COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.11.2000
COM(2000) 785 final

1999/0269 (COD)

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)

(presented by the Commission pursuant to Article 250 (2)
of the EC Treaty)

EXPLANATORY MEMORANDUM

Following the European Parliament's Opinion delivered on 7 September 2000 (first reading), the Commission presents to the Council, in accordance with Article 250 (2) of the EC Treaty, the Amended Proposal for a Directive.

The aim of the amended proposal is to clarify the original proposal, without modifying its general structure and objectives.

Of the five amendments adopted by the Parliament one has been accepted and parts of another amendment accepted in principle.

The Commission recognises that the technical progress in testing methods should be taken into account and has therefore accepted to introduce, when available, an even more reliable testing method. (Parliament's Amendment no. 1).

Furthermore, the Commission can accept in principle parts of Parliament's amendment no. 3 :

The Commission shares the Parliament's view that the risks posed by hand-made oriental carpets is likely to be low and has accepted to exempt such carpets from the example list of product categories covered by the provisions. However the Commission cannot accept that the exemption be only temporary as the low level of risk is not foreseen to change with time. The Commission can also accept, in order to further clarify the scope of the provisions, to add two more product categories to the example list.

The Commission has not accepted amendments which would extend the scope of the proposed ban. The basis for the Commission's proposal is that risks to health have been identified from azo-dyes in textiles and leather that come into close and prolonged contact with the skin. Such risks have been confirmed by the Scientific Committee in Toxicity, Ecotoxicity and the Environment.

Therefore, the Commission cannot accept Parliament's Amendments nos. 3 and 4 to ban azo-dyes in articles other than those made of textiles and leather or to include other amines. This would not be justified on the current knowledge about risks. However, if such risks are identified, the Directive could be adapted to technical progress. Nor has the Commission accepted to make the example list of product categories that are covered by the provisions exhaustive. An exhaustive list would ban azo-dyes also in certain individual articles which may not come in close contact with the skin and consequently not present any risk.

Finally, for reasons of clarity and transparency, especially for suppliers in the Third World, the Commission has proposed the most widely used and accepted testing method to show compliance. The inclusion of other testing methods has not been accepted (Parliament's Amendment no. 5).

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(Text with EEA relevance)

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[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure referred to in Article 251 of the Treaty[3],

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[4].

(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.

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1 OJ […].
2 OJ […].
3 OJ […].
4 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).

(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[5] and in individual directives based thereon, in particular Council Directive 90/394/EEC[6] and Council Directive 98/24/EC[7],

HAS 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.

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[5] OJ L 183, 29.6.1989, p. 1.
[6] OJ L 196, 26.7.1990, p. 1.
[7] OJ L 131, 5.5.1998, p. 11.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

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

Azo colourants	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: – 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.”

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-ylamine 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

	CAS number	Index number	EC number	Substances
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'-methylene-dianiline
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 Bedarfsgegenständegesetzes, Gliederungsnummer B 82.02-2, Januar 1998[1]".
2. Detection of the use of banned azodyes in the manufacture and treatment of coloured polyester fibres 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 Bedarfsgegenständen" published in "Amtliche Sammlung von Untersuchungsverfahren nach § 35 des Lebensmittel- und Bedarfsgegenständegesetzes, 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 Untersuchungsverfahren nach § 35 des Lebensmittel- und Bedarfsgegenständegesetzes, Gliederungsnummer B 82.02-3, März 1997[1]".

[1] Obtainable from the Beuth-Verlag GmbH, Berlin and Köln.