

**dti**

**THE COSMETIC PRODUCTS  
(SAFETY) REGULATIONS 2004**

Consultation on proposals to  
implement three EC Directives  
on the safety of Cosmetics

**CONSULTATION DOCUMENT**

April 2004

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dti

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We champion UK business at home and abroad. We invest heavily in world-class science and technology. We protect the rights of working people and consumers. And we stand up for fair and open markets in the UK, Europe and the world.

# Contents

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1. Executive Summary
  2. Proposals
  3. Regulatory Impact Assessment
  4. Draft Regulations
  5. What happens next?
  6. List of Consultees
- Annex A

# 1. Executive Summary

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- 1.1 This consultation document seeks views on the Government's proposals to introduce Regulations to protect consumers from unsafe cosmetic products and to prohibit, with specified timescales, the use of animals in the testing of cosmetics and their ingredients. The Regulations will also provide for enhanced labelling requirements so that the consumer is better informed.

The proposed **Cosmetic Products (Safety) Regulations 2004** (the 2004 Regulations) will implement three EC Directives on the safety of cosmetics. The 2004 Regulations will be introduced using powers in the Consumer Protection Act 1987 (the 1987 Act) and the European Communities Act 1972 (the 1972 Act). The proposed Regulations also consolidate the Cosmetic Products (Safety) Regulations 2003.

- 1.2 The 1987 Act enables the Secretary of State to make regulations in order to reasonably secure that consumers are protected from unsafe goods. The 1972 Act provides powers to introduce measures such as labelling and marketing requirements set out in EC directives for which the necessary powers are not provided under the 1987 Act.
- 1.3 There is widespread public concern over the issue of animal testing and we believe these proposals represent a positive step towards a permanent prohibition on animal testing for cosmetics. The Directive, and thus the Regulations, will also improve the level of consumer information.

## How to Respond?

- 1.4 When responding please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

1.5 Please submit your responses to this consultation by post, fax or email to

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Room 429  
Department of Trade and Industry  
1 Victoria Street  
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### **Additional copies**

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1.7 Other versions of the document in Braille, other languages or audio cassette are available on request.

### **Closing Date**

1.8 Responses must be received by **Thursday 15 July 2004**.

### **Confidentiality**

1.9 Your response may be made public by the DTI. If you do not want all or part of your response or name made public, please state this clearly in the response. Any confidentiality disclaimer that may be generated by your organisation's IT system or included as a general

statement in your fax cover sheet will be taken to apply only to information in your response for which confidentiality has been requested.

- 1.10 We will handle any personal data you provide appropriately in accordance with the Data Protection Act 1998.

### Consultees

- 1.11 We are sending this document to the consultees listed at Part 6. Please tell us if you know of others who would be interested in receiving this consultation. It is also available by request from the address listed above and on the DTI website at: [www.dti.gov.uk](http://www.dti.gov.uk)

### Enquiries

- 1.12 If you have any questions, or would like further information on this consultation please contact David Southerland on 020 7215 0371.

- 1.13 If you have comments or complaints about the way this consultation has been conducted, these should be sent to:

Louisa Renwick  
Consultation Co-ordinator  
Department of Trade and Industry  
Room 723  
1 Victoria Street  
London SW1H 0ET

[Louisa.renwick@dti.gsi.gov.uk](mailto:Louisa.renwick@dti.gsi.gov.uk)

- 1.14 A copy of the Code of Practice on Consultations may be viewed at the following website address:

<http://www.cabinet-office.gov.uk/regulation/Consultation/Code.htm>

### Consultation questions

- 1.15 The following are general questions for consultees:
- i. Do consultees, particularly those whose trade includes the manufacture, importation or sale of cosmetics believe that the

proposed Regulations will have a significant impact on competition or profitability?

- ii. If you are a small or medium sized enterprise, what costs or other burdens are associated with the introduction of the Regulations?
- iii. Are there any consequences of these regulations which we have not anticipated?
- iv. Do you consider this consultation exercise to be an effective means of disseminating information to those affected by the changes? How else could the DTI ensure these Regulations are implemented effectively?
- v. Will the proposed Regulations contribute to safer cosmetics being available and will the labelling requirements help consumers decide which cosmetics they should buy?

1.16 All comments in relation to the proposed Regulations and the proposed Regulatory Impact Assessment are most welcome

## 2. Proposals

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- 2.1 The main objective of introducing the 2004 Regulations is to implement Commission Directives 2003/15/EC (7<sup>th</sup> Amendment), 2003/83/EC (30<sup>th</sup> Amendment) and 2003/80/EC (31<sup>st</sup> Amendment) which amend Council Directive 76/768/EEC, the base Directive, on the safety of cosmetic products. Copies of the Directives can be found at the back of this document.
- 2.2 The aim of the Directives and the implementing Regulations is to protect public health in the member States by requiring cosmetic products to meet the provisions of the Directive, including restricting the use of certain cosmetic ingredients. The Regulations will gradually prohibit the use of animals in the testing of cosmetics and their ingredients.
- 2.3 Member States are required to take all necessary measures to ensure that cosmetic products may only be placed on the market subject to conditions specified in the Directives.

### The 2004 Regulations

- 2.4 The main elements of the Regulations are:
- 1) a ban on *the testing of finished cosmetic products* on animals in any member State from 11 March 2005
  - 2) a ban on *testing ingredients or combinations of ingredients* on animals within the UK 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 three 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, 11 March 2013. For the same tests there is a possibility of a single derogation for a maximum of a further 5 years
  - 3) 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 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 the cosmetics products originate

- 4) 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
- 5) 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. This will help fragrance allergy sufferers to make informed decisions as to which perfumes they can use safely
- 6) 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
- 7) in addition, 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 easily available to the public
- 8) the Regulations also supersede the requirements which were set out in Directive 93/35/EEC (the 6<sup>th</sup> Amendment) which banned the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals. The provisions in the 6<sup>th</sup> Amendment relating to the marketing ban were considered to be incompatible with WTO (World Trade Organisation) obligations.

9) Schedule 9 reproduces the open jar logo introduced in the 31<sup>st</sup> Amendment which requires an open jar logo to appear on cosmetics or their packaging. This supports the requirements in the 7<sup>th</sup> Amendment that cosmetic products with a minimum durability of more than 30 months must be marked with an indication of the period after opening for which the product can be used without harm to the consumer.

10) Finally, various administrative, rather than substantive amendments have been made to Schedules 3, 4 and 6.

**[Note: rather than reproduce the entire Schedules, these changes are at Appendix 1 to this document]**

2.5 As with the current cosmetic safety Regulations, Local Trading Standards Officers would have the primary responsibility for enforcement of the 2004 Regulations.

# Appendix 1

Amendments will be made to Annexes II, III, VI and VIIIa as set out in the attached copies of the 30<sup>th</sup> and 31<sup>st</sup> Amendments to the cosmetics Directive. In the UK implementing Regulations these annexes are transposed as Schedules.

Briefly, the amendments are:

## **Schedule 3 Part 1 (Annex II of the Directive)**

- i) Entry 94 is amended
- ii) Entry 90 is deleted
- iii) Entry 643 is amended

## **Schedule 4 Part 1 (Annex III Part 1 of the Directive)**

- i) 26 fragrance ingredients are added the new entries will be numbered 67 to 92
- ii) Entry 14 is amended
- iii) Entry numbers 60,61 & 62 are amended
- iv) Entries 93, 94 & 95 are added (these will follow on from those listed at (i) above)

## **Schedule 6 Part 1 (Annex VI Part 1 of the Directive)**

- i) Entry 36 is deleted

## **Schedule 9 (Annex VIII of the Directive)**

The open jar logo will be reproduced

## **Other amendments to the 2003 Regulations**

We are aware of a few errors in the 2003 Regulations which will need to be corrected in the 2004 regulations

Page 36 – there should be a space between entry number 11 and entry number 12.

Page 37 – entry 15c when used as a pH adjuster, column 6, the words 'can cause blindness' should be deleted.

Page 64 - entry 21 was deleted in error. It should read as in entry 21, page 60 of the Cosmetic Products (Safety) Regulations 1996.

Page 64 - entry 29 was also deleted in error. It should read as in entry 29, page 61 of the Cosmetic Products (Safety) Regulations 1996.

Some other minor typing errors will be corrected in the 2003 Regulations.

### **Schedule 8**

The wording in (b) (ii) should be corrected to:

'(ii) Continuous process: at 140°C, two bars (2,000hPa) for eight minutes or equivalent conditions.'

(This text reflects the wording in the Cosmetics Products (Safety) (Amendment) Regulations 1998 which should have been carried over to the 2003 Regulations)

### 3. Draft Regulatory Impact Assessment

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#### The Cosmetic Products (Safety) Regulations 2004

##### Proposal

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

##### Purpose and intended effect of measure

###### *Objective*

2. 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.

###### *Background*

3. The main elements of the Regulations are:

- a ban on *the testing of finished cosmetic products* on animals in any member State from the date the Directive becomes applicable, 11 March 2005
- 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 three 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, 11 March 2013. For the same tests there is a possibility of a single derogation for a maximum of a further 5 years

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

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

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

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

Finally, various administrative, rather than substantive amendments have been made to Schedules 3, 4 and 6. Schedule 9 also incorporates the open jar logo to implement the requirements of Commission Directive 2003/80/EC (the 31<sup>st</sup> Amendment).

### *Risk assessment*

4. The main objective of the Directive, and thus the Regulations, is to protect public health. It is paramount that cosmetics products are safe for use by consumers. If the Directives' proposals were not implemented the risks would be:

- an increased risk of harm to consumer health as substances banned/controlled under the directives could still be used by manufacturers;
- publicly unacceptable animal testing for cosmetic purposes could still be undertaken by disreputable companies not bound by a sense of responsibility, putting Government at risk of severe criticism that it has not lived up to certain manifesto commitments to reduce animal testing; and,
- UK manufacturers would be put at risk of competitive disadvantage as we would not have offered the same level playing field in the UK as in other member States.

### **OPTIONS**

5. The options are:

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

6. 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.

7. Option (ii) is the recommended option. The 7<sup>th</sup>, 30<sup>th</sup> and 31<sup>st</sup> 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.

8. 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 introduces an effective monitoring system.

## Costs and Benefits

### *Business sectors affected*

9. 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.

### *Benefits*

10. 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.

11. **Option (iii)**: if a voluntary code were adopted by industry, there would be limited benefit only, some suppliers will adopt the code while others will 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.

## *Costs*

12. **Option (ii):** costs to industry will be sought as part of the consultation exercise. However, 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 any 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.

13. 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.

14. 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. Information on costs will be sought as part of the consultation exercise.

15. **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 16 above such costs would be borne by the consumer.

16. 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.

## *Other Costs*

17. 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.

18. 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.

## **Equity and Fairness**

19. 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.

### **Small Firms' Impact Test**

20. As part of our initial soundings we contacted a number of small firms in the sector to identify potential costs to them as a result of the proposals.

21. Those small firms contacted indicated that as all of their labelling was carried out in house, the proposals would not have a significant impact on them in terms of time or cost. We have contacted the Small Business Service who have agreed that these proposals are unlikely to have a significant impact on small firms and that at this time there is no requirement to carry out stage one of the impact test. If any further costs or other unintended impacts on small firms as a result of these proposals are identified during the consultation period, stage one of the small firms impact test will be carried out.

### **Competition assessment**

22. When applying the competition filter test, 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.<sup>4</sup>

23. 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.

### **Enforcement and sanctions**

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

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<sup>4</sup> For details of the competition filter: [www.cabinet-office.gov.uk/regulation/\\_private/Competition/competition/index.htm](http://www.cabinet-office.gov.uk/regulation/_private/Competition/competition/index.htm)

25. The intended legislation will provide for suppliers in breach of the Regulations to be prosecuted by local authorities and for fines of up to £5000 and/or imprisonment of 6 months.

### **Consultation**

26. The consultation document lists stakeholders including government agencies and departments consulted.

27. The consultation will be carried out between April and July 2004

### **Summary and recommendation**

28. For the purpose of comparison, costs and benefits and non-recurring costs and benefits, have been annualised over 20 years using a 6% discount (and rounded to the nearest £500).

	Total Expected costs p.a
Business Measures	To be sought as part of the consultation
Government	<b>£60,000</b>

29. 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 health protection. In addition, it obviates the risk of a WTO challenge from the US or other WTO members.

30. 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.

### **Monitoring and review**

31. 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

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## 4. Draft Regulations

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DRAFT STATUTORY INSTRUMENTS

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**2004 No.**

### **CONSUMER PROTECTION**

#### **The Cosmetic Products (Safety) Regulations 2004**

*Made* - - - -

*Laid before Parliament*

*Coming into force* - -

*11th September 2004*

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987(a), consulted such organisations as appear to her to be representative of interests substantially affected by these Regulations, such other persons as she considers appropriate and the Health and Safety Commission;

And whereas the Secretary of State is a Minister designated(b) for the purposes of section 2 of the European Communities Act 1972(c) in relation to measures for safety and consumer protection as respects cosmetic products and any provisions concerning the composition, labelling, marketing, classification or description of cosmetic products and in relation to indication of origin on imported goods;

Now therefore the Secretary of State in exercise of the powers conferred on her by sections 11, 28 and 30 of the 1987 Act and by section 2(2) of the 1972 Act, hereby makes the following Regulations—

#### **Citation and commencement**

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) Regulations 2004 and shall come into force on 11th September 2004 other than the provisions set out in paragraph (2) below.

(2) The following provisions of these regulations shall come into force on 11th<sup>th</sup> March 2005—

- (a) Regulation 7(2)(c); and
- (b) Regulation 7(9)(b).

#### **Revocation**

2. The Regulations set out in Schedule 1 are hereby revoked.

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(a) 1987 c. 43.

(b) S.I. 1972/1811, S.I. 1975/1707 and S.I. 1993/2661.

(c) 1972 c.68.

## Interpretation

### 3.—(1) In these Regulations—

“agent” means an agent established within the Community appointed by a manufacturer of a cosmetic product to act on his behalf in relation to these Regulations;

“alternative method” means a testing method which is in Schedule 12 to these regulations;

“approved supply list” shall have the same meaning as in regulation 2(1) of the CHIP Regulations;

“the CHIP Regulations” means in Great Britain the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 and in Northern Ireland the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (Northern Ireland) 1995;

“common ingredients nomenclature” means the labelling nomenclature designated in the inventory of ingredients employed in cosmetic products, drawn up in accordance with the provisions of the Directive and contained in Commission Decision 96/335/EC(a), as amended or substituted from time to time;

“the Community” means the European Community and other States in the European Economic Area;

“the Confidentiality Directive” means Commission Directive 95/17/EC(b);

“the 1987 Act” means the Consumer Protection Act 1987;

“cosmetic ingredient” means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of a cosmetic product;

“cosmetic product” means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease;

“the Directive” means Council Directive 76/768/EEC(c) as amended by the Community instruments set out in Schedule 2;

“EEA Agreement” means the Agreement on the European Economic area signed at Oporto on 2<sup>nd</sup> May 1992 as amended from time to time;

“finished cosmetic product” means the cosmetic product in its final formulation as placed on the market and made available to the final consumer or its prototype;

“market research experiment” means any activity conducted for the purpose of ascertaining the opinion of persons of—

- (a) any cosmetic product;
- (b) any thing in, on or with which the cosmetic product is supplied;
- (c) the appearance or any other characteristic of the cosmetic product or any such thing; or;
- (d) the name or description under which the cosmetic product is supplied;

but a cosmetic product is not the subject of a market research experiment unless—

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(a) O.J. No. L132, 1.6.96, p.1.

(b) O.J. No L140, 23.6.95, p. 26.

(c) O.J. No. L262, 27.9.76, p. 169.

- (i) any person to whom a cosmetic product is supplied in the course of the experiment is informed, at or before the time at which it is supplied to him, that it is supplied for the purpose of a market research experiment; and
- (ii) no consideration in money or money's worth is given by such a person for the cosmetic product or any other cosmetic product supplied to him for comparison;

“Member State” means a State which is a Contracting Party to the EEA Agreement;

“preservative” means a substance which is added to a cosmetic product for the primary purpose of inhibiting the development of micro-organisms in that product;

“prototype” means a first model or design that has not been produced in batches and from which the finished cosmetic product is copied or finally developed;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly; and

“UV filter” means a substance which is added to a sunscreen cosmetic product for the primary purpose of filtering ultra violet rays for the purpose of protecting the epidermis of the user from harmful effects of such ultra violet rays.

(2) Unless the contrary intention appears, references in these Regulations to a numbered regulation or Schedule are references to the regulation or Schedule so numbered in these Regulations.

### **General requirements**

**4.**—(1) Subject to paragraph (2) below, no person shall supply any cosmetic product which is liable to cause damage to human health when it is applied under—

- (a) normal conditions of use; or
- (b) conditions of use which are reasonably foreseeable taking into account all the circumstances, including the cosmetic product's presentation, labelling, any instructions for its use and disposal and any other information or indication provided by the manufacturer, his agent or the person who supplies the cosmetic product on the first occasion that it is supplied in the Community.

(2) Paragraph (1) above shall apply only to the supply by the manufacturer in or importer into the United Kingdom or, in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person.

(3) The provision of any instructions, information or indication referred to in sub-paragraph (b) of paragraph (1) above shall not exempt any person from the obligation to comply with any other provisions of these Regulations which are applicable to him.

### **Particular requirements**

**5.**—(1) The following provisions of this regulation are without prejudice to regulation 4 and are subject to regulation 6.

(2) No person shall supply a cosmetic product which contains—

- (a) any substance listed in column 2 of Part I of Schedule 3 which is used other than as a fragrance ingredient in relation to a cosmetic product, provided that no account shall be taken of any such substance which is present only as a trace which could not reasonably have been removed during or after manufacture;
- (b) any substance listed in column 2 of Part II of Schedule 3 which is used as a fragrance ingredient in relation to a cosmetic product, provided that no account shall be taken of any such substance which is present only as a trace which could not reasonably have been removed during or after manufacture;
- (c) any substance listed in columns 2 of Schedule 4, unless the requirements in column 3, 4, 5 and (in the case of Part II) 7 of that Schedule in relation to that substance are satisfied;

- (d) any colouring agent listed in columns 1 and 2 of Schedule 5 with the exception of a cosmetic product containing a colouring agent intended solely to colour hair unless—
  - (i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that colouring agent are satisfied; or
  - (ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that colouring agent are satisfied and the cosmetic product in question was supplied on or before the date specified in column 5 of that Part;
- (e) any colouring agent which is not listed in Schedule 5 with the exception of a cosmetic product containing a colouring agent intended solely to colour hair;
- (f) any preservative listed in column 2 of Schedule 6 unless—
  - (i) the requirements in columns 3, 4 and 5 of Part I of that Schedule in relation to that preservative are satisfied; or
  - (ii) the requirements in columns 3, 4 and 5 of Part II of that Schedule in relation to that preservative are satisfied and the preservative in question is supplied on or before the date specified in column 7 of that Part;
- (g) any preservative which is not listed in Schedule 6;
- (h) any preservative listed in column 2 of Part II of Schedule 6 after the date specified in column 7 of that Part;
- (i) any UV filter listed in column 2 of Schedule 7 unless—
  - (i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that UV filter are satisfied; or
  - (ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that UV filter are satisfied and the UV filter in question is supplied on or before the date specified in column 6 of that Part; or
- (j) any UV filter which is not listed in Schedule 7.

(3) Subject to paragraphs (4) to (6) below, no person shall supply a cosmetic product which contains any of the substances designated as a specified risk material in Annex V to Regulation (EC) No. 999/2001 of the European Parliament and of the Council<sup>(a)</sup>, or any ingredient derived from any of those substances.

(4) For the purposes of paragraph (3) above, no account shall be taken of any substance referred to in that paragraph which is present in the cosmetic product only as a trace which could not reasonably have been removed during or after manufacture.

(5) Paragraph (3) above shall not prohibit the supply of a cosmetic product which contains any tallow derivative so long as the relevant method set out in Schedule 8 was used in the manufacture of that derivative and the manufacturer of the derivative has certified that that method was used in its manufacture.

(6) Paragraph (3) above shall not prohibit the supply of any cosmetic product which contains any substance or ingredient referred to in that paragraph but which was manufactured before 1<sup>st</sup> April 1998.

(7) No person shall supply a cosmetic product where the final formulation has been tested on animals using a method other than an alternative method specified in Schedule 12 to these Regulations where such testing took place after—

- (a) 11<sup>th</sup> March 2013 in relation to tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics; or
- (b) 11<sup>th</sup> March 2009 in relation to all other tests

and was undertaken in order that the cosmetic product might satisfy any requirements of these Regulations or the Directive.

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<sup>(a)</sup> O.J No. L147, 31.5.01, p.1.

(8) No person shall supply a cosmetic product which contains any ingredients or combination of ingredients which have been tested on animals using a method other than an alternative method specified in Schedule 12 to these Regulations where such testing took place after—

- (a) 11<sup>th</sup> March 2013 in relation to tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics; or
- (b) 11<sup>th</sup> March 2009 in relation to all other tests

and was undertaken in order that the cosmetic product, ingredient or combination of ingredients might satisfy any requirements of these Regulations or the Directive.

(9) No person shall test a finished cosmetic product on animals where such testing is undertaken in order that the said product might satisfy any requirements of these Regulations.

(10) No person shall test any ingredient or combination of ingredients on animals where such is undertaken in order to satisfy any requirement of these Regulations or the Directive and takes place after 11<sup>th</sup> March 2009.

(11) The supply of any cosmetic product in respect of which a claim that the product or its ingredients have not been tested on animals appears on the packaging or in any document, notice, label, ring or collar accompanying or referring to the product is only be permitted if—

- (a) the manufacturers and his suppliers have not carried out any tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;
- (b) the manufacturers and his suppliers have not commissioned any tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;
- (c) the cosmetic product contains no ingredients which have been tested by others for the purpose of developing new cosmetic products.

(12) Paragraph (11) above shall not apply to any cosmetic product placed on the market in a Member State before 11<sup>th</sup> September 2004.

(13) Any reference to testing on animals in the labelling, putting up for sale or advertising of a cosmetic product must state clearly whether the tests carried out involved the cosmetic product itself or its ingredients.

(14) No person shall supply any cosmetic product in respect of which the requirements of paragraph (13) above are not satisfied.

(15) Subject to paragraph (16) below, no person shall supply a cosmetic product containing any substances classified as carcinogenic, mutagenic or toxic for reproduction of category 1,2 or 3 in the approved supply list.

(16) The prohibition in paragraph 15 above shall not apply in respect of substances classified as carcinogenic, mutagenic or toxic for reproduction of category 3 under Annex 1 to Council Directive 67/548/EEC (a) if the person supplying the substances in question can show that it has been evaluated by the SCCNFP and has been found acceptable for use in cosmetic products in accordance with Article 4b(b) of the Directive.

#### **Authorisation by the Secretary of State**

**6.**—(1) The Secretary of State may authorise the use in a cosmetic product for a maximum period of three years of a particular substance, not being a substance or ingredient referred to in regulation 5(3) or a substance listed in Schedule 3 or 4.

(2) In giving an authorisation the Secretary of State may impose conditions relating to the use of a particular substance in a cosmetic product, and such conditions may relate to any matter which the Secretary of State considers appropriate including—

- (a) the purpose of the substance;

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(a) Council Directive 1967/548/EEC (OJ 196,16.8.67, p.1)

(b) Inserted into Council Directive 76/768/EEC by Directive 2003/15/EC (OJ L66, 11.3.03, p.26)

- (b) the type of cosmetic product;
- (c) the maximum concentration of the substance in any cosmetic product; and
- (d) information and marking requirements.

(3) The Secretary of State may on reasonable notice vary or revoke any authorisation given under paragraph (1) above.

(4) On giving, varying or revoking an authorisation, the Secretary of State shall arrange for the authorisation, variation or revocation as the case may be, to be published in such manner as she considers appropriate for bringing it to the attention of persons who, in her opinion would be likely to have an interest in it.

(5) No person shall be convicted of an offence under section 12 of the 1987 Act by reason of a cosmetic product containing a particular substance provided that at the time when but for this regulation an offence would have been committed—

- (a) the use of that particular substance in that cosmetic product was duly authorised; and
- (b) all of the conditions imposed by the authorisation were complied with.

## Marking

7.—(1) Subject to paragraphs (5)(b) and (9) to (12) below, no person shall supply a cosmetic product unless the packaging in which it is supplied bears, in lettering which is visible, indelible and easily legible, a list of its cosmetics ingredients (preceded by the word “ingredients”) in descending order of weight, the weight to be determined at the time the ingredients are added to the product.

(2) Subject to paragraphs (3), (4), (5)(a), (6) to (8), (13) and (14) below, no person shall supply a cosmetic product unless the container and packaging in which it is supplied bear the following particulars in lettering and other symbols (where appropriate) which is visible, indelible and easily legible—

- (a) the name or trade name and the address or registered office of the manufacturer of the product or of the supplier thereof, being a manufacturer or supplier established within a Member State of the Community;
- (b) in the case of a cosmetic product likely within 30 months from the manufacture thereof to cease either to comply with the requirements of regulation 4 or to fulfil the purpose for which it was intended, the words “Best before....” immediately followed by—
  - (i) the earliest date on which it is likely so to cease; or
  - (ii) an indication of where that date appears on the labelling,
 and any particular precautions to be observed to ensure that the product does not so cease before that date;
- (c) in the case of a cosmetic product—
  - (i) not falling within sub-paragraph (b) above; and
  - (ii) likely to cease either to comply with the requirements of regulation 4 or to fulfil the purpose for which it was intended after the container in which the product is contained has been opened

the symbol given in Part II of Schedule 9 to these regulations together with an indication of the period of time after opening after which the cosmetic product is likely to cease either to comply with the requirements of regulation 4 or to fulfil the purpose for which it was intended.

- (d) in the case of a cosmetic product containing a substance listed in column 2 of Schedule 4, the information specified in column 6 of that Schedule in relation to that substance;
- (e) in the case of a cosmetic product containing a preservative listed in column 2 of Schedule 6, the information specified in column 6 of that Schedule in relation to that preservative;
- (f) in the case of a cosmetic product containing a UV filter listed in column 2 of Schedule 7, the information specified in column 5 of that Schedule in relation to that UV filter;

- (g) any particular precautions to be observed in use and any special precautionary information on a cosmetic product for professional use, in particular in hairdressing (not being precautions included in the information referred to in sub-paragraphs (b), (d), (e) and (f) above;
- (h) a means of identifying the batch in which the product was manufactured (or, if the product was not manufactured in a batch, a reference from which the date and place of manufacture can be identified); and
- (i) the function of the product unless this is clear from its presentation;

Provided that the requirements specified in sub-paragraphs (b) and (h) above need not be complied with in relation to a cosmetic product which is the subject of a market research experiment.

(3) The particulars referred to in paragraph (2)(a) above may be abbreviated if such abbreviation does not prevent the person concerned from being identified.

(4) The date referred to in paragraph (2)(b) above shall include the month and the year or the day, month and year in the order given in this paragraph.

(5) The particulars referred to—

- (a) in paragraph (2)(b) to (g) and (i) above shall be in English, but this shall not prohibit the additional use of other languages;
- (b) in paragraph (1) above shall be in language easily understood by the consumer.

(6) Where it is impossible for practical reasons for the particulars referred to in paragraph (2)(c) to (g) above to appear on the container and packaging, they shall appear on a leaflet, label, tag, tape or card enclosed with the cosmetic product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 9, which must appear on the container and packaging; and where it is impracticable for reasons of size or shape for the particulars so to appear, they shall appear on a label, tag, tape or card attached to the product.

(7) Where it is impossible, for reasons of size, for the particulars referred to in paragraph (2)(h) above to appear on the container and packaging, the said particulars shall appear on the packaging.

(8) In the case of a supply of soap which is not in a container either the soap itself or the packaging in which it is exposed for supply or the container in which it was last contained before the supply shall bear the particulars referred to in paragraph (2)(a) and (h) above, and in so far as any of the particulars referred to in paragraph (2)(b) to (g) and (i) above are required they shall appear on a leaflet which shall be delivered to the buyer with the soap; and where either of the particulars referred to in paragraph (2)(a) and (h) above appears on the soap itself the requirement of indelibility shall apply only until it has been put into use.

(9) In relation to the compilation of the list of ingredients referred to in paragraph (1) above—

- (a) the following shall not be regarded as cosmetic ingredients—
  - (i) impurities in the raw materials used;
  - (ii) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product;
  - (iii) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions;
- (b) perfume and aromatic compositions and their raw materials shall be referred to by the words “perfume” or “aroma” except where the substance—
  - (i) is listed in column 2 of Schedule 4 to these regulations; and
  - (ii) is subject to a requirement listed in column 4 of that Schedule;
- (c) ingredients in concentrations of less than 1 per cent may be listed in any order after those in concentrations of 1 per cent or more;
- (d) colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination in Schedule 5;

- (e) for decorative cosmetic products marketed in several colour shades all colouring agents used in the range may be listed, provided that the words “may contain” or the symbol “+/-” are added; and
- (f) an ingredient shall be identified by the name provided for in the International Nomenclature of Cosmetic Ingredients (INCI) or in the absence of such identification, by its chemical name, its CTFA name, its European Pharmacopoeia name, its International Non-proprietary Name (INN) as recommended by the World Health Organization, its EINECS, IUPAC or CAS identification reference or its colour index number(a).

(10) Subject to paragraph (11) below, where a cosmetic product has no packaging or it is impossible for practical reasons for the list of ingredients referred to in paragraph (1) above to appear on the packaging, the list shall appear on the container; and where a cosmetic product is supplied or delivered pursuant to any supply in neither a container nor packaging, the list shall appear on the container in which the product is exposed for supply or a notice in immediate proximity to that container.

(11) Subject to paragraph (12) below, where it is impossible for practical reasons for the list of ingredients referred to in paragraph (1) above to appear on the packaging or container of a cosmetic product, it shall appear on a leaflet, label, tag, tape or card enclosed with the product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 9, which must appear on the packaging and where it is impracticable for reasons of size and shape for the list so to appear, it shall appear on a label, tag, tape or card attached to the cosmetic product.

(12) In the case of soap, bathballs and other small products, where it is impracticable for reasons of size or shape for the list of ingredients referred to in paragraph (1) above to appear on an enclosed leaflet or on a label, tag, tape or card enclosed with or attached to the product, it shall appear on a notice in immediate proximity to the consumer in which the cosmetic product is exposed for sale.

(13) Where two or more cosmetic products are supplied together as a single item, each product being in a separate container and the containers being enclosed together in packaging which bears clear and conspicuous instructions to the effect that the products must be mixed together in specified proportions before use, the particulars referred to in paragraph (2)(d) to (g) above shall appear on an enclosed leaflet and an indication shall appear on both the containers and the packaging referring the consumer to the information in the leaflet.

(14) Where a cosmetic product other than soap is supplied or delivered pursuant to a supply in neither a container nor packaging, the particulars referred to in paragraph (2) above shall appear on the container in which the product is exposed for supply or a notice in immediate proximity to that container.

(15) Paragraphs 7(2)(c) and 7(9)(b) above shall not apply to cosmetic products placed on the market in the Community prior to 11th March 2005.

## **Responsible Persons and Competent Authorities**

- 8.—**(1) For the purposes of regulations 9 (except regulation 9(5) and (6)), 10, 11 and 12—
- (a) “responsible person” means, in relation to a relevant cosmetic product,
    - (i) the manufacturer of that product;
    - (ii) the manufacturer’s agent;
    - (iii) the person to whose order that cosmetic product is manufactured; or

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(a) An ingredient’s CTFA name is the name given to it by the Cosmetics, Toiletries and Fragrances Association (CTFA) and listed in the ninth edition of the International Cosmetic Ingredient Dictionary Handbook published in 2002. Its EINECS identification reference is the reference given in the European Inventory of Existing Commercial Chemical Substances. Its IUPAC identification reference is the reference given by the International Union of Pure and Applied Chemistry. Its CAS identification reference is the reference assigned by the Chemical Abstracts Service. An ingredient’s colour index number is the number specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists. European Pharmacopoeia names, International Non-proprietary Names and EINECS, IUPAC and CAS identification references are listed in Commission Decision 96/335/EC (O.J.No. L132, 1.6.96, p.1.).

- (iv) where the manufacturer or the person to whose order the cosmetic product is manufactured is not established in the Community and either—
  - (aa) the manufacturer has not appointed an agent; or
  - (bb) the manufacturer’s agent is not the supplier of that cosmetic product,
 the person who first supplies the cosmetic product in the Community;
- (b) “competent authority” means a body responsible for requiring and receiving the information provided for in Articles 7.3, 7a.1 and 7a.4 of the Directive and granting and refusing requests for confidentiality pursuant to Article 4 of the Confidentiality Directive, and which is—
  - (i) a United Kingdom competent authority pursuant to paragraph (2) below; or
  - (ii) for the time being a competent authority of a Member State other than the United Kingdom, having been notified as a competent authority by the Member State concerned to the Commission pursuant to Articles 7.3 and 7a.5 of the Directive and Article 10 of the Confidentiality Directive.

(2) The United Kingdom competent authority shall be the Secretary of State provided that she may from time to time appoint such persons as she thinks fit to be a United Kingdom competent authority in addition to or in substitution for herself.

**Product Information**

9.—(1) Subject to paragraph (8) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall for control purposes keep readily accessible to a United Kingdom competent authority at the address or registered office specified on the container or packaging of the cosmetic product in accordance with regulation 7(2)(a) above the following information—

- (a) the qualitative and quantitative composition of the product, except to the extent that the product is composed of any perfume or perfume composition, in which case the responsible person shall only be required to keep the name and code number of the perfume or perfume composition and the identity of the supplier;
- (b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- (c) the method of manufacture which shall be in accordance with good manufacturing practice, that is to say that the cosmetic product shall be manufactured in such a way that under normal and reasonably foreseeable conditions of use it shall not endanger human health or safety;
- (d) an assessment of the safety for human health of the finished product taking into consideration the matters specified in paragraph 2 below;
- (e) an assessment of the safety for human health of the finished product in respect of cosmetic products intended for use on children under the age of 3 and for cosmetic products intended exclusively for use in external intimate hygiene;
- (f) the name and address of the person or persons, qualified in accordance with paragraph (3) below, responsible for the assessment referred to in sub-paragraph (d) above;
- (g) existing data on undesirable effects on human health resulting from use of the cosmetic product;
- (h) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product; and
- (i) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative requirements of countries which are not Member States;

(2) The assessments referred to in paragraphs (1)(d) above shall be carried out in accordance with the principles of good laboratory practice referred to in Article 1 of Council Directive 87/18/EEC (a) on the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances and shall take particular account of the following—

- (a) the general toxicological profile of each ingredient used;
- (b) the chemical structure of each ingredient;
- (c) the level of exposure of each ingredient;
- (d) the specific exposure characteristics of the areas on which the cosmetic product will be applied; and
- (e) the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

(3) Subject to paragraph (4) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall ensure that the information specified in sub-paragraphs (a) and (g) above shall be made readily accessible to the public by any appropriate means.

(4) For the purposes of paragraph (3) above, the information required under sub-paragraph (a) shall be limited to information relating to dangerous substances covered by Directive 67/548/EEC as amended.

(5) The person referred to in paragraph (1)(f) must be—

- (a) subject to paragraph (6) below, the holder of an appropriate European diploma within the meaning of section 4A of the Pharmacy Act 1954(b) or any other person who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a pharmaceutical chemist;
- (b) subject to paragraph (6) below, a person who is entitled to be registered under section 3(1) of the Medical Act 1983(c) as a fully registered medical practitioner and who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a doctor; or
- (c) the holder of a diploma within the meaning of regulation 2(1) of the European Communities (Recognition of Professional Qualifications) Regulations 1991(d) showing that the holder has the qualifications required to practise as a chartered biologist or that he has the qualifications required to practise as a chartered chemist or that he has the qualifications required to practise a profession equivalent to the profession of chartered biologist or chartered chemist in a Member State other than the United Kingdom.

(6) Any diploma or other evidence of qualification required for the purposes of paragraph (5)(a) or (b) above shall satisfy that requirement only if—

- (a) the education and training attested were received mainly within the European Community; or
- (b) the holder has spent at least three years in lawful pursuit in a Member State of the relevant profession, and such professional experience has been certified by a competent authority in a Member State (being a State which recognised a diploma or other evidence of qualification obtained in a non-Member State).

(7) Where the responsible person is the manufacturer or the person who first imports the cosmetic product into the Community he must possess appropriate experience or an appropriate level of professional qualification in accordance with the legislation and practice of the United Kingdom if it is the place of manufacture or first importation.

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(a) O.J. No. L15 17.1.87, p. 29, implemented by the Notification of New Substances (Amendment) Regulations 1991 (S.I. 1991/1914). Article 1 was amended by Commission Directive 1999/11/EC (O.J. No. L77, 23.3.99, p. 8), implemented by the Good Laboratory Practice Regulations 1999 (S.I. 1999/3106).

(b) 1954 c.61.

(c) 1983 c. 54.

(d) S.I. 1991/824, to which there is an amendment not relevant to these Regulations.

(8) Where the manufacturer manufactures a cosmetic product at two or more places within the Community, and one of those places is within the United Kingdom the responsible person may choose a single place of manufacture within the Community where the information referred to in paragraph (1) above will be kept available provided that, if requested by a United Kingdom competent authority, he informs the said authority of the location at which the said information is to be kept.

(9) Where the information referred to in paragraph (1) above is to be kept accessible to a United Kingdom competent authority it must be in English or a language readily understood by the said authority.

(10) Paragraphs 9(1)(d), 9(1)(e), 9(1)(i) and 9(2) above shall not apply in respect of cosmetic products placed on the market in the Community prior to 11<sup>th</sup> September 2004.

**10.** Where the place of manufacture or initial importation into the Community of a type of cosmetic product is within the United Kingdom, the responsible person shall notify a United Kingdom competent authority of the address of the place of manufacture or, as the case may be, initial importation into the Community of that type of cosmetic product before its first supply in the Community.

**11.—(1)** A United Kingdom competent authority may, where difficulties are encountered in providing prompt and appropriate medical treatment, require that any holder of appropriate and adequate information on substances used in cosmetic products make such information available to it, where the difficulties referred to may be overcome or eased by the provision of the said information.

(2) Where the information referred to in paragraph (1) above is made available, the United Kingdom competent authority shall ensure that it is used solely for the purposes of the treatment referred to in paragraph (1) above.

**12.—(1)** Without prejudice to the provisions of regulations 4, 5, 9 and 12, a responsible person who for reasons of trade secrecy wishes not to include one or more cosmetic ingredients in the list of cosmetic ingredients referred to in regulation 7(1) above shall submit a request to that effect to the competent authority.

(2) In this regulation “applicant” means a responsible person who submits a request for confidentiality.

(3) The applicant shall ensure that—

- (a) the request for confidentiality includes the particulars laid down in Part I of Schedule 10; and
- (b) any amendments to the particulars provided for in sub-paragraph (a) above are communicated as quickly as possible to the competent authority and, in particular, that all changes to the names of cosmetic products containing the cosmetic ingredient in respect of which confidentiality is or has been sought, are communicated to the competent authority at least 15 days before those cosmetic products are supplied under their new name.

(4) Within four months of the receipt of a request for confidentiality in respect of which the requirements of paragraph (3)(a) above are satisfied, the competent authority shall examine the request and inform the applicant in writing of its decision.

(5) If the competent authority decides to grant its approval to the applicant’s request it shall, in notifying the applicant of its decision, in accordance with paragraph (4) above, also notify him of the registration number which will replace the cosmetic ingredient in question in the list referred to in regulation 7(1), the said number to be allocated to the product in accordance with the procedure provided for in Part II of Schedule 10.

(6) If the competent authority decides to refuse to grant its approval to the applicant’s request it shall, in its notification of this refusal, include a statement of the reasons for refusal and a clear explanation of appeals procedures and their time limits.

(7) In exceptional cases the competent authority may inform the applicant in writing that a period of two months in addition to the four-month period referred to in paragraph (4) above is required for the examination of the request.

(8) Subject to paragraphs (9), (10), (11) and (12) below, a decision granting confidentiality shall be valid for a period of five years.

(9) An applicant may, by submitting a reasoned request to the competent authority, request that the period of confidentiality referred to in paragraph (8) above be extended.

(10) In the event of a reasoned request being submitted in accordance with paragraph (9) above, the competent authority shall deal with the request in accordance with paragraphs (4), (5) and (6) above.

(11) Any extension of the period of confidentiality shall not exceed three years.

(12) The competent authority may withdraw its approval to an applicant's request for confidentiality if it considers this appropriate taking into account—

- (a) any amendments to the particulars provided for in paragraph (3)(a) above which are communicated to it in accordance with paragraph (3)(b) above; and
- (b) any new information which comes to its attention which makes it imperative, particularly for compelling reasons of public health for it to so act,

and in withdrawing its approval the competent authority shall comply with the provisions of paragraphs (4), (6) and (7) above.

#### **Contravention of Regulation 9, 10 or 11**

**13.**—(1) Subject to paragraph (2) below, any contravention of a requirement of regulation 9, 10 or 11 shall be treated for all purposes as though it were a contravention of a requirement of safety regulations made under section 11 of the 1987 Act.

(2) The term of imprisonment to which a person guilty of an offence of contravening any requirement of regulation 9, 10 or 11 shall be liable on summary conviction shall not exceed three months.

#### **Contravention of Regulations 5(7) to 5(10)**

**14.**—(1) Any person who contravenes regulation 5(7), 5(8), 5(9) or 5(10), or causes or permits another person to contravene those regulations, shall be guilty of an offence.

(2) Any person guilty of an offence under paragraph (1) above shall be liable, on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months and, on conviction on indictment, to a fine not exceeding £5,000 or to imprisonment not exceeding six months.

(3) Where an offence under paragraph (1) committed by a body corporate is proved—

- (a) to have been committed with the consent or connivance of an officer, or
- (b) to be attributable to any neglect on his part,

the officer as well as the body corporate shall be guilty of that offence and shall be liable to proceeded against and punished accordingly.

(4) In paragraph (3), “officer” in relation to a body corporate, means a director, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity.

(5) If the affairs of the body corporate are managed by its members, paragraph (3) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(6) Where an offence under paragraph (1) committed by a partnership in Scotland is proved—

- (a) to have been committed with the consent and connivance of the partner, or
- (b) to be attributable to any neglect on his part,

the partner as well as the partnership shall be guilty of that offence and liable to be proceeded against and punished accordingly.

(7) In paragraph (6), partner includes a person purporting to act as a partner.

**15.** For the purposes of enforcing regulations 5(7), 5(8), 5(9) and 5(10), those regulations shall be treated as if they were safety regulations made under section 11 of the 1987 Act provided that section 12 of that Act shall not apply.

## **Enforcement**

**16.—**(1) No proceedings shall be brought and no enforcement action taken in respect of—

- (a) any failure to comply with regulations 4, 5, 7, 9, 10 and 12 in any case in which the cosmetic product is supplied for the purposes of exporting that product to any country which is not a Member State; or
- (b) any failure to comply with regulation 7(5)(a) in any case in which the enforcement authority is satisfied that the person supplying the cosmetic product reasonably believes that it will not be used in the United Kingdom.

(2) No proceedings shall be brought and no enforcement action taken in respect of any failure to comply with regulations 5(13), 5(14), 7(1), 7(2)(i), 7(5)(a), 7(5)(b), 7(6), 7(7), 7(9), 7(10), 7(11), 7(12) in the case of—

- (a) any supply of a cosmetic product before 31<sup>st</sup> December 1997 by the manufacturer in or importer into the United Kingdom or, in relation to a cosmetic product manufactured or imported into the United Kingdom on behalf of another person, by that other person, except for a supply by retail in which case no proceedings shall be brought and no enforcement action taken in respect of a supply before 31<sup>st</sup> December 1998; or
- (b) any other supply of a cosmetic product before 31<sup>st</sup> December 1998.

(3) No proceedings shall be brought and no enforcement action taken in respect of any contravention of regulation 5(7) of the Cosmetic Products (Safety) Regulations 2003(a) once these regulations have come into force.

(4) For the purposes of this regulation, “enforcement action” means any action taken pursuant to or in connection with sections 13, 14, 16, 17, 28, 29, 30 or 31 of the 1987 Act.

**17.** Any test of goods purchased under section 28 or seized under section 29 of the 1987 Act (which relate to enforcement) by or on behalf of an enforcement authority for the purpose of ascertaining whether the provisions of these Regulations have been contravened shall in all cases be carried out in accordance with the provisions of paragraphs 2 to 5 Schedule 11 and any test for which a method is specified in paragraph 6 of Schedule 11 shall be carried out in accordance with that method.

Address	<i>Name</i>
Date	Parliamentary Under Secretary of State Department

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(a) SI 2003/835 revoked by these regulations

## 5. What happens next?

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- 5.1 We intend for the Regulations to be laid before Parliament in July after the consultation has closed. The Regulations must come into force on 11 September 2004.
- 5.2 We aim to publish a report on the outcome of this consultation by 1<sup>st</sup> September 2004.

## 6. List of Consultees

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A A PAINTER, TRADING STANDARDS  
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ADAMS, WILSON & ASSOCIATES LTD  
ADVICE SERVICES ALLIANCE  
ALEXANDRA BAILEY ASSOCIATES  
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HEALTH OFFICERS  
ASSOCIATION OF DISTRICT COUNCILS  
ASSOCIATION OF INDEPENDENT  
BUSINESSES  
ASSOCIATION OF LOCAL AUTHORITIES  
OF NORTHERN IRELAND  
ASSOCIATION OF LONDON  
AUTHORITIES  
ASSOCIATION OF MANUFACTURING  
CHEMISTS  
ASSOCIATION OF PUBLIC ANALYSTS  
ASSOCIATION OF PUBLIC ANALYSTS  
ASSOCIATION OF SCOTTISH  
CHAMBERS OF COMMERCE  
  
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LAW, NOTTINGHAM  
CHRISTOPHER J S HODGES, CMS  
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ECONOMICS AND POLITICAL SCIENCE  
CONFEDERATION OF BRITISH  
INDUSTRY  
CONSUMERS ASSOCIATION  
CONSUMERS ASSOCIATION RESEARCH  
AND TESTING CENTRE  
CONSUMERS IN EUROPE GROUP  
CONVENTION OF SCOTTISH LOCAL  
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CO-OPERATIVE WOMENS GUILDS  
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ASSOCIATION OF THE BRITISH  
PHARMACEUTICAL INDUSTRY  
B BRAUN MEDICAL LTD  
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BRITISH ASSOCIATION FOR CHEMICAL  
SPECIALITIES  
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BRITISH CONTACT DERMATITIS GROUP  
BRITISH FRAGRANCE ASSOCIATION  
BRITISH IMPORTERS ASSOCIATION  
BRITISH IMPORTERS FEDERATION  
BRITISH MEDICAL ASSOCIATION  
BRITISH MEDICAL ASSOCIATION  
(SCOTTISH BRANCH)  
BRITISH SAFETY COUNCIL  
BRITISH SHOPS AND STORES  
ASSOCIATION  
BRITISH UNION FOR THE ABOLITION  
OF VIVISECTION  
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EUROPEAN COALITION TO END  
ANIMAL EXPERIMENTS  
FACULTY OF ADVOCATES  
FACULTY OF LAW, GLASGOW  
CALEDONIAN UNIVERSITY  
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FORUM OF PRIVATE BUSINESS  
GENERAL CONSUMER COUNCIL FOR NORTHERN IRELAND  
Green Alliance  
HEALTH AND SAFETY COMMISSION  
HEALTH AND SAFETY EXECUTIVE  
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INDEPENDENT RETAIL NEWS  
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INSTITUTE OF DIRECTORS  
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WOMENS NATIONAL COMMISSION

## Annex A

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### Code of Practice on Consultations

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.
7. The complete code is available on the Cabinet Office's web site address:

[www.cabinet-office.gov.uk/servicefirst/index/consultation.htm](http://www.cabinet-office.gov.uk/servicefirst/index/consultation.htm)

### Comments or complaints

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to Louisa Renwick, DTI Consultation Co-ordinator, Room 723, 1 Victoria Street, London SW1H 0ET or telephone her on 020 7215 6913 or email to: [Louisa.renwick@dti.gsi.gov.uk](mailto:Louisa.renwick@dti.gsi.gov.uk)

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