

**EXPLANATORY MEMORANDUM TO THE
COSMETIC PRODUCTS (SAFETY) (AMENDMENT) REGULATIONS 2005**

2005 No. 1815

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

2. Description

- 2.1 These Regulations amend the Cosmetic Products (Safety) Regulations 2004 (S.I. 2004/2152) (“the Principal Regulations”) to give effect to Commission Directive 2005/09/EC (OJ L 27, 29.1.2005 p. 46) which amends Council Directive 76/768/EC (OJ L 262, 27.9.1976 p.169) (“the Cosmetics Directive”) on the approximation of the laws of the Member States relating to cosmetic products.
- 2.2 The Regulation also correct typographical errors that have been identified in the Principal Regulations

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.
- 4.4 The Principal Regulations give effect to the Cosmetics Directive which imposes a variety of requirements on cosmetic products including restrictions on the substances which may be used in such products.
- 4.5. Directive 2005/9/EC amends the Cosmetics Directive by adding one UV filter (Benzoic Acid) to Annex VII, Part 1 of the Directive which lists the UV filters which cosmetic products may contain subject to the restrictions specified in that annex. These Regulations implement Directive 2005/9/EC by inserting the additional ultra violet filter into Schedule 7, Part 1 to the Principal Regulations which corresponds to Annex VII
- 4.5 Directive 2005/9/EC is a Commission Directive subject to the comitology procedure and has not therefore been subject to Parliamentary Scrutiny.
- 4.7 A Transposition Note is attached to this Memorandum

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention Of Human Rights

6.1 Not applicable.

7. Policy Background

7.1 An informal consultation exercise on the draft Regulation was conducted between 10th and 30th June 2005. An informal consultation was conducted because the amendment is minor and to avoid consultation fatigue. Further amendments with full consultation are anticipated for later in the year. The informal consultation involved contacting the respondents to the full consultation exercise conducted in April-July 2004, prior to the adoption of the Cosmetic Products (Safety) Regulations 2004. Conducted as the amendment was minor and its introduction anticipated.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) is attached to this memorandum. The RIA found that the amendment places no additional burden on business and offers best level public health protection by increasing the range of UV filters available to manufacturers of sun-care products. There will be no additional costs imposed on the public.

8.2 No additional cost will fall to the Exchequer.

9. Contact

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DEPARTMENT OF TRADE AND INDUSTRY

July 2005

Regulatory Impact Assessment

Amendment to The Cosmetic Products (Safety) (Amendment) Regulations 2005

Proposal

To transpose Commission Directive 2005/9/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 one approved UV filter to the list of approved UV filters in Schedule 7, Part 1 of the Regulations.

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, scheduling the availability of the additional UV filter.

Option (ii) under the Cosmetics Directive, UV filters have to be approved by the Scientific Committee and listed in a positive schedule. Voluntary measures would not guarantee knowledge of the availability of the ingredient.

Option (iii) would not make the information available. This could possibly restrict manufacturers and limit consumer choice.

Benefits

Economic

The Directive increases choice of UV filters available to manufacturers and to consumers. This should promote further innovation in the development of sun-care products.

Environmental

No specific benefits to the environment have been identified

Social

The Directive, if adopted, will increase the choice of UV filters available to consumers

Costs

The decision by manufacturers to use the newly available UV filter is discretionary. Any additional cost would only be for manufacturers choosing to use it. 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 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, of which this Amendment will form a part, are enforced by local authorities trading standards departments.

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) Regulations 2004. An Initial Regulatory Impact Assessment has not identified any implementation costs or potential unintended consequences. Therefore, in line with the Cabinet Office Code of Practice on Consultation, DTI has decided to use its discretion and hold an informal consultation with key interested parties rather than conduct a formal written consultation exercise on this Amendment to the Cosmetics Regulations

Summary & Recommendation

Our recommendation is that the option chosen offers the best level of public health protection by increasing the range of UV filters available to manufacturers of sun-care 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 4th July 2005

Transposition Note for Directive 2005/9/EC.

This Transposition Note is intended to show how the Department has implemented Commission Directive 2005/9/EC (O.J. L27, 29.1.05, p.46) amending Council Directive 76/768/EEC concerning cosmetic products, for the purposes of adapting Annex VII thereto to technical progress.

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 has been 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 and 2005/9/EC.

The table below shows how Commission Directive 2005/9/EC has been implemented.

Article	Objective	Implementing regulation	Responsibility (Secretary of State if not specified)
1	Amends the Cosmetics Directive by inserting an additional ultra violet filter into Part 1 of Annex VII (list of UV filters which cosmetic products may contain).	Regulation 2 amends the Principal Regulations by inserting an additional ultra violet filter into Part 1 of Schedule 7 (UV filters listed in Annex VII, Part 1 of the Directive as UV filters which cosmetic products may not contain except subject to the restrictions laid down).	
2	Requires Member States to implement Directive 2005/9/EC by 28th July 2005.	These Regulations will come into force on 28th July 2005.	
3	Administrative	n/a	
4	Administrative	n/a	