

EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) (No 3)
REGULATIONS 2007
No.3452

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

2. **Description**

2.1 The Regulations implement Commission Directive 2007/67/EC (OJ No. L305, 23.11. 2007, p.22) 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.

2.2 Directive 2007/67/EC amends the Principal Directive by extending the date until which 42 hair dye substances on the list of substances in Part 2 of Annex III are allowed. The extension allows these substances to be used in hair dyes, for an additional two years. If the amending Directive did not extend the dates for use, the substances would be banned as from 31 December 2007.

2.3 The provisions of the Directive apply from 1 January 2008.

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 Directive 2006/78/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 2007/67/EC is a Commission Directive and have not been subject to Parliamentary Scrutiny.

4.7 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 16 November -30 November 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/files/file42407.pdf>

7.2 There were no responses to the consultation.

8. Regulatory Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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

**DEPARTMENT FOR BUSINESS, ENTERPRISE & REGULATORY
REFORM**

Summary: Intervention & Options

Department /Agency: BERR	Title: Impact Assessment of The Cosmetics Products (Safety) (Amendment) (No3) Regulations 2007	
Stage: Full	Version: 2	Date: 3 December 2007
Related Publications:		

Available to view or download at:

<http://www.berr.gsi.uk/files/file42407>

Contact for enquiries: Tony Eden-Brown

Telephone: 020 7215 0360

What is the problem under consideration? Why is government intervention necessary?

The EU Directive (2007/27/EC) allows the extended use of 42 substances used in hair dyes, for an additional 2 years to allow the Joint Scientific Committee to examine the safety dossiers on each. Intervention is necessary to transpose this into UK law, otherwise the substances will become illegal for use on 1 January 2008. The use of these substances was previously extended in 2006 from the original specified period to allow for safety dossiers to be prepared.

What are the policy objectives and the intended effects?

The policy objective is to allow the continued use of the substances which are currently used widely in hair dyes, while they are being examined as to whether they are safe, and not inappropriately restrict their use.

What policy options have been considered? Please justify any preferred option.

- No intervention;
- Implement the Regulations

The preferred option is to implement, allowing time for scientific examination of the substances and allow manufacturers to continue to use them in products. The alternative would mean infraction proceedings and a number of hair colourant products being taken off the market at short notice.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? Before the two years extension has expired.

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Gareth Thomas

..... Date: 6/12/07

Summary: Analysis & Evidence

Policy Option: 1-4

Description: Pre-consultation summary of all options

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' Manufacturers and importers of hair dyes
	One-off	Yr	
	£ 0		
	Average Annual Cost (excluding one-off)		
	£ 0		Total Cost (PV) £ 0
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' As above.
	One-off	Yr	
	£ 0		
	Average Annual Benefit		
	£ 0		Total Benefit (PV) £ 0
Other key non-monetised benefits by 'main affected groups'			

Key Assumptions/Sensitivities/Risks

That continuing use of the substances can be justified.

Price Base	Time Period	Net Benefit Range (NPV) £ 0	NET BENEFIT (NPV Best estimate) £ 0
------------	-------------	---------------------------------------	---

What is the geographic coverage of the policy/option?	UK								
On what date will the policy be implemented?	1 January 2008								
Which organisation(s) will enforce the policy?	Trading								
What is the total annual cost of enforcement for these	£ N/A								
Does enforcement comply with Hampton principles?	Yes								
Will implementation go beyond minimum EU requirements?	No								
What is the value of the proposed offsetting measure per	£ N/A								
What is the value of changes in greenhouse gas emissions?	£ N/A								
Will the proposal have a significant impact on competition?	No								
Annual cost (£-£) per organisation (excluding one-off)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td>Micro</td> <td>Small</td> <td>Medium</td> <td>Large</td> </tr> <tr> <td>N/A</td> <td>N/A</td> <td>N/A</td> <td>N/A</td> </tr> </table>	Micro	Small	Medium	Large	N/A	N/A	N/A	N/A
Micro	Small	Medium	Large						
N/A	N/A	N/A	N/A						

Are any of these organisations exempt?	No	No	N/A	N/A
--	----	----	-----	-----

Impact on Admin Burdens Baseline (2005 Prices)				(Increase -
Increase	£ N/A	Decreases	£ N/A	Net
				£ N/A

Key:

Annual costs and benefits: Constant Prices

(Net) Present Value

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Amendment No3 to The Cosmetic Products (Safety) Regulations 2007

Proposal - To transpose Commission Directive 2007/67/EC into UK Law, which allows the extension of use of certain substances in hair dyes.

Purpose and intended effect of measure

Objective

The primary aim of the Cosmetic Products (Safety) Regulations 2004 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 extends the dates permitting the use of 42 substances listed in Part 2 of Annex III from 31.12. 2007 to 31.12.2009, in order that they may be evaluated by the European Commission's Scientific Committee on Consumer Products.

Risk Assessment

Options

Option (i): to fully implement the provisions of the proposed Directive

Option (ii): to do nothing

Option (i) is the recommended option. The proposed Directive is consistent with UK policy and practice on these issues. Whilst guaranteeing a high level of consumer safety, restricting the use of ingredients identified as carcinogenic, but allowing the use of the listed substances, while safety files are examined.

Option (ii) would mean that these substances would become illegal in hair dyes on 1 January 2008. This would have a severe and immediate effect on manufacturers and importers. It would probably restrict consumer choice, as a number of products would need to be removed from the market.

Benefits

The Cosmetic industry is truly international, which can be seen from the flow of trade. There are approximately 150 companies in the UK involved in the manufacturing /importing of cosmetic products. The UK cosmetic market was worth £6.8 thousand million at retail prices in 2006, of which hair colourants account for just over £221 million, around 3.25% of the market.

Economic

The extension on the restriction of use of these substances allows for their continued use in hair dyes until the safety assessments on them have been fully evaluated.

Costs

This will not impose additional costs for the reformulation of certain finished products. There would be no additional costs for consumers.

Equity & Fairness

The Directive will apply 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

As this Directive will have no effect whatsoever, we have been unable to identify any disproportionate impact on small firms as a result of this proposal. Nothing during the consultation identified any impacts or unintended consequences of the proposal for small firms.

Competition Assessment

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 Directive does 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 and the Health and Safety Commission have been consulted about these proposals during the consultation exercise.

Public Consultation

Because of the 1 January 2008 implementation date, BERR necessarily has conducted a short consultation for the implementation of the Cosmetic Product (Safety) (Amendment) (No 3) Regulations 2007, contacting key stakeholders and those who have responded to consultations to previous amendments to the Cosmetic Regulations. No responses were received as a result of the public consultation.

Summary & Recommendation

Our recommendation is that the option chosen offers the appropriate 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.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	No
Small Firms Impact Test	No	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	No
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

The Cosmetic Products (Safety)(Amendment) (No3) Regulations 2007

Transposition Table

This Transposition Table shows how the Department has implemented *Commission Directive 2007/67/EC* of 22 November 2007, amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (OJ L L305, 23.11.2007, p.22).

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 2007/22/EC (O.J. L. 101. 18.4.2007, p. 11), 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 2007 SI 2007/2400.

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 for Business, Enterprise & Regulatory Reform has lead responsibility for implementation of Directives 76/768/EEC and 2007/67/EC. The table below shows how Directive 2007/67/EC has been implemented.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	Amends the list in Part 2 of Annex III of Directive 76/768/EEC (substances that are provisionally allowed in cosmetic products) by extending the date until which some 42 items on the list are provisionally allowed.	Regulation 2 amends Part 2 of Schedule 4 to the Principal Regulations.	