Common position

COUNCIL OF THE EUROPEAN UNION

Brussels, 19 February 2002

Interinstitutional File:
1999/0269 (COD)

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

DIRECTIVE 2002/ /EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

restrictions on the marketing and use of certain dangerous substances and
preparations (azocolourants)

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 proposals from the Commission

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty.
Whereas:

(1) 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.

(2) Textile and leather articles containing certain azodyes have the capacity to release certain arylamines, which may pose cancer risks.

(3) 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 of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.  

(4) 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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(5) In order to protect human health, the use of dangerous azodyes and the placing on the market of some articles coloured with such dyes should be prohibited.

(6) For textile articles made of recycled fibres, a maximum concentration of 70 ppm for the amines listed in point 43 in the appendix to Directive 76/769/EEC should be applied. This should be the case for a transitional period until 1 January 2005 if the amines are released by the residues deriving from the previous dyeing of the same fibres. This will allow for the recycling of textiles, which has overall benefits for the environment.

(7) Harmonised testing methods are necessary for the application of this Directive. 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).

(8) In the light of new scientific knowledge, testing methods should be reviewed, including testing methods for analysing 4-amino azobenzene.

(9) In the light of new scientific knowledge, the provisions on certain azocolourants should be reviewed, in particular with regard to the need to include other materials not covered by this Directive, as well as other aromatic amines. Special attention should be paid to possible risks to children.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

Testing methods for the application of point 43 of Annex I to Directive 76/769/EEC shall be adopted by the Commission in accordance with the procedure laid down in Article 2a of that Directive.

Article 3

1. Member States shall adopt and publish, not later than ………, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

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* 12 months after the entry into force of this Directive.
They shall apply these provisions from .......... 

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

**Article 4**

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

**Article 5**

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

* 12 months after the date of entry into force of this Directive.
Annex I to Directive 76/769/EEC is hereby amended as follows:

1. The following point shall be added:

43. Azocolourants

<p>| | |</p>
<table>
<thead>
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| 1. | Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in the Appendix, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing method established in accordance with Article 2a of this Directive, may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:
|   |   |
|   | – 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. |

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.

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.

3. Not later than ………. *, the Commission shall, in the light of new scientific knowledge, review the provisions on azocolourants.

* 36 months after the date of entry into force of this Directive.”
2. The following point shall be added to the Appendix:

"Point 43 Azocoulourants

List of aromatic amines

<table>
<thead>
<tr>
<th>CAS number</th>
<th>Index number</th>
<th>EC number</th>
<th>Substances</th>
</tr>
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<tbody>
<tr>
<td>1 92-67-1</td>
<td>612-072-00-6</td>
<td>202-177-1</td>
<td>biphenyl-4-ylamine</td>
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<td></td>
<td></td>
<td></td>
<td>4-aminobiphenyl</td>
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<td></td>
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<td>xenylamine</td>
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<td>2 92-87-5</td>
<td>612-042-00-2</td>
<td>202-199-1</td>
<td>benzidine</td>
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<td>3 95-69-2</td>
<td>612-022-00-3</td>
<td>202-080-4</td>
<td>2-naphthylamine</td>
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<tr>
<td>4 91-59-8</td>
<td>611-006-00-3</td>
<td>202-591-2</td>
<td>o-aminoazotoluene</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>4-amino-2’,3-dimethylazobenzene</td>
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<td></td>
<td></td>
<td></td>
<td>4-o-tolyazo-o-toluidine</td>
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<tr>
<td>5 97-56-3</td>
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<td>7 106-47-8</td>
<td>612-137-00-9</td>
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<td>202-453-1</td>
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<td>2,4,5-trimethylaniline</td>
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<td>17 90-04-0</td>
<td>611-008-00-4</td>
<td>200-453-6</td>
<td>4-amino azobenzene</td>
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</tbody>
</table>
STATEMENT OF THE COUNCIL'S REASONS

I. Introduction

1. On 10 December 1999 the Commission submitted a proposal for a Directive based on Article 95 of the Treaty relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants).  


4. On 18 February 2002 the Council adopted its common position in accordance with Article 251 of the Treaty.

II. Aim

The aim of the Commission's proposal is to ban the use and marketing of textile and leather articles containing certain azodyes.

III. Analysis of the common position

1. The Council has been examining the proposal since the middle of 2000. The Council's Common Position is generally consistent with the Commission's amended proposal.

2. The Council incorporated one European Parliament amendment and part of two others.

3. The Council welcomed amendment 1 on the need to take technical progress in testing methods into account.

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1 OJ C 89 E, 28.03.2000, p. 67.
2 OJ C 135, 07.05.2001, p. 257.
3 OJ C 096 E, 27.03.2001, p. 269.
4 OJ C 204, 18.7.2000, p. 90.
4. The Council incorporated partly amendments 3 and 6 by removing carpets from the non-exhaustive list of product categories covered by the provisions and by adding two more products to the non-exhaustive list.

5. The Council considers that the risk assessment procedures should be completed before extending the scope of the Directive to other articles and substances. Consequently, the Council rejected amendment 4 as well as part of amendment 3.

6. As regards testing methods, the Council has opted for a solution which guarantees that the most widely used and accepted methods are always applied, and the Council therefore rejected amendment 5 on inclusion of a particular testing method.

IV. Conclusion

By incorporating wholly or partly the European Parliament amendments that improve and clarify the provisions on testing methods and articles to be covered by the Directive, the Council has endeavoured to achieve a balanced solution which takes account of the risk-assessment procedure and which guarantees a high level of health and consumer protection.

Re Article 2

Joint statement by the Council and the Commission

"The Council and the Commission are of the opinion that the testing methods should be uniformly applicable."

Statement by the Commission

"It is the intention of the Commission to establish testing methods, before the date of application of the restrictions imposed by the Directive, by a Commission Regulation."

Re Annex 1, point 43

Statement by the Commission

"The Commission takes note of concerns expressed about azo dyes in other materials than textile and leather and, in particular, about possible exposure of children to carcinogenic azo dyes from toys made of other materials. The Commission is studying possible risks posed by azo dyes in toys made of other materials and will give the issue priority in 2002, with a view to the adoption of risk reduction measures as necessary."
COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to the second subparagraph of Article 251 (2) of the EC Treaty

concerning the

common position of the Council on the adoption
Council Directive 76/769/EEC relating to restrictions on the marketing and use
of certain dangerous substances and preparations (azo colourants)
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of certain dangerous substances and preparations (azo colourants)

1. STATE OF PROCEDURE
   
   – The above mentioned proposal [COM(1999) 620 final] was adopted by the Commission on 10th December 1999 and then transmitted to the Council and European Parliament.

   – The European Parliament approved the proposal with amendments in the first reading on 7th September 2000.


   – The Economic and Social Committee gave its Opinion on 25th May 2000.

2. OBJECTIVE OF THE DIRECTIVE

   The Proposal, which is based on Article 95 of the Treaty, has the following two objectives:

   – to preserve the Internal Market by introducing harmonised provisions with regard to the marketing and use of azo colourants;

   – to provide a high level of protection of consumers’ and workers’ health by restricting the marketing and use of certain azo dyes in textile and leather articles which might come in close contact with the skin.

3. COMMENTS ON THE COMMON POSITION

3.1. General

   The Common Position follows the general lines of the Commission’s amended proposal.
Certain changes, which clarify and strengthen the provisions, were introduced.

3.2. Amendments

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

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.

The Commission shares the 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. 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 in close and prolonged contact with the skin. Such risks have been confirmed by the Scientific Committee in Toxicity, Ecotoxicity and the Environment.

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 additional testing methods has not been accepted.

3.3. The Common Position of the Council

The Common Position of the Council includes, in addition to the amendments accepted by the Commission, certain changes that would clarify and strengthen the proposed Directive.

The Common Position of the Council provides for the introduction and review of testing methods by Committee procedure. This is acceptable to the Commission as it would facilitate the introduction of the most reliable and up-to-date testing method and ensure its uniform application.

In the light of recent scientific and technical information an additional carcinogenic amine is included in the list of banned amines. The Commission can support this addition.

The Common Position provides for a time-limited exemption for recycled fibres previously dyed with azo dyes. The Commission can support this exemption as this would not pose a significant risk to consumers and would prevent serious economic implications.

Furthermore, the Commission can agree to the requirement in the Common Position of a future review of the provisions in the light of new scientific knowledge, especially with regard to possible risks to children.
4. **CONCLUSION**

The Commission supports the Common Position because it follows the lines of its amended proposal.

5. **STATEMENTS BY THE COMMISSION**

The Commission made statements on Article 2 and Annex I to the Directive and a joint statement with the Council on Article 2.