

**ETAD Information on the
19th Amendment of the Restrictions on the Marketing and Use of certain
azocolourants
(Directive 2002/61/EC of the EP and of the EC of 19 July 2002)**

1. Introduction

Following the introduction in 1994 under the German Consumer Goods Ordinance¹ of restrictions on the use of certain azo dyes in consumer goods intended to involve more than temporary contact with the skin, several other EU member states introduced similar but different regulations. In the interests of transparency and the maintenance of the Single Market, ETAD has advocated harmonisation of these restrictions at EU level under Council Directive 76/769/EEC.

With the publication of the 19th Amendment² harmonisation will be enforced by 11 September 2003 when the restriction will be enacted throughout the member states.

2. Main changes versus the German Consumer Goods Ordinance

No azo pigments are restricted under the EU Directive 2002/61/EC.

3. What Consumer Goods are affected?

Examples of consumer goods covered by the restrictions are:

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,
- footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,
- textile or leather toys and toys which include textile or leather garments,
- yarn and fabrics intended for use by the final consumer.

4. What azo dyes fall under the scope of the restriction?

Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Table 1, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof.

Azo dyes are the most important chemical class of dyes, representing 60 - 70 % of all dyes used. Only about 5 % of azo dye structures are affected by the 19th Amendment, which are already largely phased out for consumer goods in the EU.

Table 1 List of 22 aromatic amines

Aromatic amine	CAS-No.
4-Aminoazobenzene	60-09-3
o-Anisidine	90-04-0
2-Naphthylamine	91-59-8
3,3'-Dichlorobenzidine	91-94-1
4-Aminodiphenyl	92-67-1
Benzidine	92-87-5
o-Toluidine	95-53-4
4-Chloro-o-toluidine	95-69-2
4-Methyl-1,3-phenylenediamine	95-80-7
o-Aminoazotoluene	97-56-3
5-Nitro-o-toluidine	99-55-8
4,4'-Methylene-bis-(2-chloraniline)	101-14-4
4,4'-Methylenedianiline	101-77-9
4,4'-Oxydianiline	101-80-4
p-Chloraniline	106-47-8
3,3'-Dimethoxybenzidine	119-90-4
3,3'-Dimethylbenzidine	119-93-7
p-Cresidine	120-71-8
2,4,5-Trimethylaniline	137-17-7
4,4'-Thiodianiline	139-65-1
4-methoxy-m-phenylenediamine	615-05-4
4,4'-Methylenedi-o-toluidine	838-88-0

5. What are the official test methods?

The Commission, in accordance with Article 2a of Directive 76/769/EEC, should establish such methods. The testing methods should preferably be developed at European level, if appropriate by the European Committee for Standardisation (CEN). Currently, an official collection of testing methods is available in Germany according to §35 LMBG (Textile, Leather and polyester substrates)³.

6. What is meant by a false positive result?

Although the restrictions do not apply to pigments, it is known that certain azo pigments may release amines listed in Table 1 under the test conditions. These azo pigments are sufficiently soluble under the analytical test conditions to yield detectable amounts of a listed amine (i.e. greater than 30 mg/kg consumer good). ETAD member companies would provide information if such pigments are supplied.

For certain dyes a listed amine is detected under the conditions of the analytical test even though no banned azo dye is present in the consumer good. The amine is an

artefact of the test procedure, resulting from chemical reactions other than azo cleavage. Numerous examples have been reported:

1. Detection of 4-aminobiphenyl from e.g. C.I. Acid Red 1, C.I. Solvent Yellow 7. **The detection of 4-aminobiphenyl should always be treated with suspicion** as no known azo dyes or pigments would form this amine by cleavage of one or more azo bonds.

2. Detection of 2-naphthylamine from dyes based on Tobias acid. Although the official method yields smaller amounts of 2-naphthylamine than detected under more aggressive test conditions, the results are false positives as the responsible dyes do not fall within the scope of the Directive.

3. p-aminoazobenzene (4AAB): Dyes based on 4AAB would reduce not to 4AAB (itself an azo compound) but further to aniline and p-phenylenediamine (PPD). under the conditions of the current test procedure. This means that the current analytical method does not differentiate between a restricted 4AAB dye and an unrestricted dye (or more often dye mixture) which reduces to aniline and p-phenylenediamine. **No leather dyes are known to be in commerce which would reduce to 4AAB (and hence aniline and PPD) under the test conditions.**

This is addressed in a separate COTANCE/ETAD Information Note.

7. How can a retailer best ensure compliance?

Whereas the dye or pigment manufacturer is in a position to know which colorants are affected by these restrictions, it is the retailer or importer who is responsible for compliance. A textile finisher in the EU must also ensure that he does not use a banned azo dye for the manufacture of a regulated consumer item. The 19th Amendment does not require any analytical testing. If the retailer can ensure by a certification procedure, that banned azo dyes are not present, he can avoid substantial analytical costs.

A prudent importer or retailer should:

1. Seek to exclude banned azo dyes from the manufacturing chain by establishing a formal certification procedure with his suppliers. A possible format, developed by agreement of Euratex and ETAD, is illustrated in the Appendix
2. Ensure that suppliers of colorants to his manufacturing chain are fully conversant with the current regulatory requirements, and can be relied upon to provide accurate information on their products.
3. Establish a formal system for checking compliance by testing an appropriate sample of affected consumer goods. The extent of this testing can be reduced as confidence is established.

8. What are the obligations of ETAD members?

Most ETAD members no longer manufacture any of the restricted azo dyes. Some members still manufacture some of these dyes for non-restricted applications. All ETAD members are aware of the German restrictions and have specifically agreed to provide their customers with reliable information on the regulatory status of their products. Failure to provide correct information would be a serious breach of the ETAD Code of Ethics, which is binding on all members.

9. Effective Dates

Member States shall adopt and publish, not later than **11 September 2003**, the laws, regulations and administrative provisions necessary to comply with this Directive.

By way of derogation, **until 1 January 2005**, this provision shall not apply to textile articles made of **recycled fibres** if the amines are released by residues deriving from previous dyeing of the same fibres and if the listed amines are released in concentrations **below 70 ppm**.

10. References

1. Fünfte Verordnung zur Änderung der Bedarfsgegenständeverordnung, Bundesgesetzblatt, 1997, Teil 1 Nr. 24, 796-800. (See also consolidated version of Consumer Goods Ordinance, Bundesgesetzblatt, 1998, Teil 1 Nr. 1, 5-36)
2. Directive 2002/61/EC of the EP and of the EC of 19 July 2002
3. Amtliche Sammlung von Untersuchungsverfahren nach § 35 LMBG, Beuth Verlag, 10772 Berlin
 - Gliederungsnummer B 82.02-2, Januar 1998: Nachweis der Verwendung bestimmter Azofarbstoffe aus textilen Bedarfsgegenständen
 - Gliederungsnummer B 82.02-3, März 1997: Nachweis bestimmter Azofarbstoffe in Leder
 - Gliederungsnummer B 82.02-4, Januar 1998: Nachweis der Verwendung bestimmter Azofarbstoffe aus Polyesterfasern

**MODEL DECLARATION OF COMPLIANCE WITH
THE 19th AMENDMENT CONCERNING CERTAIN AZO COLORANTS**

The undersigned, duly authorised representative of (name of dye supplier)

.....
hereby certifies that the textile dyes or pigments listed below, which have been supplied to (name of
textile dyeing and finishing company)

.....
on
are not restricted under the 19th Amendment (DIRECTIVE 2002/61/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL of 19 July 2002)

List of dyes (state "all" or specify):

.....
.....
.....
.....

The undersigned further certifies that the following dyes supplied on the date and to the company
described above are restricted under the 19th Amendment referred to above:

List of azo dyes (state "none" or specify):

.....
.....
.....
.....

This company *is / is not* a member of ETAD (delete as appropriate).

Name:

Function:

Signature:

Place:Date:.....