

Public consultation on the proposed ban on the use of 49 cosmetic substances in hair dye products

(Update: 12 September 2007)

1. Subject

In light of the hair dye strategy, the Commission is considering banning the use of 49 substances used in hair dye products by amending Council Directive 76/768/EEC of 27 July 1976 (“Cosmetics Directive”).

These substances are proposed to be included in the “List of substances which must not form part of the composition of cosmetic products” under Annex II of the Cosmetics Directive.

A full listing of the substances proposed to be banned is contained in an appendix to this note.

2. Background

In view of safety concerns expressed in relation to the use of some hair dyes, the Commission agreed in April 2003 together with Member States and the stakeholders, on an overall detailed strategy to regulate hair dye substances within the framework of the Cosmetics Directive. The strategy was published as an “*Information note on the use of ingredients in permanent and non-permanent hair dye formulations (dye precursors and direct dyes)*” on the following web site of the Commission:

<http://europa.eu.int/comm/enterprise/cosmetics/doc/hairdyestrategyinternet.pdf>

The overall objective of this strategy is to regulate the use of hair dye substances on the basis of a scientific evaluation of safety data according to the most recent safety requirements of the SCCP. The main element of the strategy is a tiered, modulated approach, requiring industry to submit, by certain deadlines, safety files on hair dye substances to be assessed by the Scientific Committee on Consumer Products (SCCP).

Substances used in hair dye products for which no files were submitted before the cut-off date of 30 September 2003 (as agreed in the above mentioned strategy) will be considered for a ban, on the highest priority basis.

After a progressive banning procedure of hair dye substances without any updated safety files, the Commission is now proposing a ban of remaining 49 chemical substances which can be used for hair dyeing purposes. These substances are currently regulated as colorants in the Annex IV of the Cosmetics Directive¹. As no updated safety files on these substances, when used in hair dye products, were submitted to the SCCP for a risk assessment by the agreed deadlines, there is no evidence that these substances, when used in hair dye products, can be considered safe for human health.

¹ 2 out of the 49 substances are regulated as hair dyes in Annex III, part 1.

3. Consultation

In view of the above, the Commission invites all interested parties, including authorities of the Member States, manufacturers and related industries and consumers associations to submit their comments and information on the possible impact on the measures set out above.

With relation to the economic impact, the information should cover, *inter alia*, the following aspects:

- impact on competitiveness, markets and trade,
- direct and indirect costs for business, including SME's,
- impact for innovation and research,
- impact for specific regions, sectors or groups of workers,
- consequences for third countries and international relations,
- impact on macroeconomic environment,
- consequences for consumers and households.

Any comments, information or safety files on the relevant substances should be submitted by mail, fax or e-mail by 10 October 2007 at the latest to:

European Commission
Directorate-General Enterprise and Industry
Unit F/3, Cosmetics and Medical Devices
BREY 10/176
B-1049 Brussels
Belgium
Fax: 00 32 (0) 2 296 64 67
E-mail: entr-hairdyes@ec.europa.eu

Brussels, September 2007

APPENDIX:**List of 49 cosmetic substances proposed to be banned for use in hair dye products**

No.	Chemical name / CAS No.	Example of the salts / CAS No.	INCI - Name	CAS No.	Cosmetics Directive
1	4-[(4-aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine (CAS 3248-93-9) and its monohydrochloride salt	Benzenamine, 4-((4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl)-2-methyl-, monohydrochloride	Basic Violet 14	632-99-5	Annex IV and Annex III, part 2, no.60
2	4-(2,4-dihydroxyphenylazo)benzenesulphonic acid (CAS 2050-34-2) and its sodium salt	Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate	Acid Orange 6	547-57-9	Annex IV
3	4-hydroxy-3-[(4-sulpho-1-naphthyl)azo]naphthalene-1-sulphonic acid (CAS 13613-55-3) and its disodium salt	Disodium 4-hydroxy-3-[(4-sulphonatonaphthyl)azo]naphthalenesulphonate	Acid Red 14	3567-69-9	Annex IV
4	3-hydroxy-4-(phenylazo)-2-naphthoic acid (CAS 27757-79-5)	Calcium bis[3-hydroxy-4-(phenylazo)-2-naphthoate] or Barium bis[3-hydroxy-4-(phenylazo)-2-naphthoate] (CAS 16508-79-5)	Pigment Red 64:1	6371-76-2	Annex IV
5	2-(6-hydroxy-3-oxo-(3H)-xanthen-9-yl)benzoic acid; Fluorescein (CAS 2321-07-5)	Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate; Fluorescein disodium salt; Fluorescein dihydrochloride salt (CAS 518-47-8) or Fluorescein dipotassium salt (CAS 6417-85-2)	Acid Yellow 73 sodium salt	518-47-8	Annex IV
6	4',5'-dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; 4',5'-dibromofluorescein	4',5'-dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one, disodium salt (CAS 4372-02-5)	Solvent Red 72	596-03-2	Annex IV
7	2-(3,6-dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo (CAS 15086-94-9)	Eosine; Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate; Fluorescein, 2',4',5',7'-tetrabromo, disodium salt; or	Acid Red 87	17372-87-1	Annex IV
		Dialuminium tris[2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate]	Pigment Red 90:1 Aluminum lake	15876-39-8	Annex IV
8	Xanthylium, 9-(2-carboxyphenyl)-3-(2-methylphenyl)amino)-6-((2-methyl-4-sulphophenyl)amino)-, inner salt (CAS 10213-95-3)	Hydrogen 9-(2-carboxylatophenyl)-3-(2-methylanilino)-6-(2-methyl-4-sulphoanilino)xanthylium, monosodium salt	Acid Violet 9	6252-76-2	Annex IV
9	3',6'-dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H]xanthene)-3-one (CAS 38577-97-8)	3',6'-Dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H]xanthene)-3-one, disodium salt; or	Acid Red 95	33239-19-9	Annex IV

No.	Chemical name / CAS No.	Example of the salts / CAS No.	INCI - Name	CAS No.	Cosmetics Directive
		3',6'-dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H]xanthene)-3-one; 4',5'-Diiodofluorescein	Solvent Red 73	38577-97-8	Annex IV
10	2',4',5',7'-tetraiodofluorescein (CAS 15905-32-5)	2-(3,6-dihydroxy-2,4,5,7-tetraiodoxanthen-9-yl)benzoic acid, aluminium salt	Pigment Red 172 Aluminum lake	12227-78-0	Annex IV
11	2',4',5',7'-tetraiodofluorescein (CAS 15905-32-5)	Erythrosine sodium; Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl)benzoate	Acid Red 51	16423-68-0	Annex IV
12	1-Hydroxy-2,4-diaminobenzene and its HCl salt (CAS 137-09-7) (dihydrochloride salt)		2,4-Diaminophenol	95-86-3	Annex III, part 1, no.10
13	1,4-Dihydroxybenzene		Hydroquinone	123-31-9	Annex III, part 1, no.14
14	Bis-4,4'-dimethylaminophenol-4"-phenylaminonaphthylcarbenium chloride		Basic Blue 26	2580-56-5	Annex IV and Annex III, part 2, no.57
15	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (14700)		Ponceau SX	4548-53-2	Annex IV and Annex III, part 2, no.59
16	Riboflavin, Vitamin B2		Lactoflavin, Riboflavin	83-88-5	Annex IV
17	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)		Acid Green 1	19381-50-1	Annex IV
18	4-(phenylazo)resorcinol and its salts		Solvent Orange 1	2051-85-6	Annex IV
19	4-[(4-ethoxyphenyl)azo]naphthol and its salts		Solvent Red 3	6535-42-8	Annex IV
20	1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol and its salts		Pigment Red 4	2814-77-9	Annex IV
21	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide and its salts		Pigment Red 112	6535-46-2	Annex IV
22	N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide and its salts		Pigment Red 5	6410-41-9	Annex IV

No.	Chemical name / CAS No.	Example of the salts / CAS No.	INCI - Name	CAS No.	Cosmetics Directive
23	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate		Pigment Red 48	3564-21-4	Annex IV
24	Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate		Pigment Red 63:1	6417-83-0	Annex IV
25	Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate		Sunset Yellow	2783-94-0	Annex IV
26	Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate		Acid Red 27	915-67-3	Annex IV
27	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]		Pigment Yellow 13	5102-83-0	Annex IV
28	2,2'-[cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis[4-cyclohexylphenol]		Solvent Yellow 29	6706-82-7	Annex IV
29	1-((4-Phenylazo)phenylazo)-2-naphthol		Solvent Red 23	85-86-9	Annex IV
30	Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate		Food Black 2	2118-39-0	Annex IV
31	Tetrasodium 1-acetamido-2-hydroxy-3-(4-((4-sulphonatophenylazo)-7-sulphonato-1-naphthylazo))naphthalene-4,6-disulphonat		Brilliant Black 1	2519-30-4	Annex IV
32	Hydrogen [4-[4-(diethylamino)-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium, sodium salt		Acid Blue 1	129-17-9	Annex IV
33	Bis[hydrogen [4-[4-(diethylamino)-5'-hydroxy-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium], calcium salt		Acid Blue 3	3536-49-0	Annex IV
34	Dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)amino](4-hydroxy-2-sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt		Fast Green FCF	2353-45-9	Annex IV

No.	Chemical name / CAS No.	Example of the salts / CAS No.	INCI - Name	CAS No.	Cosmetics Directive
35	Hydrogen [4-[4-(dimethylamino)- α -(2-hydroxy-3,6-disulphonato-1-naphthyl)benzylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium, monosodium salt		Acid Green 50	3087-16-9	Annex IV
36	2-(3,6-dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo		Solvent Red 43	15086-94-9	Annex IV
37	1,3-isobenzofurandione, reaction products with methylquinoline and quinoline		Solvent Yellow 33	8003-22-3	Annex IV
38	Nigrosine		Acid Black 2	8005-03-6	Annex IV
39	8,18-dichloro-5,15-diethyl-5,15-dihydroindolo[3,2-b:3',2'-m]triphenodioxazine		Pigment Violet 23	6358-30-1	Annex IV
40	1,2-dihydroxyanthraquinone		Pigment Red 83	72-48-0	Annex IV
41	Trisodium 8-hydroxypyrene-1,3,6-trisulphonate		Solvent Green 7	6358-69-6	Annex IV
42	1-hydroxy-4-(p-toluidino)anthraquinone		Solvent Violet 13	81-48-1	Annex IV
43	1,4-bis(p-tolylamino)anthraquinone		Solvent Green 3	128-80-3	Annex IV
44	Disodium 5,5'-(2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one)disulphonate		Acid Blue 74	860-22-0	Annex IV
45	6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one		VAT Red 1	2379-74-0	Annex IV
46	5,12-dihydroquino[2,3-b]acridine-7,14-dione		Pigment Violet 19	1047-16-1	Annex IV
47	29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper		Pigment Blue 15	147-14-8	Annex IV
48	Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32]cuprate(2-)		Direct Blue 86	1330-38-7	Annex IV
49	Polychloro copper phthalocyanine		Pigment Green 7	1328-53-6	Annex IV

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Corrigendum to Commission Directive 2007/54/EC of 29 August 2007 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress 

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Commission Directive 2007/53/EC of 29 August 2007 amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress. 

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Commission Directive 2003/80/EC of 5 September 2003 establishing a symbol indicating the durability of cosmetic products in Annex VIIIa to Council Directive 76/768/EEC 


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Commission Directive 2004/88/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 (musk xylene, musk ketone) 

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Corrigendum to the Commission Directive 2004/88/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 (musk xylene, musk ketone) 

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Commission Directive 2004/94/EC of 15 September 2004 amending Council Directive 76/768/EEC as regards Annex IX 

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Commission Directive 2004/93/EC of 21 September 2004 amending Council Directive 76/768/EEC for the purpose of adapting its Annexes II and III to technical

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Commission Directive 2005/9/EC of 28 January 2005 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex VII thereto to technical progress (Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-,hexylester) 


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Corrigendum to the Commission Directive 2004/93/EC of 21 September 2004 amending Council Directive 76/768/EEC for the purpose of adapting its Annexes II and III to technical progress (15 April 2005) 


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Corrigendum to the Commission Directive 2004/93/EC of 21 September 2004 amending Council Directive 76/768/EEC for the purpose of adapting its Annexes II and III to technical progress (18 August 2005) 


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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 


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Commission Directive 2005/52/EC of 9 September 2005 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex III thereto to technical progress 


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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 


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Commission Directive 2006/65/EC of 19 July 2006 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress. 


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Commission Directive 2006/78/EC of 29 September 2006 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annex II thereto to technical progress. 


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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 thereto to technical progress. 

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
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. 

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Commission Directive 2007/22/EC of 17 April 2007 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes IV and VI thereto to technical progress. 

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