

dti

**COSMETIC PRODUCTS (SAFETY)
REGULATIONS (AMENDMENT) (NO
2) 2007**

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

MAY 2007

URN 07/985

The Department of Trade & Industry seeks your views on two technical amendments to the Cosmetic Products (Safety) Regulations 2004 (as amended).

The primary aim of the Cosmetic Products (Safety) Regulations 2004 (as amended) is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients.

One amendment adds 10 substances, numbered 1234-1243 to the list of banned ingredients, as part of the strategy on hair dyes to ensure that only safe substances are used on finished hair dye products. The other stops the use of certain substances for purposes other than preservatives and changes the conditions for use of certain substances for purposes other than as preservatives.

The opinions of business and consumers are sought on the impact of the proposed amendments.

Starting date: 15 May 2007

Closing date: 3 August 2007

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1. Executive Summary

This consultation document seeks views on the Government's proposals to introduce Regulations that add 10 substances to the list of banned substances set out in the Cosmetic Product (Safety) Regulations 2004 (as amended) and amends Part 1 of Schedule 6 restricting the use and concentrations of certain substances as preservatives and Part 1 of Schedule 4 allowing the conditions for use of certain substances for purposes other than as preservatives.

The proposed **Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2007** will implement two EC Directives on the safety of cosmetics. The 2007 Regulations will be introduced using powers in the Consumer Protection Act 1987 (the 1987 Act).

The Regulations will implement Commission Directive 2007/1/EC (OJ No. L25, 1.2.2007, p.9 "the Hair Dyes Directive"). The Hair Dyes Directive requires a number of technical amendments to the main **Cosmetic Products (Safety) Regulations 2004**, particularly in relation to substances used in hair dyes, by adding 10 substances to the list of substances not allowed in cosmetics in Schedule 3 Part 1, deletes epoxiconazole (1182) and changes its name to that referenced under number 663. The provisions are required to apply from 21 November 2007.

Following an Opinion by the Scientific Committee on Consumer Products, the Regulations also implement Commission Directive 2007/17/EC (OJ No. L82, 23.3.2007 p 27 "the Preservatives Directive"). There are several changes to the use of preservatives listed in Schedule 6 Part 1 of the main **Cosmetic Products (Safety) Regulations 2004**. Twenty three substances can now only be used in the concentrations and specified restrictions laid down in Schedule 6. Two substances, Formaldehyde paraformaldehyde (no 5) and 1-Phenoxypropan-2-ol (no 43) can now be used for non preservative purposes in concentrations other than those set out in Schedule 4. A number of other minor changes are made. These provisions are required to apply to all goods placed on the market after 23 March 2008 and all non-compliant goods must be sold or disposed of by 23 June 2008

Commission Directive 2007/1/EC must be implemented by 21 August 2007 and Commission Directive 2007/17/EC implemented by 23 September 2007.

2. 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


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Additional copies

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Electronic versions may be viewed on the DTI website at:

<http://www.dti.gov.uk/consultations/index.html>,

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 **3 August 2007** .

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

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 2 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 Cooper
Assistant Director
DTI Better Regulation Team, Bay 566
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A copy of the Code of Practice on Consultations may also 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 an impact on competition or profitability? If so, please quantify.
- 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, particularly with regard to the new restrictions on the non-preservative use of preservatives, which we have not anticipated?
- iv. Will the proposed Regulations contribute to safer cosmetics being available?
- v. What regulatory steps can be taken towards off-setting any likely increase in costs for importers complying with the regulations?
- vi. 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?

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

3. The Proposals

The main objective of introducing the 2007 Amendment No 2 to the Regulations is to implement Commission Directives 2007/1/EC and 2007/17/EC, both of which amend Council Directive 76/768/EEC, (the 'Principal Directive'), on the safety of cosmetic products. A copy of the Directives can be found at the back of this document.

The aim of the two Directives and the implementing Regulations is to protect public health in the Member States by requiring cosmetic products to meet the provisions of the Principal 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 2007 Regulations

The proposed **Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2007** will implement two EC Directives on the safety of cosmetics.

The Regulations will implement Commission Directive 2007/1/EC (OJ No. L25, 1.2.2007 p9 "Hair dyes Directive") and Commission Directive 2007/17/EC (OJ No L82, 23.3.2007, p27" Preservatives Directive").

The Hairdyes Directive adds substances with reference numbers 1234 -1243 to Annexe II and moves epoxiconazole, under reference number 1182; placing it under reference 663.

These changes are made by amending regulation 15(5) of the Cosmetic Products (Safety) Regulations 2004.

The Commission Directive's measures come into force on 21 November 2007. All products containing these substances must be sold or removed from the market by 21 February 2008.

The Preservatives Directive makes changes to Annex VI of the Principal Directive relating to the use of preservatives, their concentrations and the use of these substances for other purposes based on the Opinion of the Scientific Committee on Consumer Products (SCCP).

The Preservatives Directive restricts a number of substances that may be used as preservatives from being used in other concentrations for other purposes. These are listed in part 2 of the Annex of the Preservatives Directive and include salicylic acid and triclocarban. These can now only be used in the concentrations and restrictions set out in Annex IV. The asterix (*)

indicating that a substance may be used for non-preservative purposes in concentrations other than those allowed in Annex VI is deleted from the following entries:

1, 2, 4, 7, 12, 14, 18, 19, 21, 22, 24, 25, 26, 27, 28, 29, 30, 32, 33, 35, 37, 42 and 47

These substances can only be used in concentrations and subject to any further restrictions allowed in Annex III. However (*) is added to two substances – Formaldehyde paraformaldehyde (no 5) and 1-Phenoxypropan-2-ol (no 43).

Amendments are made to the entries for the restrictions on use for Benzoic acid its salts and its esters (no 1) and Pyrithione Zinc (INN) (no 8) in Annex VI.

Where such preservatives can be used for other purposes, the substance, its purpose and restriction on use is listed in Annex III. [Please consult the draft Statutory Instrument and Commission Directive 2007/17/EC in Annexes for details]

These changes are made to Schedule 6 and Schedule 4 Part 1 of the Cosmetic Products (Safety) Regulations 2004.

Products that are not in compliance with the Preservatives Directive cannot be placed on the market after 23 March 2008 and all products that do not comply must be sold or disposed of by 23 June 2008.

4. Draft Regulatory Impact Assessment

Amendment No2 to The Cosmetic Products (Safety) Regulations 2007

Proposal

To transpose Commission Directives 2007/1/EC and 2007/17/EC into UK Law.

Purpose and intended effect of measure

Objective

The primary aim of the Cosmetic Products (Safety) Regulations 2004 (as amended) is to protect public health by requiring cosmetic products to meet the provisions of the Regulations, including restricting the use of certain cosmetic ingredients.

Commission Directive 2007/1/EC forms part of the strategy on hair dyes to ensure that only safe substances are used in finished hair dye products. Therefore 10 substances, numbered 1234-1243 are added to the list of banned ingredients in Annex II.

Commission Directive 2007/17/EC amends Annex VI changing the restrictions on the use and concentrations of certain substances for purposes other than preservatives and Part 1 of Annex III allows the conditions for use of certain substances for purposes other than as preservatives.

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.

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.

Cost/Benefit Analysis

Economic

Directive 2007/1/EC bans the use of 10 substances as hair dyes, whose approval by the Scientific Committee for Consumer Products is not being sought by the cosmetics industry because they are not currently in use. There will, therefore be a neutral economic impact on UK manufacturers and consumers as the ingredients are not available in products sold to the general public. The economic impact of this Directive is neutral.

Directive 2007/17/EC may require some manufacturers using the substances that have their restrictions changed to engage in reformulation and re-labelling of their products. However consumer use of these products is not widespread and any increase in costs for consumers in general is likely to be marginal.

However, we have limited information on the potential market impact and we are asking consultees to provide further information.

Both Directives will apply in all Member States of the EU and the countries that are members of the EEA.

Environmental

No specific benefits to the environment have been identified.

Social

The Directives, if adopted, will improve consumer protection. The hair dyes strategy is aimed at assessing all substances that can be used in hair dyes and banning from use those that are identified as being potentially carcinogenic.

The Directive on preservatives is based on opinions of the Scientific Committee on the safe levels for usage of substances allowed as preservatives that can be used for other purposes. These additional restrictions improve consumer safety.

Costs

The cosmetics industry is truly international, which can be seen from the flow of trade. There are approximately 150 companies in the UK involved

in the manufacture/importing of cosmetic products. The UK cosmetics market was worth £6.4 billion at retail prices in 2005, of which approx 51% is manufactured in the UK. In 2005, 47% of cosmetics manufactured in the UK were exported: 33% to the rest of the EU and 17% abroad. For imported cosmetics, 71% is imported from the EU and 29% from outside the EU.

The proposed ban for 10 hair dyes is for substances that are not currently used by manufacturers. The ban will not impose additional costs in the composition of hair dyes made in the UK. Similarly, there would be no additional costs for consumers.

The use of preservatives for non preservative purposes is not widespread in cosmetics. They are only used in a few specific types of cosmetic, such as: rinse off skin treatments and self tanning products. Given the particular nature of their usage, one of the purposes of the consultation is to establish the exact impact of the Directive on the costs of the manufacturers of these products.

The consultation on this proposal asks business to comment on the likely extent of this burden and for suggestions for regulatory off-setting of any additional administrative burden.

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 new 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 2004, which are amended by these Regulations, are enforced by local authorities' trading standards departments. It is the responsibility of the manufacturers of cosmetic products made in the EU or importers of finished cosmetic products to ensure that products comply with the Regulations.

Consultation

Within Government

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

Public Consultation

The DTI will conduct a full 12 week consultation for the implementation of the Cosmetic Products (Safety) (Amendment) (No 2) Regulations 2007, contacting key stakeholders such as the Cosmetics, Toiletries and Perfumery Association and those who have responded to consultations to previous amendments to the Cosmetic Regulations and publishing the consultation on the DTI website.

Summary & Recommendation

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

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

Declaration:

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

Signed by the Minister responsible

.....
(Minster for Trade, Investment & Foreign Affairs)

Date

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2007 No. 0000

CONSUMER PROTECTION

**The Cosmetic Products (Safety) (Amendment) (No. 2)
Regulations 2007**

| | |
|-------------------------------|------|
| <i>Made</i> - - - - | 2007 |
| <i>Laid before Parliament</i> | 2007 |
| <i>Coming into force</i> - - | 2007 |

The Secretary of State makes the following Regulations in exercise of the powers conferred upon him by section 11 of the Consumer Protection Act 1987⁽¹⁾.

In accordance with section 11(5) of that Act he has consulted such organisations as appear to him to be representative of interests substantially affected by the following Regulations, such other persons as he considered appropriate and the Health and Safety Commission.

Citation, commencement and interpretation

1.—1. These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) (No.2) Regulations 2007 and shall come into force on [—].

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

Amendment of the Principal Regulations

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

(1) The following is substituted for paragraph 2(c) of Regulation 5—

“(c) any substance listed in column 2 of Schedule 4, unless the requirements in columns 3, 4, 5 and (in the case of Part II) 7 of that Schedule in relation to that substance are satisfied, except that, in relation to the substances listed in entry numbers 98 to 101, the prohibition shall not apply to the placing on the market of a cosmetic product before 23rd March 2008 or the sale or disposal to the final consumer of any such product before 23rd June 2008;”.

(2) The following is substituted for paragraph 15 of Regulation 5—

“(15) No cosmetic product containing any substance listed in Annex II to the Directive—

(a) under entry numbers 452 to 614 and 617 to 1132 (inserted into the Directive by Directive 2004/93/EC; entries 615 and 616 were omitted by Directive 2005/80/EC,

⁽¹⁾ 1987 c.43.

⁽²⁾ S.I. 2004/2152 as amended by S.I. 2004/2361, 2004/2988, 2005/1815, 2005/3346, 2006/1198, 2006/2231, 2006/2907 and 2007/[—].

entry 663 was amended by Directive 2007/1/EC and entry 687 was amended by Directive 2005/80/EC) shall be placed on the market or supplied;

- (b) under entry numbers 1133 to 1136 (inserted into the Directive by Directive 2005/42/EC) shall be placed on the market or supplied;
- (c) under entry numbers 1137 to 1181 and 1183 to 1211 (inserted into the Directive by Directive 2005/80/EC, entry 1182 was omitted by Directive 2007/1/EC) shall be placed on the market or supplied;
- (d) under entry numbers 1212 to 1233 (inserted into the Directive by Directive 2006/65/EC) shall be placed on the market or supplied;
- (e) under entry numbers 1234 to 1243 (inserted into the Directive by Directive 2007/1/EC) shall be sold or disposed of to the final consumer after 20th February 2008,

provided that no account shall be taken of any substance which is present only as a trace which would not reasonably have been removed during or after manufacture.”.

(3) At the end of Schedule 2 (List of Directives amending Directive 76/867/EEC) there is inserted—

“**47.** Commission Directive 2007/1/EC (O.J. No. L25, 01/02/2007, p.9).

48. Commission Directive 2007/17/EC (O.J. No. L82, 23/03/2007, p.27).”.

(4) At the end of Schedule 4 Part 1 there are inserted the entries and end notes in Part 1 of the Schedule to these Regulations.

(5) Schedule 6 Part 1 (List of preservatives which cosmetic products must not contain except subject to restrictions) is amended as follows—

- (a) in column 5, “A” is deleted in entry numbers 1, 2, 4, 7, 12, 14, 18, 19, 21, 22, 24, 25, 26, 27, 28, 29, 30, 32, 33, 35, 37, 42 and 47;
- (b) in column 5, “A” is inserted in entry numbers 5 and 43;
- (c) for entry number 1 there is substituted the entries in Part 2 of the Schedule to these Regulations;
- (d) for entry number 8 there is substituted the entry in Part 3 of the Schedule to these Regulations; and
- (e) entry number 36 is deleted and there is inserted in its place in column 1 “ENTRY DELETED”.

(6) The changes made by regulation 2(6) to Schedule 6 shall not apply in relation to the placing on the market of any cosmetic product before 23rd March 2008 or the sale or disposal of any such product to a final consumer before 23rd June 2008.

Revocations

3.—3. Regulation 2(2) of the Cosmetic Products (Safety) (Amendment) (No. 2) Regulations 2005(**3**) is revoked.

(1) Regulation 2 of the Cosmetic Products (Safety) (Amendment) Regulations 2006(**4**) is revoked.

(2) Regulation 2(2) of the Cosmetic Products (Safety) (Amendment) (No. 2) Regulations 2006(**5**) is revoked.

Name

(3) S.I. 2005/3346.

(4) S.I. 2006/1198.

(5) S.I. 2006/2231.

Date

Job Title
Department of Trade and Industry

SCHEDULE

Regulation 2

PART 1

Entries inserted at the end of Part 1 of Schedule 4 to the Principal Regulations

| (1) Reference Number | (2) Name of substance | (3) Purpose of substance or type of product | (4) Maximum concentration of substance in product | (5) Other requirements | (6) Required information |
|----------------------------|---|---|---|--|---|
| 98 | Salicylic acid ⁽¹⁾ (CAS No 69-72-7) | a) Rinse-off hair products b) Other products | a) 3.0 % b) 2.0 % | Not to be used in preparations for children under three years of age, except for shampoos. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | Not to be used for children under three years of age ⁽²⁾ |
| 99 | Inorganic sulfites and bisulfites ⁽³⁾ | a) Oxidative hair dye products b) Hair straightening products c) Self tanning products for the face d) Other self tanning products | a) 0.67% (expressed as free SO ₂) b) 6.7% (expressed as free SO ₂) c) 0.45% (expressed as free SO ₂) d) 0.40% (expressed as free SO ₂) | For purpose other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |
| 100 | Triclocarban ⁽⁴⁾ (CAS No 101-20-2) | Rinse-off products | 1.5% | Purity criteria: 3,3',4,4'-Tetrachloroazobenzene ≤ 1mg/kg 3,3',4,4'-Tetrachloroazoxybenzene ≤ 1mg/kg For purposes other than | |

| | | | | | |
|-----|---|------------------------|------|---|--|
| | | | | inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |
| 101 | Zinc pyrithione ⁽⁵⁾ (CAS No 13463-41-7) | Leave-on hair products | 0.1% | For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |

⁽¹⁾ As a preservative, see Schedule 6, Part 1, entry 3.

⁽²⁾ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

⁽³⁾ As a preservative, see Schedule 6, Part 1, entry 9.

⁽⁴⁾ As a preservative, see Schedule 6, Part 1, entry 23.

⁽⁵⁾ As a preservative, see Schedule 6, Part 1, entry 8.

PART 1

Entries substituted for entry number 1 in Part 1 of Schedule 6 to the Principal Regulations

| <i>(1) Reference Number</i> | <i>(2) Name of Substance</i> | <i>(3) Purpose of substance or type of product</i> | <i>(4) Maximum concentration of substance in product</i> | <i>(5) Other Require- ments</i> | <i>(6) Required Information</i> |
|-------------------------------------|---|---|--|---|---|
| 1 | Benzoic acid (CAS No 65-85-0) and its sodium salt (CAS No 532-32-1) | Rinse-off products, except oral care products: 2.5% (expressed as acid) Oral care products: 1.7% (expressed as acid) Leave-on products: 0.5% (expressed as acid) | | | |
| 1a | Salts and esters of benzoic acid not listed in entry 1 | 0.5% (expressed as acid) | | | |

PART 2

Entry substituted for entry number 8 in Part 1 of Schedule 6 to the Principal Regulations

| <i>(1)</i> <i>Reference</i> <i>Number</i> | <i>(2)</i> <i>Name of</i> <i>Substance</i> | <i>(3)</i> <i>Purpose of</i> <i>Substance or</i> <i>type of</i> <i>product</i> | <i>(4)</i> <i>Maximum</i> <i>concentration</i> <i>of substance</i> <i>in product</i> | <i>(5)</i> <i>Other</i> <i>requirements</i> | <i>(6)</i> <i>Required</i> <i>information</i> |
|---|--|--|--|---|---|
| 8 | Zinc pyrithione (CAS No 13463-41-7) | Hair products: 1.0 % Other products: 0.5% | Rinse-off products only. No use in products for oral hygiene. | A | |

EXPLANATORY NOTE

(This note is not part of the Regulations)

DIRECTIVES

COMMISSION DIRECTIVE 2007/1/EC

of 29 January 2007

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex II thereof 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 Consumer Products (SCCP),

Whereas:

(1) Following the opinions of the SCCP issued on the basis of scientific studies, the Commission together with Member States and stakeholders agreed on an overall strategy to regulate hair dye substances according to which the industry was required to submit files with scientific data on hair dye substances to be evaluated by the SCCP.

(2) The substances for which no explicit interest was expressed during the public consultation in defence of their use in hair dyes and for which no updated safety files were submitted to allow an adequate risk assessment should be included in Annex II.

(3) The substance 4-amino-3-fluorophenol has until now been considered to be covered by the general entry, reference number 22, concerning aniline, its salts and its halogenated and sulphonated derivatives. However, as it is not obvious that 4-amino-3-fluorophenol belongs to that aniline family a specific entry for that substance should be included in Annex II.

(4) For the sake of clarity, the substance epoxiconazole should be moved from the separate reference number 1182 to reference number 663 in Annex II to Directive 76/768/EEC.

(5) As no new further scientific data were submitted to the SCCP before 31 July 2006 for the evaluation of *N,N'*-dihexadecyl-*N,N'*-bis(2-hydroxyethyl)propane-diamide, that substance should be included in Annex II.

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

(7) 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

Annex II to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

Member States shall ensure that with effect from 21 February 2008, cosmetic products which fail to comply with this Directive are not sold or disposed of to the final consumer.

Article 3

1. Member States shall adopt and publish, by 21 August 2007 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 21 November 2007.

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.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2006/78/EC (OJ L 271, 30.9.2006, p. 56).

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 20th 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, 29 January 2007.

For the Commission
Günter VERHEUGEN
Vice-President

DIRECTIVES

COMMISSION DIRECTIVE 2007/17/EC

of 22 March 2007

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

symbol (*) when used in higher concentrations for other specific purposes.

Having regard to the Treaty establishing the European Community,

(5) On the basis of those safety-files, the SCCP concluded that the use of several of the preservative substances in Annex VI for other specific purposes in higher concentrations is safe.

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,

(6) The safe concentration limits for those preservative substances when used for other specific purposes should be included in Annex III to Directive 76/768/EEC. For the sake of clarity, it should be indicated for the relevant entries in Annex III that the same substance is listed in Annex VI to that Directive.

After consulting the Scientific Committee on Consumer Products,

Whereas

- (1) Annex VI to Directive 76/768/EEC establishes a list of preservatives allowed in cosmetic products. The substances listed in Annex VI marked with the symbol (*) may be used in concentrations other than those fixed in that Annex for non-preservative purposes, if the specific purpose is apparent from the presentation of the product. Nevertheless, the use of these substances may be restricted in other Annexes to that Directive.
- (2) The substances listed in Annex VI without the symbol (*) may not be used in concentrations other than those listed in that Annex and the other restrictions set out therein also apply when those substances are used for other specific purposes.
- (3) The Scientific Committee on Consumer Products, hereinafter 'the SCCP', has issued an opinion stating that the restrictions for usage level and warnings in Annex VI should also apply if the preservatives marked with the symbol (*) are used for other specific purposes.
- (4) The Commission therefore called upon the industry to submit safety files for substances listed with the
- (7) Substances that were not considered to be safe by the SCCP when used in concentrations other than those laid down in Annex VI for other specific purposes should be subject to the restrictions laid down in that Annex for use as preservatives. The symbol (*) should therefore be deleted from those substances in Annex VI.
- (8) In order to ensure a coherent approach, all substances listed in Annex VI which may also be added to cosmetic products, for other specific purposes, in higher concentrations than those laid down in that Annex should be marked with the symbol (*).
- (9) Moreover, the SCCP considered it safe to increase the maximum concentration of benzoic acid and its sodium salt in rinse-off products and oral-care products and to increase the maximum concentration of zinc pyrithione in rinse-off hair products for preservative use. It is therefore appropriate to amend reference numbers 1 and 8 of Annex VI to Directive 76/768/EEC accordingly.
- (10) The SCCP is also of the opinion that methyl dibromo glutaronitrile should not be present in any cosmetic products, as no safe use-levels in cosmetic leave-on and rinse-off products have been established. It is therefore necessary to delete that substance from reference number 36 of Annex VI to Directive 76/768/EEC.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/1/EC (OJ L 25, 1.2.2007, p. 9).

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

(12) 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 III and VI to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall take all necessary measures to ensure that from 23 March 2008 no cosmetic products which fail to comply with this Directive are placed on the market by Community manufacturers or by importers established within the Community.

Member States shall take all necessary measures to ensure that those products are not sold or disposed of to the final consumer after 23 June 2008.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 23 September 2007 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.

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 20th 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, 22 March 2007.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 76/768/EEC is amended as follows:

(1) Annex III, Part 1, is amended as follows:

Reference numbers 98 to 101 are added as indicated below:

| Reference No | Substance | Restrictions | | | Conditions of use and warnings which must be printed on the label |
|--------------|---|---|---|--|---|
| | | Field of application and/or use | Maximum authorised concentration in the finished cosmetic product | Other limitations and requirements | |
| a | b | c | d | e | f |
| 98 | Salicylic acid ⁽¹⁾ (CAS No 69-72-7) | a) Rinse-off hair products b) Other products | a) 3,0 % b) 2,0 % | Not to be used in preparations for children under three years of age, except for shampoos. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | Not to be used for children under three years of age ⁽²⁾ |
| 99 | Inorganic sulfites and bisulfites ⁽³⁾ | a) Oxidative hair dye products b) Hair straightening products c) Self tanning products for the face d) Other self tanning products | a) 0,67 % expressed as free SO ₂ b) 6,7 % expressed as free SO ₂ c) 0,45 % expressed as free SO ₂ d) 0,40 % expressed as free SO ₂ | For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |
| 100 | Triclocarban ⁽⁴⁾ (CAS No 101-20-2) | Rinse-off products | 1,5 % | Purity criteria 3,3',4,4'-Tetrachloroazobenzene ≤ 1 ppm 3,3',4,4'-Tetrachloroazoxybenzene ≤ 1 ppm For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |
| 101 | Zinc pyrithione ⁽⁵⁾ (CAS No 13463-41-7) | Leave-on hair products | 0,1 % | For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. | |

⁽¹⁾ As a preservative, see Annex VI, Part 1, No 3.

⁽²⁾ Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin.

⁽³⁾ As a preservative, see Annex VI, Part 1, No 9.

⁽⁴⁾ As a preservative, see Annex VI, Part 1, No 23.

⁽⁵⁾ As a preservative, see Annex VI, Part 1, No 8.

(2) Annex VI, Part 1, is amended as follows:

- a) In column b, the symbol (*) is deleted for the reference numbers 1, 2, 4, 7, 12, 14, 18, 19, 21, 22, 24, 25, 26, 27, 28, 29, 30, 32, 33, 35, 37, 42 and 47.
- b) In column b, the symbol (*) is added for the reference numbers 5 and 43.
- c) Reference number 1 is replaced by the following:

| Reference No | Substance | Maximum authorized concentration | limitations and requirements | Conditions of use and warnings which must be printed on the label |
|--------------|---|--|------------------------------|---|
| a | b | c | d | e |
| 1 | Benzoic acid (CAS No 65-85-0) and its sodium salt (CAS No 532-32-1) | Rinse-off products, except oral care products: 2,5 % (acid) Oral care products: 1,7 % (acid) Leave-on products: 0,5 % (acid) | | |
| 1a | Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid | 0,5 % (acid) | | |

d) Reference number 8 is replaced by the following:

| Reference No | Substance | Maximum authorized concentration | limitations and requirements | Conditions of use and warnings which must be printed on the label |
|--------------|--|---|---|---|
| a | b | c | d | e |
| 8 | Zinc pyrithione (*) (CAS No 13463-41-7) | Hair products: 1,0 % Other products: 0,5 % | Rinse-off products only. No use in products for oral hygiene. | |

e) Reference number 36 is deleted.

Annex 2

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 Cooper
Assistant Director
DTI Better Regulation Team, Bay 566
1 Victoria Street
London SW1H 0ET

 020 7215 0346

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

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