

BERR | Department for Business
Enterprise & Regulatory Reform

**THE COSMETIC PRODUCTS
(SAFETY) (AMENDMENT)
REGULATIONS 2007**

Regulatory Impact
Assessment

JUNE 2007

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Regulatory Impact Assessment

The Cosmetic Products (Safety) (Amendment) Regulations 2007

Proposal

To transpose Commission Directive 2006/78/EC into UK Law.

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 its provisions, including restricting the use of certain cosmetic ingredients. The amendment to the Cosmetic Products (Safety) Regulations 2004, the "Principal Cosmetics Regulations", implements Directive 2006/78/EC by harmonising the restrictions on the use of animal by-products in cosmetic products with the restrictions under the Animal By-Products Regulation 2002.

Under the reference to the Animal By-Products Regulation, (apart for exceptions for certain types of Category 2 material) only Category 3 material – that which is a by-product derived from animals fit for human consumption- is allowed for use in finished cosmetic products to all imported products. Under the Animal By-Products Regulation all Category 1 material is prohibited from entering the production chain for a technical product. Category 2 material is also prohibited from use in technical products, except for specific materials of certain origin, as defined in the Animal By-Products Regulation.

The European Commission will publish a Guidance Note in relation to the continued use of those particular ingredients in cosmetic products that are Category 2 material but which do not pose a risk to human health (eg certain derivatives from insects such as silk, cochineal).

Risk Assessment

Options

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

Option (ii): to request industry to adopt voluntary measures

Option (iii): to do nothing

Option (i) is the recommended option. The Directive is consistent with UK policy on these issues. It guarantees a high level of consumer safety. Implementation will be in compliance with the Government's Treaty of Rome obligations.

Option (ii) the Principal Cosmetics Products Regulations is currently out of step with the Animal By-Product Regulation. Voluntary measures would not guarantee that the restrictions on use of the ingredients would be widely known. The terms of the Directive would not be enforceable.

Option (iii) would mean UK regulation on the safety of cosmetics as out of step European legislation. This could possibly mislead importers, distributors and consumers as to the restriction on use of these ingredients. The terms of the Directive would not be enforceable. The Government would also be in breach of its obligations under the Treaty of Rome and liable to possible infraction proceedings by the Europe Commission

Cost/Benefit Analysis

Economic

Directive 2006/78 extends the restriction on the use of animal by-products set out in the Animal By-Products Regulation to imports. Finished cosmetic products made in the EU that contain animal by-products are already complying with the Directive. There will, therefore be a neutral economic impact on UK manufacturers.

Environmental

No specific costs or benefits to the environment have been identified.

Social

The Directive will improve consumer protection. Directive 2006/78 harmonises restrictions with the Animal By-Products Regulation, which lays down health rules concerning animal by-products not intended for human consumption in the interests of protecting human health.

Costs

Directive 2006/78 extends the restriction on the use of animal by-products set out in the Animal By-Products Regulation to imports of cosmetics from outside the EU. There will be an impact on imports of finished cosmetic products that contain or are made from non-category 3 materials such as tallow, which are used in the manufacture of soap

products. For example tallow from USA is classed as Category 1 material and products containing it will be banned.

In 2005 the UK cosmetics market was worth £6.3bn at retail sales prices. According to Overseas Trade statistics in 2005 imports of soap products from outside the EU were worth £14.8m at wholesale prices, while the value of imports of soap products from the US was £3.6m.

The DTI received only one response to the public consultation it held on the proposed amendment. This was from the Cosmetics, Toiletries and Perfumers Association (CTPA), who say that there will be some financial impact on overseas manufacturers who may have to reformulate their products to comply with the Animal By-Products Regulation. However no financial impact on UK based business had been identified or quantified.

The Regulations may create an additional administrative burden on the importers of finished cosmetic products containing animal by-products, particularly tallow and tallow derivatives as they may be required to provide evidence of the sourcing of the material. Importers and distributors may have to recall product that does not comply with the amendment or they are unable to provide documentation on the source material in the product. The CTPA response gave no indication what these costs are likely to be.

Subject to the publication of the European Commission's Guidance Note on the continued use of certain Category 2 materials (silk cochineal), the restriction on their use will not impose additional costs in the reformulation of certain finished products. It is not likely that there will be additional costs for consumers.

The Directive does not allow for a transition period for compliance as, in the view of European Commission, all cosmetic products sold in the EU should have been in compliance with the Animal By-Products Regulation since 2004. This may involve some costs for the removal of any non-compliant stock. Again the CTPA response gave no indication to the extent of the issue or what these costs are likely to be.

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 Regulations is extending a restriction that already applies to products manufactured in the EU to imported products, it does not have the effect of distorting or removing competition in the market. The Regulations, 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, DEFRA and the Department of Health was consulted about these proposals during the consultation exercise.

Public Consultation

DTI conducted consultation for the Cosmetic Product (Safety) (Amendment) Regulations 2007 from 19 January to 13 April 2007, contacting key stakeholders, those who have responded to consultations to previous amendments to the Cosmetic Regulations and the consultation document was published on the DTI 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

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(Minster for Trade, Investment & Foreign Affairs)

Date

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