

Amended proposal for a Directive of the European Parliament and of the Council amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants) ⁽¹⁾

(2001/C 96 E/18)

(Text with EEA relevance)

COM(2000) 785 final — 1999/0269(COD)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 29 November 2000)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF
THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure referred to in Article 251 of the Treaty,

Whereas:

- (1) Under Article 14 of the Treaty, an area without internal frontiers is to be established in which the free movement of goods, persons, services and capital is ensured.
- (2) Work on the internal market should gradually improve the quality of life, health protection and consumer safety. The measures provided for in this Directive ensure a high level of health and consumer protection.
- (3) Azodyed textile and leather articles have the capacity to release certain arylamines, which may pose cancer risks.
- (4) Limitations already adopted or planned by certain Member States on the use of azodyed textile and leather articles concern the completion and functioning of the internal market. It is therefore necessary to approximate the laws of the Member States in this field and consequently to amend Annex I to Council Directive 76/769/EEC ⁽²⁾.
- (5) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), after being consulted by the Commission, has confirmed that cancer risks posed by textile and leather goods coloured by certain azodyes give cause for concern.
- (6) In order to protect human health, the use of dangerous azocolourants and the placing on the market of some articles coloured with such dyes should be prohibited.

(7) For common fabrics, the test methods to be used in demonstrating conformity with the rules set out in this Directive are established in the Annex. The Commission will monitor very carefully the development of further test methods, and will adjust the Appendix to Directive 76/769 as soon as even more reliable test methods are available.

(8) This Directive applies without prejudice to Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC ⁽³⁾ and in individual directives based thereon, in particular Council Directive 90/394/EEC ⁽⁴⁾ and Council Directive 98/24/EC ⁽⁵⁾,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 31 December 2001 (one year after the date of the entry into force of this Directive). They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 July 2002 (eighteen months after the date of entry into force of this Directive).

2. 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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

⁽¹⁾ OJ C 89 E, 28.3.2000, p. 67.

⁽²⁾ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 99/77/EC (OJ L 207, 6.8.1999, p. 18).

⁽³⁾ OJ L 183, 29.6.1989, p. 1.

⁽⁴⁾ OJ L 196, 26.7.1990, p. 1.

⁽⁵⁾ OJ L 131, 5.5.1998, p. 11.

ANNEX

The following point 43 is added to Annex I to Directive 76/769/EEC:

'Azo colourants	<ol style="list-style-type: none"> 1. Azodyes that may release, by reductive cleavage of one or more azo groups, one or more of the aromatic amines listed in Appendix, in concentrations above 30 ppm in the finished articles, according to the testing method specified in Appendix, may not be used in textile and leather articles which have the potential of coming into direct and prolonged contact with the human skin or oral cavity, such as: <ul style="list-style-type: none"> — clothing, sleeping-bags, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, — footwear, purses worn round the neck, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, — textile or leather toys and toys which include textile or leather garments, — carpets (except for handmade oriental carpets). 2. Furthermore, the textile and leather articles referred to in point 1 above may not be placed on the market unless they conform to the requirements set out in that point.'
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The following is added to the Appendix to Annex I to Directive 76/769/EEC:

'Point 43 Azo colourants

A. List of aromatic amines

	CAS number	Index number	EC number	Substances
1	92-67-1	612-072-00-6	202-177-1	Biphenyl-4-ylamin 4-aminobiphenyl xenylamine
2	92-87-5	612-042-00-2	202-199-1	Benzidine
3	95-69-2		202-441-6	4-chloro-o-toluidine
4	91-59-8	612-022-00-3	202-080-4	2-naphthylamine
5	97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine
6	99-55-8		202-765-8	5-nitro-o-toluidine
7	106-47-8		203-401-0	4-chloroaniline
8	615-05-4		210-406-1	4-methoxy-m-phenylenediamine
9	101-77-9	612-051-00-1	202-974-4	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane
10	91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine
11	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine o-dianisidine
12	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine
13	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o-toluidine
14	120-71-8		204-419-1	6-methoxy-m-toluidine p-cresidine
15	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis- (2-chloro-aniline) 2,2'-dichloro-4,4'-methylenedianiline

	CAS number	Index number	EC number	Substances
16	101-80-4		202-977-0	4,4'-oxydianiline
17	139-65-1		205-370-9	4,4'-thiodianiline
18	95-53-4	612-091-00-X	202-429-0	o-toluidine 2-aminotoluene
19	95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenediamine
20	137-17-7		205-282-0	2,4,5-trimethylaniline
21	90-04-0	612-035-00-4	201-963-1	o-anisidine 2-methoxyaniline

B. Analytical methods

Analysis	Method
1. Detection of the use of banned azodyes in the manufacture and treatment of coloured textile commodities, particularly those made of cellulose and protein fibres (cotton, viscose, wool, silk).	1. The presence of the amines listed in section A above are to be tested according to the German official method of analysis referred to as "Untersuchung von Bedarfsgegenständen — Nachweis der Verwendung bestimmter Azofarbstoffe aus textilen Bedarfsgegenständen", published in the "Amtliche Sammlung von Untersuchungsverfahren nach § 35 des Lebensmittel- und Bedarfsgegenstände-gesetzes, Gliederungsnummer B 82.02-2, Januar 1998 ⁽¹⁾ ".
2. Detection of the use of banned azodyes in the manufacture and treatment of coloured polyester fibre commodities.	2. The presence of the amines listed in section A above are to be tested according to the German official method of analysis referred to as "Untersuchung von Bedarfsgegenständen — Nachweis der Verwendung bestimmter Azofarbstoffe aus Polyesterfasern Bedarfsge-genständen", published in "Amtliche Sammlung von Untersuchungs-verfahren nach § 35 des Lebensmittel- und Bedarfsgegenstände-ge-setzes, Gliederungsnummer B 82.02-4, Januar 1998 ⁽¹⁾ ".
3. Detection of the use of banned azodyes in the manufacture and treatment of coloured leather commodities.	3. The presence of the amines listed in section A above are to be tested according to the German official method of analysis referred to as "Untersuchung von Bedarfsgegenständen — Nachweis bestimmter Azofarbstoffe in Leder", published in "Amtliche Sammlung von Unter-suchungsverfahren nach § 35 des Lebensmittel- und Bedarfsgegen-stände-gesetzes, Gliederungsnummer B 82.02-3, März 1997 ⁽¹⁾ ".

⁽¹⁾ Obtainable from the Beuth-Verlag GmbH, Berlin and Köln.