

**dti**

**THE COSMETIC PRODUCTS  
(SAFETY) (AMENDMENT)  
REGULATIONS 2006**

**Consultation on proposal to  
implement an EC Directive on  
the safety of Cosmetic Products**

**URN 06/696**

**January 2006**

## **THE COSMETIC PRODUCTS (SAFETY) (AMENDMENT) REGULATIONS 2006**

### **Consultation on proposal to implement an EC Directive on the safety of Cosmetic Products**

The aim of the Regulations is to implement European Commission Directive 2005/80/EC. The objective 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 Directive.

The Cosmetics Directive (76/768/EEC) prohibits the use in cosmetic products of substances classified as CMRs of category 1, 2 and 3, under Annex I of Council Directive 67/548/EEC on the approximations of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Certain substances classed as category 3 had been allowed in cosmetic products, subject to approval by the Scientific Committee on Cosmetic and Non-food Products and the Scientific Committee on Consumer Products. Other CMRs classed as category 1 & 2 were not yet listed in Annex II.

The implementation of the Directive is an administrative update of the lists and classification of CMRs. Of these 75 substances only 1 is currently used in cosmetic products. It is used by a small number of manufacturers in hair dyes. However, its continued use is not being supported by the cosmetics industry, which have chosen not to submit a dossier to the Scientific Committee.

The purpose of the consultation is to advise of the proposed changes and seek the views of interested parties.

Issued	24 January 2006
Respond by	14 April 2006
Enquiries to	Ian Parsons
Tel	020 7215 0360
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# 1. Executive Summary

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This consultation document seeks views on the Government's proposals to introduce Regulations that amend Annex II to the Directive by adding substances to the list of those that are not permitted for use in cosmetic products. The Regulations also make minor amendments to Schedule 4 Part I.

The proposed **Cosmetic Products (Safety) (Amendment) Regulations 2006** will implement an EC Directive on the safety of cosmetics. The 2006 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 2005/80/EC (OJ No. L303, 22.11.2005, p.32). The Directive makes a number of technical amendments to the main **Cosmetic Products (Safety) Regulations 2004**:

Adds 75 substances classified as carcinogenic, mutagenic or repro-toxic (CMRs) to those substances listed in Annex II (entry numbers 1137-1211) restricted under Article 5 (15) of the Principal Regulations – prohibited from use in cosmetic products. These substances must not be used in products placed on the market after 21 August 2006 or supplied after 22 November 2006.

It also amends the names under two entries and deletes one entry in Schedule 4 Part 1.

The implementation of the Directive is an administrative update of the lists and classification of CMRs. Of these 75 substances only 1 is currently used in cosmetic products. It is used by a small number of manufacturers in hair dyes. However, its continued use is not being supported by the cosmetics industry, which have chosen not to submit a dossier to the Scientific Committee.

The Directive requires Member States to transpose it into national law by 22 May 2006.

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  
Department of Trade and Industry  
Room 428  
1 Victoria Street  
London SW1H 0ET  
Tel: 020 7215 0361  
Fax: 020 7215 0357  
[sue.pain@dti.gsi.gov.uk](mailto:sue.pain@dti.gsi.gov.uk)

## Additional copies

Additional copies of this consultation document may be made without seeking permission.

Printed copies of this consultation document may be obtained by post from:

DTI Publications Orderline  
ADMAIL 528  
London SW1 W 8YT

 0845 015 0010  
Fax 0845 015 0020  
Email [www.dti.gov.uk/publications](http://www.dti.gov.uk/publications)

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](mailto: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 14 April 2006**.

## 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.

## Complaints

The Code of Practice on Consultation can be found at Annex A 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

 020 7215 6206  
Email [nick.vanbenschoten@dti.gsi.gov.uk](mailto: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

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The main objective of introducing the 2006 Amendment to the Regulations is to implement Commission Directive 2005/80/EC which amends Council Directive 76/768/EEC, the base Directive, on the safety of cosmetic products. A Copy of the Directive can be found at the back of this document.

The aim of the Directive 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 Cosmetics Directive (76/768/EEC) prohibits the use in cosmetic products substances classified as CMRs of category 1, 2 and 3, under Annexe I of Council Directive 67/548/EEC on the approximations of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Certain substances classed as category 3 have been allowed in cosmetic products, subject to approval by the Scientific Committee on Cosmetic and Non-food Products and the Scientific Committee on Consumer Products. Other CMRs classed as category 1 or 2 are not yet listed in Annexe II of the Cosmetics Directive.

The implementation of the Directive is an administrative update of the lists and classification of CMRs. Of these 75 substances only 1 is currently used in cosmetic products. It is used by a small number of manufacturers in hair dyes. However, its continued use is not being supported by the cosmetics industry, which have chosen not to submit a dossier to the Scientific Committee.

### **The 2006 Regulations**

The proposed **Cosmetic Products (Safety) (Amendment) Regulations 2006** will implement an EC Directive on the safety of cosmetics. The 2006 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 2005/80/EC (OJ No. L303, 22.11.2005, p.32). The Directive does the following:

Adds 75 substances classified as carcinogenic, mutagenic or repro-toxic (CMRs) to those substances listed in Annexe II (entry numbers 1137-1211) restricted under Article 5 (15) of the Principal Regulations as category 3 CMRs – prohibited from use in cosmetic products. These substances must not be used in products placed on the market after 21 August 2006 or supplied after 22 November 2006.

Schedule 4 Part 1 is amended as follows—

the name of the substance in entry 1a is replaced by “Boric acid, borates and tetraborates with the exception of the substance N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate”;

the name of the substance in entry 8 is replaced by “p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine (see Note 1), with the exception of those derivatives listed elsewhere in this Schedule”; and

entry 19 (Phenol and its alkali salts) is deleted and there is inserted in its place in Column 1 “ENTRY DELETED”.

The Directive requires Member States to transpose it into national law by 22 May 2006.

As with the current Cosmetic Products (Safety) Regulations, Local Authority Trading Standards Officers would have the primary responsibility for enforcement of the 2006 Regulations.

### 3. Draft Regulatory Impact Assessment

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#### **Amendment to The Cosmetic Products (Safety) Regulations 2006**

##### **Proposal**

To transpose Commission Directive 2005/80/EC 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 Directive adds 75 substances that are classified carcinogenic, mutagenic or toxic to reproduction (CMRs) to the list of banned ingredients in Annexe II – prohibited from use in all cosmetic products.

The Regulation also makes a number of changes to the naming of entries in Schedule 4 Part I.

##### **Rationale for Government Intervention**

The Cosmetics Directive (76/768/EEC) prohibits the use in cosmetic products of substances classified as CMRs of category 1, 2 and 3, under Annexe I of Council Directive 67/548/EEC on the approximations of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Certain substances classed as category 3 have been allowed in cosmetic products, subject to approval by the Scientific Committee on Cosmetic and Non-food Products and the Scientific Committee on Consumer Products.

The implementation of the Directive is an administrative update of the lists and classification of CMRs. Of these 75 substances only 1 is currently used in cosmetic products. It is used by a small number of manufacturers in hair dyes. However, its continued use is not being supported by the cosmetics industry, which have chosen not to submit a dossier to the Scientific Committee. Other CMRs classed as category 1 or 2 are not yet listed in Annexe II of the Cosmetics Directive.

## 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 CMRs.

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 Directive bans the use of certain substances as ingredients in cosmetic products, which may incur costs in the reformulation of certain finished products.

### *Environmental*

No specific benefits to the environment have been identified.

### *Social*

The Directive, if adopted, will improve consumer protection. The restriction on substances identified as being CMRs is in the interests of improving consumer safety.

## Costs

The choice of manufacturers to use allowed ingredients is discretionary. The restriction and prohibition on certain ingredients may incur cost on manufacturers. Only one of the substances listed is used in cosmetic products – as an ingredient in hair dyes. It is not widely used, but will require a small number of manufacturers to reformulate their product to take account of the new Regulations. It is unlikely that there will be any 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 Directive, 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***

DTI conducted a full consultation for the implementation of the Cosmetic Product (Safety) (Amendment) Regulations 2006.

## **Summary & Recommendation**

Our recommendation is that the option chosen offers the best level of public health protection by extending the restrictions on the use of specific substances in finished cosmetic products.

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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London SW1H 0ET

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## 4. Draft Regulations

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### STATUTORY INSTRUMENTS

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## 2006 No. DRAFT 12/1/06 16.40

### CONSUMER PROTECTION

#### The Cosmetic Products (Safety) (Amendment) Regulations 2006

<i>Made</i> - - - -	2006
<i>Laid before Parliament</i>	2006
<i>Coming into force</i> - -	22nd May 2006

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<sup>(1)</sup> and section 2 of the European Communities Act 1972<sup>(2)</sup>.

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 considers appropriate and the Health and Safety Commission.

The Secretary of State is a Minister designated<sup>(3)</sup> for the purposes of section 2 of the European Communities Act 1972 in relation to measures for safety and consumer protection as respects cosmetic products and any provisions concerning the composition, and marketing of cosmetic products.

#### Citation, commencement and interpretation

—(1) These Regulations may be cited as the Cosmetic Products (Safety) (Amendment) Regulations 2006 and shall come into force on 22nd May 2006.

In these Regulations “the Principal Regulations” means the Cosmetic Products (Safety) Regulations 2004<sup>(4)</sup>.

#### Amendment to the Principal Regulations

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

In regulation 5(15)(a) for “under entry numbers 452 to 1132 (inserted into the Directive by Directive 2004/93/EC)” substitute “under entry numbers 452 to 614 and 617 to 1132 (inserted into the Directive by Directive 2004/93/EC with entry 687 as amended by Directive 2005/80/EC)”.

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<sup>(1)</sup> 1987 c. 43.

<sup>(2)</sup> 1972 c. 68.

<sup>(3)</sup> S.I. 1972/1811 and 1993/2661.

<sup>(4)</sup> S.I. 2004/2152 as amended by 2004/2361, 2004/2988, 2005/1815 and 2005/3346.

After regulation 5(15)(b) insert—

- “(c) under entry numbers 1137 to 1211 (inserted by Directive 2005/80/EC) shall be—
- (i) placed on the market after 21st August 2006;
  - (ii) supplied after 22nd November 2006.”

In Schedule 2 at the end there is inserted—

“**45.** Commission Directive 2005/80/EC (O.J. No. L303, 22.11.2005, p.32)”.

Schedule 4 Part 1 is amended as follows—

the name of the substance in entry 1a is replaced by “Boric acid, borates and tetraborates with the exception of the substance N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate”;

the name of the substance in entry 8 is replaced by “p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine (see Note 1), with the exception of those derivatives listed elsewhere in this Schedule”; and

entry 19 (Phenol and its alkali salts) is deleted and there is inserted in its place in Column 1 “ENTRY DELETED”.

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

Date

#### **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 Directive 2005/80/EC (O.J. No. L303, 22.11.2005, p.32) which amends 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.

Regulation 2(2) and (3) amends the list of substances which cosmetic products may not contain by adding further substances which are classified as carcinogenic, mutagenic or toxic to reproduction. Regulation 2(5) amends the list of substances in Part 1 of Schedule 4 to the principal Regulations of substances which cosmetic products must not contain except subject to restrictions.

A regulatory impact assessment of the effect that these Regulations will have on costs to businesses is available 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](http://www.dti.gov.uk)).

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## 5. What happens next?

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We intend for the Regulations to be laid before Parliament in May after the consultation has closed. The Regulations must come into force on 22 May 2006.

We aim to publish a report on the outcome of this consultation by **30 June 2006**

# 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:

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

 020 7215 6206

Email [nick.vanbenschoten@dti.gsi.gov.uk](mailto:nick.vanbenschoten@dti.gsi.gov.uk)

## COMMISSION DIRECTIVE 2005/80/EC

of 21 November 2005

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Directive 67/548/EEC should also be included in Annex II to Directive 76/768/EEC, except if they have been evaluated by the SCCP and found acceptable for use in cosmetic products.

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 <sup>(1)</sup>, and in particular Article 4b and Article 8(2) thereof,

(4) Substances classified as CMR of category 1 and 2 listed in Annex III, Part 1 to Directive 76/768/EEC should be deleted, since these substances are now listed in Annex II to Directive 76/768/EEC and therefore must not form part of the composition of cosmetic products.

After consulting the Scientific Committee on Consumer Products,

(5) Commission Directive 2004/93/EC <sup>(5)</sup> provided for the insertion in Annex II to Directive 76/768/EEC of certain substances which were already listed there. That Annex should therefore be amended for the sake of clarity.

Whereas:

(1) Directive 76/768/EEC, as amended by Directive 2003/15/EC of the European Parliament and of the Council <sup>(2)</sup>, prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1, 2 and 3, under Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances <sup>(3)</sup>, but allows the use of substances classified in category 3 pursuant to Directive 67/548/EEC subject to evaluation and approval by the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers SCCNFP, replaced by the Scientific Committee on Consumer Products (SCCP) by Commission Decision 2004/210 <sup>(4)</sup>.

(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*

Annexes II and III to Directive 76/768/EEC are amended in accordance with the text set out in the Annex to this Directive.

*Article 2*

Member States shall take all necessary measures to ensure that from 22 August 2006 cosmetic products which fail to comply with this Directive are not 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 22 November 2006.

<sup>(1)</sup> OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2005/52/EC (OJ L 234, 10.9.2005, p. 9).

<sup>(2)</sup> OJ L 66, 11.3.2003, p. 26.

<sup>(3)</sup> OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

<sup>(4)</sup> OJ L 66, 4.3.2004, p. 45.

<sup>(5)</sup> OJ L 300, 25.9.2004, p. 13.

*Article 3*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 22 May 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.

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 third 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, 21 November 2005.

*For the Commission*  
Günter VERHEUGEN  
*Vice-President*

## ANNEX

Annexes II and III to Directive 76/768/EEC are amended as follows:

1. Annex II is amended as follows:

- (a) the entries under reference numbers 615 and 616 are deleted;
- (b) the entry under reference number 687 is replaced by the following:  
'687. dinitrotoluene, technical grade (Cas No 121-14-2)';
- (c) the following reference numbers 1137 and 1211 are added:

Ref. No	Chemical name	CAS No EC No
1137	isobutyl nitrite	542-56-3
1138	isoprene (stabilized) (2-methyl-1,3-butadiene)	78-79-5
1139	1-bromopropane n-propyl bromide	106-94-5
1140	chloroprene (stabilized) (2-chlorobuta-1,3-diene)	126-99-8
1141	1,2,3-trichloropropane	96-18-4
1142	ethylene glycol dimethyl ether (EGDME)	110-71-4
1143	dinocap (ISO)	39300-45-3
1144	diaminotoluene, technical product -mixture of [4-methyl-m-phenylene diamine] <sup>(1)</sup> and [2-methyl-m-phenylene diamine] <sup>(2)</sup> methyl-phenylenediamine	25376-45-8
1145	p-chlorobenzotrichloride	5216-25-1
1146	diphenylether; octabromo derivate	32536-52-0
1147	1,2-bis(2-methoxyethoxy)ethane triethylene glycol dimethyl ether (TEGDME)	112-49-2
1148	tetrahydrothiopyran-3-carboxaldehyde	61571-06-0
1149	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	90-94-8
1150	oxiranemethanol, 4-methylbenzene-sulfonate, (S)-	70987-78-9
1151	1,2-benzenedicarboxylic acid, dipentylester, branched and linear [1] n-pentyl-isopentylphthalate [2] di-n-pentyl phthalate [3] diisopentylphthalate [4]	84777-06-0 [1] -[2] 131-18-0 [3] 605-50-5 [4]
1152	benzyl butyl phthalate (BBP)	85-68-7
1153	1,2-benzenedicarboxylic acid di-C 7-11, branched and linear alkylesters	68515-42-4

Ref. No	Chemical name	CAS No EC No
1154	a mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate and trisodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-oxido-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate	EC No 402-660-9
1155	(methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diy)))-1,1'-dipyridinium dichloride dihydrochloride	EC No 401-500-5
1156	2-[2-hydroxy-3-(2-chlorophenyl) carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)-2-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]fluoren-9-one	EC No 420-580-2
1157	azafenidin	68049-83-2
1158	2,4,5-trimethylaniline [1] 2,4,5-trimethylaniline hydrochloride [2]	137-17-7 [1] 21436-97-5 [2]
1159	4,4'-thiodianiline and its salts	139-65-1
1160	4,4'-oxydianiline (p-aminophenyl ether) and its salts	101-80-4
1161	N,N,N',N'-tetramethyl-4,4'-methylenedianiline	101-61-1
1162	6-methoxy-m-toluidine (p-cresidine)	120-71-8
1163	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2
1164	a mixture of: 1,3,5-tris(3-aminomethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione and a mixture of oligomers of 3,5-bis(3-aminomethylphenyl)-1-poly[3,5-bis(3-aminomethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione	EC No 421-550-1
1165	2-nitrotoluene	88-72-2
1166	tributyl phosphate	126-73-8
1167	naphthalene	91-20-3
1168	nonylphenol [1] 4-nonylphenol, branched [2]	25154-52-3 [1] 84852-15-3 [2]
1169	1,1,2-trichloroethane	79-00-5
1170	pentachloroethane	76-01-7
1171	vinylidene chloride (1,1-dichloroethylene)	75-35-4
1172	allyl chloride (3-chloropropene)	107-05-1
1173	1,4-dichlorobenzene (p-dichlorobenzene)	106-46-7
1174	bis(2-chloroethyl) ether	111-44-4
1175	phenol	108-95-2
1176	bisphenol A (4,4'-isopropylidenediphenol)	80-05-7
1177	trioxymethylene (1,3,5-trioxan)	110-88-3
1178	propargite (ISO)	2312-35-8

Ref. No	Chemical name	CAS No EC No
1179	1-chloro-4-nitrobenzene	100-00-5
1180	molinate (ISO)	221 2-67-1
1181	fenpropimorph	67 564-91-4
1182	epoxiconazole	1 33855-98-8
1183	methyl isocyanate	624-83-9
1184	N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate	118612-00-3
1185	O,O'-(ethenylmethylsilylene) di[(4-methylpentan-2-one) oxime]	EC No 421-870-1
1186	a 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chromanil)resorcinol-4-yl-tris(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chromanil)resorcinolbis(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)	1 40698-96-0
1187	a mixture of: reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxo-naphthalenesulfonate (1:2) and reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3)	EC No 417-980-4
1188	malachite green hydrochloride [1] malachite green oxalate [2]	569-64-2 [1] 18015-76-4 [2]
1189	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	107 534-96-3
1190	5-(3-butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino)propyl]-3-hydroxy-cyclohex-2-en-1-one	138164-12-2
1191	trans-4-phenyl-L-proline	96 314-26-0
1192	bromoxynil heptanoate (ISO)	56634-95-8
1193	a mixture of: 5-[[4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl) azo]-2,5-diethoxyphenyl]azo]-2-[(3-phosphonophenyl)azo]benzoic acid and 5-[[4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl]azo]-3-[(3-phosphonophenyl) azo]benzoic acid	163879-69-4
1194	2-{4-(2-ammoniopropylamino)-6-[4-hydroxy-3-(5-methyl-2-methoxy-4-sulfamoylphenylazo)-2-sulfonatonaphth-7-ylamino]-1,3,5-triazin-2-ylamino}-2-aminopropyl formate	EC No 424-260-3
1195	5-nitro-o-toluidine [1] 5-nitro-o-toluidine hydrochloride [2]	99-55-8 [1] 51085-52-0 [2]
1196	1-(1-naphthylmethyl)quinolinium	65 322-65-8
1197	(R)-5-bromo-3-(1-methyl-2-pyrrolidinyl methyl)-1H-indole	143322-57-0
1198	pymetrozine (ISO)	123312-89-0
1199	oxadiargyl (ISO)	39807-15-3
1200	chlorotoluron (3-(3-chloro-p-tolyl)-1,1-dimethylurea)	15545-48-9
1201	N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl] acetamide	EC No 416-860-9

Ref. No	Chemical name	CAS No EC No
1202	1,3-bis(vinylsulfonylacetamido)-propane	93629-90-4
1203	p-phenetidine (4-ethoxyaniline)	156-43-4
1204	m-phenylenediamine and its salts	108-45-2
1205	residues (coal tar), creosote oil distn., if it contains > 0,005 % w/w benzo[a]pyrene	92061-93-3
1206	creosote oil, acenaphthene fraction, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	90640-84-9
1207	creosote oil, if it contains > 0,005 % w/w benzo[a]pyrene	61789-28-4
1208	creosote, if it contains > 0,005 % w/w benzo[a]pyrene	8001-58-9
1209	creosote oil, high-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	70321-79-8
1210	extract residues (coal), creosote oil acid, wash oil extract residue, if it contains > 0,005 % w/w benzo[a]pyrene	122384-77-4
1211	creosote oil, low-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	70321-80-1

(<sup>1</sup>) for the individual ingredient see reference number 364 in Annex II.

(<sup>2</sup>) for the individual ingredient see reference number 413 in Annex II.

2. Annex III, part one, is amended as follows:

- (a) the entry under reference number 19 is deleted;
- (b) under reference number 1a, column b the words 'Boric acid, borates and tetraborates' are replaced by 'Boric acid, borates and tetraborates with the exception of substance No in Annex II';
- (c) under reference number 8, column b the words '*m*- and *p*-Phenylenediamine, their *N*-substituted derivatives and their salts; *N*-substituted derivatives of *o*-Phenylenediamine (<sup>2</sup>), with exception of those derivatives listed elsewhere in this Annex' are replaced by '*p*-Phenylenediamine, its *N*-substituted derivatives and its salts; *N*-substituted derivatives of *o*-Phenylenediamine (<sup>2</sup>), with exception of those derivatives listed elsewhere in this Annex'.

END