EXPLANATORY MEMORANDUM TO THE COSMETICS (SAFETY) (AMENDMENT NO 2) REGULATIONS 2005

SI 2005/3346

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

The memorandum contains information for the Joint Committee on Statutory Instruments.

DESCRIPTION

2.1 These Regulations implement European Parliament and Council Directives 2005/42/EC (OJ L 158, 20.6.2005 p 17) 2005/52/EC (OJ L 234 10.9.2003 p9), which amend the Council Directive 76/768/EC (OJ L 262, 27.7.1976 p. 169) on the approximation of the laws of the Member States relating to protect public health by requiring cosmetic products to meet the provisions of the Directive.

2.2 Directive 2005/42/EC makes a number of technical amendments to the main **Cosmetic Products (Safety) Regulations 2004**: adding 4 new substances to the list of banned ingredients, when they are used as fragrance ingredients; deletes 3 colours as permitted colouring agents; amends the use of one preservative and allows the use of a new preservative. The Directive requires member States to transpose it into national law by 31 December 2005. Article 2 of the proposed Regulations clarifies the dates applicable in Article 5 (15) of the Principal Regulations on the restriction of certain substances classified as carcinogenic, mutagenic or repro-toxic in Annexe II.

2.3 Directive 2005/52/EC amends dates in Schedule 4, Part 2 of the Cosmetic Products (Safety) Regulations 2004 for the use of two groups of certain colours permitted as colouring agents.

2.4 The substance ‘Methyleugenol’ is moved from part 1 to part 2 of Schedule 3.

MATTERS OF SPECIAL INTEREST TO THE JOINT COMMITTEE ON STATUTORY INSTRUMENTS

3.1 Directives 2005/42/EC and 2005/52/EC require Member States to bring into force implementing legislation by 31 December 2005.

LEGISLATIVE BACKGROUND

4.1 These Regulations are made under section 11 of the Consumer Protection Act 1987.

4.2 As stated above, Directive 2005/42/EC and 2005/52/EC require the Commission to introduce a ban on the use of certain substances and restrictions on the use of other substances. Previously the DTI submitted for Scrutiny an Explanatory Memorandum (official text not available) on 11/12/02 on an “Amended Proposal for a Directive of the EP & Council amending for the 7th time Council Directive 76/768/EEC on the approximation of laws of Member States relating to cosmetic

products” (2003/15/EC). The Commons European Scrutiny Committee considered it politically and legally important and cleared it (Report 5, Item 24098, Sess 02/03. The Lords Select Committee on the EU cleared it in Sub-Committee on 29/1/03 (Progress of Scrutiny 3/2/03, Session 02/03).

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 2005/42/EC and Directive 2005/52/EC were made under the co-decision procedure and have not been subject to Parliamentary Scrutiny.

4.6 A Transposition Note is attached to this Memorandum.

EXTENT

5.1 Consumer safety is a reserved matter and therefore the instrument will apply to the whole of the United Kingdom.

EUROPEAN CONVENTION OF HUMAN RIGHTS

6.1 In the Department’s view, these Regulations are compatible with the European Convention on Human Rights.

POLICY BACKGROUND

7.1 A consultation exercise for the Amendments was conducted in September-November 2005 prior to the adoption of the Directive. The consultation document was sent to over 200 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 four responses were received, and these were supportive of the proposal. Some minor changes have been made to the proposed regulations following the consultation exercise. A Report on the consultation exercise will be published on the DTI website in December 2005.

REGULATORY IMPACT

8.1 The primary objectives of the Regulations are to protect public health by restricting the use of certain ingredients in cosmetic products and introducing prohibitions on the use of other specified ingredients in cosmetic products.

8.2 A Regulatory Impact Assessment (RIA) and Transposition Note have been prepared and are attached to this memorandum.

COSTS TO THE PUBLIC

9.1 There will be no additional costs imposed on the public.

COSTS TO THE EXCHEQUER

10.1 No additional costs will fall to the Exchequer.

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DEPARTMENT OF TRADE AND INDUSTRY
….. December 2005

Regulatory Impact Assessment

Amendment to The Cosmetic Products (Safety) Regulations 2005

Proposal

To transpose Commission Directives 2005/42/EC and 2005/52/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 Directives adds adding 4 new substances to the list of banned ingredients when they are used as fragrance ingredients; deleting 3 colours as permitted colouring agents; amends the use of one preservative and allows the use of a new preservatives and extends the dates allowed for the use of certain colours used as colouring agents.

Risk Assessment

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 allergens.

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 Directives improves the choice of preservatives available, allows continued use of colours as colouring agents available to manufacturers and consumers. It also bans the use of certain ingredients as fragrances that are available to manufacturers, which may incur costs in the reformulation of certain finished products.

Environmental
No specific benefits to the environment have been identified

Social
The Directives, if adopted will improve consumer protection. The restriction on ingredients as fragrances will remove certain allergens from the market in the interests of improving consumer safety.

Costs
The choice of manufacturer to use allowed ingredients is discretionary. The restriction on certain ingredients as fragrance may incur cost on manufacturers. There would be no 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. Nevertheless if, during the proposed consultation we identify impacts or unintended consequences of the proposal on small firms, further work to assess this impact will be undertaken and the position reviewed

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, it is unlikely to have the effect of distorting or removing competition in the market. The Directives, 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, of which this Amendment will form a part, 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) (No 2) Regulations 2005.

Summary & Recommendation

Our recommendation is that the option chosen offers the best level of public health protection by extending the restrictions on 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, Competition and Consumers)

Date 5th December 2005

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Transposition Note for Directives 2005/42/EC and 2005/52/EC.

This Transposition Note shows how the Department has implemented Commission Directives **2005/42/EC,** amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II, IV & VI thereto to technical progress (O.J. L158, 21.6.2005, p.17) and **2005/52/EC,** amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex III thereto to technical progress (O.J. L234, 9.9.2005, p.9).

Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products imposes various prohibitions and restrictions on the use of specified substances in cosmetic products. It is currently implemented by the Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) ("the Principal Regulations").

The Department of Trade and Industry has lead responsibility for implementation of Directives 76/768/EEC, 2005/42/EC and 2005/52/EC.

The table below shows how Commission Directive 2005/42/EC has been implemented.

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends the Annexes to the Cosmetics Directive by: • Adding 4 fragrance ingredients to Annex II of the Directive (Prohibited substances); • Deleting 3 colouring agents from Part 1 of Annex IV (Permitted colouring agents); and • Amending reference number 53 and adding reference number 57 to Part 1 of Annex VI (Permitted preservatives)	Regulation 2 amends the Principal Regulations by: • Amending paragraph 15 of regulation 5 by inserting a new paragraph (15(b) to prohibit the supply or placing on the market of the new fragrance ingredients (reg. 2(2)); • Deleting the 3 colouring agents from Part 1 of Schedule 5 (reg. 2(6)); and • Amending Part 1 of Schedule 6 to substitute the substance with the reference number 53 and insert the substance with the reference number 57 (reg. 2(8)).	
2	Requires Member States to ensure that cosmetic products which do not comply with Annexes II and IV of the Directive are not placed on the market after 31 March 2006	Regulation 2(2) amends paragraph 15 of Regulation 5 of the Principal Regulations, to prohibit the placing on the market / supply of products containing the new substances after 31 March 2006	
3	Requires Member States to implement Directive 2005/42/EC by 31 December 2005. Implementing legislation should contain a reference to this Directive.	These Regulations will come into force on 31 December 2005. Schedule 2 to the Principal Regulations is amended to include a reference to this Directive. The Explanatory Note to the Regulations also refers to this Directive.	
4 & 5	Administrative	N/a	

The table below shows how Commission Directive 2005/52/EC has been implemented.

Article	**Objective**	**Implementing regulation**	**Responsibility** (Secretary of State if not specified)
1	Amends Part 2, column g of the Annex III to the Directive (Prohibited substances subject to certain conditions and requirements) to put back the dates of compliance for certain substances.	Regulation 2(5) amends Part 2 of Schedule 4 to the Principal Regulations to introduce the new dates.	
2	Requires Member States to implement Directive 2005/52/EC by 1 January 2006. Implementing legislation should contain a reference to this Directive.	These Regulations will come into force on 31 December 2005. Schedule 2 to the Principal Regulations is amended to include a reference to this Directive.	
3 & 4	Administrative	N/a	