

**EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) (No 2)
REGULATIONS 2007
2007 No. 2400**

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

2. **Description**

2.1 The Regulations implement Commission Directive 2007/1/EC (OJ No. L25, 01.02.2007, p.9) and Commission Directive 2007/17/EC (OJ No. L82, 23.03.2007 p.27) which amend Council Directive 76/768/EC (OJ L 262, 27.09.1976 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.

2.2 Directive 2007/1/EC adds 10 substances (reference numbers 1234 - 1243) to the list of substances not allowed in cosmetics in Annex II of the Principal Directive, deletes reference number 1182 for epoxiconazole and inserts this substance under the revised reference number 663. The provisions are required to apply from 21 November 2007.

2.3 Directive 2007/17/EC makes several changes to the allowed use of preservatives in cosmetic products. Twenty three substances can now only be used in the concentrations and with the specified restrictions set out in Annex VI of the Principal Directive. Two substances, Formaldehyde paraformaldehyde (no 5) and 1-Phenoxypropan-2-ol (no 43) can now be used for non preservative purposes in concentrations other than those set out in Annex IV. A number of other minor changes are made. These provisions are required to apply to all goods placed on the market from 23 March 2008 and all non-compliant goods must be sold or disposed of by 23 June 2008.

2.4 The Regulations also re-implement some parts of Commission Directives: 2004/93/EC (OJ No L300 25/09/2004 p.13); 2005/42/EC (OJ No. L158 , 21/06/2005, p.17); 2005/80/EC (OJ No. L303, 22/11/2005, p. 32) and 2006/65/EC (OJ No. L198, 20/07/2006, p.11).

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 the Directives 2007/1/EC and 2007/17/EC.

4.2 As stated above, the Directive requires Member States to ban the use of certain substances in cosmetic products. 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).

4.4 The Department of Trade & Industry 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".

4.5 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).

4.6 Directives 2007/1/EC and 2007/17/EC are Commission Directives and have not been subject to Parliamentary Scrutiny.

4.8 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

5.1 Consumer safety of goods 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 15 May -3 August 2007. The consultation document was sent to manufacturers, trade associations, consumer groups, individuals and other interested parties. The consultation document was also published on the BERR website at:

<http://www.berr.gov.uk/consultations/page39429.html>

7.2 There were two responses to the consultation from the UK trade association, the Cosmetics, Toiletries and Perfumery Association (CTPA), which represents 85% of UK manufacturers of cosmetic products and Trading Standards South East, neither indicated that the Directive would have a major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products or ingredients of cosmetic products. The CTPA made some detailed drafting points which have been incorporated in the final instrument.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

Ian Parsons at the Consumer and Competition Policy Directorate, Department for Business, Enterprise & Regulatory Reform, tel 020 7215 0360 or e-mail: ian.parsons@berr.gsi.gov.uk can answer any queries regarding the instrument.

DEPARTMENT FOR BUSINESS, ENTERPRISE & REGULATORY REFORM

14th August 2007

Regulatory Impact Assessment

The Cosmetic Products (Safety) (Amendment) (No 2) Regulations 2007

Proposal

To transpose Commission Directives 2007/1/EC and 2007/17/EC into UK Law.

Purpose and intended effect of measure

Objective

The primary aim of the Cosmetic Products (Safety) Regulations 2004 (as amended) is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients.

Commission Directive 2007/1/EC forms part of the strategy on hair dyes to ensure that only safe substances are used in finished hair dye products. Therefore 10 substances, numbered 1234-1243 are added to the list of banned ingredients in Annex II.

Commission Directive 2007/17/EC amends Annex VI changing the restrictions on the use and concentrations of certain substances for purposes other than preservatives and Part 1 of Annex III allows the conditions for use of certain substances for purposes other than as preservatives.

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.

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.

Cost/Benefit Analysis

Economic

Directive 2007/1/EC bans the use of 10 substances as hair dyes, whose approval by the Scientific Committee for Consumer Products is not being sought by the cosmetics industry because they are not in use in finished hair colouring products marketed in the EU. There will, therefore be a neutral economic impact on UK manufacturers and consumers as the ingredients are not available in products sold to the general public. The economic impact of this Directive is neutral.

Directive 2007/17/EC may require some manufacturers using the substances that have their restrictions changed to engage in reformulation and re-labelling of their products. However consumer use of these products is not widespread and any increase in costs for consumers in general is likely to be marginal.

However, we had limited information on the potential market impact, particularly of Directive 2007/17/EC and we asked consultees to provide further information. We received two responses to the consultation: from the UK trade association, the Cosmetics, Toiletries and Perfumery Association (CTPA), which represents 85% of UK manufacturers of cosmetic products and Trading Standards South East. Neither indicated that the Directive would have a major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products or ingredients of cosmetic products.

Both Directives will apply in all Member States of the EU and the countries that are members of the EEA.

Environmental

No specific benefits to the environment have been identified.

Social

The Directives, if adopted, will improve consumer protection. The hair dyes strategy is aimed at assessing all substances that can be used in hair dyes and banning from use those that are identified as being potentially carcinogenic.

The Directive on preservatives is based on opinions of the Scientific Committee on the safe levels for usage of substances allowed as preservatives that can be used for other purposes. These additional restrictions improve consumer safety.

Costs

The cosmetics industry is truly international, which can be seen from the flow of trade. There are approximately 150 companies in the UK involved in the manufacture/importing of cosmetic products. The UK cosmetics market was worth £6.4 billion at retail prices in 2005, of which approx 51% is manufactured in the UK. In 2005, 47% of cosmetics manufactured in the UK were exported: 33% to the rest of the EU and 17% abroad. For imported cosmetics, 71% is imported from the EU and 29% from outside the EU.

The proposed ban for 10 hair dyes is for substances that are not currently used by manufacturers. The ban will not impose additional costs in the composition of hair dyes made in the UK. Similarly, there would be no additional costs for consumers.

The use of preservatives for non preservative purposes is not widespread in cosmetics. They are only used in a few specific types of cosmetic, such as: rinse off skin treatments and self tanning products. Given the particular nature of their usage, one of the purposes of the consultation was to establish the exact impact of the Directive on the costs of the manufacturers of these products. No additional information on this matter was gained as a result of the public consultation.

The consultation on this proposal asked business to comment on the likely extent of this burden and for suggestions for regulatory off-setting of any additional administrative burden. No information on this matter was gained as a result of the public consultation.

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 new 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 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

BERR conducted a full 12 week consultation, from May 15 to August 3 2007, for the implementation of the Cosmetic Products (Safety) (Amendment) (No 2) Regulations 2007, contacting key stakeholders such as the Cosmetics, Toiletries and Perfumery Association and those who have responded to consultations to previous amendments to the Cosmetic Regulations and publishing the consultation on the BERR website.

Summary & Recommendation

Our recommendation is that the option chosen offers the best level of public health protection by making the Regulations.

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

Malcolm Wicks

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(Minister of State for Energy, Department for Business, Enterprise & Regulatory Reform)

Date 14th August 2007

Transposition Note for Directives 2007/1/EC, 2007/17/EC, 2004/42/EC, 2005/80/EC,

This Transposition Note shows how the Department for Business, Enterprise & Regulatory Reform has implemented for the first time by the Cosmetic Products (Safety) (Amendment) (No. 2) Regulations 2007:

1. Commission Directive 2007/1/EC amending Council Directive 76/768/EEC concerning cosmetic products, for the purpose of adapting Annex II thereof to technical progress (O.J. L25 1.2.2007 p.9); and
2. Commission Directive 2007/17/EC amending Council Directive 76/768/EEC concerning cosmetic products, for the purpose of adapting Annexes III and VI thereto to technical progress (O.J. L82 23.3.2007 p.27).

The note also shows how parts of the following Directives have been re-implemented in the Regulations:

3. Commission Directive 2004/93/EC amending Council Directive 76/768/EEC concerning cosmetic products Commission Directive
4. Commission Directive 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);
5. Commission Directive 2005/80/EC amending Council Directive 76/768/EEC concerning cosmetic products Commission Directive
6. Commission Directive 2006/65/EC amending Council Directive 76/768/EEC concerning cosmetic products Commission Directive

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.

Directive 2007/1/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex	Amends Annex II to Directive 76/768/EEC (list of substances prohibited in cosmetics) by amending entry 663, omitting entry 1182 and inserting entries 1234 to 1243.	Regulation 2 amends the Cosmetic Products (Safety) Regulations 2004 (the Principal Regulations). Regulation 2(3) replaces paragraph (15) of regulation 5 of the 2005 Regulations. New sub-paragraph (a) of paragraph (15) implements amended entry 663, sub-paragraph (c) the omission of entry 1182, and paragraph (e) the addition of entries 1234 to 1243.	
2	Cosmetic products which fail to comply with the Directive not to be sold or disposed of to the final consumer from 21/2/2008.	Regulation 2(3) inserting new paragraph 15(5)(e) into the Principal Regulations.	
3(1)	Provisions contained in the Directive must be applied from 21 November 2007. Upon the adoption of the provisions, there shall be a	Regulation 1(1) provides that the Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2007 shall come into force on 7th September 2007. The Explanatory Note refers to the Directive.	

	reference to this Directive.		
3(2)	Requirement to communication to Commission implementing provisions.	No need to implement.	
4 and 5	Entry into force of Directive and address to Member States	No need to implement.	

Directive 2007/17/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex para (1)	Amends Annex III to Directive 76/768/EEC (substances permitted in cosmetics subject to restrictions) to add substances 98 to 101.	Regulation 2(5) and Schedule 2 Part 1 inserts entries 98-101 into Schedule 4 to the Principal Regulations.	
1 and Annex para (2)	Amends Annex VI Part I to Directive 76/768/EEC (list of preservatives permitted in cosmetics) by amending a number of entries, replacing entry 1 with new 1 and 1a, replacing entry no 8 and deleting entry number 36.	Regulation 2(6)(a) and (b) amend the entries in Part 1 of Schedule 6 to the Principal Regulations, regulation 2(6). Part 2 of Schedule 2 substitutes the new entries for entry 1 in Part 1 of Schedule 6; regulation 2(6)(d) substitutes entry number 8 and regulation 2(6)(e) deletes entry number 36.	
2	Cosmetic products which fail to comply with the	Regulation 2(7)	

	Directive not to be placed on the market from 23/3/2008 or disposed of to the final consumer after 23/6/2008/..		
3(1)	Provisions must be applied from 12/09/2007. Upon the adoption of the provisions, they shall contain a reference to this Directive.	Regulation 1(1) entry into force date of 7th September 2007. The Explanatory Note refers to the Directive	
4	Entry into force and address to Member States.	No need to implement.	

Directive 2004/93/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex.	Amends Annex II (list of substances prohibited in cosmetics) by inserting entries number 452 to 1132.	Regulation 2(3) replaces paragraph (15) of regulation 5 of the Principal Regulations. New paragraph (15)(a) implements these amendments to Annex II with the subsequent amendments made by Directive 2005/80/EC.	
Remainder of Directive		Implemented by S.I. 2005/3346.	

Directive 2005/42/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex	Amends Annex II	Regulation 2(3)	

paragraph 1.	(list of substances prohibited in cosmetics), in accordance with the Annex by adding three entries.	replaces paragraph (15) of regulation 5 of the Principal Regulations. New sub-paragraph (b) of paragraph (15) implements the amendments to Annex II..	
Remainder of Directive		Implemented by S.I. 2005/3346.	

Directive 2005/80/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex paragraph 1(a) to (c)	Amends Annexes II (list of substances prohibited in cosmetics) and III (substances permitted in cosmetics subject to restrictions) of Directive 76/768/EEC Omits entries 615 and 616, replaces entry 687 and adds new entries 1137 to 1211	Regulation 2(3) replaces paragraph (15) of regulation 5 of the Principal Regulations. New sub-paragraph (a) of paragraph (15) omits entries 615 and 616 and refers to new entry 687. New sub-paragraph (c) refers to entries 1137 to 1211 with 1182 omitted by Directive 2007/1/EC.	
Remainder of Directive	.	Implemented by SI 2006/1198.	

Directive 2006/65/EC

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1 and Annex paragraph 1.	Amends Annex II (list of substances prohibited in cosmetics) of Directive 76/768/EEC Inserts entries 1212 to 1233.	Regulation 2(3) replaces paragraph (15) of regulation 5 of the Principal Regulations. New paragraph (15)(d) refers to entries 1212 to 1233.	
Remainder of Directive		Implemented by S.I. 2006/2231.	