

**EXPLANATORY MEMORANDUM TO**  
**THE COSMETICS (SAFETY) (AMENDMENT) (No 2) REGULATIONS 2006**  
**2006 No. [2231]**

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 2006/65/EC (OJ No. L198, 20.7.2006, p.11 “the Directive”), 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 2006/65/EC contains the latest amendments to the Principal Regulations to substances used in hair dyes, by adding 22 substances to the list of substances not allowed in cosmetics in Schedule 3 Part 1 and makes amendments to the restrictions on ingredients in Schedule 4 Part 1, deleting 4 substances and extending the date for the temporary use of other substances until the 31 December 2007.

2.2 The prohibition in respect of the 22 substances applies to products placed on the market after 31 November 2006; the other amendments also come into force on 1 September 2006.

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

3.1 The Committee’s attention is drawn to non-compliance with the ‘21 day rule’. The Commission Directive was only published in the Official Journal on 20 July 2006. The powers under which the Regulations are made oblige the Secretary of State to consult. Hence the Department conducted the consultation described in para 7.1. Allowing for time to prepare and publish the consultation and to consult prevented the Department from complying with the rule because it needed to ensure that the Regulations come into force on the due date: 1 September 2006, as the existing restrictions on 18 of the substances expires on 31 August 2006.

**4. Legislative Background**

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

4.2 As stated above, the Directive requires Member States to ban the use of certain substances and change restrictions on the use of others 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).

4.3 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 2006/65 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 instrument is 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 31 July –7 August 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://www.dti.gov.uk/consultations/page32644.html>

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. The 22 substances to be banned are not used in hair dyes. Four responses were received, and these were supportive of the proposal. A Report on the consultation exercise will be published on the DTI website in September 2006.

## **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](mailto:ian.parsons@dti.gsi.gov.uk) can answer any queries regarding the instrument.

**DEPARTMENT OF TRADE AND INDUSTRY**

.....August 2006

# Regulatory Impact Assessment

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## Amendment No2 to The Cosmetic Products (Safety) Regulations 2006

### Proposal

To transpose Commission Directive 2006/65/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. The Commission Directive forms part of the strategy on hair dyes to ensure that only safe substances are used in finished hair dye products. Therefore 22 substances, numbered 1212-1233 are added to the list of banned ingredients in Annex II, 4 substances are deleted from column g of Part 2 of Annex III and the date of restriction on the other substances listed is amended to 31.12.2007.

## 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 carcinogenic.

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 from use in hair dyes. Certain hair dyes have been identified as being potentially carcinogenic and the continued use of all hair dyes has to be supported by scientific data and safety assessments. The 22 substances being banned are not being supported by the cosmetics industry. The extension on the restriction on other substances allows for their continued use in hair dyes until the safety assessments on them have been fully evaluated.

#### *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.

#### *Costs*

The banned substances are not used by manufacturers. The ban will not impose additional costs in the reformulation of certain finished products. There would be no additional costs for consumers. The extension of

the restriction on the other substances allows manufacturers to continue to use them while the safety assessment process is completed.

### **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***

Because of the 1 September implementation date, DTI conducted a short consultation for the implementation of the Cosmetic Product (Safety) (Amendment) (No 2) Regulations 2006, contacting key stakeholders such as the Cosmetics, Perfumers and Toiletries Association and those who have responded to consultations to previous amendments to the Cosmetic Regulations.

### **Summary & Recommendation**

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

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*  
**Minster for Energy**

**15th August 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

## Transposition Note for Directive 2006/65/EC.

This Transposition Note shows how the Department has implemented Commission Directive 2006/65/EC amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress (O.J. No. L198, 20.07.2006, p.11).

Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (O.J. No. 262, 27.9.76, p.169) as last amended by Commission Directive 2005/80/EC (O.J. L303, 22.11.2005, p.32) imposes prohibitions and restrictions on the use of specified substances in cosmetic products. It has been implemented by the Cosmetic Products (Safety) Regulations 2004 (SI 2004/2152) (“the Principal Regulations”) as last amended by the Cosmetic Products (Safety) (Amendment) Regulations 2006 (2006/1198).

The Department of Trade and Industry has lead responsibility for the implementation of Directives 76/768/EEC and 2006/65/EC. 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 table below shows how Directive 2006/65/EC has been implemented.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	<p>Amends Annexes II and III to Directive 76/768/EEC by:</p> <p>(a) adding 22 hair dye substances to Annex II of the Directive (prohibited substances);</p> <p>(b) deleting four hair dye substances from Part 2 of Annex III of the Directive (provisionally allowed);</p> <p>(c) amending Part 2, column g of Annex III to the Directive (provisionally allowed) to put back the dates of compliance for certain substances.</p>	<p>Regulation 2 amends the Principal Regulations by:</p> <p>(a) inserting a new paragraph (d) in regulation 5(15)(c) prohibiting the 22 hair dye substances;</p> <p>(b) deleting the four hair dye substances from Part 2 of Schedule 4;</p> <p>(c) amending the dates in Part 2 of Schedule 4 up to which the substances may be supplied.</p>	

2	Requires Member States to ensure that cosmetic products which do not comply with the Directive are not placed on the market or supplied from 1st December 2006.	Regulation 2(1) amends regulation 15(5) of the Principal Regulations to prohibit the supply or placing on the market of the hair dye substances after 31st November 2006.	
3	Requires Member States to implement the Directive by 1st September 2006 and that implementing legislation refer to the Directive.	<p>These Regulations will come into force on 1st September 2006.</p> <p>Regulation 2(4) amends to the list of Directives in Schedule 2 to the Principal Regulations which those Regulations implement by adding Directive 2006/65/EC. The Explanatory Note to the Regulations also refers to the Directive.</p>	
4 and 5	Entry in force etc	Do not require implementation	