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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.1999
COM(1999) 620 final

1999/0269 (COD)

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)

EXPLANATORY MEMORANDUM

1. BACKGROUND

Certain azo dyes used in textiles and leather pose a risk of cancer for consumers and workers. Several Member States have introduced or notified national legislation banning certain carcinogenic azocolourants. The need for harmonisation in the field of azodyes is also generally accepted by industry and trade.

As a result of these discussions, the Commission proceeded with a study programme consisting of three studies, a risk assessment, a cost-benefit analysis and a study on the effects of a ban in supplying countries, concluding that:

- the current exposure situation for consumers is undesirable;
- following the national bans, most of the EU-based companies have already eliminated azodyes of concern from their product range and developed the use of replacement dyes. Hence, industry perceives the additional costs of a European ban as limited, and only associated with the need to show compliance by testing and certification;
- the principle problem faced by producers in developing countries in adapting to a ban concern timing, information and testing;
- in order to be WTO- consistent, restrictions on some azodyes need to be well justified by health risk to the consumers.

On 18 January 1999, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), delivered its opinion, concluding that the cancer risks associated with the use of certain azodyes give cause for concern. The Committee confirmed that azodyes which on cleavage form any of the carcinogenic amines classified as carcinogenic cat 1 or 2, and in addition 8 amines on the German MAK list, are of special concern.

On 8 March 1999, the Working Group on limitations on marketing and use of dangerous substances and preparations gave favourable advice on the Commission's proposal to ban the dangerous azodyes and to propose a testing method demonstrating compliance with the legal requirements.

2. PROPOSAL FOR AN AMENDMENT TO DIRECTIVE 76/769/EEC ON AZOCOLOURANTS

A proposal of a European Parliament and Council Directive amending for the nineteenth time Directive 76/769/EEC on azocolourants is hereby submitted.

In order to protect human health, this Directive prohibits the use of dangerous azocolourants, and the placing on the market of some textiles and leather articles coloured with such substances. As confirmed by the CSTEE, only the soluble azocolourants are bioavailable and consequently pose a risk to human health. The azocolourants encompass the azodyes, which by definition are soluble, plus a very small fraction of azopigments which are also soluble. As those pigments were not yet

risk assessed, they are not the subject of specific provisions in this directive, but provisions could be included at a later stage by adaptation to technical progress.

The restricted azodyes are those which have the capacity to release by reductive cleavage of one or more azo groups, any of the 21 aromatic amines listed in the appendix of the Directive.

The test methods to be used in demonstrating conformity with this Directive are defined in an Appendix to the Directive and refer to the official German analytical method, which is currently used worldwide. This testing methods do not yet detect accurately some of the carcinogenic aromatic amines released by the azocolourants, like for instance 4-aminoazobenzene. This carcinogenic arylamine is subject to be added to the list of prohibited substances as soon as an appropriate analytical method has been developed allowing the verification of compliance to the prohibition.

3. JUSTIFICATION FOR PROPOSAL AND CONSIDERATIONS OF SUBSIDIARITY

What are the objectives of the proposal in relation to the Community's obligations?

The first objective of the proposal is to protect public health.

The second objective is to preserve the internal market.

Does the initiatives arise out of an exclusive Community competence or a shared competence?

The action to preserve the internal market for dangerous substances falls within the exclusive competence of the Community. This competence was established by Council Directive 76/769/EEC.

What are the courses of action available to the Community?

The only course of action available is a proposal to amend for the nineteenth time Directive 76/769/EEC.

Are uniform rules necessary? Is it not sufficient to establish targets to be implemented by Member States?

The proposed nineteenth amendment establishes uniform rules for the circulation of azodyes and textile and leather articles coloured with them. It also guarantees high level of protection of public health. The proposed nineteenth amendment is the only way to meet these goals. Targets would be insufficient.

4. RATIONALE OF THE PROPOSAL

The need for this proposal arose since 1992 when several Member States adopted measures phasing out the use of azodyes in textile and leather articles. Hence only a EU-wide harmonisation could avoid disrupting the internal market.

5. COSTS AND BENEFITS

5.1. Costs

The proposed Directive should pose only minor problems to the EU industry or trade, since most of the companies have already adapted to the national bans and developed substitutes.

5.2. Benefits

The benefit of the proposal is to protect public health.

6. PROPORTIONALITY

The nineteenth amendment would yield benefits in terms of protecting public health. This would be achieved at low costs.

7. CONSULTATIONS PERFORMED IN PREPARING THE PROPOSED NINETEENTH AMENDMENT

Advice on the preparation of the proposal was sought through several meetings involving experts from Member States and from Trade and Industry, represented by EURATEX (European Apparel and Textile Organisation), CEFIC (European Chemical Industry Council), COTANCE (Confederation of National Association of Tanners and Dressers of the EC), FTA (Foreign Trade Association), EUROCOMMERCE and ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers).

8. CONFORMITY WITH THE TREATY

This proposal is intended to facilitate a high level of protection of public health and is therefore in conformity with Article 95(3) of the Treaty.

The proposal does not call for any special provisions of the kind referred to in Article 15 of the Treaty.

It is in conformity with Article 5.

9. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 95 of the Treaty, the Codecision Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

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)

(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 Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure referred to in Article 251 of the Treaty³,

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/EEC⁴.

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).

- (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.
- (8) This Directive applies without prejudice to Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC⁵ and in individual directives based thereon, in particular Council Directive 90/394/EEC⁶ and Council Directive 98/24/EC⁷,

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*.

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.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament
The President*

*For the Council
The President*

ANNEX

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

“43 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, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items,- footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers,- textile or leather toys and toys which include textile or leather garments,- 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-ylamine 4-aminobiphenyl xenyamine
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

	CAS number	Index number	EC number	Substances
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.