EXPLANATORY MEMORANDUM TO

THE COSMETICS (SAFETY) (AMENDMENT) REGULATIONS 2007

2007 No. 1623

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 2006/78 (O.J. No. L271, 30.9.2006, p.56) 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. Commission Directive 2006/78/EC references the Animal By-Products Regulation ((EC) No. 1774/2002).

2.2 The Animal By-Products Regulation lays down strict animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of all animal by-products. There are 3 Categories of animal by-product: Category 1 material is very high risk; Category 2 includes other high-risk material; Category 3 is the lowest risk category as it is material from animals that are fit for human consumption. The Department for Environment, Food and Rural Affairs are responsible for the implementation of the Animal By-Products Regulation in the UK.

2.3 The Animal By-Products Regulation prohibits the use of Category 1 and restricts the use of Category 2 material in technical products (which include cosmetic products). The Animal By-Products Regulation is directly applicable in the UK and so these materials have not been able to be used in the UK (or anywhere in the EU) in the manufacture of cosmetic products since 2003.

2.4 Directive 2006/78/EC has the effect of applying the ban on the use of Category 1 and restriction on Category 2 materials to cosmetic products manufactured anywhere in the world.

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 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".

4.5 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 Directive 2006/78 is a Commission Directive and has not been subject to Parliamentary Scrutiny.

4.7 Directive 2006/78 is being transposed after the 30 March 2007 date set by the European Commission. The Department of Trade & Industry sought clarification from the European Commission and the Department of Environment, Food and Rural Affairs on a number of technical points related to the application of the Animal By-Products Regulation. This delayed the launch of the full consultation. The need to seek further clarification on points raised by a response to the consultation delayed transposition further.

4.8 A Transposition Note is attached to this Memorandum.

5. Territorial Extent and Application

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 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 19 January – 13 April 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 DTI website at:

http://www.dti.gov.uk/consultations/page36858.html

7.2 There was only one response to the consultation from the UK trade association, the Cosmetics, Toiletries and Perfumery Association (CTPA), which represents 85% of UK manufacturers of cosmetic products, did not indicate that the Directive would have a major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products of ingredients of cosmetic products.

7.3 However, the CTPA also objected to the implementation of the amendment, on the basis that there is a lack of clarity and conflicting interpretation of the definition of terms 'technical products' and 'processed ingredients' used in the Animal By-Products Regulation, which would cause confusion, particularly with regard to the import of cosmetics containing tallow or tallow derivatives. The Animal By-Products Regulation is currently under review and CTPA argue that an amendment to the Cosmetics Directive should be held over until that process is complete and the Animal By-Products Regulation amended. After the consultation, the Department of Trade & Industry consulted with DEFRA and the European Commission on these points. They are both of the opinion that as cosmetics containing animal by-products manufactured in the EU comply with the Animal By-Products Regulation, then so must imported cosmetics containing animal by-products. That it is not advisable to wait until the Animal By-Products Regulation itself is amended, which is likely to take at least two years. On this basis the Department has decided to implement the Directive.

7.4 The Department of Trade and Industry considers that there is good reason to consolidate the Cosmetic Product (Safety) Regulations 20004 (as amended) as this is the seventh amendment to the Regulations. The timing of the consolidation will be dependent on the publication by the European Commission of further amendments to the Cosmetics Directive (76/768/EC) and resources being made available in the DTI.

8. Regulatory Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact:

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 can answer any queries regarding the instrument.

DEPARTMENT OF TRADE AND INDUSTRY
7th June 2007

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 it's 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

Jim Fitzpatrick
(Parliamentary Under-Secretary of State for Employment Relations and Postal Services)
Department of Trade and Industry

7th June 2007

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Transposition Note for Directive 2006/76/EC.

This Transposition Note shows how the Department has implemented Commission Directive 2006/78/EC amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexe II thereto to technical progress (O.J. No. L271, 30.9.2006, p.56).

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) imposes prohibition on the use of substances defined as Category 1 material and Category 2 material in Articles 4 and 5 of Regulation (EC) No 1774/2002 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) (No 2) Regulations 2006 (2006/2231).

The Department of Trade and Industry has lead responsibility for the implementation of Directives 76/768/EEC and 2006/78/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	Amends Directive 76/768/EC by requiring Member States to imposer a prohibition on any person supplying a cosmetic product which contains any of the substances defined as Category 1 material or Category 2 material in Articles 4 and 5 of Regulation (EC) No 1774/2002 of the European Parliament and of the Council	Regulation 2(2) substitutes a new regulation 5 (3) which imposes the prohibition set out in Article 1. Paragraph (5) of regulation 5 and Schedule 8 of the Principal Regulations are revoked as they deal with an exception for tallow derivatives that has been removed by Directive 2006/78/EC.. Paragraph (6) of Regulation 5 of the Principal regulations has also been revoked as this provided an exception for products manufactured before 1st April 1998.	
2	Requires Member States to include a reference to this Directive with provisions	In Schedule 2 (List of Directives amending Directive 76/867/EEC) at the end there is inserted— "**47.** Commission Directive 2006/78 (O.J. No. L271, 30.9.2006, p.56)".	