

dti

**THE COSMETIC PRODUCTS
(SAFETY) (AMENDMENT) (No 2)
REGULATIONS 2005**

Consultation on proposals to
implement two EC Directives on
the safety of Cosmetic Products

CONSULTATION DOCUMENT

September 2005

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dti

The DTI drives our ambition of 'prosperity for all' by working to create the best environment for business success in the UK. We help people and companies become more productive by promoting enterprise, innovation and creativity.

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.

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1. Executive Summary

This consultation document seeks views on the Government's proposals to introduce Regulations that amend Part 2 of Annex III to the Directive by changing the dates that particular substances are permitted. The Regulations will also amend annexes II, IV and VI of the main Regulations by inserting additional substances or by amending existing entries in these Annexes.

The proposed **Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2005** will implement two EC Directives on the safety of cosmetics. The 2005 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 Regulations will implement Commission Directive 2005/42/EC (OJ No. L158, 20.6.2005, p.17). The Directive makes a number of technical amendments to the main **Cosmetic Products (Safety) Regulations 2004**: adding 4 new substances to the list of banned ingredients, when they are used as fragrance ingredients; deletes 3 colours as permitted colouring agents; amends the use of one preservative and allows the use of a new preservative.

The Directive requires Member States to transpose it into national law by 31 December 2005.

Article 2 of the proposed Regulations clarifies the dates applicable in Article 5 (15) of the Principal Regulations on the restriction of certain substances classified as carcinogenic, mutagenic or repro-toxic in Annex II.

The Regulations will also implement a Commission Directive (this is currently still in draft but is expected to be published in the Official Journal in September) amending dates in Schedule 4, Part 2 of the Cosmetic Products (Safety) Regulations 2004 for the use of certain colours permitted as colouring agents: entries 1 to 22 for the date "31.12.2005" changed to "31.8.2006"; entries 23-60 for the date "31.12.2005" changed to "31.12.2006". The implementation date for this Directive is expected also to be 31st December 2005 and we are therefore taking this opportunity to transpose it.

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.

How to Respond?

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.

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


Sue Pain
Consumer and Competition Policy Directorate
Room 428
Department of Trade and Industry
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 0361
Fax: 020 7215 0357
sue.pain@dti.gsi.gov.uk

Additional copies

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London SW1 W 8YT

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Electronic versions may be viewed on the DTI website at:

<http://www.dti.gov.uk/ccp/consultations.htm> , or
<http://www.dti.gov.uk/consultations/>

Help with Queries

If you have any questions about the issues discussed in this consultation document, please contact Ian Parsons.

 020 7215 0360
E-mail Ian.Parsons@dti.gsi.gov.uk

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

Closing Date

Responses must be received by **Friday 25 November 2005**.

Confidentiality

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.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

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

Consultees

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

Complaints

The Code of Practice on Consultation can be found at Annex E to this document.

If you wish to make a complaint about, or comment on, the way in which this consultation has been conducted, please contact:

Nick Van Benschoten
Consultation Co-ordinator
DTI Better Regulation Team, Bay 4113
1 Victoria Street
London SW1H 0ET

 0207 215 6206

Email nick.vanbenschoten@dti.gsi.gov.uk

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

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?

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

2. Proposals

The main objective of introducing the 2005 Amendment No 2 to the Regulations is to implement Commission Directives 2005/42/EC , 2005/xx/EC (XX 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.

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.

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 2005 Regulations

The proposed **Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2005** will implement two EC Directives on the safety of cosmetics. The 2005 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 Regulations will implement Commission Directive 2005/42/EC (OJ No. L158, 20.6.2005, p.17). The Directive does the following:

- i) adds 4 new substances (costus root oil (*Saussurea lappa* Clarke); 7-Ethoxy-4-methylcoumarin; hexahydrocoumarin; peru balsam (*Myroxylon pereirae*)) into Annex II, banned ingredients, when they are used as fragrance ingredients, these will require entries in the corresponding schedule in our Regulations – Schedule 3 part 2;
- ii) deletes 3 colours (CI 12150; CI 20170; CI 27290) from Annex IV part 1, permitted colouring agents, these will require deletion from the corresponding schedule in our Regulations – Schedule 5 part 1;
- iii) amends entry number 53 (Benzethonium chloride) in Annex VI part 1, permitted preservatives, this will require amending in the corresponding schedule in our Regulations – Schedule 6 part 1 and,
- iv) permits the use of a new preservative, entry number 57 in Annex VI part 1 (Methylisothiazollinone), this will require an additional entry in the corresponding schedule in our Regulations – Schedule 6 part 1.

The Directive requires member States to transpose it into national law by 31 December 2005.

The Regulations also implements a draft Commission Directive (to be published in the Official Journal in September) amending dates in Schedule 4, Part 2 of the Cosmetic Products (Safety) Regulations 2004:

- i) entries 1 to 22 for the date “31.12.2005” in the 7th column wherever it occurs there is substituted “31.8.2006”;
- ii) entries 23-60 for the date “31.12.2005” in the 7th column wherever it occurs there is substituted “31.12.2006”.

The substances listed in this Schedule are all hair dyes and the amending Directive is part of the Commission’s strategy on hair dyes, allowing extra time for the submission of safety dossiers to the Scientific Committee for Consumer Products.

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

3. Draft Regulatory Impact Assessment

Amendment to The Cosmetic Products (Safety) Regulations 2005

Proposal

To transpose Commission Directive 2005/42/EC and a Draft Directive (to be published in the Official Journal in September) into UK Law.

Purpose and intended effect of measure

Objective

The primary aim of the Cosmetic Products (Safety) Regulations is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients. The Directives adds adding 4 new substances to the list of banned ingredients when they are used as fragrance ingredients; deleting 3 colours as permitted colouring agents; amends the use of one preservative and allows the use of a new preservatives and extends the dates allowed for the use of certain colours used as colouring agents.

Risk Assessment

Options

Option (i): to fully implement the provisions of the proposed Directive, if adopted.

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

Option (iii): to do nothing

Option (i) is the recommended option. The proposed Directive is consistent with UK policy and practice on these issues. It guarantees a high level of consumer safety, restricting the use of ingredients identified as allergens.

Option (ii) under the Cosmetics Directive, substances used as ingredients in cosmetic products are subject to approval by the Scientific Committee. Those not allowed or allowed with restrictions are in a positive schedule. Voluntary measures would not guarantee knowledge of the restrictions on use of the ingredients.

Option (iii) would not make the information available. This could possibly mislead manufacturers and consumers as to the safety of these particular ingredients.

Benefits

Economic

The Directives improves the choice of preservatives available, allows continued use of colours as colouring agents available to manufacturers and consumers. It also bans the use of certain ingredients as fragrances that are available to manufacturers, which may incur costs in the reformulation of certain finished products.

Environmental

No specific benefits to the environment have been identified

Social

The Directives, if adopted will improve consumer protection. The restriction on ingredients as fragrances will remove certain allergens from the market in the interests of improving consumer safety.

Costs

The choice of manufacturer to use allowed ingredients is discretionary. The restriction on certain ingredients as fragrance may incur cost on manufacturers. There would be no additional costs for consumers.

Equity & Fairness

The overriding consideration of the Directive is the safety of consumers. The Directive will impact equally across the particular sectors of industry affected and will be implemented in all Member States.

Consultation with small business: the Small Firms Impact Test

On the advice of the Small Business Service, stage one of the Small Firms Impact Test was carried out by contacting small businesses and the industry trade association. We were unable to identify any disproportionate impact on small firms as a result of this proposal. Nevertheless if, during the proposed consultation we identify impacts or unintended consequences of the proposal on small firms, further work to assess this impact will be undertaken and the position reviewed

Competition Assessment

Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment filter, the results indicated that, as the proposed Directive would not introduce any restrictions, it is unlikely

to have the effect of distorting or removing competition in the market. The Directives, if adopted, would not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others.

Enforcement & Sanctions

The Cosmetic Products (Safety) Regulations, which are amended by these Regulations, are enforced by local authorities trading standards departments. It is the responsibility of the manufacturers of cosmetic products made in the EU or importers of finished cosmetic products to ensure that products comply with the Regulations.

Consultation

Within Government

The relevant interested department: the Department of Health was consulted about these proposals during the consultation exercise.

Public Consultation

DTI conducted a full consultation for the implementation of the Cosmetic Product (Safety) (Amendment) (No 3) Regulations 2005.

Summary & Recommendation

Our recommendation is that the option chosen offers the best level of public health protection by .

Our legal obligations under the Treaty of Rome compel us to implement this Directive into UK law.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the Minister responsible

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

Date

Contact point

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4. Draft Regulations

STATUTORY INSTRUMENTS

2005 No.

CONSUMER PROTECTION

The Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2005

Made - - - - - ***
Laid before Parliament - - - - - ***
Coming into force - - - - - *31st December 2005*

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987⁽¹⁾, consulted such organisations as appear to him to be representative of interests substantially affected by the following Regulations, such other persons as he considers appropriate and the Health and Safety Commission;

Now therefore, the Secretary of State in exercise of the powers conferred upon him by section 11 of the said Act hereby makes the following Regulations:

Citation, commencement and interpretation

—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2005 and shall come into force on 31st December 2005.

In these Regulations “the Principal Regulations” means the Cosmetic Products (Safety) Regulations 2004⁽²⁾.

Amendment to the Principal Regulations

—(2) The Principal Regulations are amended as follows.

In regulation 5 for paragraph 15 there is substituted—

“(15) (a) No cosmetic product containing any substance listed in Annex II to the Directive under entry numbers 452 to 1132 (inserted into the Directive by Directive 2004/93/EC) shall be—

- (i) placed on the market after 1st January 2005;
- (ii) supplied after 1st April 2005;

(b) No cosmetic product containing any substance listed in Annex II to the Directive under entry numbers 1133 to 1136 (inserted into the Directive by Directive 2005/42/EC) shall be placed on the market or supplied after 30th March 2006.”

⁽¹⁾ 1987 c. 43.

⁽²⁾ S.I. 2004/2152 as amended by 2004/2361, 2004/2988 and 2005/1815.

In Schedule 2 at the end there is inserted “43. Commission Directive 2005/42/EC (O.J. No. L158, 20.6.2005, p.17)”;

In Schedule 3—

in Part 1 at the end there is inserted the entry in Part 1 of the Schedule to these Regulations;

in Part 2 for the entry numbered 29 there is substituted “ENTRY DELETED”.

In Schedule 4 in Part 2—

in the entries numbered 1 to 22 for the date “31.12.2005” in the 7th column wherever it occurs there is substituted “31.8.2006”;

in the entries numbered 23 to 60 for the date “31.12.2005” in the 7th column wherever it occurs there is substituted “31.12.2006”.

Subject to paragraph 7, in Schedule 5 in Part 1 the entries in the table numbered 12150, 20170 and 27290 are omitted.

Paragraph (6) shall only have effect in relation to cosmetic products supplied after 30th March 2006;

In Schedule 6 in Part 1—

for the entry numbered 53 there is substituted the corresponding entry in Part 2 of the Schedule to these Regulations;

at the end there is inserted the entry numbered 57 in Part 2 of the Schedule to these Regulations.

Gerry Sutcliffe
Parliamentary Under Secretary of State
for Employment Relations and Consumer Affairs
Department of Trade and Industry

Date

SCHEDULE

Regulation 2

PART 1

Entry inserted at the end of Part 1 of Schedule 3 to the Principal Regulations

<i>(1)</i> <i>Number in this Schedule</i>	<i>(2)</i> <i>Name of Substance</i>	<i>(3)</i> <i>Cross-reference to this Schedule</i>	<i>(4)</i> <i>Cross-reference to Annex II of the Directive</i>
770	Methyleugenol (except for normal content in the natural essences used, and provided that the concentration does not exceed: (a) 0.01 per cent in fine fragrance; (b) 0.004 per cent in eau de toilette; (c) 0.002 per cent	-	451

in fragrance cream;
 (d) 0.001 per cent
 in rinse-off products;
 and
 (e) 0.0002 per
 cent in other leave-on
 products and oral
 hygiene products)

PART 2

Entries inserted into Part 1 of Schedule 6 to the Principal Regulations

(1) <i>Reference Number</i>	(2) <i>Name of Substance</i>	(3) <i>Purpose of Substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
53	Benzethonium Chloride (INCI)	(a) Rinse-off products (b) Leave-on products other than for oral care use	0.1% 0.1%		
57	Methylisothia- zolinone (INCI)		0.01%		

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Cosmetic Products (Safety) Regulations 2004 (“the Principal Regulations”) to give effect to Commission Directives 2005/42/EC (O.J. No. L158, 20.6.2005, p.17) and --- which amend Council Directive 76/768/EEC (O.J. L262, 27.9.1976, p.169) on the approximation of the laws of the Member States on cosmetic products (“the Directive”). The Directive has been implemented by the Principal Regulations.

Directive 2005/42/EC amends the Directive by adding 4 substances to the list of banned substances in annex II and deletes 3 substances from the list of permitted colouring agents in annex IV with the result that cosmetic products containing these substances will be prohibited (the prohibition on the use of colouring agents does not extend to cosmetic products containing colouring agents intended solely to colour hair). Directive 2005/42/EC also amends the list of permitted preservatives in annex VI to the Directive by amending entry 53 and by inserting entry 57.

Regulation 2 in these Regulations amends regulation 5, Schedule 5 and 6 respectively in the Principal Regulations to give effect to the above amendments. In accordance with Directive 2005/42/EC, the substances prohibited by these Regulations will be prohibited from 30th March 2006.

Directive --- amends Part 2 of Annex III (list of substances permitted subject to restrictions) to the Directive by changing the date until which substances 1-22 and 23-60 are permitted to 31.8.2006 and 31.12.2006 respectively. Regulation 2 amends Schedule 4, Part 2 to the Principal Regulations which implements annex III to give effect to these amendments.

These Regulations also delete entry 29 from Part 2 of Schedule 3 to the Principal Regulations (substances banned for use in fragrances) and inserts it into Part 1 of that Schedule (substances banned for use in all cosmetic products) with the result that entry 29 is now prohibited for all purposes in cosmetic products.

A regulatory impact assessment of the effect that these Regulations will have on costs to business is available from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET. Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET and on the DTI website (www.dti.gov.uk).

5. What happens next?

We intend for the Regulations to be laid before Parliament in July after the consultation has closed. The Regulations must come into force on 31 December 2005.

We aim to publish a report on the outcome of this consultation by
31 December 2005

6. List of Consultees

LORNA MEAD LTD
CMS CAMERON MCKENNA
NATURAL ACTIVE MINERALS
RESOURCE COMPANY LTD
SAFWAY STORES PLC
WARREN MURTON
ALEXANDRA BAILEY ASSOCIATES
BRITISH UNION FOR THE ABOLITION
OF VIVISECTION
COSMETICS INTERNATIONAL
LEICESTER CITY LIBRARIES
PITROK LTD
JAMONT UK LTD
SOCIETY OF DYERS AND COLOURISTS
AROMATHERAPY TRADE COUNCIL
FORUM OF PRIVATE BUSINESS
EUROPEAN COALITION TO END
ANIMAL EXPERIMENTS
ROYAL INSTITUTE OF PUBLIC HEALTH
AND HYGIENE
RETAIL DISTRIBUTORS ASSOCIATION
THE BODY SHOP INTERNATIONAL PLC
NATUREWATCH TRUST
NATIONAL FEDERATION OF SELF
EMPLOYED AND SMALL BUSINESSES
INSTITUTE OF PACKAGING
MAIL ORDER TRADERS' ASSOCIATION
HEALTH FOOD MANUFACTURERS'
ASSOCIATION
IFAW
PARLIAMENTARY COMMITTEE OF THE
COOPERATIVE UNION LTD
OFFICE OF FAIR TRADING
FEDERATION OF WHOLESALE
ORGANISATIONS
RSPCA
ROCHE NICHOLAS
NORTHANTS TRADING STANDARDS
SCOTTISH HOME AND HEALTH
DEPARTMENT
INSTITUTE OF SCOTTISH DIRECTORS
OF CONSUMER PROTECTION
INSTITUTE OF CONSUMER ADVISERS
ROYAL ENVIRONMENTAL HEALTH
INSTITUTE OF SCOTLAND
BRITISH IMPORTERS FEDERATION
BRITISH SAFETY COUNCIL
CONSUMERS ASSOCIATION
BRITISH MEDICAL ASSOCIATION
(SCOTTISH BRANCH)
SOCIETY OF COSMETIC SCIENTISTS
PHARMACEUTICAL ASSOCIATION OF
GREAT BRITAIN
CHEMICAL INDUSTRIES ASSOCIATION
BRITISH FRAGRANCE ASSOCIATION
BRITISH CARIBBEAN AFRO SOCIETY OF
HAIRDRESSERS OF THE UK
BSI
MEDICAL RESEARCH COUNCIL
ABBOTT LABORATORIES LTD
UKCPI
CTPA
BRITISH CONTACT DERMATITIS GROUP
ASSOCIATION OF MANUFACTURING
CHEMISTS
FCO
DEPARTMENT OF HEALTH
THE UK INTER PROFESSIONAL GROUP
A A PAINTER, TRADING STANDARDS
CONSULTANT
ROLAND ROWELL, CONSULTANT IN
MARKETING LAW
BAMA
ASSOCIATION OF THE BRITISH
PHARMACEUTICAL INDUSTRY
CABINET OFFICE
AMTAC LABORATORIES LTD
ASSOCIATION OF BRITISH CHAMBERS
OF COMMERCE
ASSOCIATION OF COUNTY COUNCILS
ASSOCIATION OF DISTRICT COUNCILS
ASSOCIATION OF LOCAL AUTHORITIES
OF NORTHERN IRELAND
ASSOCIATION OF PUBLIC ANALYSTS
BEDFORDSHIRE COUNTY COUNCIL
BELFAST CITY COUNCIL
BHS PLC
ASSOCIATION OF COUNTY PUBLIC
HEALTH OFFICERS
ASSOCIATION OF LONDON
AUTHORITIES
ASSOCIATION OF INDEPENDENT
BUSINESSES
ADAMS, WILSON & ASSOCIATES LTD
BRITISH MEDICAL ASSOCIATION
BRITISH IMPORTERS ASSOCIATION
BRITISH SHOPS AND STORES
ASSOCIATION
CONFEDERATION OF BRITISH
INDUSTRY
CONSUMERS IN EUROPE GROUP
LGC
TRADING STANDARDS, BOARD OF
INDUSTRY, GUERNSEY
CONSUMERS ASSOCIATION RESEARCH
AND TESTING CENTRE
CONVENTION OF SCOTTISH LOCAL
AUTHORITIES

THE SOCIETY OF CHIEF OFFICERS OF
TRADING STANDARDS IN
SCOTLAND
DIRECT SELLING ASSOCIATION
HEALTH AND SAFETY EXECUTIVE FOR
NORTHERN IRELAND
DHSS (NI)
FEDERATION OF WOMENS INSTITUTES
OF NORTHERN IRELAND
GENERAL CONSUMER COUNCIL FOR
NORTHERN IRELAND
Green Alliance
HIGHLAND REGIONAL COUNCIL
THE CHARTERED INSTITUTE OF
ENVIRONMENTAL HEALTH
IRISH CO-OPERATIVE WOMENS GUILD
ISVA
ARDS BOROUGH COUNCIL
TSI LTD
INSTITUTE OF CONSUMER AFFAIRS
KENSINGTON HIGH STREET
ASSOCIATION
MARIE CURIE CANCER CARE, SHOPS
DEPARTMENT
NORTHERN IRELAND WHOLESALE
MERCHANTS & MANUFACTURERS
ASSOCIATION LTD
NATIONAL FEDERATION OF
CONSUMER GROUPS
THE COMPANIES OF ANCIENT
SUNLIGHT
NATIONAL ASSOCIATION OF
SHOPKEEPERS
NATIONAL FEDERATION OF WOMENS
INSTITUTES
ASSOCIATION OF SCOTTISH
CHAMBERS OF COMMERCE
NORTHERN IRELAND SAFETY COUNCIL
NATIONAL ASSOCIATION OF LOCAL
COUNCILS
NATIONAL CONSUMER COUNCIL
NATIONAL ASSOCIATION OF CITIZENS
ADVICE BUREAUX
NATIONAL STANDARDS AUTHORITY
NATIONAL COUNCIL OF WOMEN OF
GREAT BRITAIN
NORTHERN IRELAND HOUSEWIVES
LEAGUE
THE OXFORD STREET ASSOCIATION
PRODUCT ASSURANCE LTD
QATC (EUROPE) LTD
FACULTY OF PUBLIC HEALTH
MEDICINE
THE ROYAL ENVIRONMENTAL HEALTH
INSTITUTE OF SCOTLAND
SCOTTISH TRADE UNION CONGRESS
NORTH CORNWALL DISTRICT COUNCIL
NORTHERN IRELAND CHAMBER OF
COMMERCE & INDUSTRY
CWS

LACORS
THE WEST OF ENGLAND COUNTIES
SAFETY LIASON GROUP
UNIVERSITY OF SUNDERLAND
NATIONAL CHAMBER OF TRADE LTD
SCOTTISH CHAMBER OF COMMERCE
SCOTTISH CONSUMER COUNCIL
TOWNSWOMENS GUILDS
TRADES UNION CONGRESS
READING TRADING STANDARDS
DEPARTMENT
NORTHERN GROUP PUBLIC HEALTH
DEPARTMENT
THE LAW SOCIETY
LAW SOCIETY OF SCOTLAND
THE HONG KONG STANDARDS AND
TESTING CENTRE LTD
INDEPENDENT RETAIL NEWS
BRITISH ASSOCIATION FOR CHEMICAL
SPECIALITIES
HEALTH VISITORS ASSOCIATION
TESCO
ICE ERGONOMICS
DEPARTMENT OF LAW, ABERYSTWYTH
FACULTY OF LAW, GLASGOW
CALEDONIAN UNIVERSITY
ROSPA
JOHN LEWIS PARTNERSHIP
HONG KONG GOVERNMENT OFFICE
THE NEWSPAPER PUBLISHERS
ASSOCIATION LTD
HEALTH AND SAFETY EXECUTIVE
HEALTH AND SAFETY COMMISSION
WOMENS FORUM NORTHERN IRELAND
WOMENS NATIONAL COMMISSION
THE GENERAL COUNCIL OF THE BAR
PLAIN ENGLISH CAMPAIGN
FACULTY OF ADVOCATES
THE CARDIFF BUSINESS PARTNERSHIP
ASSOCIATION OF PUBLIC ANALYSTS
INSTITUTE OF DIRECTORS
CORNWALL COUNTY COUNCIL
TRADING STANDARDS
EAST DUNBARTONSHIRE COUNCIL
NATIONAL FEDERATION OF RETAIL
NEWSAGENTS
CO-OPERATIVE WOMENS GUILDS
FEDERATION OF SMALL BUSINESSES
LAWCO CONSULTANCY LTD
FEDERATION OF INDEPENDENT
ADVICE CENTRES
LAW CENTRES FEDERATION
ADVICE SERVICES ALLIANCE
DTI SMALL BUSINESS SERVICE
DEFRA
CITIZENS ADVICE SCOTLAND
QVC
LAYTONS
JAN KUSMIREK
LOCAL GOVERNMENT ASSOCIATION

PROFESSIONAL SOLUTIONS
SCOTLAND OFFICE
SCOTTISH EXECUTIVE
WALES OFFICE
NATIONAL ASSEMBLY FOR WALES
NORTHERN IRELAND OFFICE, LONDON
NORTHERN IRELAND OFFICE, BELFAST
KENNETH GREEN ASSOCIATES
TOYS R US LTD
BTHA
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NAILS AND BEAUTY PROMOTIONS
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DAVIS SCHOTTLANDER & DAVIS LTD
SCOTAROMA
MRS KERSTIN MAPP
ESSENCE OF PURITY
SOAP ARTISTRY
PAULA RENOUF, AROMATHERAPIST
THE FOREST SOAP FACTORY
HEBRIDEAN SOAP CO
DIVINE EARTH SOAP
RICHARD BRAGG, MANCHESTER
UNIVERSITY
PROFESSOR STEPHEN WEATHERILL,
UNIVERSITY OF OXFORD

SIMON WHITTAKER, ST JOHN'S
COLLEGE, OXFORD
CHRISTIAN TWIG-FLESNER, DEPT OF
LAW, NOTTINGHAM
PROFESSOR HUGH BEALE, LAW
COMMISSION
PROFESSOR GEOFFREY WOODROFFE,
BRUNEL UNIVERSITY
COWAN ERVINE, UNIVERSITY OF
DUNDEE
DEBORAH PARRY, UNIVERSITY OF
HULL
PETER CARTWRIGHT, UNIVERSITY OF
NOTTINGHAM
PROFESSOR DAVID OUGHTON, DE
MONTFORT UNIVERSITY
COLIN SCOTT, LONDON SCHOOL OF
ECONOMICS AND POLITICAL SCIENCE
PROFESSOR HUGH COLLINS, LONDON
SCHOOL OF ECONOMICS AND
POLITICAL SCIENCE
ROBERT BRADGATE, UNIVERSITY OF
SHEFFIELD
PROFESSOR GERAINT HOWELLS,
UNIVERSITY OF SHEFFIELD
CHRISTOPHER J S HODGES, CMS
CAMERON MCKENNA
CHRIS WILLET, DE MONTFORT
UNIVERSITY

Annex A

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

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:

Nick Van Benschoten
Consultation Co-ordinator
DTI Better Regulation Team, Bay 4113
1 Victoria Street
London SW1H 0ET



0207 215 6206

Email nick.vanbenschoten@dti.gsi.gov.uk

Annexe B

COMMISSION DIRECTIVE 2005/42/EC

of 20 June 2005

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II, IV and VI thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (1), and in particular Article 8(2) thereof, After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers,

Whereas:

(1) On the basis of the assessment of the cutaneous toxicities of costus root oil (*Saussurea lappa Clarke*), 7-Ethoxy-4- methylcoumarin, hexahydrocoumarin and peru balsam (*Myroxylon pereirae*), the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) is of the opinion that those substances should not be used as fragrance ingredients in cosmetic products. They should therefore be included in Annex II to Directive 76/768/EEC.

(2) Azo-dyes CI 12150, CI 20170 and CI 27290 are included in Part 1 of Annex IV to Directive 76/768/EEC as colouring agents which are allowed for use in cosmetic products. The safety of those colorants has been questioned on the ground that they may form carcinogenic amines during metabolism. The SCCNFP is of the opinion, based on the available information, that the use of the colorants CI 12150, CI 20170 and CI 27290 poses a risk to the health of the consumer as they may release one or more carcinogenic aromatic amines. Those colorants should therefore be excluded from Part 1 of Annex IV to Directive 76/768/EEC.

(3) Benzethonium chloride is included as reference number 53 in Part 1 of Annex VI to Directive 76/768/EEC as a preservative which may be employed in rinse-off cosmetic products up to a concentration of 0,1 %. It is the opinion of the SCCNFP that Benzethonium chloride should also be allowed to be employed in leave-on cosmetic products other than for oral care use up to a concentration of 0,1 %. The entry under the reference number 53 in Part 1 of Annex VI to Directive 76/768/EEC should therefore be amended accordingly.

(4) The SCCNFP is of the opinion that Methylisothiazolinone does not pose a risk to the health of consumers if employed in finished cosmetic products as a preservative up to a concentration of 0,01 %. Methylisothiazolinone should therefore be included in Part 1 of Annex VI to Directive 76/768/EEC as reference number 57.

(5) Directive 76/768/EEC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, IV and VI to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall take the necessary measures to ensure that from 31 March 2006 cosmetic products which fail to comply with Annexes II and IV of Directive 76/768/EEC as amended by this Directive are not placed on the market by Community manufacturers or by importers established within the Community, nor sold or disposed of to the final consumer.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. 21.6.2005 EN Official Journal of the European Union L 158/17 (1) OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2005/9/EC (OJ L 27, 29.1.2005, p. 46).

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.
Done at Brussels, 20 June 2005.

For the Commission
Günter VERHEUGEN
Vice-President

L 158/18 EN Official Journal of the European Union 21.6.2005
ANNEX

The Annexes to Directive 76/768/EEC are amended as follows:

1. in Annex II, the following reference numbers are added:
 '1133. Costus root oil (*Saussurea lappa Clarke*) (CAS No 8023-88-9), when used as a fragrance ingredient
 1134. 7-Ethoxy-4-methylcoumarin (CAS No 87-05-8), when used as a fragrance ingredient
 1135. Hexahydrocoumarin (CAS No 700-82-3), when used as a fragrance ingredient
 1136. Peru balsam (INCI name: *Myroxylon pereirae*; CAS No 8007-00-9), when used as a fragrance ingredient'

2. in Part 1 of Annex IV, colouring agents CI 12150, CI 20170 and CI 27290 are deleted.

3. Part 1 of Annex VI is amended as follows:

(a) the reference number 53 is replaced by the following:

Reference Number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
------------------	-----------	----------------------------------	------------------------------	---

a	b	c	d	e
---	---	---	---	---

'53	Benzethonium Chloride (INCI)	0,1 %	(a) Rinse-off products (b) Leave-on products other than for oral care use'	
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(b) the following entry is added as reference number 57:

Reference Number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
------------------	-----------	----------------------------------	------------------------------	---

a	b	c	d	e
---	---	---	---	---

'57	Methylisothiazolinone (INCI)	0,01 %'		
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21.6.2005 EN Official Journal of the European Union L 158/19

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (3), and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers,
Whereas:

- (1) Commission Directive 2004/87/EC of 7 September 2004 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress, extended until 31 December 2005 the provisional use of sixty hair dyes listed in Part 2 of the Annex III to Directive 76/768/EEC under the reference numbers 1 to 60 (4).
- (2) According to the hair dye strategy, published in the internet, it was agreed with the Member States and stakeholders that the date of July 2005 would be appropriate for the presentation to the Scientific Committee on Consumer Products (SCCP) of the additional information on the above hair dyes.
- (3) Additional information concerning thirty eight hair dyes listed in Annex III, Part 2 of Directive 76/768/EEC has been submitted by the industry. This information has to be evaluated by the SCCP. Definitive regulation of those hair dyes, on the basis of such evaluations, and its implementation into the laws of Member States will not be possible before 31 December 2006. Therefore, their provisional use in cosmetic products under the restrictions and conditions laid down in Annex III, Part 2 should be prolonged until 31 December 2006.
- (4) For twenty two hair dyes listed in Annex III, Part 2 of Directive 76/768/EEC such additional information has not been submitted. Definitive regulation of those hair dyes will be considered after the appropriate procedures are carried out. Such definitive regulation and its implementation into the laws of Member States will not be possible before 31 August 2006. Therefore, their provisional use in cosmetic products under the restrictions and conditions laid down in Annex III, Part 2 should be prolonged until 31 August 2006.

3 OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive ____ (OJ L ____).

4 OJ L 287, 8.09.2004, p. 4.

- (5) Directive 76/768/EEC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Part 2, column g of the Annex III to Directive 76/768/EEC is amended as follows:

- (1) for reference numbers 1, 2, 8, 13, 15, 17, 23, 30, 34, 40, 41, 42, 43, 45, 46, 51, 52, 53, 54, 57, 59 and 60 the date “31.12.2005” is replaced by “31.08.2006”.
- (2) for reference numbers 3, 4, 5, 6, 7, 9, 10, 11, 12, 14, 16, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 31, 32, 33, 35, 36, 37, 38, 39, 44, 47, 48, 49, 50, 55, 56 and 58 the date “31.12.2005” is replaced by “31.12.2006”.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission
[...]
Member of the Commission