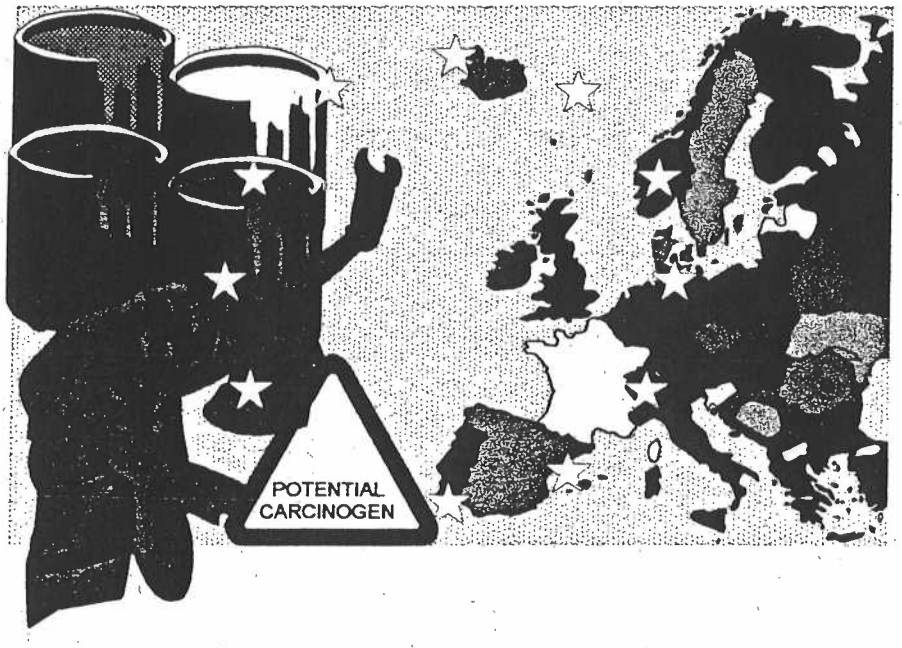
Analysis of the Advantages and Drawbacks of Banning Azo-Dyes and Products Treated with Azo-Dyes



Final Report

for Directorate General III
of the European Commission
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July 1997

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prepared for

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Directorate General III (Industry)

by

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EXECUTIVE SUMMARY

1. INTRODUCTION

In 1993, the German Government notified the European Commission (EC) of its proposed ban (notification 93/243/D) on certain consumer goods dyed with azo dyes which may release, through reductive cleavage, one of 20 listed arylamines. Since April 1996, it has been an offence in Germany to use azo dyes which may release the banned arylamines in the manufacture of most skin contacting consumer goods and from the beginning of 1999 restrictions will be extended to the sale of such products. The Dutch and French Governments have also implemented similar bans and Austria, Denmark and Sweden are expected to be preparing similar domestic legislation.

In order to harmonise the single market, extension of these bans is being considered by the EC. To this end, the EC wishes to establish the net advantages and drawbacks of banning certain azo dyes and using alternatives, and seeks an analysis of the economic effects on Member States from such a ban. This is being undertaken through the application of risk-benefit analysis techniques, such as those discussed in *Risk Benefit Analysis of Existing Substances* (DoE, 1995); *Risk Benefit Analysis of Hazardous Substances* (RPA, 1992); and *Draft Technical Guidance Document on Development of Risk Reduction Strategies*, produced for the EU for use under the Existing Substances Regulation (EEC 793/73).

2. AZO DYES

Azo dyes have been used for many years in the textiles, printing, cosmetic, drug and food industries. An azo compound takes the form of R-N=N-R (where R is an aromatic ring). There are 3,000 azo colorants, made up of 2,000 azo dyes and 1,000 azo pigments. Although these 2,000 azo dyes represent 20% of available dyes (by dye type), 60% to 80% of dyes currently in use (by volume) are azo dyes; for the Western European market in 1991, this represented between 52,000 and 70,000 tonnes of dyes valued at ECU 550 million. Azo dyes are widely used because the arylamines on which they are based are reactive, inexpensive, convenient and make stable and technically good products. In addition, they offer a wide range of shades and brilliance of colour. In the main, azo dyes are direct dyes and are used on cotton and wool and to some extent silk and leather.

The dyes of concern to this study are those which can release carcinogenic arylamines, such as benzidine, from dyed clothing. Between the late 1960s and early 1980s the manufacture of benzidine-based dyes ceased in Europe following evidence of their carcinogenic properties. However, demand continues to be met by manufacturers in countries such as China, India, Korea, Mexico and Taiwan. Thus, although European dye producers have alternatives to these dyes and to others which will be impacted by national legislation, these are more expensive than traditional dyes imported from developing countries and take-up has been poor.

For over 100 years it has been recognised that workers involved in the production of certain azo dyes suffered increased incidents of bladder cancer. Studies have identified

that azo dyes themselves are not necessarily carcinogenic or toxic, but some of the component arylamines are carcinogenic. In 1989, a study produced by the Massachusetts Institute of Technology (MIT) in the United States demonstrated that azo dyes can be caused to 'run' by sweat and are then able to enter the blood stream via the skin. Acute toxicity tests undertaken by the Environmental and Toxicological Association of the Dyes and Organic Pigments Manufacturers (ETAD) on over 4,000 dyes identified that only about 1% (i.e. 40) were toxic. Of the remainder, about 90% showed either very slight or no toxicity and the remainder (about 9%) fell somewhere in-between.

3. THE POLICY CONTEXT

In 1993, the German Government notified the European Commission (EC) of its proposed ban on certain azo colorants (Consumer Goods Ordinance, notification 93/243/D) which may break down into one of 20 arylamines. Following several complaints, the EC officially informed Germany in September 1996 that they were infringing the criteria of proportionality and so required a postponement to the ban and a mutual recognition clause that test results from other Member States were valid. The recently adopted 5th Amendment (96/404/D), which is sufficient under the criteria of proportionality, has made it an offence since April 1996 to use the banned azo dyes in Germany for the manufacture of skin contacting consumer goods (although this is delayed until April 1997 for leather goods and 2000 for recycled textiles). From the beginning of 1999 it also will be an offence to sell skin contacting azo dyed consumer goods containing more than 30 mg/kg of the specified arylamines (although this is delayed until 2000 for recycled textiles and does not affect secondhand goods or protective clothing such as uniforms).

The Dutch ban is similar to that described for Germany and came into force on 1st August 1996. It relates to the same arylamines, to clothing, footwear and bedding and none of the banned arylamines are permitted to exceed 30 mg/kg. Under this ban, items which release the banned arylamines may be sold until September 1997, if they were ordered prior to August 1996. Furthermore, second hand items, protective items and items produced from "recovered fibres" which release the banned arylamines may be sold in the Netherlands until 2000.

Austria, Denmark and Sweden are expected to be preparing similar domestic azo legislation, however, Austrian restrictions are likely to cover 21 arylamines.

Three of the arylamines banned under the German and Dutch bans (4-aminobiphenyl (92-67-1), benzidine (92-87-5) and 2-naphthylamine (91-59-8)) are listed and controlled as individual substances under the Marketing and Use of Dangerous Substances Directive 76/769/EEC. In addition, another nine of the banned arylamines are already classified as Category 1 or 2 carcinogens under Annex I of the Dangerous Substances Directive and so may not be used alone or in preparations placed on the market for sale to the general public above certain concentrations. There is still uncertainty over whether other arylamines are of a similar risk category.

For the purposes of this study, it has been assumed that the German ban on azo dyes will be extended across the EU.

4. NATURE OF THE DYE, TEXTILE AND LEATHER GOODS INDUSTRY

Two hundred companies (and perhaps 25,000 workers) are involved in the manufacture and/or import of dyes in Europe. Fifty percent of these are located in Italy, the UK and Germany. Most European dye producers have ceased production of the azo dyes of concern (i.e. those which reductively cleave carcinogenic arylamines) and have developed alternatives to these dyes. However, these are more expensive than traditional dyes imported from developing countries and take-up has been poor.

The textile and clothing chain of trade includes yarn producers, weavers, dyers, finishers and clothing manufacturers. Across the EU, there are 60,000 enterprises in the clothing sector, 60,000 in the textiles sector and a further 5,000 finishing enterprises. Over 90% of these enterprises are located in just six countries: Italy, Spain, the UK, Germany, Portugal and France. Around 2.4 million people are employed in the clothing and textile sectors (90% in the above six countries) representing 10% of all those employed by the European manufacturing sector. However, many EU-based textile and clothing producers are moving production to lower cost countries such as Morocco or Poland to compete with lower priced imports.

There are just over 14,000 footwear enterprises in Europe of which over half are based in Italy. Most of these enterprises are small.

In 1993, 63% of all clothing and textile imports were from 10 major suppliers. The five main importing countries were China, Turkey, Hong Kong, India and Austria (not yet a member of the EU). At this time 66% of all textile and clothing exports went to only 10 countries with the major markets being the USA, Switzerland, Austria, Japan and Poland.

5. EFFECTS ON TRADE OF CURRENT AND PROPOSED LEGISLATION

Between 1,200 and 3,000 tonnes of 'affected' dyes were consumed within Western Europe in 1991. This represented about ECU 19.5 million.

The control of azo dyes at an EU or Member State level will require that replacements are found for the arylamines on which these are based. As a result of the German ban, alternatives are required for around 200 or 300 azo dyes. Reformulation of a dye requires substituting the carcinogenic arylamine with another (non-carcinogenic arylamine). Reformulation takes time and money, but this has already been absorbed by the majority of European dye manufacturers as replacements have already been developed. Indeed, national bans on the use of some azo dyes have benefited European producers who are now able to sell these alternatives. Extension of the ban across Europe as a whole would increase the sale of alternatives further.

Alternative dyes can be around three times more expensive than the products which they replace, however, this represents less than 1% on end product (e.g. clothing or footwear) prices. In addition, some of the qualities and colours offered by the affected azo dyes may not be offered by the alternatives. Responses to the questionnaire indicate that most companies have already taken steps to ensure that the products they supply are free from

the restricted arylamines. On this basis, most companies have already incurred the costs associated with using replacement dyes (i.e. the additional costs associated with a European ban would be small). However, if azo pigments or additional arylamines were included in the ban, then costs could increase significantly.

The main costs associated with national bans on certain azo dyes have arisen from the need to demonstrate compliance via certification. The need for certification has impacted all levels of the chain of trade, from dye manufacturers to retailers, although the drivers appear to have been retailers and importers. Testing of products to demonstrate compliance can be costly (around ECU 150 per test). In addition, it is problematical due to: confusion over exactly what is to be tested; the effects of impurities on the test results; variable results from different test houses; difficulties in testing leathers; the lack of a standard approach to testing; and the production of false positives. If extended across Europe, a ban on the use of some azo dyes would need to address these issues.

55% of those involved in the production of textile and leather goods indicated via the questionnaire that the German and Dutch bans have had a negative impact on their company in the form of generating uncertainty and lack of confidence, inconvenience and financial costs.

6. HUMAN HEALTH AND ENVIRONMENTAL RISKS

The use of some azo dyes poses occupational risks to those involved in the manufacture of dyes and dyed-products and also to consumers of "skin-contactable" dyed products such as clothing, bedding and footwear. Other risks to human health such as those associated with contact dermatitis are thought to be insignificant.

Research indicates that exposure to benzidine at 0.3 ng/person/day will result in 1 chance in a million (1×10^{-6}) of developing a fatal cancer over a lifetime. Using assumptions on exposure levels in the EU it is possible to estimate that azo dyes based on carcinogenic arylamines could result around 40 deaths per year. Using ECU 2.2 million as an estimate of the mean value of a statistical life, the carcinogenic risks associated with the arylamines of concern can be valued at ECU 85 million.

Most commonly, replacements for azo dyes are based on other arylamines with new coupling components. Given that as many as 300 different azo dyes may need to be replaced, that each dye may be replaced with a number of alternatives and that many of these alternatives have not yet been developed, it is difficult to comment on the associated human health risks. That said, the replacement arylamines should be less carcinogenic than those which they replace and thus should reduce risks associated with fatal cancers.

With respect to the environment, the sale and use of dyed garments pose little risk and any impacts associated with the replacement of certain azo dyes will be small.

7. THE TRADE-OFFS

In risk-benefit terms, restrictions on azo dyes are justified if the reductions in risk outweigh the costs of implementation. If it is assumed that end product prices will increase by 1% and that this increase is passed onto the consumer, then taking the turnover of the EU clothing sector as ECU 63.7 billion per annum and assuming that 5% of all clothing is associated with the affected azo dyes, these associated end product price increases could be around ECU 32 million per annum.

Given that the carcinogenic risks associated with the arylamines of concern can be valued at ECU 85 million (and setting aside all other costs and benefits), restrictions on affected azo dyes would be justified if testing costs were less than £53 million per annum, in other words if there were fewer than 350,000 tests per annum (at ECU 150 each). Thus, each of the 60,000 EU-based clothing companies would need to undertake only 6 tests per annum for the costs of restrictions to outweigh the benefits.

With respect to trade-offs between key groups in the chain of trade, in the first instance, costs will be incurred by producers and importers, however, it is likely, that these costs will eventually be passed onto consumers. Thus, as would be expected, benefits accrue to some consumers while the remainder bear the increased costs of end-products.

As a result of an EU-wide ban, imports of dyes, dyed raw materials and finished goods into the Community are likely to decline to some extent, at least in the short term. Exports from the EU may also decline as companies are unable to supply demand for garments dyed with the restricted azo dyes outside the EU. In the longer term, imports of goods into the Community could possibly regain some of this lost ground as a result of moves such as the development of alternative dyes by suppliers and suppliers being able to provide certificates of compliance which can be trusted.

8. CONCLUSIONS AND RECOMMENDATIONS

The introduction of national legislation has led to costs to industry which, in the main, have been associated with the need to demonstrate compliance with legislation. Although other costs have been incurred, industry perceives these to be small when compared with those arising from testing and certification (see Section 5).

Industry feels that if legislation restricting the use of azo dyes is necessary (i.e. if the risks are found to be unacceptable) then legislation should be harmonised at a European level to reduce impacts upon them. The findings of the risk-benefit analysis support this view.

> ***Recommendation 1**: Restrictions on the use of azo dyes should be harmonised at an EU level.*

> ***Recommendation 2**: One of the aims of harmonisation should be to address some of the problems experienced by industry in meeting the requirements of national bans.*

***Recommendation 3**: Decisions concerning the control of hazardous substances should be based on a thorough consideration of the risks posed by a substance and its alternatives and of the costs and benefits of a range of control options.*

1. INTRODUCTION

1.1 Background to the Study

In 1993, the German Government notified the European Commission (EC) of its proposed ban (notification 93/243/D) on certain consumer goods dyed with azo dyes which may release, through reductive cleavage, one of 20 listed arylamines. This decision results from concern that these arylamines may be carcinogenic to humans once internalised.

Since April 1996, it has been an offence in Germany to use azo dyes which may release the banned arylamines in the manufacture of most skin contacting consumer goods. Furthermore, it will be an offence from the beginning of 1999 to sell the majority of skin contacting consumer goods which have been dyed with the affected azo dyes and so which may release the banned arylamines. The Dutch and French Governments have also implemented similar bans to that notified by the German Government and Austria, Denmark and Sweden are expected to be preparing similar domestic legislation, although formal notifications have not been received by the EC.

In order to harmonise the single market, extension of these bans is being considered by the EC.

1.2 The Aims and Scope of the Study

The EC wished to establish the net advantages and drawbacks (particularly to human health) of banning certain azo dyes and using alternatives, and sought an analysis of the economic effects on Member States of such a ban. This study was principally concerned with examining the advantages and drawbacks of banning the affected dyes and products dyed with them which are intended to come into contact with the skin.

The study intended that the overall advantages of implementing a Europe-wide ban should be examined through an analysis of the reduced risks to human health, while taking account of any increases in human health risks from the use of alternatives. Drawbacks to the ban were considered in terms of the effects on trade, and the Study Specification specifically requested examination of the following:

- effects on EU external trade and on the internal market;
- effects on importers;
- effects on producers, e.g. the textile and leather industry;
- effects on consumers; and
- overall effects on intra-Community trade.

This study was one of three concurrent contracts undertaken with respect to European azo dye legislation. The other two studies were a risk assessment undertaken by the Laboratory of Government Chemists (LGC) and an assessment of the impacts on developing countries of an EU-wide ban undertaken by ERM Economics. Thus, work for this study was carefully targeted so as not to overlap with that for the other two contracts.

1.3 Approach to the Study

Overview of Risk-Benefit Analysis

The study objectives were met through the application of Risk-Benefit Analysis techniques. This approach builds on that which has been established for similar studies in the European Union (EU) and work which has been undertaken in the UK on the development of Risk-Benefit Analysis. For example, it draws on previous work on the development of risk-benefit methodology: *Risk Benefit Analysis of Existing Substances* (DoE, 1995); *Risk Benefit Analysis of Hazardous Substances* (RPA, 1992); and *Draft Technical Guidance Document on Development of Risk Reduction Strategies*, produced for the EU for use under the Existing Substances Regulation (EEC 793/73)[1].

A Risk-Benefit Analysis approach can help to improve consistency at all levels of decision making by providing a rational framework for weighing-up the advantages and disadvantages of alternative choices. It requires that risks from the use of a substance of concern are compared with the risks posed by any alternatives that would be taken-up in its place following implementation of proposed risk reduction options. Impacts on industry, the environment and human health are given separate consideration. If the benefits of control outweigh the risks or costs of 'no control' then the control action is justified. This type of assessment can be carried out at three different levels:

1) a qualitative Risk-Benefit Analysis, where the risks and benefits of each option can be described, but are not quantified;

2) a semi-quantitative, semi-qualitative Risk-Benefit Analysis, where the impacts of each option can be described but only some are quantified or valued in monetary terms; and

3) a Cost-Benefit Analysis, where all of the identified costs and benefits are quantified and valued in monetary terms.

The degree to which a fully quantified Cost-Benefit Analysis is possible depends entirely on the availability of data.

Stages of Work

The Interim Report set out, in mostly qualitative terms, the key findings of the data collection, review and consultation. Work involved literature searches of in-house CD-roms and on-line facilities, and sourcing key documents through consultation. The consultation involved contact with a range of trade associations across Europe, key companies and representatives from each Member State.

Four separate questionnaires were developed, one for distribution to the textiles and leather goods industry in general and three separate ones aimed specifically at dye manufacturers, dyers and finishers, and producers of finished goods. These were distributed to the members of trade associations via the associations themselves. Some trade associations preferred to question their members directly rather than distribute the questionnaires in order to ensure

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1 Analysis of an option to control the risks associated with a substance must take account of the effectiveness, practicality and economic impact of that option. Marketing and use restrictions must be supported by an analysis of the advantages and drawbacks of the substance and of the availability of replacement substances.

feed-back in time for the reports. Overall, the response rate to the questionnaire was very good, with 72 received in total. In addition, more general telephone discussions and detailed written responses highlighted industry's enthusiasm for involvement in the study and desire for EU harmonisation of azo dye legislation. A full list of consultees is presented in Annex 1.

Following submission of the Interim Report, the process of data collection, review and consultation continued, focusing on the collation of information to enable quantification of impacts where possible. A discussion seminar was held in Brussels by Directorate General III (Industry) involving the Dangerous Substances Working Group on azo dyes on 8th April 1997, in which the interim findings of the three concurrent contracts were discussed. As far as possible, comments and additional data provided by those present at this meeting have been incorporated into this report.

As a result of this seminar, a fifth questionnaire was developed and distributed to wholesalers and retailers (importers) of textiles and leather goods so as to ensure their full inclusion in the consultation process. A total of 31 responses were received from this group.

1.4 Structure of the Report

Section 2 provides a summary of the application of azo dyes, describing the dyes themselves and the environmental and human health risks associated with their use. Section 3 then sets out the status of EU policy, describing the current and proposed bans in individual Member States and at an EU level. As such, this summarises the regulatory requirements both with and without EU-harmonisation. Section 4 describes the nature of the dye, textile and leather goods industry across Europe, drawing out differences between Member States and setting out quantitative data where available.

Section 5 describes the affects on trade and industry of both the EU non-harmonised and EU harmonised approaches to the legislation and control of potentially carcinogenic arylamines from azo dyes. This analysis uses the trade data described in Section 4, the findings of the questionnaires, consultation, company statements, discussion documents and formal responses to the notifications and German Amending Ordinance to quantify impacts where possible. Section 6 discusses the impacts of both EU non-harmonised and EU harmonised approaches to legislation on human health and the environment. Section 7 sets down the trade-offs associated with the existing and proposed legislative frameworks while conclusions and recommendations are presented in Section 8.

2. AZO DYES

2.1 Introduction

Since the 1960s it has been acknowledged within the 'western' dyeing trade that certain azo dyes pose health risks. However, these risks are not presented by all azo dyes. It is important in identifying the advantages and drawbacks of a pan-European ban to identify which substances are of concern.

This Section describes the dyeing process and the extent to which azo dyes are used. Azo dye application within the textiles and leather industry is then set out, together with the benefits of using them. These benefits are then compared with the risks to the environment and human health arising from their use.

2.2 Azo Dyes in the Dyeing Process

2.2.1 The Dyeing Process

The dyeing process is very complex with the desired colour usually being achieved through the mixing of various dyes. Consultation suggests that this is undertaken by trial and error, despite the increasing computerisation of the industry. As such, resulting colours are often reliant on the skill of the dyer and their experience with different dyes (pers comm, 1997).

Current estimates suggest that there are around 38,000 different colorants and between 7,000 to 8,000 individual chemical structures listed on the Colour Index List (CBI, 1996). As not all dyes are listed, it is considered that there may be more than 10,000 individual dyes available (EFTA, 1996; pers comm, 1997).

Dyes are not used at 100% concentration but are diluted and may have cutting agents added prior to use. For textiles, the average concentration of dye in the resulting solution is around 4% to 5%. For leathers, a greater concentration is required, around 8% to 10%, due to difficulties with dyes being taken-up by the substrate (pers comm, 1997).

In addition to being classified by their colour, dyes are also classified by their application properties and their chemical structure. Those dyes commonly used in the textiles industry fall into one of eight application groups[2] (EFTA, 1996):

- acid;
- azoic or naphtol;
- basic;
- direct;
- disperse;
- reactive;
- sulphur; and
- vat.

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[2] Pigments are also used to colour materials but as these form a separate group of insoluble colorants they are outside the remit of this study. As there has been confusion over the terminology used by the German Government and its interpretation by industry, it should be noted that in this Report, use of the word "dye" is not intended to include "pigment" and the word "colorant" is used to include both "dyes" and "pigments".

The most commonly used group of dyes is reactive dyes, followed by vat dyes due to the long lasting nature of the colours offered (EFTA, 1996). Each of these groups tend to be applied to different substrates, for example acid dyes are applied to natural protein fibres such as wool and silk, direct dyes are applied to cellulosic fibres (cotton and rayon), while disperse dyes are applied to synthetic fibres. While these groups may have an affinity to particular substrates, their use on other substances may also be acceptable (Besnoy, 1986).

In terms of colour, each specific dye is unique in the qualities it offers the dyer and the consumer. The 'scope' of a dye determines the range of shades that it can achieve on the substrate to which it is applied. For example, one dye may have a very similar hue to another, but the ability of the two dyes to achieve a broad range of shades in, say, the bright red area of colour may be very different. Similarly, specific dyes offer very particular characteristics with respect to 'metamerism'. This is the aspect of a dye which shows different colours under different lighting conditions (Besnoy, 1986).

The choice of actual dye used is further dictated by a number of application and physical factors. These may include the following: colour fastness (in wet conditions, under normal handling, and also in light); speed of transfer of dye onto the substrate being dyed (and so mechanical processes available); 'substantivity' of a dye (i.e. its affinity for different substrates); rate of build-up (i.e. the relationship between adding more dye and the depth of shade achieved); solubility; stability once mixed-up; reactivity to pH changes during the dyeing process; staining characteristics (for example, whether in a fabric of mixed substrates the dye will stain each differently); foaming characteristics, which in turn affect the mechanical and temperature of processes to which it can be applied; and finishing characteristics (i.e. the extent to which the resulting shade is affected by any finishing applied to the fabric).

When mixing more than one dye, the properties of each dye in the mixture need to be considered in terms of the above factors, and their compatibility established. The cost of the dye is also a significant factor in a dyer's decision to use a particular dye.

2.2.2 Application of Azo Dyes

As outlined above, dyes are classified by their colour, their application properties and also their chemical structure. All azo dyes are similar in terms of their chemical structure with other chemical structures including anthraquinone and methine (Besnoy, 1986). In the azo group of dyestuffs, literature suggests that there are around 3,000 azo colorants (including pigments) and 2,000 actual azo dyes (excluding pigments; EFTA, 1996; pers comm, 1997). Azo dyes therefore comprise around 20% of all available dyes (by dye type). Of the above dye application groups, azo dyes can be acid, azoic/naphtol, basic, direct or disperse dyes but are most commonly direct (EFTA, 1996). A description of each of these is given in Table 2.2(a).

2.2.3 Structure and Method of Azo Dye Production

In terms of chemical structure, an azo compound takes the form of R-N=N-R (where R is an aromatic ring). Thus, a double nitrogen bond forms the join between two aromatic amines (or arylamines). To produce azo dyes requires diazotisation of an aromatic amine (or arylamine) to form a diazonium salt. This is then reacted with a coupling component (Dti, 1997). The coupling component may or may not be another arylamine, and it is the mixture of the amine and the coupling component and the relationship between them which gives a dye its resulting colour (pers comm, 1997).

Table 2.2(a): Description of Dyes which may be Azo Dyes			
Dye	**Materials Applied to**	**Description**	**Benefits**
Acid	Wool Silk Nylon	Dye baths are mixed with formic acid, acetic acid or sulphur acid	Mediocre fixing efficiency
Azoic or Naphtol	Cotton	Mainly used for bright red colours	High efficiency Good colour fastness
Basic	Natural fibres Polyacrylic	These are cationic colouring agents	
Direct	Cotton Flax Rayon	Consist mainly of (poly)azo components Dyeing usually occurs in a dye bath containing salt or acid	Good colour fastness Short and easy dyeing process, so cost efficient
Disperse	Synthetic fibres	Consist of azo or anthraquinone compounds	Dyes are washable Mediocre fixing efficiency
Source: EFTA. 1996.			

There are two types of amine available, aromatic/aryl and aliphatic. As described above, arylamines are ringed in nature, while aliphatic amines are chained. This makes arylamines more stable during the required coupling process, whereas the aliphatic amines would decompose before or during the coupling process (pers comm, 1997). In general, arylamines are reactive, cheap and convenient and also make stable and technically good products.

2.3 Use and Benefits of Azo Dyes

2.3.1 General Application

Azo dyes have been used for many years in the textiles, printing, cosmetic, drug and food industries. In addition, azo dyes are used by customs as permanent markers for petroleum products, as well as for detecting flaws in welded steel (pers comm, 1997). Within the textile and leather industry, they are used to colour a wide range of common items from toys and bedclothes through to wigs and spectacle frames.

Consultation suggests that in the textile and leather goods industry azo dyes tend to be used mostly on cotton and wool and to some extent silk and leather (pers comm, 1997).

2.3.2 Extent of Use

Between 60% and 80% of dyes currently in use (by volume) are azo dyes[3] and they represent about 65% of the total dye market (pers comm, 1997; Dti, 1997). Data from 1991 suggest that the European market for textile dyestuffs was around 87 thousand tonnes, valued at ECU 847

[3] Quantities and values stated in this paragraph relate to all azo dyes and not just those which are associated with the 20 arylamines restricted by German legislation.

million ($US 1,084 million). Of this, therefore, azo dyes can be estimated to comprise between 52 and 70 thousand tonnes of dyes, valuing around ECU 547 million ($US 700 million; SRI, 1993). Data to suggest differences in use by Member State have not been identified.

2.3.3 Trends in Production and Use

Trends in the production and use of certain azo dyes have been affected by voluntary bans and regulation within Member States in Europe since the 1960s, following evidence of increased risk of bladder cancer amongst exposed dye workers.

In 1957, a voluntary code of practice for carcinogenic amines was established by the Association of British Chemical Manufacturers following evidence in 1954 that benzidine-based dyes induced bladder cancer in workers. In the UK, the use of benzidine- and 2-naphthylamine-containing azo dyes was banned in 1967 under the Carcinogenic Substances Regulations. Thus, in the UK, manufacture ceased in the late 1960s. In Germany, Switzerland and Japan, major producers ceased manufacture of benzidine-based dyes in the early 1970s. In Italy, Spain, Holland and France, minor production continued until the last manufacturer (Zeneca/Francolo) ceased production in about 1982[4] (UK and ETAD, 1996).

Benzidine and 2-naphthylamine were the two most commonly used substances in dyestuffs at that time and alternatives have been produced since their ban. However, directly comparable alternatives in terms of technical quality and low price have still not been identified. This has meant that much of the demand in Europe for these dyes has been met by importers from developing countries, such as Argentina, Brazil, China, India (who produced an estimated 4,000 tonnes in 1993, of which 50% was sold for export), Korea, Mexico and Taiwan (UK and ETAD, 1996). Thus, while the risks to European manufacturers of these dyes have been reduced, risks to European dyers and the dye manufacturers in developing countries are still present.

European producers of dyes have been preparing for other legislation to control the European use of benzidine-based dyes and other azo dyes. Thus, on the whole, they have been developing alternatives since the 1970s. In most cases, the up-take of these dyes has not been good due to them being of more expensive than those produced and imported from developing countries (see Section 5.2 for further information).

2.3.4 Benefits of Use

Azo dyes are particularly favoured due to their apparent technical excellence, the wide range of shades and brilliance of the colours offered and comparatively low price (pers comm, 1997). As set out above, the arylamines used in azo dyes are chemically valuable as they are reactive, easy to handle, inexpensive and convenient. In addition, as they have been used in dyes since the end of the 19th century, they are well established within the dye trade.

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[4] This was apparently a buy-out deal insisted upon by ICI (pers com, 1997).

2.4 Concerns with Current Use

2.4.1 Overview

On the whole, risks and concerns arising from the current use of some azo dyes relate to the human carcinogenicity of some of the component arylamines. As set out in Section 1, it has not been within the remit of this study to undertake a detailed assessment of the risks to human health from arylamines and, indeed, care has been taken to avoid overlap with work being undertaken by the other two concurrent contracts. As the results of the risk assessment are not yet available, however, a general discussion of the risks posed by some arylamines is presented below. The aim of this is to provide some background context against which to make a preliminary assessment of the change in risks and benefits to human health of moving to alternative dyestuffs. As such, it is not intended to provide an exhaustive examination of current data.

As well as an assessment of changes in human health risk, Risk-Benefit Analysis requires consideration of the change in environmental risk associated with moving from a substance of concern to alternatives. Thus, a short discussion of the environmental risks associated with azo dyes is presented, although specific data with respect to the arylamines under consideration are not available.

2.4.2 Carcinogenic Potential

Azo dyes themselves are not necessarily carcinogenic or toxic. However, some of the component arylamines are carcinogenic. For these cancer causing components to become available within the human body (i.e. bioavailable), the azo groups which make-up the dye need to be reductively split into the corresponding arylamines. As the arylamines are bound in the molecule of the dye, it was initially considered that they were secure and not able to cleave. However, studies have identified that reductive cleavage can occur in the human gut through reactions stimulated by liver enzymes and intestinal bacteria (Dti, 1997). The arylamines may also be released during storage through exposure to light or heat (CBI, 1996; pers comm, 1997).

Basically, there are two types of arylamines - water soluble and fat soluble. Water soluble arylamines are characterised by the sulphonic group and these are not carcinogenic. It is only some of the fat soluble, lipophilic arylamines (which are not water soluble) which show carcinogenic potential. Although the arylamines of concern are fat soluble, they can be made into water soluble dyes. Thus, it is the water soluble azo dyes which, on reductive cleavage, form fat soluble/lipophilic arylamines that may be carcinogenic to humans which are of concern to this study (pers comm, 1997).

In 1989, a study produced by the Massachusetts Institute of Technology (MIT) in the US demonstrated that azo dyes can be made to 'run' by sweat and are then able to enter the blood stream via the skin (OJ No C 125, 1990). In terms of consumer risk from wearing garments dyed with azo dyes, the issue is whether the dye can enter the skin and then the arylamine become bioavailable. Recent risk assessments (for example that awaited from the Laboratory of Government Chemists commissioned by the EC) have apparently therefore focused on which of the arylamines within azo dyes can become bioavailable through extended skin contact, and which of these have similar structures to pre-determined carcinogenic groups.

2.4.3 Benzidine- and 2-Naphthylamine-based Dyes

For over 100 years, it has been recognised that workers involved in the production of benzidine-based azo dyes suffered increased incidents of bladder cancer (see Rehn 1895, cited in Brown & DeVito, 1993). In the 1930s, studies undertaken by ICI and Ciba confirmed that both benzidine and 2-naphthylamine caused increased incidents of bladder cancer among workers (pers comm, 1997). However, it was not until an extensive study undertaken over a period of 30 years was published in 1957 (Case et al, cited in Brown & DeVito, 1993) that conclusive evidence was provided that benzidine was carcinogenic. Similar reports of high risk were also produced in Japan, France, the US, Russia and Germany. One retrospective study of workers from just one factory clearly highlighted the degree of risk, with 17 out of 76 workers exposed to benzidine developing bladder tumours (in UK and ETAD, 1996).

In evidence provided by the US Environmental Protection Agency (EPA) for its proposed restrictions on the manufacture, processing and/or import of benzidine-based substances, 12 dyes are listed as metabolising to benzidine in animals. Of these, Direct Black 38 (CAS No. 1937-37-7), Direct Blue 6 (CAS No. 2602-46-2) and Direct Brown 95 (CAS No. 16071-8-6) showed statistically significant, dose-related incidents of tumours in the liver, skin and Zymbal gland over five and thirteen weeks following oral administration (Federal Register, 1995).

These benzidine-based dyes are classified by the International Agency for Research on Cancer (IACR) as Group 2A chemicals. As such, they are carcinogenic in animals and are probable carcinogens in humans and similar toxicity is expected from all benzidine-based dyes. Furthermore, NIOSH recommends that all benzidine-based dyes are recognised as potential human carcinogens (Federal Register, 1995).

The Dutch Government (Rijksinstituut voor Volksgezondheid en Milieu; RIVM) prepared a risk analysis of arylamines released by azo dyes prior to implementing an associated ban. In this, they list benzidine and 2-naphthylamine as "Category 1" and state that "It is known that benzidine and its salts can be readily absorbed through the intact human skin". Severe, recurrent eczematous dermatitis has been evidenced following acute exposure and dermal sensitisation and contact dermatitis has been reported following chronic exposure. Through occupational exposure, benzidine is, therefore, described as being "causally associated with an increased risk of bladder cancer" while 2-naphthylamine is described as being "causally associated with the occurrence of bladder cancer" (RIVM, 1996).

2.4.4 Other Arylamines

Although the focus of concern has been on the carcinogenic properties of benzidine- and 2-naphthylamine-based dyes, there is also concern that other azo dyes may reductively cleave into potentially carcinogenic arylamines. For example, in its restrictions on benzidine-based dyes, the US EPA recognised that benzidine-congener-based dyes, including tolidine- and non-metallised dianisidine-based dyes, may also pose similar risks (Federal Register, 1995).

In the RIVM risk analysis (1996), o-tolidine (also known as 3,3'-dimethylbenzidine) and o-anisidine are both listed as "Category 2B". It reports that no conclusive epidemiological data on occurrence of cancer in workers are available. Tests in animals (mice, rats and hamsters) suggest that forestomach papillomas and transitional cell carcinomas of the bladder may result from internalisation of these arylamines. The metabolism of o-tolidine is known to be similar to that of benzidine and it is "readily absorbed through human skin" (RIVM, 1996). Under the requirements set by Regulation 793/93/EEC, the Austrian Ministry of the Environment is undertaking a risk assessment of o-anisidine which is currently at its first draft stage.

1-naphthylamine and aniline are both listed in the RIVM risk analysis as "Category 3". 1-naphthylamine appeared to cause "an excess occurrence of bladder cancer" in workers exposed for over five years. However, as the analysis states, 1-naphthylamine may, at that time, have contained 4-10% 2-naphthylamine and tests on mice, hamsters and dogs were inconclusive. Similarly, tests on mice also provided insufficient data with respect to the carcinogenicity of aniline (RIVM, 1996).

Table 2.4(a) summarises the level of proof of human carcinogenicity for some arylamines.

Table 2.4(a): Summary of Human Carcinogenicity of Some Arylamines

Arylamine	Evidence of Human Carcinogenicity
2-naphthylamine	Good evidence
4-biphenylamine	
Benzidine	
N,N-bis (2-chloroethyl)-naphthylamine	
N-phenyl-2-naphthylamine	Some evidence
2,5-diaminotoluene	Slight evidence
3,3'-dimethylbenzidine	
4,4'-methylenebis (2-chloroaniline)	
1-naphthylamine	Slight evidence but intermixed with other amines
3,3'-dichlorobenzidine	
3,3'-dimethoxybenzidine	
4-nitrobiphenyl	
Magenta	
Auramine	Slight or None
3,3'-dimethyl-4-chlorobenzidine	None
Aniline	
Anthranelic Acid	

Source: Cartwright. 1983 as cited in Brown & DeVito. 1993.

2.4.5 Specific Azo Dyes

In terms of tests on specific dyes, the IACR have, to date, tested 34 azo dyes for carcinogenicity (1975; 1982) and found that three were "probably carcinogenic to humans" from the 'commercial material', with these being Direct Black 38, Direct Blue 6 and Direct Brown 95 (all benzidine-based, as cited above). A further eight were "possibly carcinogenic to humans" and for the remainder results were inconclusive (OJ No C 125, 1990; Brown & DeVito, 1993).

The Finnish Government considers azo dyes to be sensitisers and reports several cases of anaphylactic and delayed hypersensitivity reactions, including various respiratory difficulties and urticaria. The most common 'azo dye agents' causing contact dermatitis are reported to be (NPCAWH, 1997): Disperse Yellow 3; Disperse Yellow 4; Disperse Orange 3; Disperse Orange 76; Disperse Black 1; Disperse Black 2; Disperse Red 1 and Disperse Blue 124.

Acute toxicity tests undertaken by ETAD on over 4,000 dyes identified that only about 1% (i.e. 40) were toxic. Of the remainder, about 90% showed either very slight or no toxicity and the rest (about 9%) fell somewhere in-between (EFTA, 1996).

2.4.6 Environment

In general, environmental risks stemming from the dyeing industry are associated with the use and disposal of dyes, for example contamination and pollution of surface water. Some of the arylamines potentially released from azo dyes, for example 4,4'-methylenedianiline (CAS No. 101-77-9), are listed under European Legislation as being dangerous for the environment as well as to human health and so must carry the appropriate warning. As concerns over azo dyes have been focused on the human health risks associated with the carcinogenicity of component arylamines, few studies have been identified which describe their specific environmental risks. However, some data are presented in Table 2.4(b) for certain arylamines.

Table 2.4(b): Environmental Risk from Arylamines

Arylamine	Ecotoxicity	Bioaccumulation Potential	Environmental Fate
4-aminobiphenyl	High	Medium	Moderate biodegradation in water and soil
benzidine	High	Low	Moderate biodegradation in water and soil
2-chloro-o-toluidine	No Data	Medium	Rapid photo-oxidation; slow biodegradation in water and may bind irreversibly to soil
2-naphthylamine	No Data	Medium	Moderate photo degradation. Slow biodegradation in soil
p-chloroaniline	High to Moderate	Low	Rapid photo-oxidation and rapid to moderate bio- and photo degradation in soil
4,4'-methylenedianiline	High	Low	May bind strongly to humic material, slow biodegradation
3,3'-dichlorobenzidine	Very High	High	Slow biodegradation in soil and water and possible rapid photo-degradation
3,3'-dimethoxybenzidine	Low	High	Moderate to slow biodegradation in soil and water. May bind irreversibly to humic acids and be reversibly oxidised by metal ions.
4,4'-methylenebis (2-chloroaniline)	No Data	Medium	Slow biodegradation in soil water evidenced. Photo degradation possible as well as irreversible binding to humic acids
o-toluidine	High to Moderate	Low	Rapid biodegradation in soil and water. Possible irreversible binding to humic acids
o-anisidine	No Data	Low	Rapid photo-oxidation in air. Slow biodegradation in soil and water. Small amounts will be ionised at neutral pH

Source: Croners. 1997.

3. THE POLICY CONTEXT

3.1 Introduction

To establish the impacts of an EU-harmonisation of legislation to control the carcinogenic risks from the arylamines of concern (i.e. those which, through reductive cleavage, may be released from azo dyes and associated consumer goods), it is necessary to set out the current regulatory framework. As described in Section 2, concern over the use of some azo dyes has stemmed from the carcinogenic risk posed by benzidine-based dyes. In Europe, attempts to control risks to human health from some azo dyes began in Germany and were followed by similar action in the Netherlands and France. Other Member States are also in the process of implementing their own domestic legislation. This is permitted under the criteria of proportionality whereby Member States may take action above and beyond that required under Commission Directives if it is the only method by which human life can be protected.

The current situation is described below in terms of the legislation which may occur in Europe without EU-harmonisation. As the German ban forms the basis for other Member State bans, this is given more detailed discussion. The framework under which EU-harmonisation can occur is then described, and the hypothetical method of implementation is set out.

3.2 The Current Situation

3.2.1 The German Ban

Background and Development

In 1993, the German Government notified the European Commission (EC) of its proposed ban (to take effect in 1995) under their Consumer Goods Ordinance (notification 93/243/D) of certain azo colorants which may break down into one of the following 20 listed arylamines:

Arylamine	CAS Number
4-aminobiphenyl	92-67-1
benzidine	92-87-5
2-chloro-o-toluidine	95-69-2
2-naphthylamine	91-59-8
o-aminoazotoluene	97-56-3
5-nitro-o-toluidine	99-55-8
p-chloroaniline	106-47-8
4-methoxy-m-phenylenediamine	615-05-4
4,4'-methylenedianiline	101-77-9
3,3'-dichlorobenzidine	91-94-1
3,3'-dimethoxybenzidine	119-90-4
3,3'-dimethylbenzidine	119-93-7
4,4'-methylenedi-o-toluidine	838-88-0
6-methoxy-m-toluidine	120-71-8
4,4'-methylenebis (2-chloroaniline)	101-14-4
4,4'-oxydianiline	101-80-4
4,4'-thiodianiline	139-65-1
o-toluidine	95-53-4
4-methyl-m-phenylenediamine	95-80-7
2,4,5-trimethylaniline	137-17-7

The above list stems from a list of substances which are classified by the German MAK Commission as carcinogenic in terms of occupational exposure, MAK III A1 and MAK III A2 (ETAD, 1993; pers comm, 1997). Consultation suggests that this initial notification followed the strengthening of voluntary eco-labelling within Germany over the previous five to six years. In order to display the desired (and in some cases required) eco-labels (for example the Ökotex 100 range of labels) suppliers had to prove that their products did not contain or release the above-listed amines. Legislation was, therefore, less stringent than the voluntary requirements and the German Government apparently wished to bring legislation in line. However, consultation suggests that there are arylamines (p-aminoazobenzidine [60-09-03] and o-anisidine [90-04-0]) which are listed as being banned in terms of eco-labelling but not in terms of domestic legislation (although these are generally considered not to be bioavailable; pers comm, 1997).

Since first notifying the EC in 1993, the German Government has proposed a total of five Amending Ordinances to the initial ban, which have postponed the implementation of the initial ban on several occasions. Thus, the German ban has still not been fully implemented.

Intra-Community Trade

The delay in implementation has been due, in part, to complaints that the ban would create a barrier to intra-Community trade. Although Member States are permitted to create such barriers through implementation of national legislation to protect human life, for example, this is only permissible where national actions are "in proportion to the objective being pursued and where that objective cannot be achieved through measures which have a less restrictive effect on intra-Community trade" (pers comm, 1997). The Commission's view was that this criterion had not been met in this case and, in September 1996, the EC informed Germany that it was infringing the criteria of proportionality. As a result, the ban was postponed.

The recently adopted 5th Amendment (96/404/D) took account of the EC complaint (i.e. the Ordnance is now sufficient under the criteria of proportionality). The amendment made it an offence in Germany, from April 1996, to use azo dyes which may reductively cleave any of the banned arylamines for the manufacture of consumer goods (although this is delayed until April 1997 for leather goods and 2000 for recycled textiles). From the beginning of 1999, it will also be an offence to sell consumer goods which may release the banned arylamines (although this is delayed until 2000 for recycled textiles and does not affect secondhand goods or protective clothing such as uniforms).

Goods Affected

Under the German ban, no component of any good which may "have more than temporary contact with the skin" may contain or release any of the banned arylamines. For a while this caused confusion among the textile and leather industry, but the 5th Amendment has provided more guidance in this area. An indication of the type of goods covered are listed as clothing, bedclothes, towels, masks, hair-parts, wigs and artificial eyelashes, jewellery, money bags, chair covers, diapers and other sanitary items. With respect to leather goods in particular, watch straps and leather breast pouches (popular in Germany to carry personal papers around the neck, under clothing) are included.

Testing and Compliance

The German Consumer Goods Ordnance prevents the manufacture or sale of consumer goods which release concentrations in excess of 30 mg/kg of the banned arylamines when tested[5]. To ensure adherence to the criteria of proportionality, the EC has requested mutual recognition of the test results from other Member States. To this end, the 5th Amendment sets out that the German authorities accept tests undertaken in other Member States as evidence that the banned arylamines will not be released.

Some reports indicate that there is no standard test agreed by the Länder (responsible authorities in Germany) and so results are accepted from the three available gas chromatography techniques (Dti, 1997). However, consultation suggests that the German Government has notified the EC of one standard test for textiles but has not yet put forward one standard test for leathers (pers comm, 1997).

Despite efforts being made by the Federal Institute for Consumer Health Protection and Veterinary Medicine, the German Government conceded to the EC in 1995 that a reliable and repeatable test method did not yet exist (pers comm, 1997). It is commonly agreed that the available tests are highly variable in their results and there are concerns within the textile and leather industry that false positives are achieved (Dti, 1997; pers comm, 1997). Furthermore, the German ban requires that the 'consumer good' be tested and this is interpreted differently both between laboratories and between Member States (pers comm, 1997). These and other issues pertinent to implementation of and compliance with any restrictions on arylamines released from dyestuffs are given further discussion in Section 5.

Two provisional analytical methods published prior to September 1996 were (ETAD, 1996):

- the Bundesgesundheitsblatt 2/96, 78-81 which is particularly applicable to cellulose and protein fibres; and
- Norm Entwurf DIN-NMP 552 Nachweis von Azofarbstoffen in Ledern, die bei reduktiver Spaltung der Azo gruppe bestimmte primäre aromatische Amine freisetzen, which is applicable to leather (although other sources refer to test method DIN 53316 for leathers and it is unclear whether these are different).

3.2.2 Other Individual Member State Bans

The Dutch Ban

The Dutch azo dyes ban came into force on the 1st August 1996. It relates to clothing, footwear and bedding which release the same selected arylamines as those listed under the German ban. Items may be sold until September 1997 which release the banned arylamines if they were ordered prior to August 1996. Furthermore, second hand items, protective items and items produced from "recovered fibres" which release the banned arylamines may be sold in the Netherlands until 2000.

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5 Initially the German Ordinance required that no level of a restricted arylamine should be released through reductive cleavage from a consumer good. However, as this proved to result in a large number of false positives, the level was increased to what is now 30mg/kg.

Although implementation of the German ban began before the Dutch ban was drafted, the Dutch ban has been implemented first. Before its implementation, wide consultations were held with manufacturers, consumers and importers. It is because this last group needed time to clear their existing stocks, that a time-lag was incorporated into the legislation.

Literature suggests that, as appears to be the case for the German ban, no standard test method has been declared, although two are put forward in the legislation (CBI, 1996). Confusion has been caused in test houses and industry, however, as the legislation stipulates that either 3 or 30 mg/kg of banned arylamine are permitted, depending on the test method employed. Consultation with Dutch authorities has confirmed that it is intended for the regulations to be amended such that the permissible limit is 30 mg/kg (not 3 mg/kg; pers comm, 1997). If the 3 mg/kg prevailed then the likelihood of false positive results would increase.

The Dutch authorities are currently investigating the feasibility of implementing wider azo dye bans with respect to their use in other sectors (such as food and paper).

The French Ban

It is understood that France has been circulating its draft intentions since 1995 and at the Commission's meeting in Brussels (8th April, 1997) the French authorities stated that they notified the Commission of their domestic azo dye ban in the middle of March (CBI, 1996; pers comm, 1997). No further details of the French legislation were available but it is expected that the ban is similar to that prescribed by Germany.

Austrian Proposals

A similar ordinance to that being implemented by the German authorities is planned by the Austrian Ministry for Health. Discussions to this effect have been held by the Austrian Committee on Articles of Daily Use (established by the Austrian law on food stuffs - Codexkommission gemäß Lebeensmittelgesetz, 1975). Both the Ministry for the Environment and the Ministry for Health have undertaken studies to this end.

Implementation of an Austrian ordinance would be based on the substances listed on the MAK-Werte Liste (referring to workplace exposure), published by the Austrian Ministry of Labour and Social Affairs. It is understood that this would place restrictions on the release of 21 arylamines, and so would include an additional arylamine to that restricted under the German and Dutch bans. Indeed, the Austrian Federal Ministry of the Environment has indicated that it is interested in as large as possible number of proven carcinogenic arylamines being included in legislation with the 20 arylamines in the German Ordnance being considered the absolute minimum (Austrian Federal Ministry of the Environment, 1997).

Other Member States

It is understood that Denmark and Sweden are also in the process of compiling their own domestic legislation with regard to similar arylamine bans, but the EC is yet to receive notification to this effect (CBI, 1996; pers comm, 1997). Sweden, for example, was expected to notify the EC of its ban in January 1997 (CBI, 1996; pers comm, 1997).

3.2.3 Summary of Non-EU Harmonisation

Although the majority of Member State bans appear to be framed on the German ban, all are slightly different. Where data permit, the differences between the German, Dutch and Austrian bans are set out in Box 3(a). As this illustrates, the consumer items covered are not the same under the German and Dutch bans (with respect to protective items).

The Dutch ban relates to the sale of goods, while the German ban also relates to the manufacture of goods. The timescales for implementation and the sectors of industry affected are also different, as importers in the Netherlands have until September 1997 to clear existing stocks, but no reference is made to this group in the German ban. In Austria, the most significant difference is that there is an additional arylamine which is not covered by either the German or Dutch bans.

Given these differences, it seem reasonable to assume that the bans by France, Denmark and Sweden may also be different. Indeed, they will most definitely differ in terms of timescales of implementation. At its worst, all of the variables within each ban may vary, such as the specified arylamines, the permitted test method and limits of detection, consumer goods affected and certain sectors of exempt industry.

Several consultees have stressed that if this current state of affairs is allowed to continue there will be chaos with respect to intra-community trade.

Box 3(a): Illustration of Differences Between German, Dutch and Proposed Austrian Bans

The German Ban:	*The Dutch Ban:*	*Proposed Austrian Ban*
Use of certain azo dyes banned for manufacture of textile consumer goods in April 1996: April 1997 for leather goods; 2000 for recycled textiles Sale of consumer goods containing certain azo dyes banned from 1999; 2000 for recycled textiles; does not affect secondhand goods or protective clothing	Sale of consumer goods containing certain azo dyes banned after August 1996 unless ordered earlier; September 1997 if otherwise; 2000 for second hand items, protective items and items produced from "recovered fibres"	Timescales not known, but will be different to both German and Dutch bans
affects: clothing, bedclothes, towels, masks, hair-parts, wigs and artificial eyelashes, jewellery, money bags, chair covers, diapers and other sanitary items	affects: clothing, footwear and bedding	affected goods unknown
none of 20 banned arylamines are permitted to exceed 30 mg/kg	none of same 20 banned arylamines are permitted to exceed 30 mg/kg or 3 mg/kg (depending on the test used)	none of 21 arylamines will be permitted to limits which are as yet unspecified

3.3 An EU-Harmonised Ban

3.3.1 Current Framework for Control

Azo dyes are not generally listed as substances which pose health risks and as a result are not subject to individual control under EU legislation. However, this is not the case for some of the arylamines on which they are based.

In order to implement an EU-wide ban, the substance to be controlled must first fulfill the classification criteria set out in the Dangerous Substances Directive (67/548/EEC) - i.e. it must be 'dangerous' as defined by the Directive. In this instance, a carcinogenic arylamine would be classified as dangerous on the basis that it represented one of a group of "carcinogenic substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidences" (Article 2(21)). Substances which have been classified by the EC under 67/548/EEC appear on Annex I to the Directive which sets out the risk phrases and labelling requirements for each of the substances listed on it.

Under the Marketing and Use of Dangerous Substances Directive (76/769/EEC), dangerous substances and preparations which are listed in its Annex are subject to specified controls. Three of the arylamines listed on the German MAK III list (4-aminobiphenyl (92-67-1), benzidine (92-87-5) and 2-naphthylamine (91-59-8)) are listed in this manner and "may not be used in concentrations equal to or greater than 0.1% by weight in substances and preparations placed on the market".

In addition to those specifically listed, the Annex to Directive 76/769/EEC also controls (Annex 1, point 29):

> substances which appear in Annex I to Directive 67/548/EEC classified as carcinogen Category 1 or carcinogen Category 2 and labelled at least as "Toxic (T)" or with risk phrase R45: "May cause cancer" or risk phrase R49: "May cause cancer by inhalation".

These substances may not be sold to the general public. The same restriction also applies to preparations which contain such a substance in a concentration higher than that specified in the substance-specific limits set out in Annex I of Directive 67/548/EEC, or in Table VI, point 6 of Annex 1 of Council Directive 88/379/EEC (which sets a limit of ≥ 0.1%). This restriction therefore applies to a further twelve of the 20 arylamines listed on the German MAK III list which are classified as Category 1 or 2 carcinogens in Annex I to Directive 67/548/EEC.

A risk assessment of o-anisidine is currently being undertaken by Austria in fulfilment of its responsibilities under the Existing Substances Regulation (793/93/EEC). A draft of the final report has been received by the Austrian Ministry of the Environment and so its findings are awaited. Given this, o-anisidine is not yet controlled under EU legislation. o-anisidine is currently controlled voluntarily by eco-labelling in Germany, but is not included on the German or Dutch list of banned arylamines.

3.3.2 Expected Implementation of an EU-Wide Ban

If an EU-wide ban on the use of specific azo dyes and products dyed with them were to be implemented, it would be to protect consumers from the carcinogenic risks associated with some arylamines. Although a number of arylamines have already been identified as potentially causing cancer, there is still uncertainty over whether the others pose similar risks. The

implementation of a ban would require identification of the azo dyes which may be taken in through the skin and which may then release one of the arylamines of concern. Identification of these arylamines is one of the aims of the risk assessment which is currently being undertaken (by the Laboratory of Government Chemists).

An EU-wide ban may either stipulate the arylamines which must not be released via a specified test from azo dyed goods, or may take the dye-specific approach and so ban certain azo dyes which are known to release the arylamines of concern. Whichever approach is adopted, implementation will be through the framework set by Directives 67/548/EEC and 76/769/EEC as described above. At the outset, it is most likely that consumer goods will be banned from sale if they release a Category 1 or 2 carcinogen under certain test conditions. It is expected that the substances controlled under an EU-wide ban may be added to over time as additional data become available.

In the absence of additional data, the Commission wishes an hypothetical EU-harmonised ban to be considered as being the same as the German ban[6].

3.4 Summary of Substances Affected

It has been particularly difficult to identify which azo dyes are affected by the German ban, the Dutch ban and potentially affected by an EU-wide ban. Several lists have been prepared which attempt to inform industry as to which azo dyes may release the arylamines banned under the German MAK III list (see for example those produced by the Centre for the Promotion of Imports from developing countries, 1996, and the European Fair Trade Association, 1997). All of these stress that they are incomplete and/or contain dyes which may in fact not release any of the banned arylamines.

As there may be between 200 and 300 azo dyes affected by the German legislation, it is not feasible for an exhaustive list to be produced. In addition, consultation suggests that some suppliers simply change the name or code of their dye while maintaining the dye formulation if one of their dyes appears on the circulating list (pers comm, 1997). It is therefore impossible to ensure that any such list is accurate and up-to-date. However, it is known that the majority of azo dyes to be affected are direct dyes (pers comm, 1997; CBI, 1996).

A comparison of the arylamines which are banned from release from consumer goods under German legislation and those which are controlled under the Marketing and Use Directive (76/769/EEC) is presented in Table 3.4(a). This table also highlights the arylamines which are currently listed as potential carcinogens under Directive 67/548/EEC (i.e. the arylamines which are included in Annex I to that Directive).

6 Pigments are not included in the hypothetical EU harmonised ban.

Table 3.4(a): Categorisation of Potentially Carcinogenic Arylamines

Arylamine	CAS No.	Controlled in Germany?			Listed in Dangerous Substances Directive 67/548/EEC?			EINECS No.	Controlled under Marketing and Use Directive 76/769/EEC?	
		Listed on the German MAK List?		Controlled under Eco -labelling?	Carcinogenic Category		Nota			
		A1	A2		1	2			As individual	As appears in 67/548
4-aminobiphenyl *(Same as biphenyl-4-amine)*	92-67-1	✓		✓	✓		E		✓	
benzidine	92-87-5	✓		✓	✓		E		✓	
2-chloro-o-toluidine	95-69-2	✓		✓						
2-naphthylamine	91-59-8	✓		✓	✓		E		✓	
o-aminoazotoluene	97-56-3		✓	✓		✓				✓
5-nitro-o-toluidine	99-55-8		✓	✓						
p-chloroaniline	106-47-8		✓	✓						
4-methoxy-m-phenylenediamine (*Same as 2,4-diaminoanisole)*	615-05-4		✓	✓						
4,4'-methylenedianiline *(Same as 4,4'-diaminodiphenyl methane)*	101-77-9		✓	✓		✓	E	202-974-4		✓
3,3'-dichlorobenzidine	91-94-1		✓	✓		✓	E	202-109-0		✓
3,3'-dimethoxybenzidine *(Same as o-dianisidine)*	119-90-4		✓	✓		✓	E			✓
3,3'-dimethylbenzidine *(Same as o-tolidine)*	119-93-7		✓	✓		✓	E			✓

Cont'd . . .

Table 3.4a): Categorisation of Potentially Carcinogenic Arylamines . . . cont'd.

Arylamine	CAS No.	Controlled in Germany?			Listed in Dangerous Substances Directive 67/548/EEC?			EINECS No.	Controlled under Marketing and Use Directive 76/769/EEC?	
		Listed on the German MAK List?		Controlled under Eco -labelling?	Carcinogenic Category		Nota			
		A1	A2		1	2			As individual	As appears in 67/548
4,4'-methylenedi-o-toluidine	838-88-0		✓	✓		✓	E	212-658-8		✓
6-methoxy-m-toluidine *(Same as p-cresidine)*	120-71-8		✓	✓						
4,4'-methylenebis (2-chloroaniline)	101-14-4		✓	✓		✓	E			✓
4,4'-oxydianiline	101-80-4		✓	✓						
4,4'-thiodianiline	139-65-1		✓	✓						
o-toluidine	95-53-4		✓	✓		✓	E	202-429-0		✓
4-methyl-m-phenylenediamine	95-80-7		✓	✓		✓	E	202-453-1		✓
2,4,5-trimethylaniline	137-17-7		✓	✓						
p-aminoazobenzene	60-09-3					✓				✓
o-anisidine	90-04-0		✓*	✓		✓	E	201-963-1		✓

Key: * = this substance is listed on the German MAK III list but is ***not*** covered by the domestic ban relating to azo dyes (pers comm, 1997).
Sources: pers comm, 1997; EC Directive 67/548/EEC; EC Directive 76/769/EEC.

4. NATURE OF DYE, TEXTILE AND LEATHER GOODS INDUSTRY

4.1 Introduction

As set out above, drawbacks to an EU-wide ban have been considered in terms of the effects on trade, and the Study Specification has specifically requested examination of the following:

- effects on EU external trade and the internal market;
- effects on importers;
- effects on producers; e.g. the textile and leather industry;
- effects on consumers; and
- overall effects on intra-Community trade.

In order to measure the trade impacts of proposed legislation, it is important to understand the nature of the industry in terms of the chain of trade, number and size of companies involved, and whether or not the trade is the same across all Member States. It is considered that impacts of both the current non-EU harmonised approach to regulation and the proposed EU-wide ban will affect the European dye industry and the textile and leather goods industry differently. This section examines the dye industry and the textile and leather goods industry separately so as to ensure that any differences between them are drawn out in the analysis. In addition, the discussion considers impacts on importers, producers and consumers where differences exist.

4.2 The Dye Industry

4.2.1 Overview of the Chain of Trade

The chain of trade with respect to the manufacture and supply of dyes is relatively straightforward. Chemical companies supply the raw ingredients which dye manufacturers then construct into dyes. Dyes can be processed or formulated by separate companies who then supply the consumer with the dye itself. Sometimes all of these processes are undertaken by one company. A large number of smaller enterprises exist across Member States, however, which import, formulate or supply dyes to consumers, but do not manufacture them. From data supplied by ETAD, it appears that there may be considerable intra-European trade in dyes. In a list of dye manufacturers and importers, around 35% are described as being dye manufacturers, but not necessarily in the Member State in which they are listed.

4.2.2 Number of Enterprises By Member State

Drawing on data prepared by ETAD, Table 4.2(a) indicates the number of dye producers and importers by Member State (for which data exist). It is understood that those companies listed as manufacturers may also import pre-manufactured dyes from outside Europe (for example from India). As such, they may also be importers of dyes into Europe, although they are only expected to supply the country under which they are listed.

From Table 4.2(a), and taking the number of companies as an indication of dye production, it can be seen that Austria, Belgium and Greece appear to be more reliant on the supply of dyes from other Member States than on their own domestic manufacturing. Italy, the UK and Germany have by far the largest number of dye manufacturers, suggesting that their dyeing industry is larger and perhaps more diverse than other Member States. Of these countries, Italy appears to be the most self-reliant in terms of dye manufacture and supply.

Table 4.2(a): EU Dye Manufacturers and Importers by Member State				
Member State	**Number of Manufacturers**	**Number of Importers***	**Total**	**Ratio of Importers: Manufacturers**
Austria	2	3	5	1.5
Belgium	3	4	7	1.33
Denmark	5	3	8	0.60
Finland	5	2	7	0.40
France	12	7	19	0.58
Germany	22	8	30	0.36
Greece	5	7	12	1.40
Ireland	0	1	1	-
Italy	34	2	36	0.06
Netherlands	13	2	15	0.15
Portugal	9	2	11	0.22
Spain	9	2	11	0.22
Sweden	5	1	6	0.20
UK	27	8	35	0.30
TOTAL	*151*	*52*	*203*	

Key: * = i.e. companies defined by ETAD as those "which are known to manufacture dyes, but not necessarily in the Member State under which they are listed".

France, the Netherlands, Greece, Portugal and Spain are all supplied by a moderate number of both domestic and importing dye companies. Ireland is unique in that its dyeing industry appears to be supplied by only one company, and this is an importer.

With respect to the European-based manufacturers and importers of dyes, the following companies appear to be present in most Member States, and so are most dominant across Europe (EFTA, 1996; pers comm, 1997; ETAD, 1995):

- Ciba Geigy (Switzerland);
- Bayer/DyStar (Germany);
- BASF/ Zeneca (UK);
- Hoechst (Germany); and
- Clariant/Sandoz (Switzerland).

4.2.3 Size of Enterprises

Number of Employees

Based on data received from three of the large Europe-wide dye manufacturers/suppliers, all of these enterprises can be expected to have more than 200 employees. Indeed, employment figures of 4,000 or 5,000 would not be unreasonable. Thus, for all of these larger companies there may be as many as 25,000 people employed in the manufacture and supply of dyes in and to Europe.

As Italy, the UK and Germany have a large number of domestic dye suppliers, it could be expected that many are smaller than the companies which supply on a Europe-wide basis. Thus, these countries, as well as perhaps France and Italy, could be expected to have a large number of niche-market production and supply enterprises.

Turnover

Dye manufacturer and supply turnover varies considerably up to around ECU 2 billion for a large Europe-wide supplier of dyes. More specific data were not available.

4.2.4 Production and Consumption

Consultation suggests that not all dye manufacturers and suppliers offer complete ranges of dyes, but specialise in one particular area of dyeing. Thus, independent dye suppliers may dominate the blue or red colour range, or cater specifically for, say, carpet or synthetic dyers.

Specific data on the level of production and consumption of azo dyes within Europe and each Member State are not available. However, it is known that azo dyes are most commonly direct dyes, with some being acid dyes. The Western European textile dyestuff market in 1991 for these two dye types and for all dyes is presented in Table 4.2(b). These data should be treated with caution, however, as consultees have warned that they may be unreliable in terms of what has been measured; for example do the statistics represent the actual weight of the dyes, or the weight in diluted form, mixed with cutting agents and at what strength?

Table 4.2(b): Western European Textile Dyestuff Market in 1991

Dye Type	Quantity (thousands of metric tons)	Value of Market ($US)	Value per kg ($US)
Direct	9	76 million	8
Acid	24	339 million	14
All dyes	87	1,084 million	-

Source: SRI International, 1993.

Consultation and written responses suggest that no 'reputable' dye manufacturers within Europe produce the dyes which may release the arylamines banned under German legislation (pers comm, 1997). For example, one large international dye manufacturer stated that they withdrew the banned azo dyes in 1992.

It is understood that European members of ETAD represent 90% or more of European dye production by volume. As all ETAD members apparently no longer produce these dyes, 10% of dye volume could contain the arylamines of concern (pers comm, 1997). For example, there are unconfirmed reports that a small amount of production is continuing in Greece (pers comm, 1997). However, as it is the application of some azo dyes that is restricted in Germany, the Netherlands and France, the dyes themselves can still be used in these countries for other applications. Consultation suggests that some European manufacturers are still producing the 'affected' azo dyes for uses other than skin-contacting clothing or for use in other sectors. For example, under occupational legislation (TRGS) in Germany, there is apparently a ban on azo solvent dyes which would cleave the carcinogenic amines. However, use is still permitted by customs for the identification of petroleum and for identifying flaws in welded stainless steel.

Despite the production of these dyes having virtually ceased by European manufacturers, their supply is still continuing from outside Europe. Table 4.2(c) sets out the imports into European Member States for acid, direct and all dyes from extra-EU countries.

Table 4.2(c): Imports of Dyestuffs into the "European Community" from "Outside Western Europe" (1992; volume in metric tons)

Supplying Country	Acid Dye	Direct Dye	All Dyes
Argentina	1101	138	1407
Brazil	271	20	434
China	1269	462	3923
Czecho-Slovakia	1030	386	1936
Egypt	21	2	107
India	1401	1211	5987
Indonesia	0	37	265
Japan	85	217	2443
Mexico	6	2	59
Poland	457	171	721
Rumania	62	5	71
Russia c.	31	18	347
South Africa	1	1	3
South Korea	154	446	1737
Taiwan	483	354	1497
Thailand	12	182	300
US	456	682	2329
Other	111	167	373
Total	6951	4501	23939

Source: SRI, 1993.

4.3 The Textile and Leather Goods Industry

4.3.1 Chain of Trade

The textile and leather goods industry supplies the clothing and footwear sectors. The chain of trade is very complex. At any stage in the chain, goods can be imported, exported or dyed. Thus, in some cases, dyeing can take place as the final process, but it is also possible for dying to be one of the first processes, even taking place prior to the production of yarn itself (such as when whole fleeces of wool are dyed before being spun).

In general terms, it is possible to specify certain processes which are undertaken in the production of clothing and other items intended to come into prolonged skin contact. These include yarn and textile production (such as weaving), dyeing, manufacturing the item itself, finishing and retailing the finished item. Some companies undertake just one process, such as commission dyers and finishers who dye batches of goods to achieve pre-determined colour specifications. There are other companies which, for example, produce yarn which is specifically bought by velvet manufacturers, who then sell onto other manufacturers for production of the finished item. There are European companies who import raw and undyed yarn, those who import pre-dyed yarn and those who produce undyed yarn and export it for dying. Thus, the supply of materials along the chain can involve a multiplicity of independent processes, or may involve just one company from yarn to garment production.

In order to compete with lower priced goods imported from outside Europe, many textile and clothing producers are decentralising to lower-cost countries, such as Morocco or Poland. For example, Poland has become one of Europe's main foreign partners in the clothing industry's 'outward processing trade', where textiles are exported for re-importation as garments (Panorama, nd).

4.3.2 Number of Enterprises By Member State

Across the whole of Europe, the EU textile and clothing industry comprises around 125,000 enterprises, with roughly 60,000 each in the textiles and clothing sectors, and 5,000 in the finishing sector (OETH, 1995). The distribution of these enterprises by Member State is presented in Table 4.3(a) overleaf.

As the data presented in the Table clearly indicate, Italy has half of the number of textile enterprises, 30% of the number of clothing enterprises and 40% of the number of finishing enterprises across the whole of Europe. In terms of the share of the number of textile enterprises, Spain, the UK, Germany, Portugal and then France have decreasing proportions after Italy. Over 90% of European textile enterprises are located in these six countries. After Italy, Germany has 20% of clothing enterprises, and this is followed by the UK, Portugal, France and then Spain. However, around 95% of European clothing enterprises are located in the same six countries as for textiles. The same countries also have the greatest number of finishing enterprises.

In general, the number of enterprises involved in the textiles sector is far greater than the number involved in the leather sector. For example, in the Netherlands, based on membership of domestic trade associations, the Dutch Government report that there are around 450 textile enterprises (which is comparable with the data presented in Table 4.3(a)), while for the leather sector the number of enterprises is less at around 70. In terms of the leather sector overall, in 1993, it was estimated that there were around 14,225 footwear enterprises in Europe; more than half of these were Italian-based (Panorama, nd).

Table 4.3(a): Number and Distribution of Enterprises By Member State and Category (1993)						
Member State	**Textiles***		**Clothing**		**Finishing**	
	Number of Enterprises	% of EU Total	Number of Enterprises	% of EU Total	Number of Enterprises	% of EU Total
Germany	5,125	8.5	11,495	19.1	695	15.1
France	3,811	6.3	6,697	11.1	385	8.4
Italy	30,679	50.7	18,956	31.5	1,990	43.2
Netherlands	310	0.5	190	0.3	25	0.5
Belgium	1,357	2.2	1,215	2.0	131	2.8
Luxembourg	17	<0.1	20	<0.1	-	-
UK	5,676	9.4	7,604	12.6	534	11.6
Ireland	201	0.3	198	0.3	-	-
Denmark	595	1.0	445	0.7	18	0.4
Spain	6,648	11.0	4,700	7.8	745	16.2
Greece	2,035	3.4	1,034	1.7	80	1.7
Portugal	4,028	6.7	7,595	12.6	-	-
EU	60,482		60,149		4,603	

Key: * this includes the industry sectors of wool, cotton, silk, linen, knitting, household textiles, flax, hemp and ramie, jute, carpets, other and miscellaneous textiles.

Source: OETH, 1995.

In terms of those trading in textile and leather goods, the Dutch Government suggests that chain stores and other retailers comprise 18,000 outlets employing around 75,000 people. With respect to shoe retailers, the Dutch Government estimates that there are around 3,750 points of sale, employing around 16,000 people. If this is taken to be an average for each Member State, then there may be around 270,000 textile and leather goods outlets employing 1 million people across the whole of Europe.

4.3.3 Size of Enterprises

Number of Employees

Overall, the number employed in the European textiles, clothing, footwear and leather sectors (excluding the retail sector) was around 2.5 million in 1994, but this has been in general decline since 1984. Between them, the textile and clothing industries employed around 2.4 million in 1993, representing about 10% of employment in the European manufacturing sector overall. The clothing industry in particular is labour intensive, employing around 1 million people in 1993, dominated mainly by employment in Italy, Germany, France and the UK (Panorama, nd; OETH, 1996).

In the clothing and textile sector, around 600,000 people are employed by "small firms". For the textiles sector alone, 72% of enterprises employed less than 20 people in 1993 (representing 233,000 in total). Slightly more enterprises in the clothing sector, 85%, employ less than 20 people (Panorama, nd). In contrast to these figures, with respect to questionnaire respondents, around 12% of companies have less than 50 employees, 55% have between 50 and 250 employees and 32% have over 250 employees[7]. It is expected that these differences are due to an under-representation of small enterprises in the questionnaire responses.

On average, the European clothing industry employs 17 people per enterprise, while the average textile enterprise employs 27 people. For the footwear sector, enterprises employ 20 people on average (Panorama, nd). However, employment by Member State and by sector may vary. For example, based on Dutch figures, it appears that an average textile and leather goods retail outlet employs 4 people, while other textile enterprises employ an average of 44 people, or 36 for leather enterprises. With respect to Portugal, the response from the Associação Portuguesa de Têxteis suggests that their textile industry is dominated by Small and Medium Enterprises (SMEs) as all replies to their questionnaire with respect to azo dye usage were from SMEs (pers comm, 1997). In terms of different sectors, the knitting industry appears to employ around 30% of the European workforce engaged in the textile and clothing industry. Indeed, the knitting industry apparently represented 39% of textile employment in Italy (OETH, 1995).

Table 4.3(b) overleaf sets out the number of employees within the textiles, clothing and finishing industries by Member State. As this clearly indicates, the Italian textile and clothing industry employs the largest number of people followed by the UK, Germany, Portugal, Spain and France. Together, employment in these countries represents over 90% of total European employment in the textiles and clothing industries (OETH, 1995).

Consultation suggests that the leather industry is traditionally a craft undertaken by small companies and this is still reflected in the size of companies and nature of the industry. Even the larger retail outlets are apparently supplied by comparatively small producers (pers comm, 1997). It has also been commented that the size of companies involved in the leather sector will differ by Member State. For example in Portugal, Spain and Greece it is expected that there is a larger number of SMEs than for other Member States (pers comm, 1997).

Turnover

As an indication of the different size of enterprises involved in the textile and clothing industries across Member States, Table 4.3(c) overleaf sets out an average turnover for enterprises in each of the three sectors. This is derived from the overall turnover by industry sector for each Member State, which has been divided among the number of enterprises for each country. The countries have also been ranked, where 1 indicates the Member State with the highest average enterprise turnover.

Table 4.3(c) illustrates that Italy has the lowest average enterprise turnover for the textiles sector. As Italy also has the highest number of employees and highest number of enterprises of all Member States for this industry sector, this suggests that enterprises are small, and perhaps that wages are low. The same also appears true to some extent for Spain and Portugal, particularly with respect to the clothing and finishing sectors.

7 These percentages become 15%, 46% and 30% respectively if wholesalers and retailers are included.

Table 4.3(b): Number of Employees and Distribution of Employment by Member State and Category (1994)

Member State	Textiles*		Clothing		Finishing	
	Number of Employees	% of EU Total	Number of Employees	% of EU Total	Number of Employees	% of EU Total
Germany	175,585	13.3	111,307	11.5	19,193	15.8
France	140,905	10.6	139,035	14.3	13,404	11.0
Italy	364,324	27.5	222,751	22.9	39,776	32.7
Netherlands	18,200	1.4	7,183	0.7	3,648	3.0
Belgium	45,326	3.4	21,772	2.2	4,163	3.4
Luxembourg	385	<0.1	376	<0.1	-	-
UK	201,957	15.3	168,757	17.4	19,794	16.3
Ireland	10,113	0.8	8,326	0.9	-	-
Denmark	12,549	0.9	8,854	0.9	698	0.6
Spain	148,368	11.2	133,483	13.7	18,561	15.2
Greece	43,594	3.3	28,015	2.9	2,528	2.1
Portugal	162,405	12.3	121,143	12.5	-	-
EU	1,323,711		971,002		121,765	

Key: * this includes the industry sectors of wool, cotton, silk, linen, knitting, household textiles, flax, hemp and ramie, jute, carpets, other and miscellaneous textiles.

Source: OETH, 1995.

For individual companies (excluding wholesalers and retailers), 52% of respondents to the questionnaire had turnovers in excess of ECU 6.2 million (£5 million) per annum. Only 5% of respondents had annual turnovers between ECU 0.62 million (£0.5 million) and ECU 1.2 million (£1 million), and the remaining 43% had turnovers of between ECU 1.2 million (£1 million) and ECU 6.2 million (£5 million) per annum[8]. Again, this implies that perhaps questionnaire responses were dominated by larger rather than smaller enterprises.

4.2.4 Production

The EU as a Whole

Over half of the textiles and leathers produced in Europe are consumed by the clothing and footwear industry. Of the textiles, clothing, footwear and leather sectors, the textiles and clothing industries represent about 85% of total production, while footwear and leather represent around about 7% (Panorama, nd). Across the whole of Europe, the textile and clothing industry had a turnover of ECU 170 billion in 1994. Of this, the knitting industry is particularly strong, generating around 25% of overall turnover (OETH, 1995).

8 If wholesalers and retailers are included, these percentages become 62%, 3% and 35% respectively.

Table 4.3(c): Average Size of Enterprises and Rank by Member State and Category (1993/94)

Member State	Textiles*		Clothing		Finishing	
	Average Turnover of Enterprises (Mn ECU)	Rank Order of Average Size of Enterprises	Average Turnover of Enterprises (Mn ECU)	Rank Order of Average Size of Enterprises	Average Turnover of Enterprises (Mn ECU)	Rank Order of Average Size of Enterprises
Germany	3.83	6	1.15	7	2.94	4
France	4.35	3	1.61	3	4.32	1
Italy	1.02	12	1.03	8	1.49	7
Netherlands	8.35	2	3.68	1	-	-
Belgium	4.3	4	1.77	2	3.14	3
Luxembourg	11.18	1	1.35	6	-	-
UK	2.18	7	0.98	10	2.26	5
Ireland	4.1	5	1.52	4	-	-
Denmark	2.13	8	1.41	5	3.39	2
Spain	1.09	10	1.01	9	0.8	8
Greece	1.04	11	0.9	11	2.1	6
Portugal	1.19	9	0.4	12	-	-

Key: * this includes the industry sectors of wool, cotton, silk, linen, knitting, household textiles, flax, hemp and ramie, jute, carpets, other and miscellaneous textiles.

Source: OETH, 1995.

On a global scale, Europe produces about 45% more textiles and clothing than the US and double that of Japan. Consumption of textiles and clothing is also very high in Europe, being 66% higher than the US in 1992 and three times that for Japan (Panorama, nd). In 1993, the textile and clothing market had a total retail value, including VAT, of ECU 230 billion (OETH, 1995).

Imports of goods into Europe from the ten major supplying countries represented 63% of all textiles and clothing in 1993 (Panorama, nd). Large imports of clothing and raw materials from outside Europe have been partly responsible for the European trade deficit in the textile and clothing industries of ECU 13 billion between 1991 and 1993, and this is expected to worsen (Panorama, nd).

In terms of exports, in 1993, around 66% of exports of textiles and clothing went to only 10 countries with the major foreign markets being the USA, Switzerland, Austria (then outside the EU), Japan and Poland. The European textile and clothing industry represents around 7% of exports of manufactured products to extra-EU countries (OETH, 1995). Despite an increase in 'outward processing trade' in the case of assembling garments (described above), textile production itself is apparently still strong within Europe.

Responses from the questionnaires suggest that the majority of textile and leather goods enterprises export their goods, with the majority of these exporting to intra-EU countries. This may be due to the Europe-wide nature of some of the larger retail outlets, such as Marks and Spencer and C&A, who are supplied from all Member States. Overall, 72% of respondents export their goods. With respect to wholesalers and retailers, all of those responding to the questionnaire have goods which are imported from outside the EU.

Differences Between Member States

Table 4.3(d) illustrates the distribution of EU turnover for textiles, clothing and finishing by Member State. As would be expected, in terms of overall turnover, the textiles and clothing industries are mainly concentrated in Italy, Germany, France and the UK. Spain also holds a moderate share of the market. Of these, Italy is by far the strongest country in terms of turnover. The share of turnover in the clothing and finishing industries in France and Germany is greater than for their share of textiles, while the UK is fairly equal across all three sectors.

Table 4.3(d): % Distribution of Overall EU Turnover by Member State (1994)

Member State	Textiles*	Clothing	Finishing
	% of EU Total Turnover for Textiles	% of EU Total Turnover for Clothing	% of EU Total Turnover for Finishing
Germany	18.7	20.9	22.4
France	15.8	17.0	18.3
Italy	29.9	30.7	32.5
Netherlands	2.5	1.1	-
Belgium	5.6	3.4	4.5
Luxembourg	0.2	<0.1	-
UK	11.8	11.8	13.2
Ireland	0.8	0.5	-
Denmark	1.2	1.0	0.7
Spain	6.9	7.5	6.6
Greece	2.0	1.5	1.8
Portugal	4.6	4.8	-

Key: * this includes the industry sectors of wool, cotton, silk, linen, knitting, household textiles, flax, hemp and ramie, jute, carpets, other and miscellaneous textiles.

Source: OETH, 1995.

For countries where data exist, Table 4.3(e) sets out imports and exports in terms of the percentage supplied to extra-EU countries and to intra-EU countries. As this shows, in terms of imports, Germany, the UK, Italy and Denmark all import more textiles and clothing goods from extra-EU countries than they do from intra-EU countries.

Table 4.3(e): % EU Internal and External Trade in Textiles and Clothing by Countries (1994)				
Member State	**Imports**		**Exports**	
	% Extra - EU	% Intra - EU	% Extra - EU	% Intra - EU
BENELUX	44	56	27	73
Denmark	56	44	54	46
France	44	56	42	58
Germany	63	37	54	46
Greece	28	72	24	76
Ireland	20	80	19	81
Italy	57	43	42	58
Netherlands	48	52	22	78
Portugal	15	85	23	77
Spain	32	68	42	58
UK	59	41	39	61
Source: OETH, 1995.				

Portugal and Ireland both import noticeably low quantities of goods from extra-EU suppliers compared with their supply from intra-EU enterprises. Greece and Spain also import comparatively low levels from extra-EU countries, while the other countries for which data exist appear almost evenly supplied.

In terms of exports, Germany and Denmark are the only Member States to supply more to extra-EU countries than they do to intra-EU countries. Over two-thirds of exports from Ireland, the Netherlands, Portugal, Greece and Benelux countries are to other European Member States.

5. EFFECTS ON TRADE OF CURRENT AND PROPOSED LEGISLATION

5.1 Overview

The general effects on trade of restrictions on the release of carcinogenic arylamines from garments dyed with azo dyes are discussed below in terms of restrictions at both national and EU levels (i.e. the non-EU and EU harmonised approaches).

The data presented draw on the responses to the questionnaires distributed to industry, as well as wider consultation and the trade information presented in Section 4. The level of response and the interest displayed in this issue by industry and trade associations has been high (over 100 completed questionnaires were received) with several organisations and individuals also wishing to discuss issues at length by telephone and through meetings.

5.2 Costs and Benefits to Dye Manufacturers

5.2.1 Volume and Value of Azo Dyes Affected

Data suggest that:

- the volume and value of azo dye use comprises around 70% of that for all dyes (pers comm. 1997); and
- between 2% and 5% of azo dyes (by type) may release, through reductive cleavage, the potentially carcinogenic arylamines (pers comm, 1997).

Using these assumptions and data on the European textile dyestuff market set out in Table 4.2(b) in Section 4, it can be estimated that between 1,200 and 3,000 tonnes of 'affected' dyes were consumed within Western Europe in 1991[9]. This represented about ECU 19.5 million ($US 25 million).

5.2.2 The Production of Compliant Dyes

Reformulation of a dye requires substituting the carcinogenic arylamine with another (non-carcinogenic arylamine). In order to achieve the same shade of colour, the replacement arylamine needs to be balanced with a coupling component, with different coupling components being employed so that one arylamine can give a blue, a black or even a red dye. Reformulation takes time and money, but this has already been absorbed by the majority of dye manufacturers as replacements have already been developed.

In some cases, alternative dyes may still contain or be based on one of the restricted arylamines, but will not reductively cleave the restricted arylamine above the 30 mg/kg concentration limit when a dyed garment is tested. This is possible because dyes are never used at full, 100% concentration. In textiles, dyestuffs tend to be diluted to around 4% or 5% on the weight of the substrate, while for leathers the dilution is nearer 8% or 10% (due to difficulties in up-take). In some cases, a dye manufacturer or formulator is known to have simply 're-worked' the dye chemistry such that the dyed goods should not fail the German test by cleaving a restricted arylamine above the limits permitted.

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9 87 thousand metric tons x 70% x 2% (or 5%).

As set out in previous sections, almost all dye manufacturers in Europe have been developing alternatives to the 'affected' dyes since the 1970s. Furthermore, in 1991/92 despite some of these amines being classified as R40 (may cause long term effects), members of ETAD were advised to label some of products containing listed arylamines as potential carcinogens. As no producer wants to sell potential carcinogens, they moved to other formulations (pers comm, 1997).

On the basis of the above, it appears that German and other legislation will have little impact on most dye manufacturers with the costs associated with reformulation of dyes impacting mainly on smaller dye manufacturers, especially those based outside Europe. It has been reported that the larger dye producers were more advanced in this area than smaller ones by the time the German ban began implementation (pers comm, 1997). Indeed, the 15% of ETAD's members which were unable to replace their formulations with non-carcinogenic arylamines tended to be the smaller ones based outside Europe in countries such as Brazil, Argentina and India (pers com, 1997).

Suppliers of dyes who import from manufacturers based outside Europe appear to be the most impacted in this sector as it has been more difficult for them to be sure that the products they supply to dyers are in fact compliant with the German, Dutch and French regulations. It has been commented that the larger European-based dye manufacturers not only expected this but counted on it as a means of increasing their market share by selling more compliant products to European-based suppliers (pers comm, 1997).

5.2.3 Increased Competition

In the leather dye sector in particular there is currently a "price war", especially over black dyes, and it is considered by dye suppliers that arylamine legislation has fuelled this price war.

Manufacturers outside Europe are very aware of the situation within Europe and recognise that certain dyes are increasing in demand. For example, when benzidine-based dyes were restricted in Europe, extra-European producers of dyes continued to produce these dyes in order to continue supplying European suppliers. They were able to make these at reduced costs and, within a short length of time, were undercutting the European-manufactured alternatives.

Black is the largest dye consumed for leather and the majority of supplies into Europe are from South America, India and the Far East. This is where the least expensive dyes are being manufactured and, although control over the dye structure is reduced in these dyes (compared with those produced in Europe), all Europe-based dye suppliers are buying from the same manufacturing countries. Black dyes are available from these countries at between one third and one quarter of the price of European manufacturers. Take Logonyl Black NT (Acid Black 210) for example; three or four years ago this sold for between ECU 9.40 and ECU 12.50 (£7.50 and £10) per kg but now the market value is between ECU 5 and ECU 5.60 (£4 and £4.50) per kg. The suppliers of this dye in Europe buy it from countries such as India where it costs around ECU 2.50 (£2.00) per kg.

The market price of benzidine-based dyes sold in Europe apparently keeps falling as manufacturers keep undercutting each other to win trade. As a result, some Europe-based dye suppliers have decided to introduce price thresholds, where they have internally stipulated the lowest price per kg at which they are prepared to sell dyes within Europe (pers comm, 1997).

One further impact of this increased competition is that the larger European-based dye manufacturers are apparently moving to less-expensive producer countries for their manufacturing processes in order to remain competitive in Europe (pers comm, 1997).

5.2.4 Increased Market Share for European Dye Manufacturers

Despite increased competition in some areas, European-based dye manufacturers consider that, overall, the legislation has increased their market share as they are now able to sell their higher priced azo dye alternatives.

In general, considering textile dyes as well as leather dyes, replacement products are more expensive than those containing the restricted arylamines (around three times as much). Consequently, although the alternatives have been available from European suppliers for some years, they have not been selling well. For example, Direct Black 38, which is the main leather dye used in the world is apparently a very cheap dye but is not produced in Europe due to it containing benzidine. Consequently, although every European dye manufacturer could offer alternatives to this dye prior to the national bans, Direct Black 38 could still be supplied from extra-EU manufacturers at very low cost and the alternatives did not sell. However, with restrictions on the use of Direct Black 38 in finished goods in some countries, this is no longer the case.

Since the implementation of the German ban, not only have European dyers increased their consumption of alternatives, but some EU-based dye producers have also been approached by dyers based outside Europe (such as Bangladesh) wishing to purchase compliant dyes in order to continue selling to Europe (pers comm. 1997). Thus, it appears that the sale of alternative dyes produced within Europe to both intra- and extra-EU countries has increased.

All Europe-based dye manufacturers to respond the questionnaire stated that they are or would experience these trade benefits. However, increased price competition suggests that these benefits may be short-lived. As one consultee from a medium-sized Europe-based leather dye supplier commented, even though many believe that the legislation may have been introduced (at least in part) to stem competition from extra-European based manufacturers, it has achieved "absolutely nothing other than shooting the dye trade in the foot".

5.2.5 Impacts of an EU Ban

The development of European legislation to replace national legislation would result in extension of the impacts set out above. In other words, European dye manufacturers would find increased markets for their azo dye alternatives, while manufacturers outside the Union would find their markets reduced. On the basis of the above discussion, it appears that most affected dyes are imported and that the negative impacts of restrictions on azo dyes would be mostly felt by dye manufacturers outside the EU. Data presented in Table 4.2(c) indicate that India and China are the main exporters of dyes to the EU and could thus be the most affected.

With respect to Europe, it is expected that restrictions will be more likely to benefit the larger dye manufacturers, rather than the smaller specialised companies. Based on the discussions in Section 4.2, the largest number of dye manufacturers are located in Italy, which is the most self-reliant country in terms of the domestic ratio of manufacturers:importers. These companies are most likely to be small, and be supplying other select and diverse companies. As a result, it is possible that across Member States impacts to Italian trade may be greatest following implementation of an EU-wide ban. In addition, Italy consumes a large volume of

Direct Black 38[10] for its large leather trade (which represents half of Europe's manufacturers). The smaller, more diverse suppliers of this dye may face greater problems replacing it than those in other Member States.

Given that restrictions on the sale of azo dyed products would impact all companies which supply the EU, changes in the dye market would not be restricted to Europe. On this basis, the volume of affected dyes could be higher than that indicated above. Consultation with dye producers suggests that the current global rate of consumption for four of the 'affected' azo dyes may be as follows:

Dye	*Arylamine-base*	*World-Wide Market*
Acid Red 85	benzidine	300 to 400t per year
Acid Red 114	o-tolidine	700 to 800t per year
Acid Black 29	benzidine	50 to 70t per year
Direct Black 38	benzidine	1,000t per year

5.3 Costs Associated with Supplying Compliant Textiles, Clothing and Leather Goods

5.3.1 The Need to Find Replacement Dyes

In general terms, the main group driven to seek replacement dyes, suppliers or products as a result of the national bans appears to be the dyers. That said, the effects upon this group have been variable. Many respondents indicated that they had either changed their dyes over a number of years (as the issue has been emerging over the last twenty years) or were not using the affected dyes in the first place. Some respondents used perhaps three of the affected dyes in small amounts and so found moving to alternatives relatively straightforward. Others, however, stated that they had invested considerable amounts of time into identifying compliant products. For example, one respondent to the questionnaire stated that, although only two azo dyes of significance to them were affected by the German and Dutch bans, this meant that reformulation of 55 shades was required (pers comm, 1997).

Each of the 200 or 300 affected azo dyes may have a number of replacement or alternative products, and the decision governing which is most appropriate for each dyer is complex (as discussed in Section 2). From consultation, the following examples were quoted:

Affected Dye	*Alternative Dye*
Disperse Orange 149	Disperse Orange 95
Disperse Red 151(Colour Index No. 26130)	Disperse Red 153
Acid Red 114 (Colour Index No. 23635)	Erionyl 3G

Some of the alternative dyes are direct substitutes for the affected dyes. This means that the alternatives can be used exactly as the affected dyes were. However, in many cases the alternative dye is different in chemical structure and so cannot be used with the same mixture of dyes as the affected dye was, or in the same processes. As a consequence, reformulation of dyes is required by the dyer to achieve the same quality and colour requirements.

10 It is known that about 600t of black dyes used in Italy contain some percentage (100% or less) of Direct Black 38, so consumption may be 200 or 400t per year (pers comm, 1997).

The choice of alternatives is very varied, with manufacturers of dyes producing their own lists of affected dyes and recommended alternatives. However, these may not always be useful or guide the dyer. Take Acid Red 114 for example; two consultees have replaced Acid Red 114 with Erionyl 3G in order to maintain the brightness of red offered by the affected dye. Erionyl 3G is not a direct substitute for Acid Red 114 and so reformulation has been required. In contrast, the manufacturer of Erionyl 3G lists the dye as being an alternative to Acid Red 85 (not Acid Red 114), while a consultee from the US states that they have found another direct substitute for Acid Red 114 (alternative is unknown).

5.3.2 Direct Costs Associated with Replacement Dyes

Despite difficulties in finding replacement dyes, all dyers responding to the Consultants' questionnaire implied that alternatives to banned azo dyes are available. However, eight respondents claimed that these alternatives are more costly. One respondent stated that their company had switched from one of the banned azo dyes to an alternative at a cost of around ECU 865 (£700) per annum, but that for them this was "negligible". Others to comment on the scale of price increase suggested that alternatives were between two and sometimes seven times as costly as the banned azo dyes[11]. One specific azo dye still in use by a respondent (Acid Red 114) cost ECU 6.00 (£4.85) while the alternative dye (Erionyl 3G) cost ECU 18.50 (£15.00), representing a three-fold price increase. One respondent stated that the more costly alternatives are being applied to 5% of their volume of production and so product costs for these goods could be expected to have increased.

With respect to changes in end product price, consultation has indicated that for the textile and clothing trade in general (pers comm, 1997):

- the use of alternatives to the restricted azo dyes may have increased dying costs by around 5% on average;
- dying costs represent between 10% to 30% of textile costs; and
- that raw material costs (as a whole) represent around 50% of end-product costs.

On this basis, increases in dye costs represent less that 1% of end product prices and should have only a minor impact on these.

The effects of changes in dye costs are expected to be of the same order of magnitude in the leather trade. For example, for one shoe manufacturer, a move away from azo dyes was expected to increase leather costs by around £0.25 per pair with shoes selling for between £20 and £60. Despite this increase in costs being small, the manufacturer has indicated that this could be significant as margins are small and because the trend within the shoe trade is for reductions (and not increases) in price.

5.3.3 Indirect Costs Arising from Replacement Dyes

A small number of respondents also identified indirect costs arising from the use of replacement dyes. In particular, some of the qualities and colours offered by the affected azo dyes may not be offered by the alternatives. For example, with respect to the leather trade in particular, the quality of dyes available for black suedes has been particularly badly affected and so the previously achieved level of quality is more difficult to maintain using the

11 It has been suggested by another consultee that increases of the order of 700% are associated with pigments and not azo dyes.

alternatives. There have been particular problems with achieving consistent depth of colour across skins. resulting in patchy blacks. This may have implications with respect to continued supply of quality items and may encourage customers to switch to other suppliers. There may also be a need for skin dyers to increase the concentration at which dyes are applied. However, if the alternative dye still contains some of the restricted arylamines, then the finished consumer good may be more prone to fail the German, Dutch and French tests if concentrations are increased. This would also increase the dyeing component of the end price, so prices for such goods may increase to compensate the dyer.

With respect to those in the textiles sector, one respondent has commented that their dye selection has been affected by moving to alternatives and one company suggested that some colours cannot be achieved using "azo-free" dyestuff. However, consultation with dye trade associations indicates that the actual colour achieved is largely dependent on the skill of the dyer and other numerous interplaying factors, and that banning the associated azo dyes should not affect colour range for textiles (pers com, 1997).

This reference to "azo-free" dyes indicates confusion caused by partial- and mis-information, particularly amongst those with little technical understanding of the dyeing processes involved. It appears that some companies are requesting that their suppliers provide azo-free products on the mis-understanding that all azo-dyes are banned under German, Dutch and French legislation. Given the extent of azo dye use, a request for "azo-free" goods would result in only 20% of currently used dyes being available to them or their suppliers and so colour range would be impacted.

Finally, given that under the Austrian proposals an additional arylamine is to be restricted, there may be additional costs associated with this ban. It is expected that the additional arylamine will be either o-anisidine or p-aminoazobenzene. Dyes which contain these arylamines are apparently used extensively, for example o-anisidine is used as a precursor to Disperse Orange 29. There is considerable concern throughout industry that, if these amines are included in the restrictions, costs will be significant. One company, for example, has indicated that dye suppliers are moving away from these products in anticipation. and "in every case the replacement dye is inferior in shade or performance".

5.3.4 The Impacts of an EU Ban

The costs associated with implementing restrictions on azo dyes at a European level will vary across companies depending on the nature of the in-house procedures and actions taken to date.

Some companies acted swiftly to comply with the first German notification in 1993 to ensure that they could continue trading across Europe. In reality, these companies had effective in-house procedures which were, and still are, in advance of the implementation of the German legislation. For example, all suppliers in all countries were informed in 1995 that C&A would not accept any garments (including shoes and accessories) which may release any of restricted arylamines. and this has remained in effect despite postponement of the German ban (pers comm, 1997). Marks & Spencer also introduced their first Environmental Code of Practice for Dyeing, Printing and Finishing in 1995 and within this they stipulated a ban on the use of affected azo dyes. Again, this has been in effect since 1995 despite the German postponements (pers comm, 1997).

Trade associations such as Euratex and ETAD have made every effort to keep their members and the industry informed as to the current status of the bans and yet some companies are still

unaware that the bans even exist. For example, 8% of those responding to the Consultants' questionnaire were unaware of one or both of the German and Dutch bans and there was confusion over implementation dates. Some respondents have been in receipt of data from a variety of sources which imply that the German ban is being contested. This has led some companies to believe that the ban is still awaiting judgement and so is not in effect. In addition, many companies operating within the textile and leather goods industry are unaware that the German ban, with respect to the circulation of consumer goods containing the banned substances, is deferred until the beginning of 1999.

Current Use of Azo Dyes

In general terms, responses to the questionnaire indicate that most companies have already taken steps to ensure that the products they supply are free from the restricted arylamines. 85% of respondents involved in the production of clothing, textiles and leather categorically stated that they do not use any azo dyes which may release any of the arylamines banned under the proposed EU-wide ban. For example, the Associação Portuguesa de Têxteis has indicated that all of the ten respondents to their questionnaire have stated that they do not use any of the substances banned under the German legislation. Similarly, Associazione Nobilitazione Tessile, the Italian trade association representing dyers and finshers, has indicated that none of its members used the banned azo dyes. Furthermore, a response to the Consultants from Interlaine (Committee of the Wool Textile Industry in the EEC) also states that the European wool-textile industry makes little, if any, use of these dyes (pers comm, 1997). The Dutch trade association Textielvereniging KRL has also responded that their domestic textile industry has not used these dyes for many years.

Responses to the questionnaire indicate that slightly fewer retailers and wholesalers (75%) had taken steps to eliminate the azo dyes banned by German and Dutch legislation from their product ranges. A further 22% were unsure whether their products contained these dyes, compared with only 12% of those involved in production. In this respect, the Dutch trade association FENECON indicates that there is likely to be some unintentional use of the restricted azo dyes (pers com, 1997); while a separate consultee has suggested that unintentional use may be high, with around 50% of companies involved in the textiles and leather goods industry importing materials which do contain the restricted arylamines, despite certificates having been supplied that they are compliant with the German and Dutch legislation. Apparently there is evidence to support this for goods imported into and sold in France, Spain, Portugal and the Netherlands (pers comm, 1997).

Only four of the 101 respondents to the questionnaire (i.e. 4% of respondents) still 'use' the azo dyes of concern under the proposed EU-wide legislation. With respect to production:

- Company A commission dyes and supplies man-made and natural processed fibres to spinners in Finland, Germany and Sweden. The UK-based company uses Acid Red 114 in volumes of 40 kg per month which is supplied by a company in the UK. This azo dye is used on loose fibres which are then spun to make upholstery and carpets, supplied to UK manufacturers. The products dyed with this azo dye represent less than 5% of the company's annual turnover which is between £1 million (ECU 1.2 million) and £5 million (ECU 6.2 million); and

- Company B spins and dyes carpet yarn which is supplied to UK carpet manufacturers. The UK-based company uses Polar Red RS (apparently the same as Acid Red 114) in volumes of around 200 kg per annum which is supplied by a UK company. This azo dye is used on yarn which is sold on to the UK carpet trade. The

products dyed with this azo dye represent a fraction of 1% of the company's annual turnover which is between £1 million (ECU 1.2 million) and £5 million (ECU 6.2 million).

Although upholstery would be covered by the proposed EU-wide ban, it is understood that carpeting would be excluded. Both of these are UK-based companies and a similar proportion of users may also exist in other Member States (i.e. around 3% of the textile and leather goods industry).

With respect to retailers and wholesalers:

- Company C is a Dutch wholesaler importing textile and leather from China, India and Bangladesh for distribution in Germany, the UK and the Netherlands. The company is aware of the Dutch and German bans and thus supplies affected goods (mainly those associated with benzidine-based dyes) to the UK only. Its supplier is working on the development of alternative dyes and soon its whole range will be free of the banned dyes; and

- Company D is a Dutch importer sourcing products from China, Bangladesh, Pakistan and Indonesia for distribution in Germany, Belgium and the Netherlands. As above, the company is aware of the Dutch and German bans and thus supplies affected goods to Belgium only. These good are produced exclusively in China.

5.4 Demonstrating Compliance Via Certification

5.4.1 The Need for Certification

In order to demonstrate compliance with azo dye restrictions, companies are required to provide certificates (or underwritten guarantees) stating that the arylamines will not be released from azo dyes or azo dyed garments. This in turn requires testing to ensure compliance.

The need for certification has impacted all levels of the chain of trade, from dye manufacturers to retailers, although the drivers appear to have been retailers and importers. Of those which responded to the questionnaire, 80% of retailers, wholesalers and importers have asked their suppliers for decrees or declarations certifying that their goods are compliant. With respect to EU-based producers, over 30% have been asked for certification. A response received from an Italian textile company states categorically that the German and Dutch legislation "have caused more red tape" in that, without written declarations, their clients will no longer trade with them. All responses to the Consultants from wider European trade associations and companies have stressed this issue as having had a serious impact on them or their members. Basically, all affected companies have been required to seek declarations of compliance from their suppliers, with this then passed along the chain of trade. Some respondents additionally stated that, despite these declarations having been provided, there is still uncertainty over whether the goods are in fact compliant. In addition, one respondent commented that they have been requested by a customer to provide a guarantee that they would pay all court fees should the products be found to be in breach of the legislation (at an estimated cost of 100,000 DM).

Some respondents have stated that they only use suppliers of goods and products which they can be sure are compliant. Whether this was the case prior to the German legislation is not

known, but some shifting of trade has taken place in order that supplying companies can ensure compliance. Almost half of the retailers, wholesalers and importers responding to the Consultants' questionnaire indicated that they had been forced to switch to alternative suppliers or products as a result of the German and Dutch bans. However, it appears that these alternative suppliers and products are typically from within the same supplying country. With respect to producers, a German textile company responded that some deliveries from the Far East had been rejected when they first introduced their in-house legislation in 1992 as the suppliers were unable to provide the necessary certification. Another German textile company also stated that they had particular problems with a supply of ready made garments and fabric from Italy (particularly with the lower cost products such as linings) and leather jackets from India which contained some of the banned substances. In addition, the Associação Portuguesa de Têxteis have commented that some of their respondents were forced to change their dyers in order to ensure compliance.

Many textile and leather goods enterprises are concerned that, although certificates have been provided by their suppliers claiming that the banned azo dyes have not been used, they cannot be absolutely sure without undertaking tests on the items themselves. Furthermore, as the chain of trade is complex, in that importing and exporting may occur at any point, there is always some degree of uncertainty as to the exact history of any item with respect to its production and dyeing. This is placing an enormous amount of responsibility on the supplying companies and is generating distrust within factions of the chain of trade.

5.4.2 Impacts Along the Chain of Trade

Impacts on Dye Manufacturers

It appear that the burden of proof of compliance with the arylamine bans is falling on dye manufacturers[12]. Although many lists of 'banned' azo dyes are in circulation, advice to industry from all sectors is to consult with the dye producers for confirmation. Consultation indicates that the majority of dye manufacturers and suppliers have been approached for certificates stating that their products do not contain the restricted arylamines. As one large European supplier of dyes commented, each time a new domestic Member State ban is expected, dyers demand new under-written guarantees that the products they are being supplied with are compliant. Most suppliers now appear to have standard certificates of compliance. This demand for information and certification is causing an administrative burden to these producers and suppliers.

It appears that the impacts of providing certificates may be greater for smaller suppliers who import dyes from outside Europe, as the structure of the dyes is less reliable. Similarly, it may not be possible for dye suppliers to provide certificates stating that none of the restricted arylamines are present in the dye, as the arylamines may indeed be present. It is expected that the smaller manufacturers and suppliers will be less able to formulate these arylamines out of their products altogether and so provide such assurances, despite the dyes resulting in compliant consumer goods. Thus, the demands of the textile and leather goods trade for unreasonable certification of dyes (together with an unreliable test method) may result in these smaller dye manufacturers and suppliers being less able to retain their market share.

12 In contradiction, however, consultation suggests that only one of the larger European dye manufacturers actually tests their dyes for compliance.

Impacts on Importers of Textiles and Leathers

Importers of textile and leather goods into Germany, the Netherlands and France are those most affected by current legislation. As it is the importers who are responsible under the German legislation, they face prison sentences of up to three years and/or hefty fines if imported products are found to be non-compliant. They are, therefore, caught between the legislators (and retailers) and the suppliers in extra-European countries. Thus, importers are carrying the burden of compliance, along with those exporting to Europe. This is particularly important in countries such as Germany where between 80% and 90% of clothes for sale (by volume) are imported (85% in 1992). In Germany (excluding the ex-DDR), 34% of these imports came from within the EU while 66% were supplied from outside the EU. In terms of the commercial value of these products, clothing imported into Germany in 1993 represented 79% of total value (excluding knitted items; pers comm, 1997).

Ensuring that products are compliant is particularly difficult. Some companies importing into Germany, the Netherlands and France have found that their traditional suppliers (such as those in South America) have preferred to supply other markets rather than test their goods for compliance. In addition, some suppliers have threatened to increase their prices in order to supply compliant goods.

Compliance has been made particularly difficult as it is still unclear precisely what is controlled under each of the bans. For example, for a hand-bag, is it the whole bag or just the strap (skin-contactable part) which needs to be compliant?

Impacts on Suppliers

Apparently, some intra-EU suppliers of goods to Germany (such as those in Southern Europe) are finding it more difficult to comply with the German legislation than countries in Asia. This is due to the fact that the Asian countries, to date, have made considerable efforts to maintain their supply of goods to Germany.

In general terms, if the supply of goods to Germany, the Netherlands and France is insignificant to a company, then it may consider withdrawing from the market rather than facing increased production costs or administrative burdens. Thus consumer choice in Europe may be affected. This is particularly true of 'alternative' clothing. For example, it has been commented that the small supplier of goods in India may be unaware of the legislation. Furthermore, such a supplier probably will not know the chemical structure of the dyes he uses and will not be able to afford to test them. Any certificate provided to an importer that the resulting consumer good is compliant will be unreliable. It could be expected that the importer of this type of consumer good to Germany, the Netherlands or France would face a reduced supply of this good (at least in the short term). Not only is the importer faced with seeking alternative suppliers, but there may be a whole sector of consumer items which will become unavailable across the three countries. The extent to which this will occur is unknown. Fair trade importers such as Traidcraft advertise that many of their goods are made with "natural dyes" and this appears to be a growing trend. Consequently, it may be the case that the suppliers of these goods are not using the affected azo dyes to begin with or are switching from their use.

5.4.3 The Costs of Certification

The most significant cost relating to the implementation of the German ban has been the need to test for the banned arylamines. As indicated above, these have been required by some

companies in order to supply a certificate to their customers, or by companies wishing to test their own or externally supplied material as part of Due Diligence. In this respect, some companies test a batch of their goods annually as part of Due Diligence to ensure that certificates from their suppliers are reliable. 70% of retailers, wholesalers and importers responding to the Consultants' questionnaire indicated that they have undertaken testing to ensure compliance with legislation.

Quotes for carrying out tests vary considerably and the following have been suggested:

- ECU 49 for a test in Hong Kong (HK$ 500; pers comm, 1997);
- ECU 81 (200 Dutch Gilders; pers comm, 1997);
- ECU 74 for a test in Germany or in Holland (£60; pers comm, 1997);
- ECU 133 for a first colour test in Sweden and ECU 85 for a second colour (SEK 1400 and 900 respectively; pers. comm,, 1997);
- ECU 148 for a test in the UK (£120; pers comm, 1997);
- ECU 246 each in the UK (£200; pers comm, 1997);
- ECU 495 for a test of leather goods in the UK (£400; pers comm, 1997);
- ECU 1000 to test 10 leathers in the UK (£800; per comm, 1997);
- ECU 1,200 - ECU 1,500 per test in order to supply a certificate for a UK-based company (£1,000 to £1,200; pers com, 1997); and
- ECU 2,500 to register fabrics under Ökotex 101 (£2,000; pers comm, 1997).

There is obviously a significant difference between the above quotes and this may suggest differences in the test being undertaken rather than differences in the costs between test houses. For example, the less expensive tests may be 'positive-negative' which simply measure for compliance, while the more expensive ones may provide a more complex result in order for the company to register under Ökotex 101 or meet specified customer requirements.

Consultation has suggested that tests in Germany cost less at one test house as they invested in 12 dedicated 'HPLC' machines and have not received the expected demand; thus, they offer reduced price tests to encourage throughput (pers comm, 1997). In the UK, several consultees have indicated that the average price for a test is around ECU 148 (£120) and that this should be fairly standard throughout Member State test houses.

Some consultees have stated that if they were to be required to test their materials to prove compliance, rather than simply providing a declaration, then they would reconsider exporting to Germany, the Netherlands and France (pers comm, 1997). It is this issue of ensuring compliance that has had the greatest impact on the industry, although it appears that the majority of companies in the textile and leather goods industry have handed the responsibility of testing along the chain of trade. As previously indicated, some consultees have suggested that they are not completely satisfied that declarations from their suppliers are any proof that the banned azo dyes are not being used, but they are reluctant to carry out the expensive tests themselves to ensure that the products are compliant.

With respect to individual companies, the questionnaire elicited the following information on the overall costs of testing:

- one UK company with 1,000 employees has budgeted for test costs of £100,000 per annum, based on tests by colourway and by fabric costing around £160 each. Thus, they are expecting to undertake 625 tests each year to ensure compliance with the German and Dutch legislation, once fully implemented;

- one Dutch wholesaler indicated that costs have increased by 5% as a result of testing while another indicated that the need to increase product costs has resulted in lost turnover in export markets. One French retailer/wholesaler indicated testing would result in increased prices of the order of 0.5%; and

- one of the large Scandinavian retailers with 130 European outlets has experienced testing costs of ECU 50,000 (£40,000) to date while another employing almost 2,000 people across Sweden, Norway and Finland considers that testing will costs around ECU 250,000 (£200,000) and increase prices by around 1%.

In addition, the British Interior Textiles Association estimates that the compliance cost associated with the German and Dutch bans could be £3 million for the companies which it represents (assumed to be an annual cost).

5.4.4 Impacts of an EU Ban

Under a ban at the EU level, the need for certification would continue and would doubtless involve more in the supply chain. With respect to importers, who appear to be particularly affected by certification costs, around half of the clothing for sale (by volume) within the EU is imported from external suppliers (39% in 1992 and 43% in 1993). As Table 4.3(e) shows, the UK, Italy and Denmark all import more textiles and clothing from extra-European countries than from intra-European countries. Thus, importers in these countries may be more adversely affected than those in other Member States. On the other hand, as Portugal and Ireland both appear to import very little from outside Europe, impacts to importers in these countries could be expected to be minimal.

The adoption of an EU-wide framework for control would also provide the opportunity to address some of the problems associated with certification and testing, including the need for clearer legislation.

The Need for Clearer Legislation

Currently, in the national legislation, consultees suggest that there is a lack of clarity over:

- whether a certificate is acceptable as compliance or whether testing is required; and
- where in the chain of trade a declaration of compliance (or testing) is required.

For example, is testing required prior to a dye or fabric being exported from a supplying country and, if so, is this acceptable proof of compliance; or, are importers required to test for compliance prior to accepting a good into Europe?

Problems with Testing

There are also reported to be a number of problems with testing including:

- the effects of some impurities: concern that the currently available tests may classify goods as being in breach of the legislation due to arylamines being released which stem from impurities rather than the use of azo dyes specifically. On this basis, industry believes that the German, Dutch and French legislation cannot be reliably enforced;

- a lack of facilities: even for companies wishing to act responsibly and so remove carcinogens from their products, the testing facilities are apparently not available for them to do so (pers comm, 1997);

- variable results: tests that are currently available produce very variable results, sometimes not producing any meaningful results at all. For example, a leather dye supplier had one dye from a single batch tested by five different test houses across Europe and the results for each were different (pers comm, 1997);

- difficulties in testing leathers: testing textiles is apparently reasonably straightforward compared with testing leathers. Textiles are usually fairly pure, despite sometimes having complex surface finishes. Leathers on the other hand contain inherent fats, oils and greases which cause separation problems. Consequently it is difficult to extract substances to test at the outset (pers comm, 1997);

- the lack of a standard approach to testing: as the German legislation does not stipulate one standard approach to testing, the approach adopted can vary by laboratory (pers comm, 1997). For example, some laboratories may choose to grind-up and test sections of fabric in direct proportion to the manner in which they appear in the garment, while other laboratories may simply randomly test the ground-up powder (pers comm, 1997);

- the appropriateness of tests: industry complains that the tests are too severe and generate arylamines that may not become bioavailable when present in azo dyes that are worn next to the skin and so the tests do not measure carcinogenic risk to humans (pers comm, 1997); and

- false positives: the reducing agents used which cleave to the amines are indiscriminant and so false positives are produced, putting into doubt all similar test methods (pers comm, 1997).

With respect to the last of these, for example, the arylamine 4-aminodiphenyl has apparently never been used as a base for azo dyes because documentation since 1910 indicates that it has no dyeing value. However, some form of synthesis other than reductive cleavage must be occurring during the test itself as in some cases it appears in the test results. Also, some soluble non-azo dyes tested positive for five of the restricted arylamines.

The German test method DIN 53316 acknowledges the problems for leather goods, in that results of 30 mg/kg or over for 4-aminodiphenyl or 2-amino napthylene are insufficient as an unequivocal positive result. However, the legislation and the test method do not give guidance on further testing in these cases. From data presented by the British Leather Confederation, the majority of failures (98%) have been due to detection of the arylamine 4-aminodiphenyl (pers comm, 1997), which makes it uncertain as to whether the leather good is a 'pass' or 'fail' in Germany, the Netherlands and France. One dye manufacturer has suggested that "any dye made from aniline N - coupled to H acid or one of its derivatives - would result in 4-aminodiphenyl by re-arrangement during cleavage" (pers comm, 1997).

As a result of these problems, if an importer brings an item into Germany believing it to be free of the banned azo dyes, and yet it tests positive for one of the listed arylamines, their supplier may be at fault, or the test results may be at fault. This obviously leaves importers feeling vulnerable. An example of the culmination of this confusion for three traders along the footwear chain of trade is given in Box 5(a) overleaf.

Box 5(a): Typical Confusion over Certification and Testing

Company A:

Is a German-based company supplying dyes to leather producers around the world.
The tests give their goods false-positives, for example 4-amino biphenyl (CAS 92-67-1) is tested as occurring, and yet has never been used in azo dyes due to its poor performance.
Some dyestuffs have been altered so that the resulting dilution of arylamine is below that required by the test procedures, but the arylamine is still present.
The alternative dye (Direct Black 155 BFS) is the same as before (Direct Black 155 BFN), but the chemistry is 'modified', so their customers continue to receive it.
Their customer, Company B is requesting a certificate which states that the banned arylamines are not present in this and other dyes.
It would, however, be untruthful for them to provide such a certificate.

Company B:

Is supplied by dyes from Company A to dye and supply leathers and suedes to manufacturers.
Continues to use the 'modified' dye supplied by Company A (Direct Black 155 BFS) to dye black suede (although this has sometimes resulted in patchy coverage).
Has been advised by a trade association to request a certificate from Company A stating that the restricted arylamines will not be released from the dyes.
In preparation for the German ban, Company A provided a certificate to this effect, but since problems with false-positives, the wording 'should not' has replaced 'will not'.
This wording is not sufficient for Company B to be sure that their products would be compliant.
Advice from legal professionals suggests that they are not able to provide the certificate requested from Company C.

Company C:

Produces suede shoes, among other products, from suede provided by Company B.
Over several months has had to return skins due to patchy coverage from replacement dye.
Has been advised by a trade association to request certificate from Company B that none of the banned azo dyestuffs are used, and that there are no legal obstacles to the sale and circulation of these goods in Germany.

The three companies are still trading with each other, despite associated frustrations, but have yet to find a satisfactory solution to their problems.

5.5 Summary of Impacts

5.5.1 The German, Dutch and French Bans

The Production of Textile and Leather Goods

With respect to the producers in the textile and leather goods chain of trade, 55% of questionnaire respondents stated that the German and Dutch bans have had a negative impact on their company. In general, three areas of impact have been experienced, largely due to the German ban:

- uncertainty and lack of confidence;
- inconvenience; and
- financial costs.

With respect to the first of these, consultation suggests that all producers, bar dye manufacturers, are experiencing a certain degree of confusion with respect to:

- the time frames of the national bans;
- partial- and mis-information on the substances actually banned and the status of the bans in each country; and
- certification and testing for compliance with legislation.

Of the 55% of respondents to have experienced some negative impacts following the German government notifying the EC of their intended ban, 72% responded that this impact was one of inconvenience. Thus, 40% of total respondents had a negative impact stemming from inconvenience due to the German ban. These impacts include two main areas:

- the need to seek declarations and certificates from suppliers in order to provide evidence to customers that supplied goods are compliant with the German, Dutch and French legislation; and

- the need to seek alternative dyes, suppliers or products in order to ensure compliance.

The second of these has impacted a smaller number of respondents than those affected by the need to provide certificates of compliance; the largest sector of the industry to have been affected appears to be the dyers themselves.

The German ban in particular appears to have caused some form of financial cost to 27% of those responding to the questionnaire and having expressed a negative impact. Thus, around 16% of all companies to have responded have experienced a negative financial impact from the German ban. These costs have been three-fold:

- increased production costs due to the alternative dyes being more expensive;
- reduced quality and range of dyes available potentially impacting trade; and
- the costs associated with testing in order to prove compliance.

Retailers, Wholesalers and Importers

With respect to the retailers, wholesalers and importers of textiles and leather goods, over 90% of questionnaire respondents who were aware of the German and Dutch bans stated that these have had a negative impact on their company. As indicated above, 80% have found it necessary to ask their suppliers to provide certification and 70% have undertaken testing to ensure compliance with legislation.

5.5.2 An EU Ban

The responses with respect to the impacts on industry of an EU-wide ban are much more varied than those for the German and Dutch bans. Of those involved in the production of textile and leather goods (and responding specifically to this section of the questionnaire):

- 58% perceive no impact on them from such a ban;
- 11% stated that an EU-wide ban would have a positive impact on their company; and
- 26% perceive that such a ban would have a negative impact on them.

For retailers, wholesalers and importers:

- 18% are unsure as to the impact on them from such a ban;
- 42% stated that an EU-wide ban would benefit their company; and
- 40% perceive that such a ban would not benefit their company.

Those Expecting No Impact

As the majority of textile and leather goods companies claim to be compliant with German, Dutch and French bans, any actions that an EU-wide ban would require have largely been undertaken. Companies and trade associations have responded that the same testing costs would apply as for current bans and similar declarations of compliance would be required.

Some of the respondents to the questionnaire (about 10% of producers) suggested that they would only experience no impacts if the list of banned substances remains the same under an EU-wide ban as those listed under the German and Dutch bans. It may be the case that these companies are perhaps larger companies who supply the German and Dutch markets. However, responses suggest that these larger companies are in fact supplied by Small and Medium sized Enterprises (SMEs) and that the whole range of company sizes are already compliant with the German. Dutch and French legislation. Furthermore, 77% of respondents supply the international market and so will already be affected by existing legislation.

Those Expecting Positive Impacts

A large number (42%) of retailers, wholesalers and importers indicated that an EU-wide ban would benefit their company. Almost all of these claimed that benefits would result from the creation of a 'level playing field' with all companies across the EU being subject to the same requirements. Of the 11% of producers stating that an EU-wide ban would have a positive impact on their company, the majority perceived that this would reduce the level of uncertainty and lack of confidence which is currently influencing the trade following the German ban. In addition, it was felt that such a ban would require a standard test for the arylamines, clarification over the testing and certification required and an agreed limit which would further reduce uncertainty. It has also been commented that the real or perceived quality of consumer goods should be higher as they will not contain carcinogens.

Others predicted that an EU-wide ban would be advantageous in that it would prevent competition within the EU from less expensive, lower quality dyes and dyers. This opinion was also expressed by other respondents who suggested that the only impacts of an EU-wide ban would be on competitors importing inexpensive dyes from the Far East and the developing world, thus favouring internal EU business.

Those Expecting Negative Impacts

Only a handful of retailers, wholesalers and importers indicated that extension of the German and Dutch bans across the EU as a whole would have a negative impact on their company. The reason for this is an increase in compliance costs. In contrast, one company indicated that extension of the ban would eliminate use of the azo dyes of concern and thus that there would be no need for testing in the longer term.

With respect to those involved in the production of textiles and leather goods, a considerable proportion of respondents, 26% in total, perceived that an EU-wide ban would have a negative impact on them. Of these, 43% perceived that this would be one of inconvenience rather than financial cost, representing 11% of total respondents. Overall, the nature of impacts appears to be more marginal than for impacts stemming from the German and Dutch bans, with many respondents being unsure as to the precise nature of expected impacts. However, where impacts are stated, they appear to be similar to those for the German and Dutch bans in terms of the need to issue and seek certificates, test for compliance and switch to using alternatives.

It appears that those companies to already have taken action following the German and Dutch bans perceive increased inconvenience following implementation of an EU-wide ban only if more substances are banned. For respondents who have not been required to take action with respect to the German and Dutch bans, the action required following an EU-wide ban would be the same as the action already undertaken by companies affected by the German and Dutch bans, as set out above. Largely, these impacts relate to concern over the reliability of the testing procedures currently available, and the specific nature of such a ban. For example, one respondent stated that without a standardised testing system prior to implementation, companies all along the chain of trade will be very confused.

Some companies are expecting financial cost impacts with these relating to the need to move to more costly alternative dyes and concerns that the alternatives are more difficult to apply and may not offer the desired range of colours. With respect to the first of these, one company stated that their production costs could rise and this would reduce their turnover. Lost turnover was quoted by a number of respondents as a perceived impact, but the extent of losses and whether this will be realised following an EU-wide ban is unknown[13]. It has also been indicated that as unit costs increase with a switch to alternative dyes, there would be some loss of business to developing countries. A respondent from the leather sector indicated that problems may be experienced with controlling 'uppers' from India, and so it appears that the majority of impacts from an EU-wide ban relating to identifying compliant dyes may be experienced by supplying countries rather than by internal EU trade. However, it also appears that some supplying countries will be handing any associated costs along the chain of trade, which may result in an increase in prices of products traditionally supplied by these less expensive producers.

If pigments were included in a ban, then some companies would be severely affected. One respondent claimed that 90% of their business would be affected. Similarly, another company was concerned that if the azo colorants used in textile finishing were affected then they could lose 50% of their business. It is important, therefore, for the Europe-wide ban to address some of the uncertainties and issues of confusion that have been presented by the German, Dutch and French bans in order to stem additional negative impacts to companies.

Again, some companies perceive that they would be required to undertake costly testing. In particular, a UK test house specialising in the testing of leathers suggested that demand for tests is dominated by large companies and should testing be required by SMEs in the leather sector, costs to them could be significant (pers comm, 1997). Some respondents indicated that if the testing requirements were different under an EU-wide ban such that they had to test every material, then they would be very concerned.

13 It may be the case that these impacts arise from a misunderstanding over the nature of an EU ban, for example a belief that this will impact more dyes than current German legislation.

6. EFFECTS ON HUMAN HEALTH AND ENVIRONMENTAL RISKS

6.1 The Human Health Risks Associated with Azo Dyes

6.1.1 Overview of the Risks to Human Health

Some azo dyes are of concern as a result of the carcinogenic properties of some of the arylamines on which they are based. As discussed in Section 2, there is evidence that some arylamines (for example benzidine and 2-napthylamine) and the azo dyes which reductively cleave to these arylamines are carcinogenic to humans. Thus, the use of these arylamines poses occupational risks to those involved in the manufacture of dyes and dyed-products and also to consumers of "skin-contactable" dyed products such as clothing, bedding and footwear.

In terms of other risks to human health, it has been reported that 1 to 2% of all cases of contact dermatitis are associated with textiles (Melliand Textilberichte, 1996). In all observed cases, the causal agent was thought to be the dyestuff and in particular disperse dyes which are know to be skin sensitisers. Although some azo dyes are disperse dyes, these are mainly associated with direct dyes. On this basis, the contact dermatitis risks to consumers of skin contactable azo dyed clothing should be insignificant.

6.1.2 Carcinogenic Risks

The risks of a human developing cancer from the arylamines of concern vary according to the degree (level) and route of exposure. For example, a dye worker involved in the production of benzidine-based dyes could be expected to internalise the dye if no precautionary measures are in place. Thus, bioavailability of the carcinogenic benzidine is likely. However, the wearer of a garment dyed with this dye is less likely to internalise the dye and so the carcinogenic risk will not be so great.

In terms of exposure, the US EPA has predicted that workers involved in the manufacture of benzidine-based dyes have the greatest exposure, in particular those weighing powder dyes. The EPA also expressed concern that workers operating dyeing machinery may have high exposure (Federal Register, 1995). Exposure to azo dyes via clothing will be lower than that associated with dye production and use. Research by the Danish Environmental Protection Agency (DEPA, 1997) has examined the levels of azo dyes in textiles using a test which mimics skin exposure by sweat. Of 34 samples of children's toys and textiles:

- 18 were associated with aromatic amines;
- of these, 8 were associated with the arylamines of concern (i.e. those defined by German legislation); but
- only one of the samples gave rise to arylamines in excess of 30 ppm (i.e. above the limit set down in German legislation).

With respect to other skin-contacting textiles (including towels, clothing, etc.), out of 26 samples:

- 16 were associated with aromatic amines;
- of these, 9 were associated with the arylamines of concern; and
- again, only one of the samples gave rise to arylamines in excess of 30 ppm .

From the Dutch notification to the EC, it would appear that the Dutch ban on azo dyes was due to research[14] which indicated that the risk of developing a fatal cancer from contact with clothing dyed with a benzidine-based azo dye was not negligible (FENECON, 1996; Secretary of State for Public Health, Welfare and Sport in the Netherlands, n.d.). In this instance, a negligible risk was considered to be one chance in one million (1×10^{-6}) of developing a fatal cancer and was associated with individual exposure to benzidine at 0.3 ng/person/day over a lifetime. A benzidine exposure rate was derived from an estimate of the total free azo dye in a new garment and other assumptions such as the number of new garments purchased each year. On this basis, the risks were estimated to be:

- between 5×10^{-5} and 1×10^{-6} per lifetime for garments washed before use; and
- between 3×10^{-4} and 6×10^{-6} per lifetime for garments with no pre-washing.

In the absence of findings from the LGC risk assessment, an approximation of the number of expected deaths across the whole of Europe associated with non-occupational exposure to azo dyes is set out in Box 6(a).

As Box 6(a) shows, across all Member States there may be between 0.3 and 77 cancer deaths per annum from exposure to clothes dyed with azo dyes which, on reductive cleavage, may release carcinogenic arylamines above 30 ppm. To put the highest of these numbers in context it should be noted that this assumes that more than 25% of all clothing on the market is dyed with affected azo dyes. Levels in some EU Member States are known to be lower than this and will have dropped further since the implementation of the national bans. In addition, the risks are based on consideration of the worst case arylamine, i.e. benzidine. Furthermore, the estimate assumes that new clothes are bought frequently, are worn without pre-washing and are worn often. On this basis, the actual number of cancer related deaths is likely to be much lower, by a factor of 2 or more.

6.1.3 Cost of Cancer Deaths from Exposure to Affected Azo Dyed Clothing

A variety of different estimates for the value of a human life have been calculated using a range of different economic valuation techniques. These techniques include the contingent valuation and contingent ranking methods, human capital approach, wage risk premia as well as the social consumption equivalent model. A thorough description of these techniques is not considered appropriate here and the publications *Risk Benefit Analysis of Existing Substances* (DoE, 1995) and *Risk Benefit Analysis of Hazardous Substances* (RPA, 1992) provide further guidance.

Internationally derived estimates of the mean value of a statistical life range from around ECU 0.7 million (£0.6 million in 1995) to ECU 5.75 million (£4.7 million in 1995; Environment Agency, 1996). Considering 21 different estimates, the average value of life is around ECU 2.2 million (£1.75 million in 1995). Thus, cancer deaths per annum across the EU from exposure to azo dyed clothing which may release, by reductive cleavage, carcinogenic arylamines, can be valued at between ECU 0.66 million and ECU 170 million per annum with a best estimate of around ECU 85 million assuming 38 deaths per annum.

[14] Undertaken at the Rijksinstituut voor Volksgezondheid and Milieuhygiëne (RIVM, the Dutch National Institute of Public Health and Environmental Hygiene).

Box 6(a): Indication of the Number of Expected Deaths in Europe from Non-occupational Exposure to Garments Dyed with Affected Azo Dyes

The ERM Economics Interim Report sets out that German tests in 1994 "indicated that approximately 25% of clothing on the market then, and dyed outside Germany, were coloured with the azo dyes that are now restricted" (ERM Economics, not published, based on data in Textile Asia, June 1996, p74). Thus, it follows that 25% of imported goods were dyed with the restricted dyes. It is known that in 1992 around 56% of the volume of clothes for sale in Germany was imported from outside Europe[15], and for the EU as a whole around 50% of clothing for sale is imported from external suppliers (pers comm, 1997)[16]. In the absence of data on the use of restricted azo dyes in domestically produced German clothing, it can be assumed that 25% of all clothing sold in Germany is associated with the restricted azo dyes. With respect to other EU Member States, data from the Netherlands[17] suggests that 5% of clothing sold could be dyed with the azo dyes of concern, while that for Denmark indicates that the figure could range between 23% and 35%. However, even where azo dyes are widely used, only around 5% of clothing will result in exposure levels in excess of 30 ppm[18].

Using Dutch data on the risks associated with clothes dyed with benzidine-based azo dyes and assuming that an average lifetime is 70 years, the annual cancer death risk from exposure to garments dyed with the affected azo dyes is estimated to be:

- between 7.1×10^{-7} and 1.4×10^{-8} per person per annum for garments washed before use; and
- between 4.2×10^{-6} and 8.6×10^{-8} per person per annum for garments with no pre-washing.

Data published in 1996 by the Office for Official Publications of the European Communities (in their document *Exploring Europe*, part of the Europe on the Move series) states the population of the 15 Member States as 367,100,900.

Thus, assuming that current consumer exposure to azo dye levels in excess of 30ppm is between 5%, the number of related expected cancer deaths across all Member States can be estimated to be in the range of 0.3 (for a garment which was washed before use[19]) to 77 (for a garment with no pre-washing[20])

6.1.4 The Risks Associated with Alternatives to Carcinogenic Azo Dyes

The control of azo dyes at an EU or Member State level will require that replacements are found for these dyes. At the simplest level, replacement dyes may be based on reduced quantities of the arylamines of concern and in such instances the human health risks should be reduced in proportion to the reduction in arylamine use.

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15 In 1992, 85% of clothing by volume was imported to Germany, 66% of which came from suppliers outside the EU and 34% from EU-based suppliers (pers comm, 1997).

16 39% for the whole EU in 1992, 43% in 1993 and 56% for Germany in 1994 suggests around 50% overall.

17 Information supplied by Euratex reports that a 1995 study carried out by the Netherlands Health Protection Inspectorate showed that about 5% of samples investigated contained the azo dyes of concern.

18 As determined by Danish tests described above.

19 (367 million x 1.4×10^{-8}) x 5%

20 (367 million x 4.2×10^{-6}) x 5%

In other cases, and probably more commonly (see Section 5), replacements will be based on other arylamines with new coupling components. Given that as many as 300 different azo dyes may need to be replaced, that each dye may be replaced with a number of alternatives and that many of these alternatives have not yet been developed, it is difficult to comment on the associated change in human health risks. That said, the replacement arylamines should be less carcinogenic than those which they replace and thus should reduce risks associated with fatal cancers. The change in risks associated with other effects such as dermatitis are equally unknown but should be small.

6.2 The Environmental Risks Associated with Azo Dyes

As indicated above, the main concerns with azo dyes relate to human health. With respect to the environment, the sale and use of dyed garments poses little risk and any impacts associated with the replacement of certain azo dyes will be small.

With respect to dye manufacture and use, normal discharges from facilities should be controlled in a manner which is commensurate with the associated risk and abnormal releases (such as those associated with accidents) should be rare. Thus, in general terms, the replacement of certain azo dyes should have little impact on levels of environmental risk.

7. THE TRADE-OFFS

7.1 Introduction

The trade-offs associated with the implementation of an harmonised EU framework for the control of risks associated with azo dyed products are set out in Table 7.1(a). This also presents information on the advantages and disadvantages of the development of legislation by individual Member States (i.e. the current situation) and on the state of the market for affected products prior to the development of any dye-specific legislation.

For the purposes of this assessment (and in line with the advice of the Commission) it has been assumed that the restrictions posed by an harmonised EU framework will mirror German legislation in this area (except that pigments are excluded from restrictions). The key components of the proposed framework and that which exists at present are also set out in Table 7.1(a) with more detailed information on national azo dye legislation and other relevant EU legislation (for example the Dangerous Substances Directive) in Section 3.

7.2 The Overall Benefits of Restrictions

In risk-benefit terms, restrictions on azo dyes are justified if the reductions in risk outweigh the costs of implementation. Although it has not been possible to develop valuations of all the costs and benefits associated with a ban, the following figures are relevant:

- exposure to azo dyed clothing which may release, by reductive cleavage, carcinogenic arylamines, could lead to cancer deaths (with a best estimate of 38) which can be valued at around ECU 85 million per annum;
- increased dye costs have the potential to increase end product prices by the order of around 1%; and
- a large number of tests will be required in order to demonstrate compliance with legislation and that each test will cost an average of ECU 150 per test.

If it is assumed that end product prices will increase by 1% and that this increase is passed onto the consumer, then taking the turnover of the EU clothing sector (i.e. excluding textiles and knitting) as ECU 63.7 billion per annum (Euratex, 1997) and assuming that 5% of all clothing is associated with the affected azo dyes, these associated end product price increases could be around ECU 32 million per annum.

On this basis (and setting aside all other costs and benefits), restrictions on affected azo dyes would be justified if testing costs were less than £53 million per annum, in other words if there were fewer than 350,000 tests per annum (at ECU 150 each). Given that there are around 60,000 clothing enterprises in the EU (see Table 4.3(a) in Section 4), each company would need to undertake only 6 tests for there to be 360,000 manufacturer-related tests per annum across the EU (i.e. for the costs of restrictions to outweigh the benefits). Although some companies may not undertake any tests, others undertake many more tests than this. For example, as set out in Section 5, one UK clothing manufacturing company with 1,000 employees has budgeted for test costs of £100,000 per annum, based on tests by colourway and by fabric costing around £160. Thus, they are expecting to undertake 625 tests each year to ensure compliance with the German and Dutch legislation, once fully implemented.

Table 7.1(a): Trade-Offs Associated with Restrictions on the Use of Azo Dyes by Individual Member States and at an EU Level			
Affected Area or Group	**Pre-ban Situation (i.e. pre April 1996)**	**Non-EU Harmonisation**	**EU Harmonisation**
The Legislative Framework	12 (of the 20 MAK III) arylamines are classified as Category 1 or 2 carcinogens under the Dangerous Substances Directive (67/548/EEC) and must be labelled as such. 3 (of the 20 MAK III) arylamines are controlled by the Marketing and Use of Dangerous Substances Directive (76/769/EEC) and "may not be used in concentrations equal to or greater than 0.1% by weight in substances and preparations placed on the market".	Legislation to restrict the use of some arylamines is being implemented in Germany, the Netherlands and Austria. Legislation is also being drafted by France, Denmark and Sweden. Legislation differs across Member States in terms of the affected arylamines (and thus azo dyes); affected consumer goods; timescales of implementation; whether manufacture of goods is prohibited; and perhaps the permitted test methods and limits of detection of the arylamines in the dyed products.	Europe-wide restrictions on the manufacture and sale of "skin contactable" dyed products which may release any of 20 specified arylamines.
Dye Manufacturers	In Europe, production of benzidine based dyes ceased in the 1970s and in the early 1990's most dye manufacturers ceased production of the azo dyes of concern. European manufacturers developed alternatives but the market for these has been small	Market for alternatives to restricted dyes has increased with the implementation of national legislation and this has benefited European dye manufacturers with alternatives dyes.	Further increase in the market for alternative dyes both inside and outside Europe. Loss of market to manufacturers based outside the EU which will need to develop alternative products.

Cont'd...

Table 7.1(a): Trade-Offs Associated with Restrictions on the Use of Azo Dyes by Individual Member States and at an EU Level ... cont'd			
Textile, Clothing and Leather Industry	A few of the larger companies operating in this sector had moved away from the use of affected azo dyes prior to the implementation of national legislation.	Legislation introduced by individual Member States, especially Germany, has resulted in many companies moving away from the use of affected azo dyes altogether, not just for the affected markets. Dyers have experienced some increases in costs associated with the purchase of more expensive alternative dyes. In most cases, these appear to have been absorbed by the dyers or elsewhere along the chain of trade with little overall impact on product prices. The range of national legislation results in confusion concerning the dyes and products affected. The main impact appears to be the need to demonstrate compliance with legislation and associated testing requirements. This has resulted in administrative costs, testing costs and liability issues. This affects all in the supply chain to some degree.	Those companies which still use azo dyes and their associated products will be forced to use alternatives. Affected companies are likely to be small companies based in and selling to Member States which are not affected by national legislation. Harmonisation would remove confusion concerning the nature of affected products. The costs associated with compliance and testing could be large unless action is taken by Europe to iron out the difficulties encountered by those implementing national legislation.
Human Health and Environmental Impacts	The main concern is the risks to consumers arising from the carcinogenic properties of some arylamines. With respect to occupational risks, European manufacture of affected dyes ceased some time ago.	Reductions in carcinogenic risks to consumers in affected Member States. Occupational benefits to dye manufacturers outside the EU. Environmental impacts are not known but should be small.	Reductions in carcinogenic risks to all EU consumers. Increased occupational benefits to dye manufacturers outside the EU. Environmental impacts are not known but should be small.

On the basis of the above discussion, it appears that the costs of restricting azo dyes at an EU level could outweigh the associated benefits. However, as indicated above, there are a number of costs and benefits which are excluded from the analysis (mainly because it has not been possible to quantify these). For example, additional costs associated with implementing the restriction include:

- costs to textile, knitting and footwear enterprises;
- administrative costs associated with compliance with legislation; and
- others associated with the use of alternative dyes such as those arising from more difficult application, poorer quality, etc.

In contrast, however, the estimates of costs presented above include costs which have already been incurred as a result of actions taken to comply with national bans. In assessing the costs of an EU-wide ban, such sunk costs should be removed from the analysis.

Finally, there are a number of issues associated with the change in risks arising from a restriction on the use of certain azo dyes. Firstly, the above analysis assumes that replacement of the azo dyes with alternative substances will eliminate carcinogenic risks. If this is not the case, the benefits of risk reduction will have been over-estimated. Secondly, the data used in the analysis are uncertain. In particular, while a best estimate has been made of the value of carcinogenic risks associated with the use of the azo dyes of concern, data in Section 6 suggests that the upper and lower bound estimates of cancer-related risk could differ by two orders of magnitude.

The large degree of uncertainty surrounding risk levels highlights the need for the risk assessment which is being undertaken by LGC. Current restrictions on the use of azo dyes are based on incomplete assessments of risk, and, in the case of the Dutch restrictions, on an assumption that a risk of greater than one chance in one million (1×10^{-6}) of developing a fatal cancer over a lifetime is not negligible and should be reduced. Although a risk of 1×10^{-6} per lifetime (or 1.4×10^{-8} per year taking an average lifetime of 70 years) has been used as an individual risk criterion for some 'cancer' risks in relation to some substances (notably for dioxins in the US), it is not an internationally accepted standard. Indeed, there is no internationally accepted standard with various individual risk criteria in use. For example, in Hong Kong, the acceptable level of individual risk is set at one chance in 100,000 per year of becoming a fatality. In the UK, the criterion for fatalities (as used by the Health & Safety Executive for example) is of the order of one chance in a million per year (i.e. two orders of magnitude greater than that used by the Dutch Government).

7.3 Impacts on Key Groups within the Chain of Trade

As indicated in Table 7.1(a) and discussed in detail in Section 5, all those along the chain of trade have been impacted to some extent by national restrictions on the use of azo dyes. In line with the study specification, Table 7.3(a) indicates:

- effects on importers;
- effects on producers, e.g. the textile and leather industry; and
- effects on consumers.

Table 7.3(a): Effects on Key Groups of Restrictions on Azo Dyes		
Group/Trading Area	**Benefits**	**Costs**
Producers	Increased market for European dye manufacturers	Reductions in the market for dye manufacturers outside the EU Increased costs to dyers associated with higher priced alternatives, difficulties with dye applications, etc. These costs may be passed further down the chain of trade. Due to the extremely competitive nature of the footwear industry, increases in raw material prices maybe more significant for manufacturers of footwear than manufacturers of clothing. Costs associated with testing and certification to ensure compliance. The trend is for certification costs to be passed up the chain of trade to dye manufacturers. Testing costs can be incurred at any point in the chain but especially by manufacturers (and importers - see below).
Importers	None identified	To ensure compliance with legislation, some importers are incurring testing costs especially where goods are sourced outside the EU and where the chain of trade is complex and often unknown.
Consumers	Reductions in carcinogenic risks	(Possible) small increases in clothing prices (Possible) reductions in colour range and quality for some items of clothing

As would be expected, in terms of the trade-offs between these groups, benefits accrue to some consumers while the remainder bear the increased costs of end-products; While, in the first instance, costs will be incurred by producers and importers in the chain of trade, it is likely, that the costs of restrictions will eventually be passed onto consumers.

The study specification also requires that consideration is given to impacts of an EU wide restriction on the use of azo dyes on trade within and between the Community. In general terms, it is considered that the harmonisation of legislation will have the following effects. At least in the short term, imports of dyes, dyed raw materials and finished goods into the Community are likely to decline to some extent. This decline will result from an inability of foreign suppliers to meet the requirement of legislation and a preference for a short and explicit chain of trade. This decline will be met by a corresponding increase in intra-community trade with the increase being aided by the harmonisation of legislation across Member States.

Exports from the EU may also decline as companies are unable to supply demand for garments dyed with the restricted azo dyes outside the EU.

In the longer term, imports of goods into the Community could possibly regain some of this lost ground. This would result from moves such as the development of alternative dyes by suppliers, suppliers being able to provide certificates of compliance which can be trusted and an increase in the trend for establishing cheaper manufacturing bases in countries such as Poland and Morocco.

8. CONCLUSIONS AND RECOMMENDATIONS

8.1 Conclusions

8.1.1 Overview

At present, the use of certain azo dyes is restricted in some countries of the European Union while these substances and associated end products can be traded freely elsewhere in the Community. These restrictions vary by Member State in terms of the nature of substances and products affected and other factors such as implementation date (see Section 3).

The introduction of national legislation has led to costs to industry which, in the main, have been associated with the need to demonstrate compliance with legislation. Although other costs have been incurred, industry perceives these to be small when compared with those arising from testing and certification (see Section 5).

Industry feels that if legislation restricting the use of azo dyes is necessary (i.e. if the risks are found to be unacceptable) then legislation should be harmonised at a European level to reduce impacts upon them. The findings of the risk-benefit analysis support this view.

8.1.2 The Costs and Benefits of Adopting a Harmonised Approach

The development of national legislation restricting the use of the azo dyes of concern (i.e. those which reductively cleave one of a group of specified carcinogenic arylamines) has resulted in a number of costs to industry (as set out in Section 5). These include:

- increased dye costs;
- some possible reductions in colour range and dye quality;
- costs associated with testing end-products to establish compliance with legislation; and
- administrative costs associated with establishing compliance along the chain of trade.

Consultation with industry indicates that while restrictions apply to only a few Member States, many EU-based companies have eliminated the azo dyes of concern from their entire product range. Thus, the development of legislation at an EU level would have no further impact on these companies. Given that a survey of European companies indicates that most companies are of this type, harmonisation of legislation across Europe should result in few additional costs to European producers[21]. Indeed, if EU legislation is carefully drafted and implemented, then harmonisation should result in a reduction in compliance costs to industry. These savings can be made by ensuring that legislation clearly sets out testing and certification requirements while at the same time ensuring that efforts are made to reduce or eliminate the numerous problems associated with testing (see Section 5.4.3).

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21 The survey population is not representative of the range of companies across the EU in that most responses are from larger multinational companies and smaller companies based in a limited number of Member States. It is likely that small companies which do not export to countries with existing azo dye legislation will incur costs as a result of harmonisation. That said, wider consultation indicates that a large number of companies will not incur additional costs.

8.1.3 The Best Option for the Control of Azo Dyes

Implicit in the above discussion are the assumptions that:

- the risks associated with the azo dyes of concern are such that they should be reduced; and
- that the best risk reduction option is to restrict the use of these azo dyes.

However, the first of these has yet to be established (for all the restricted azo dyes) while the second has never been tested.

Discussions with industry have indicated frustration that existing legislation appears not to be based on a thorough assessment of risks and, while a risk assessment is being undertaken by LGC, this will be too late to influence national legislation and perhaps too late to influence decisions concerning EU harmonisation. With respect to this last point, given the existence of legislation at a Member State level and its associated effects, harmonisation with the aim of restricting the use of azo dyes across the EU appears to be the best option whatever the findings of the risk assessment. However, prior to the development of national legislation, the situation may have been different. For example, the (limited) assessment of risks undertaken for this study (see Section 6) indicates that order of magnitude reductions in risk could be achieved simply by encouraging consumers to wash garments prior to wearing. If such an action would have been sufficient to reduce risks to an acceptable level then the costs to industry would have been small compared with those arising from restrictions in use.

8.2 Recommendations

***Recommendation 1**: Restrictions on the use of azo dyes should be harmonised at an EU level.*

***Recommendation 2**: One of the aims of harmonisation should be to address some of the problems experienced by industry in meeting the requirements of national bans.*

***Recommendation 3**: Decisions concerning the control of hazardous substances should be based on a thorough consideration of the risks posed by a substance and its alternatives and of the costs and benefits of a range of control options.*

With respect to the second of these, the Commission should ensure that testing requirements are clearly defined, easily implemented and proportionate in the burden placed on industry with regard to the reduction in health risks.

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ANNEX 1:

LIST OF CONSULTEES

1. Trade Associations

A.N.I.V.E.C. (Portugal)
Associaçâo Portuguesa de Texteis
Associazione Nobilitazione Tessile
Association Hellenique Du Pret-a-porter (Greece)
British Apparel and Textile Confederation
British Importers Association
British Interir Textiles Association
British Leather Confederation
British Luggage and Leather Goods Association
British Footwear Association
British Luggage and Leather Goods Association
Bundesverbandbekleidungsindustrie (Germany)
CEC *European Footwear Manufacturers Association*
CIA *Chemical Industries Association*
CIRFS (EU-Belgium)
CITA (International - Germany)
CITH
Confederation of British Industry
Confederation of British Wool Textiles
Confêdêration Europeenne Du Lin et Du Chanvre (EU-France)
Coñsejo Intertextil Espagñol (Spain)
Co-ordination Committee for the Textile Industries in the EC
Customs & Excise (N'ch)
EFTA (European Fair Trade Association)
ETAD *Environmental & Toxicological Association of the Dyes and Organic Pigments Manufacturers*
Eurocoton (EU-Belgium)
EURATEX
EuroCommerce
European Clothing Association
European Sporting Goods Association
European Textile Finishers Association/Dutch textile Federation
Eurostat
Fachverband der bekleidungsindustrie Osterreichs
Fachverband Der Textilindustrie Österreichs
Fair Trade Foundation
Febeltex (Belgium)
Federacao Intertextil Potuguesa
Federation Belge Des Industries De L'habillement
Federacion Española De Empresas De La Confeccion
Federation of Danish Textile and Clothing Industries
Federtessile (Italy)
FENECON (the Netherlands)
Foreign Trade Association
German Clothing Association
German Textile Federation
Gesamttextil e.V. (Germany)
Institute of Export
Interlaine (EU-Belgium)
Internationaler bund textil und Bekleidung

Irish Textiles Federation & Irish Business and Employers Confederation
Knitting Industries Federation Ltd.
Leather Technology Centre (UK)
Mailleurop (EU-Belgium)
Moda Industria (Italy)
OETH
SATRA
SERVATEX (Germany)
SGMA (Sporting Goods Manufacturers Association)
Society of Dyers and Colourists (UK)
Tekoindustrierna (Sweden)
Textielvereniging KRL (Fenetextiel; the Netherlands)
Textile Distribution Association
Textile Finishers Association (UK)
Textile Finishing Group
Textile Institute
Textile Services Association
Tekstelitollisuuslitto (Finland)
Union Des Industries De L'habillement (France)
Union Des Industries Textiles (France)
Union Intertextile Hellenique (Greece)
Verein zur förderung des Norddeutschen Textileinzelhandels e.V.
V.A.T.E.V.A. (Finland)
World Federation Sporting Goods Industry (WFSGI)

2. Respondents to Questionnaire

AB G W Greiff & Co
AB Lindex
Abtwilfit
Allen & Caswell Ltd.
Anttila OV
Argos Distributors Limited
Associated Independent Stores Limited
ATC Dyers
B S Silks Ltd.
Barker Shoes
Bayer
Benson Turner (Dyers) Ltd.
Blackburn and Sutcliffe
Bottom Line
Brookside Dyers & Finishers
Celio
Century Dyeing (branch of ATC Manufacturing)
Cherry Lewis Ltd.
Church & Co. (Footwear) Ltd,
Ciba Speciality Chemicals Inc.
Clarks International
Cooper & Roe Ltd.
C V Home Furnishings
CVC Stevensons

C W Hall Ltd.
CWS Retail
Desmond & Sons Ltd.
Dewhirst Plc.
Draper of Glastonbury
Dunnicliff Bros.
Dystar
Ellos AB
E Walters (Ludlow) Ltd.
Gardiner Bros & Co (Leather)
Gustov Schmenger GmbH and Co.
Halens Postorder Borås
Haynes & Cann Ltd.
H.E.M. bv
HI King (UK) Ltd.
IKEA of Sweden AB
Intres B.V.
J & J Cash Ltd.
Jashua Wardle Ltd.
John Lewis Partnership
Johnstons of Elgin
K Raymakers & Sons Ltd.
KappAhl AB
Kesko
Liberty
Lion Brouwn B.V.
Lissauer's Textiles B.V.
Loughborough Dyeworks
Magazÿn de Bÿenkorf bv.
Martins (Leic) Ltd.
Milliken Industrials Ltd.
Modea Bekleidungsmarkt GmbH
Mondial International
Parkland Manufacturing Co. Ltd.
Perivale-Gutermann Ltd.
Pippi Børnetøj
Pongees Ltd.
Pretty Polly
Priory Footwear Ltd.
Quelle Schickedanz AG & Co.
Reima-Tutta Oy
Sanders & Sanders Ltd.
Secteur Textile
Shiloh Spinners Ltd.
Shirley Dyeing & Finishing Ltd.
Sonae Comércio e Serviços S.A.
South Knighton Dye Works Ltd.
Startrite Shoes Ltd.
Stylo Barratts Shoes Ltd
Tack Lea Works
Tecnic Shoe Co. Ltd.
Texsport B.V.

Textile Finishing Group (Nottm) Ltd.
The Walsden Printing Co.
Theta Fashion Dyers
Totectors Ltd.
Walshaw Drake (Allied Textiles)
Walter Walker & Sons
Welbeck Fabric Dyers
Westertex (Loughborough) Ltd.
Wigstons Dyers
William Denby & Sons Ltd.
William Reed Weaving
Z. Hinchcliffe & Sons Ltd.

3. **Other Industry**

Allied Textiles Companies Plc (UK)
Anokhi
Barbour Campbell Threads
BASF
Bayer
Benetton Spa (Italy)
Brookeside Dyers & Finishers
Bulmer & Lumb (UK)
C&A
Century
Chargeurs Malesherbes (France)
Ciba
Clariant
Clifford Collins
Coats Viyella (UK)
Courtauld's Fibres
Courtauld's Textiles
CREM
Crown Agents
Danish Commerce and Services
Desmonds
Devanlay (France)
Dollfus Mieg & Cie (France)
Ecotox Textile Dyes
Escada AG (Germany)
Evolution
Exhibition Bulletin
Fabrica Textil Riopele (Portugal)
Grupo Tavex (Spain)
Head in the Clouds
Hugo Boss
Inghirami Group (Italy)
Intercolour Industries
ISF Chemicals
Klaus Steilmann Gmbh & Co KG (Germany)
Legler Industria Tessile (Italy)

L J Specialities
Marks & Spencers (UK)
Martins (Leic) Ltd
Marzotto Spa (Italy)
Max Mara Fashion Group (Italy)
Miroglio Tessile SPA (Italy)
Monsoon (UK)
NEC
OXFAM (UK)
Pretty Polly
William Reed Weaving
SANDOZ
SATRA Technology Centre (UK)
Shirley Dyeing and Finishing Ltd.
Steilmann
Sthal Chemicals
Tack Lea Works
Textile Finishing Group
Totectors
Tradecraft (UK)
Trumpeler Oils
Tumi
TUV (Germany)
Uco (Belgium)

4. Others

Department of Trade and Industry (UK)
Direccao Geral Da Industria (Portugal)
Directorate General XV (Mr. Junghanns)
ERM Economics (UK)
Federal Ministry for Environment, Youth and the Family (Austria)
Health & Safety Authority (Ireland)
Health & Safety Executive (UK)
Laboratory of Government Chemists (UK)
Miljø & Energi Ministeriet (Denmark)
Ministere De L'environment (Belgium)
Ministère Du Travail (Luxembourg)
Ministère Industrie, Poste Et Télécommunications (France)
Ministerio Sanidad Y Consumo (Spain)
Ministero Sanità (Italy)
Ministry of Environment (Finland)
Ministry of Environment & Energy (Denmark)
Ministry of Finance (Greece)
Ministry of Health, Welfare and Sport (Netherlands)
National Chemicals Inspectorate (Sweden)
National Product Control Agency for Welfare and Health (Finland)
Norwegian Pollution Control Authority