations under the Treaty of Rome compel us to implement this Directive into UK law.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the Minister responsible

Gerry Sutcliffe
(Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs)

Date *27th April 2006*

Contact point

Ian Parsons
Consumer and Competition Policy Directorate
Room 428
1 Victoria Street
London SW1H OET

Tel: 020 7215 0360
Fax: 020 7215 0357

Ian.Parsons@dti.gsi.gov.uk

The Cosmetic Products (Safety)(Amendment) Regulations 2006

Transposition Table

This Transposition Table shows how the Department has implemented Commission Directive **2005/80/EC** of 21 November 2005**,** amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress (OJ L L303, 22.11.2005, p.32).

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 2005/52/EC ((O.J. L. 234, 10.9.2005, p.9) imposes prohibitions and restrictions on the use of specified substances in cosmetic products. It is implemented by the Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) ("the Principal Regulations") as last amended by the Cosmetic Products (Safety) (Amendment)(No. 2) Regulations 2005 SI 2005/3346.

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 of Trade and Industry has lead responsibility for implementation of Directives 76/768/EEC and 2005/80/EC. The table below shows how Directive 2005/42/EC has been implemented.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	**Amends the list in Annex II of 76/768/EEC of substances that are not allowed in cosmetic products by:** **(a) deleting entries 615 and 616;** **(b) replacing entry number 687;** **(c) adding entry numbers 1137-1211 (carcinogenic, mutagenic and repro-toxic substances (CMRs))** **(d) amending the list in Annex III of substances which cosmetics may not contain except subject to restrictions and conditions**	**(a) and (b) Regulation 2(2) amends regulation 5(15)(a) of the Principal Regulations to omit these entries and to replace entry 687;** **(c) Regulation 2(3) inserts a new regulation 5(15)(c) in the Principal Regulations which adds the CMRs in entry nos 1137-1211 to those banned under by the Regulations;** **(d) regulation 2(5) amends Part 1 of Schedule 4 to the Principal Regulations.**	
2	**Requires Member States to ensure that cosmetics which fail to comply with the Directive are not placed on the market from 22/8/2006 or sold to final consumers after 22/11/2006**	**Regulation 3 inserts a new regulation 5(15)(c) in the Principal Regulations which transposes in (c)(i) and (ii) these requirements**	