EXPLANATORY MEMORANDUM TO THE

COSMETIC PRODUCTS (SAFETY) (AMENDMENT) (No.2) REGULATIONS 2004

2004 No. 2988

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 ("the Principal Regulations") to give effect to 3 Commission Directives: Commission Directives 2004/87/EC (OJ L 287, 8.9.2004 p.4) 2004/88/EC (OJ L 287, 8.9.2004 p.5) and 2004/93/EC (OJ L 300, 25.9.2004 p.13) which amend Council Directive 76/768/EC (OJ L 262, 27.7.1976 p.169) ("the Directive") on the approximation of the laws of the Member States relating to cosmetic products.

2.2 Directive 2004/87/EC postpones until 31st December 2005 the date until which the hair dyes listed in Annexe III to the Directive are permitted. Prior to this they were only permitted until 30th September 2004.

2.3 Under Directive 2004/88/EC, musk xylene and musk ketone are to be permitted subject to certain restrictions. They had previously been permitted only provisionally.

2.4 Directive 2003/15/EC required the Commission to introduce a prohibition on the use of substances classified as carcinogenic, mutagenic or toxic to reproduction ("CMR's"). Directive 2004/93/EC prohibits the use of most CMR's.

2.5 The Regulations also correct typographical errors that have been identified in the Principal Regulations and address issues identified by the Joint Committee on Statutory Instruments in its 32nd report.

3. Matters of Special Interest to the Joint Committee on Statutory Instruments

3.1 *Transposition date:* Directives 2004/87/EC, 2004/88/EC and 2004/93/EC require Member States to bring into force implementing legislation by 1st October 2004. Directives 2004/87/EC and 2004/88/EC were published in the Official Journal on 8th September 2004 and 2004/93/EC on 25th September 2004. In view of the need to consult on the Regulations, there was insufficient time to make them before 1st October 2004.

3.2 *CMR's:* Pursuant to Directive 2003/15/EC, directive 2004/93/EC prohibits the majority of CMR's. 2004/93/EC came into force on 25th September 2004. The Department incorrectly considered 2003/15/EC to introduce a substantive ban on CMR's and accordingly regulation 5(15) to the Principal Regulations, which came into force on 11th September 2004, prohibited their use in cosmetic products. The result of this was that CMR's were prohibited under domestic legislation a little over 2 weeks before the Directive required Member States to prohibit them. In addition to this, a small number of CMR's were banned under domestic law without having been prohibited under the Directive.

3.3 These Regulations address the issue above by replacing regulation 5(15) to give effect to Directive 2004/93/EC. CMR's are generally not used in cosmetic products and accordingly, the early implementation of the above prohibition is unlikely to have had any practical effect. However, in order to avoid any disparity between EU and domestic law, regulation 2(5)(b) inserts provisions prohibiting enforcement action and proceedings in respect of the previous prohibition.

3.4 *Cross-reference to the Directive:* As stated above, CMR's are not generally used in cosmetic products and the Department decided not to reproduce the list of some 650 CMR's in the Regulations themselves as doing so would render the Regulations unnecessarily complicated. Therefore the Regulations prohibit CMR's by cross-reference to Annex II to the Directive (as last amended by 2004/94/EC). Industry has welcomed this approach.

3.5 *Enforcement:* Prior to the introduction of these Regulations, the Principal Regulations provided that certain substances listed in Part 2 of Schedule 4 should only be permitted until 30th September 2004. Directive 2004/87/EC postpones that date until 31st December 2005. For the reasons given above, there has been a delay in transposing this Directive and the Department therefore considers it necessary to insert 2(5)(b) which prohibits enforcement action arising out of the supply of these substances after 30th September 2004.

4. Legislative Background

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

4.2 As stated above, Directive 2003/15/EC required the Commission to introduce a prohibition on the use of CMR's. The DTI submitted an Explanatory Memorandum (official text not available) on 11/12/02 on an "Amended Proposal for a Directive of the EP & Council amending for the 7th time Council Directive76/768/EEC on the approximation of laws of Member States relating to cosmetic products" (2003/15/EC). The Commons European Scrutiny Committee considered it politically

and legally important and cleared it (Report 5, Item 24098, Sess 02/03. The Lords Select Committee on the EU cleared it in Sub-Committee on 29/1/03 (Progress of Scrutiny 3/2/03, Session 02/03).

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 Directives 2004/87/EC, 2004/88/EC and 2004/93/EC are Commission Directives subject to the comitology procedure and have not therefore 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 instrument will apply to the whole of the United Kingdom.

6. **European Convention on Human Rights**

6.1 In the my view, these Regulations are compatible with the European Convention on Human Rights.

7. Policy background

7.1 A mini consultation exercise on the draft Regulations was conducted between 29th October 2004 and 4th November 2004.. This involved contacting the respondents to the consultation exercise conducted in April-July 2004, prior to the adoption of the Cosmetic Products (Safety) Regulations 2004.

7.2 The results of that exercise indicated that the Regulations would not have any major impact on manufacturers, importers, wholesalers and retailers of finished cosmetic products or ingredients of cosmetic products. Ten responses were received which were all broadly supportive of the proposal.

8. Impact

8.1 The primary objectives of the Regulations are to protect public health by restricting the use of certain ingredients in cosmetic products and introduce prohibitions, with specified timescales, on the uses of animals in the testing of cosmetics and their ingredients.

8.2 No Regulatory Impact Assessment (RIA) has been prepared for these amendments as they are not considered economically significant. A full RIA was prepared and submitted with the main Cosmetic Products (Safety) Regulations 2004, a copy of which is attached.

8.3 There will be no additional costs imposed on the public.

8.4 No additional costs will fall to the Exchequer.

9. Contact

IAN PARSONS
Bay 572
Consumer and Competition Policy Directorate
Department of Trade and Industry
1 Victoria Street
London, SWIH 0ET

ian.parsons@dti.gsi.gov.uk

DEPARTMENT OF TRADE AND INDUSTRY
…..November 2004

Final Regulatory Impact Assessment

The Cosmetic Products (Safety) Regulations 2004

1. Issue

1.1 To transpose Commission Directives 2003/15/EC (7th Amendment),[1] 2003/83/EC (30th Amendment)[2] and 2003/80/EC (31st Amendment)[3] into UK law. The Regulations also consolidate the Cosmetic Products (Safety) Regulations 2003.

2. Objective

2.1 The primary aim of the 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 Regulations also introduce prohibitions, with specified timescales, on the use of animals in the testing of cosmetics and their ingredients.

3. Background

3.1 The main elements of the Regulations are:

3.2 A ban on *the testing of finished cosmetic products* on animals in any member State from the date the Directive becomes applicable i.e. 11 March 2003;

3.3 A ban on *testing ingredients or combinations of ingredients* on animals within member States as soon as an alternative method has been published by the EC and, in any case, alternative tests must be developed 6 years after entry into force of the Directive i.e. 11 March 2009 or earlier if a validated alternative test is available. In relation to tests concerning repeat-dose toxicity, reproductive toxicity and toxicokinetics, for which no alternatives are yet under consideration, the deadline will be 10 years after entry into force of the Directive i.e. 11 March 2013. For the same tests there is a possibility of the Commission re-considering the issue if no alternative tests are validated within the period specified. The Commission also has power, in exceptional circumstances, to authorise a derogation in respect of a particular substances.

3.4 A total ban on the *marketing of finished cosmetic products* which have been tested on animals, and a total ban on the *marketing of cosmetic*

---

1 Directive 2003/15/EC of 27 February 2003 amending Council Directive 76/768/EEC relating to cosmetic products.

2 Directive 2003/83/2003 of 24September 2003 amending Annexes II, III and VI to Council directive 76/768/EEC relating to cosmetic products.

3 Directive 2003/80/EC of 5 September 2003 amending Annex VIIIa (establishing the open jar symbol) to Council Directive 76/768/EEC

products the ingredients or combinations of ingredients of which have been tested on animals, which will operate in the same way as the ingredient test ban described above. The marketing ban will apply no matter where in the world the cosmetics products originate;

3.5 Substances classified as Category 1, 2, and 3 Carcinogens, Mutagens and Substances Toxic to Reproduction (CMRs) in Annex 1 of the Dangerous Substances Directive will be prohibited. Substances in Category 3 may, however, be used if their use is safe in the opinion of the EC's Scientific Committee (the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers).;

3.6 The Regulations permit manufacturers to claim that their products have not been tested on animals subject to certain conditions. The Commission will produce guidance on such claims.

3.7 The Regulations also require that 26 fragrance/perfume ingredients, which were never listed individually but rather just listed as 'perfume', must be listed in the ingredients list as an individual substance when their concentration exceeds specified amounts;

3.8 All cosmetic products must have a safety assessment carried out before they are placed on the market and be made available, upon request, to enforcement authorities. Specific safety assessments must be carried out for cosmetic products intended for children under the age of three and for cosmetic products intended for external intimate hygiene;

3.9 Safety information must be made available to the public, i.e. products with a durability of 30 months or more must carry an open jar logo and an indication of how long they may be safely used once opened. Information on cosmetic ingredients/substances and any known adverse effects must also be made easily available to the public;

3.10 The Regulations supersede the requirements which were set out in Directive 93/35/EEC (the 6th Amendment) which banned the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals. The provisions in the 6th Amendment relating to the marketing ban were considered to be incompatible with WTO (World Trade Organisation) obligations.

3.11 Finally, the regulations amend Schedules 3,4 and 6 by adding, deleting or amending particular entries. . Schedule 9 also incorporates the open jar logo to implement the requirements of Commission Directive 2003/80/EC (the 31st Amendment). A new Schedule 13 has been added to contain a list of Category 3 CMR's, which have been evaluated as safe by the SCCNFP. The Schedule currently contains no entries.

4. Risk assessment

4.1 The main objective of the Directive, and thus the Regulations, is to protect public health. It is paramount that cosmetic products are safe for use by consumers.

5. Options

5.1 The options are:

(i) do nothing;
(ii) implement the directives through regulations; or,
(iii) request industry to adopt voluntary measures.

5.2 Option (i) would mean that cosmetics would continue to be tested on animals. The use of animals in the testing of cosmetics and their ingredients is an emotive subject and the UK has sought for many years to have the activity banned (there has been no testing of cosmetics on animals in the UK since 1997). The proposed 2004 Regulations also provide for safety information to accompany cosmetics and to be made available through manufacturers which will help consumers to make more informed decisions when they are buying cosmetics. In addition, by not implementing the three directives the UK runs the real possibility of infraction proceedings.

5.3 Option (ii) is the recommended option. The 7th, 30th and 31st Amendments will produce harmonised rules for the control of the safety of cosmetics and lead to the gradual prohibition on the use of animals in the testing of cosmetics and their ingredients. On matters of public safety, it is paramount that cosmetic products available to the general public conform to a set standard.

5.4 Option (iii) would rely on industry adhering to voluntary guidelines or targets. However, this could not guarantee as high a level of consumer safety as Option (ii) and would necessitate agreeing draft guidelines and introducing an effective monitoring system.

6. Benefits

Business sectors affected

6.1 The Regulations will mainly affect manufacturers and importers who will, over time, have to move from having their products tested on animals. Manufacturers and importers will also have to change the labelling on their products to meet the requirements of the Regulations. Wholesalers and retailers of cosmetic products will also be affected but only to the point that they will have to ensure that the products they are supplying meet the labelling requirements. The cosmetic industry has a number of multinational companies with sizeable turnovers. However, there are also a number of small and medium companies with smaller turnovers.

6.2 The benefit of Option (ii) is that a permanent prohibition on animal testing for finished cosmetic products will focus industry to advance validated alternative methods for the testing of chemicals in cosmetics. There is widespread public concern over the issue of animal testing and the Directive will improve the level of consumer information regarding cosmetic products and their manufacture. In addition, it will avoid any possible WTO compliance difficulties with the current Regulations.

6.3 Option (iii): if a voluntary code were adopted by industry, there would be limited benefit only as some suppliers would adopt the code while others would not. It would prove difficult to enforce. Partial compliance would not benefit the consumer and indeed not applying the labelling requirements could be detrimental to consumers. The possible WTO difficulties with the current marketing ban would still require action.

7. Costs

7.1 Option (ii): Costs to industry were sought as part of the consultation exercise. One leading trade association states that currently UK based industry does not test finished products or ingredients on animals and is unlikely to commission such testing on ingredients. The UK already has a voluntary ban on animal testing in place, which prevents the testing on animals of <u>any</u> cosmetic product or ingredients or combinations of ingredients. The ban was introduced by the Home Office when all testing licences were returned on a voluntary basis by test houses. Industry would therefore not experience any direct costs as a result of the testing ban.

7.2 However, a number of UK companies have EU subsidiaries and those companies might have additional costs but they are unlikely to have any significant effect on the manufacturing costs.

7.3 There will be some additional labelling costs for industry as a result of the Directive. While these could be significant, they are likely to be absorbed as part of the industry's tendency to repackage on a frequent basis and costs

passed onto the consumer. The main trade association for Cosmetics in the UK, the Cosmetics Toiletry and Perfumery Association (CTPA) inform us that;

"whilst this is true given sufficient time, industry normally phases the facelifts of its brands in a rotation so that they are not done all at once. Artwork is revised regularly over a two or three year cycle. As a result of the Seventh Amendment, 20 or 30% of brands will have had artwork changes outside of this normal cycle – at significant cost. Those companies that have waited for publication of the guidance on Period After Opening are worse off in that they have a very much shorter time in which to make these changes but at least they will not have to label certain products excluded by the guidance.

Conversely, those companies which decided to label PAO early to minimise costs will find that the guidance does not require certain of these products to be labelled at all".

7.4 Option (iii): For those companies who complied with a voluntary code there would be costs involved in meeting the new labelling requirements but as mentioned in 7.3 above such costs would be borne by the consumer.

7.5 There will also be development and running costs incurred by the European trade association (COLIPA) in setting up a directory of cosmetic ingredients and known adverse effects associated with some substances/ingredients.

8. Other Costs

8.1 Additional costs, such as those resulting from new labelling, would probably be passed on to the consumer, at least in part. However, consumers are generally willing to pay a little more for improved safety information. Information received as a result of the consultation exercise shows that for an average SME the costs associated with producing new labelling to take account of the 'period after opening' requirements are:

"Because of the lateness in agreeing guidance on the application of the Period After Opening labelling (still not published), a significant quantity of stock will need over labelling.

This company's premium product range consists of six different products distributed in a commercial arrangement with a small company. Minimum production runs for each product variant are 25,000 units.

On average, 13,890 units of each variant will need over labelling at an estimated cost of 21p per unit. This is comprised of the following elements:

Cost of label including printing plates	***10p per unit***
Cost of unpacking stock, applying label and repacking	***8p per unit***
Transport from warehouses	***0.6p per unit***

Originating artwork	***1.6p per unit***
Cost of cutter tools used to cut out the labels from the printed materials	***0.8p per unit***
Total:	***21p per unit***

Total cost of reworking these 83,340 units is approximately £17,500.

In addition, approximately 10,000 printed but unfilled cans will need to be written off or over-labelled:

- the cans are valued at £2,600.

- costs of relabelling are estimated at 17p per unit. This is cheaper than the reworking of the filled stock as transport and unpacking costs are reduced.

The cost of reworking these 10,000 cans is £1,700.

Total cost to rework this product range is £19,200".

Another SME has informed us that their costs for new labels for a skincare range, for a 6-year (approximately) supply of labels is £22,000, this currently represents about 40% of the company's annual profit.

One large UK manufacturer and retailer has estimated that

"the direct cost of changing all cosmetic product labels is approximately £500,000 shown against a worldwide sales turnover of approximately £700 million".

8.2 In addition, the Regulations will be enforced by local authority trading standards departments and there are likely to be additional burdens for enforcement. An initial estimate of £60,000 has been provided by the Local Authorities Co-ordinators of Regulatory Services (LACORS). The costs refer to both pre and post market surveillance.

9. Equity and Fairness

9.1 It is considered that the proposed measure should impact equally across the whole industry. Indeed, those businesses that would comply with voluntary guidelines or targets could complain with justification that they were behaving responsibly whilst others in industry were not. Although the overriding factor is consumer safety, the Regulations will prohibit the use of animals in cosmetic testing and will enable consumers to identify more easily products that have not been tested on animals**.**

10. Small Firms' Impact Test

10.1 There will be some additional labelling costs for small businesses as a result of the labelling requirements. A group of SMEs who are members of the main trade association, the CTPA, has estimated that for the average SME with a turnover of £5 - £15 million per annum the costs will be about £100,000 per company. There are very many small companies (two to three people) manufacturing soaps /creams. DTI directly contacted 14 SMEs as part of the preparation of this RIA. Generally the only costs they are concerned about are those relating to labelling and it would appear that these costs would be insignificant because labelling is often produced in house.

11. Competition assessment

11.1 When applying the Competition Assessment Filter, the results indicate there is likely to be little in the way of negative effects on competition – that is, all the questions with the exception of question 4 were answered in the negative. On that basis there is no need to undertake a detailed Competition Assessment.[4]

11.2 The proposed Regulations will apply to all suppliers of cosmetics. We therefore consider that there are no competition issues, that is, no barriers to trade or competition are created. Indeed, The Regulations will set harmonised requirements to ensure that all involved in the manufacture and supply of products can compete on an equal footing.

12. Enforcement and sanctions

12.1 The Regulations will be enforced by local authority trading standards departments.

12.2 The intended legislation will provide for suppliers in breach to be prosecuted by local authorities and to be liable on summary conviction to a fine of up to £5,000 or imprisonment not exceeding 6 months. Breach of the provisions relating to animal testing will be punishable on summary conviction

---

4 For details of the competition filter: www.cabinet-office.gov.uk/regulation/_private/Competition/competition/index.htm

with a fine not exceeding £5,000 or imprisonment not exceeding 3 months or on indictment, with a fine or imprisonment not exceeding 6 months.

13. Consultation

13.1 The consultation document lists government agencies, Government departments, industry, trade associations, academics and other interested parties consulted.

13.2 Consultation was carried out from April to July 2004.

14. Recommendation

14.1 The 7th Amendment to the Cosmetics Directive was adopted at European level by the EU Member States and the European Commission, as offering the highest level of protection of the public health. In addition, it obviates the risk of a WTO challenge from the US or other WTO members**.**

14.2 Our recommendation is that the option chosen offers the best level of public health protection and introduces a permanent ban on animal testing for finished cosmetic products. Our legal obligations under the Treaty of Rome also compel us to implement this directive into UK law.

15. Monitoring and review

15.1 Local Authority Trading Standards Departments will monitor the application of the Regulations. The European Commission will seek member States' views on the application of the Directive and consider what action, if any, may be appropriate**.**

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the Minister responsible

……..
(Parliamentary Under-Secretary of State for Employment Relations, Competition and Consumers)

Date……

Contact: David Southerland, CCPrc, Room 427, 1 Victoria Street, London SW1H 0ET

Tel: 020 7215 0371

Fax: 020 7215 0357

Email: david.southerland@dti.gsi.gov.uk