

**EXPLANATORY MEMORANDUM TO THE
THE CONTROLS ON CERTAIN AZO DYES AND “BLUE COLOURANT”
(AMENDMENT) REGULATIONS 2004**

2004 No.2913

1. This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. DESCRIPTION

- 2.1. These Regulations give effect to Commission Directive 2004/21/EC (O.J. No.L57, 25.2.2004, p.4) which adapts to technical progress for the 13th time Council Directive 76/769/EEC (O.J. No. L262, 27.9.76, p. 201) on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
- 2.2. Directive 76/769/EEC seeks to protect human health and the environment in the Member States by restricting the use of the dangerous substances and preparations listed in Annex 1 to that Directive. Member States are required to take all necessary measures to ensure that the dangerous substances and preparations listed in Annex 1 may only be placed on the market or used subject to the conditions specified in the Directive.
- 2.3. Directive 2002/61/EC of the European Parliament and of the Council (O.J. No. L243, 11.9.2002, p.15) amended for the 19th time Directive 76/769/EEC by adding “azocolourants” to the list of substances in Annex 1. It prohibits the use of certain azocolourants in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity. This Directive has been implemented in the United Kingdom by the Controls on Certain Azo Dyes and “Blue Colourant” Regulations 2003 (S.I. 2004/3310) (“the Principal Regulations”).
- 2.4. Directive 2004/21/EC prescribes the testing methods for azocolourants, developed by the European Committee for Standardisation (CEN), to be used in the application of Directive 2002/61/EC. The attached Regulations implement Directive 2004/21/EC by amending the Principal Regulations.

3. MATTERS OF SPECIAL INTEREST TO THE JOINT COMMITTEE ON STATUTORY INSTRUMENTS

3.1. Directive 2004/21/EC requires Member States to bring into force laws, regulations and administrative provisions necessary to comply with the Directive by 31st December 2004.

4. LEGISLATIVE BACKGROUND

4.1. These Regulations are made under section 11 of the Consumer Protection Act 1987. A Transposition Note is attached to this Memorandum.

5. EXTENT

5.1. Consumer safety is a reserved matter and therefore the instrument will apply to the whole of the United Kingdom.

6. EUROPEAN CONVENTION ON HUMAN RIGHTS

6.1. The Parliamentary Under Secretary of State for Employment Relations, Postal Services and Consumers, Mr Gerry Sutcliffe MP has made the following statement regarding the Human Rights:

“In my view, these Regulations are compatible with the European Convention on Human Rights”.

7. POLICY BACKGROUND

7.1. A consultation exercise on the implementation of Directive 2002/61/EC was carried out in September 2003. The consultation document, sent to industry and other interested parties, included Directive 2002/61/EC, a proposed draft statutory instrument for implementing that Directive, as well as a copy of Commission Communication 2003/C 214/02 (O.J. No.C214, 9.9.2003, p.2) which advised of the proposed test methods to be used in demonstrating compliance with Directive 2002/61/EC. Having, therefore, consulted with industry and other interested parties and advised them of the proposed testing methods, the Department did not carry out a further consultation exercise concerning Directive 2004/21/EC but, instead, informed all the original consultees, by letter, of its adoption. No comments concerning the methods specified were received.

8. REGULATORY IMPACT

8.1. The Regulations will provide for harmonised standards (test methods), to be used to demonstrate compliance with Directive 2002/61EC.

8.2. A Regulatory Impact Assessment (RIA), which covered the costs of testing, was prepared in relation to the Principal Regulations. In consequence, no further RIA has been prepared for these Regulations. A copy of the RIA, together with the draft Statutory Instrument and the Transposition Note, are attached to this memorandum.

9. COSTS TO THE PUBLIC

9.1. There will be no additional costs imposed on the public.

10. COSTS TO THE EXCHEQUER

10.1. No additional costs will fall to the Exchequer.

11. CONTACT

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DEPARTMENT OF TRADE AND INDUSTRY

8 November 2004

TRANSPPOSITION NOTE

THE CONTROLS ON CERTAIN AZO DYES AND “BLUE COLOURANT” (AMENDMENT) REGULATIONS 2004

The Controls on Certain Azo Dyes and “Blue Colourant” (Amendment) Regulations 2004 give effect to European Commission Directive 2004/21/EC of 24 February 2004 relating to restrictions on the marketing and use of ‘azo colourants’ (thirteenth adaptation to technical progress of Council Directive 76/769/EEC). The table below shows how the provisions of the Directive have been transposed into national law in the Order.

Article	Purpose	Implementation
Article 1	Amends Annex I to Directive 76/69/EEC by inserting a list of the testing methods required to be used for determining whether the maximum permitted concentrations of azo dyes have been exceeded.	Regulation 2 transposes this article by amending the Controls on Certain Azo Dyes and “Blue Colourant” Regulations 2003 (SI2003/3310) to insert a new Schedule 3.
Article 2	Requirement to implement the Directive by 31 December 2004, to include a reference to the Directive in the implementing legislation and to communicate to the Commission the measures transposing the Directive.	Regulation 1 provides that the Regulations are to come into force on 31 December 2004, the Explanatory Note to the Regulations and this note refer to the Directive. Otherwise does not require transposition.
Article 3	Entry into force of the Directive.	Does not require transposition.
Article 4	Addresses Directive to Member States.	Does not require transposition.

THE CONTROLS ON CERTAIN AZO DYES AND 'BLUE COLOURANT' REGULATIONS 2003

Regulatory Impact Assessment

PURPOSE AND INTENDED EFFECT

Issue and Objectives

1. Azocolourants (which include both pigments and dyes) are used to colour, amongst other things, textiles and leather. They have the potential to break down into constituents called amines. Some of these amines are known to be carcinogenic. Directives 2002/61/EC and 2003/3/EC prohibit the marketing and use, in the manufacture of certain textile and leather goods, of those azo dyes that can cleave (split) into one or more of the carcinogenic amines listed in the Annex to Directive 2002/61/EC and of the dye ('blue colourant') listed in Annex to Directive 2003/3/EC. The textile and leather goods affected are those that have the potential to come into direct and prolonged contact with human skin or the mouth: they include clothing, footwear and toys.

Risk assessment

2. The greatest risk of release of carcinogenic amines from azo dyes occurs during the dyeing process and during the manufacture of dyed textiles and leather into consumer goods. However, the potential for worker exposure to the amines and thus any risk to human health is already regulated by the general duties in the Control of Substances Hazardous to Health Regulations (COSHH). Employers are under a duty not to use such hazardous substances at all or to control exposure such that workers are not put at risk. Carcinogenic amines can also be released from azo-dyed materials through skin contact (sweat can cause azo dyes in clothes to break down) and ingestion (e.g. children sucking azo-dyed materials used in clothes or toys). 'Blue colourant' has a high aquatic toxicity, is not easily degradable and reaches the environment via wastewater. Although the actual risk of these azo dyes is considered to be minimal, in principle it has raised concerns about the potential for consumer exposure and the environment.

OPTIONS

3. For a number of years the European dyestuff industry has operated a voluntary ban on the manufacture of azo dyes that can cleave into the amines identified. As far as we can tell, this voluntary ban has operated very effectively and we are not aware of any manufacture of these azo dyes within the European Union (EU). Additionally, we believe 'blue colourant' is not used anywhere in the UK.

4. However, it is possible that affected azo dyes manufactured outside the EU, or dyed leather and textiles and finished leather and textile goods produced there using these azo dyes, may be being imported for marketing and use within the EU. This would present the risks of occupational and consumer exposure outlined in paragraph 2 above. We are aware that legislative action has been taken in India to ban the marketing and use of a number of azo dyes, but it is unclear how rigorously this is being enforced.

5. Some other EU Member States already have domestic bans on the marketing and use of these azo dyes. There was broad support among Member States for a harmonized EU-wide approach to the problem and the European Commission (EC) was anxious to achieve this in order to preserve the internal market. The EC Directives are consistent with current UK policy and practice on this issue therefore the UK supported the legislative ban rather than rely on the existing voluntary arrangements. Directive 2002/61/EC was adopted on 19 July 2002 and published in the Official Journal of the European Communities (OJ) on 11 September 2002 (OJ Ref L243/15). Directive 2003/3/EC was adopted on 6 January 2003 and published in the OJ on 9 January 2003 (OJ Ref L4/12).

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

6. Information to derive the likely benefit and impact to society from implementing the EC Directives comes from the Statistics Directorate of the Department of Trade and Industry (DTI) and the Health and Safety Executive's (HSE) Policy Group¹. To estimate costs, 25 businesses and industry associations including 4 small businesses were contacted. There were 9 responses. The base year for appraisal is year 2002/2003.

¹ HSE prepared the initial RIA during negotiations on the European Commission's proposal (COM(1999) 620 final) and it has been updated in the light of the adopted Directives.

BENEFITS

Health and safety benefits

7. As noted in paragraph 3, the voluntary ban on the manufacture of those azo dyes that can cleave into the amines covered by Directive 2002/61/EC has operated very effectively and there is no known manufacture of the azo dyes concerned within Europe. However, there are concerns that azo dyes manufactured outside Europe, particularly in Asia and Africa, or textiles and leather dyed there using these azo dyes, may be imported and used in the EU.

8. There is no evidence of these azo dyes, or textiles and leather dyed using them, being imported into Great Britain (GB). However, it is possible that a small percentage of GB imports of textiles and leather from these countries may have been dyed using the azo dyes concerned. In the event that between 1% and 5% of these imports have been dyed using azo dyes, between 600 and 3000 metric tonnes of the textiles and leather (£2.4 - £11.9 million in 2002/2003 prices) that are imported into Great Britain each year may contain one or more of the azo dyes affected by the prohibition¹.

9. British companies also import finished products from countries outside the EU. The products that may have been produced using the azo dyes affected by the prohibition that are most likely to have a health impact are clothing, footwear and bed linen. If we again assume that between 1% and 5% of the imports contain the affected azo dyes, between 2,000 and 11,000 metric tonnes of the clothing and footwear (£19.9 - £99.5 million in 2002/2003 prices) that are imported into Great Britain each year could contain one or more of the azo dyes concerned.

10. When the Directive is transposed into UK law the possible negative health effects to UK workers and consumers resulting from contact with such imports will be eliminated. However, we do not have information on the current negative health impact of azo dyes in Great Britain. Therefore, such benefits are unquantifiable.

¹Information on UK imports of textiles and leather goods was supplied by the Statistics Directorate of the Department of Trade and Industry. Northern Ireland imports were assumed to be about 2.3% of total UK imports.

COSTS

Business sectors affected

11 The companies in Great Britain that would be affected by the prohibition are those involved in the import, production or sale of certain textiles, leather and associated goods and manufacture of azo dyes. The textiles and leather products concerned include:

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

Compliance costs to business

12. The purpose of Directive 2002/61/EC was to substitute an existing voluntary ban with enforceable law. HSE estimates that in Great Britain there is almost complete compliance with the voluntary ban. Information from the companies and industry associations contacted suggests that most companies are not importing goods that may have been dyed with the listed azo dyes. All but one company claimed the prohibition would not affect their importation of leather and textile goods.

13. For any companies still using these azo dyes, substitutes for them are readily available and switching to these is not expected to have any impact on sales. Indeed, one large retail company reported that they could pass on the extra cost to consumers without any reduction in sales.

14. However, there may be some cost implications of industry compliance with the prohibition. British firms importing either dyed textiles and leather for manufacture into goods covered by the prohibition, or finished textile and leather goods, would - if challenged by the regulatory authorities - need to be able to demonstrate that their products are free from the azo dyes covered. British importers can, in the first instance, seek confirmation of this from their overseas suppliers.

15. If this evidence cannot be obtained from the overseas supplier then it will be necessary for the British company to test the material concerned, using the test method developed by the European Commission, to show that banned azo dyes have not been used. The testing procedure results in the destruction of a sample of the leather or textile and costs between £105 and £126 per test.

16. It is difficult to estimate the cost to British industry of performing such tests. If British importers can secure reliable evidence from their overseas suppliers that their products do not contain azo dyes affected by the prohibition then they will not need to conduct tests themselves. The extent of the need for testing will also be partly determined by the composition of imports into Great Britain. A company importing a large consignment of identical items would only need to conduct one test; a consignment containing a variety of items made from different fabrics or dyed in different colours might necessitate several tests. One company has estimated a need for approximately 144,000 tests per annum. We attempted to estimate these costs for all businesses concerned but were unable to obtain sufficient data. The cost of testing is therefore unquantifiable.

17. Failure to pass a test for one of the azo dyes covered by the prohibition would mean that a British company could not sell the product in the EU. If the illegal items could not be returned to the supplier then the British company could be faced with substantial costs. It may also face the additional cost of having to source a new supplier. We have been unable to obtain information on either of these potential costs and so they are also unquantifiable.

18. There may also be some potential costs arising from the inclusion of 4-aminoazobenzene to the list of substances. Information from the British leather industry suggests that there is no test that can unequivocally identify whether or not this substance has been used in dyeing leather. As a consequence, a large number of false positives may result from testing. It has not been possible to estimate the likely cost to industry. One industry source has indicated it could be substantial and disproportionate to the risk. However, the European Commission has stated that this substance is not widely used in dyeing materials.

19. The purpose of Directive 2003/3/EC is to address environmental concerns. 'Blue colourant' has a high aquatic toxicity, is not easily degradable and reaches the environment via wastewater. However, as previously stated 'blue colourant' is not manufactured or used in the UK and so there are no compliance costs for industry.

Costs to Government Department

20. There are not expected to be any additional costs.

Total costs to society

21. Owing to the existing voluntary ban on the manufacture of these azo dyes in the EU, any usage of them in Great Britain in the manufacture of textile and leather goods is thought to be minimal. Substitutes for these azo dyes are already available at little additional cost; any company still using azo dyes that will be prohibited would experience little difficulty or expense in switching to a substitute product. One of the companies contacted reported that they did not expect the small extra cost to have any impact on their sales. Consumers may face an additional cost if companies raise their prices in order to pay for substitute dyes, but we believe that any such increase would be negligible in relation to the total cost of the finished product.

22. Some British firms may need to pay for their imported supplies to be tested if they cannot secure confirmation from their suppliers that the goods do not contain azo dyes affected by the prohibition. Some firms may also need to find alternatives if their current supplies of ready-dyed goods are found to contain the affected azo dyes. These may also result in costs that may be passed on to the consumer, which we have been unable to quantify.

IMPACT ON SMALL BUSINESSES, CHARITIES AND VOLUNTARY ORGANISATIONS

23. In order to establish the effects of the prohibition on small businesses, during negotiations, four companies were contacted. One company explained that it began using substitutes for these azo dyes two years ago and as a result it could see no additional costs of making the voluntary ban legally binding. A second company stated that the prohibition may have an impact on its sales in non-EC countries and that a legal ban may well force them to drop many lines. This is despite the fact that the company tries to avoid using dyes covered by the voluntary ban whenever possible. If small companies were currently using azo dyes covered by the voluntary ban then a legally binding prohibition would have a disproportionate effect on them. However, substitutes for the azo dyes affected are available at little extra cost and a legal ban is unlikely to cause small firms to remove products from the market since costs can be passed on to consumers with only a minimal impact on sales.

24. One charity organisation contacted was unable to estimate the proportion of its products that may be affected by the prohibition. They indicated that some of their suppliers will be able

to use substitutes and some will not. The organisation would be forced to stop using any supplier who could not meet the legal requirements. They wished to emphasise that this would be counter to their objective of 'sustainable livelihood'.

ENVIRONMENTAL IMPACTS

25. The adopted Directives are not expected to have any impact on the environment. In the UK, 'Blue colourant' is not manufactured or used so the environmental benefits have been realised.

BALANCE OF COSTS AND BENEFITS

26. For the vast majority of companies working with leather and textiles, the prohibition will not impose any extra cost. If some of the current imports of textiles and leather goods have been dyed using these azo dyes, the prohibition will reduce the negative health impact due to exposure to these products. During negotiations on the EC's proposal, the initial RIA was revised, however given the paucity of information available, we concluded that further effort to estimate more detailed cost and benefits was unlikely to be justified.

Uncertainties


27. The greatest uncertainty concerns the quantity of textiles and leather containing azo dyes that are currently imported into Great Britain. Although we have no evidence of any such imports, it is possible that a small number are entering Great Britain. The quantity of such imports would have implications on the size of the health benefits to be gained from adopting the EC Directives. There is also uncertainty surrounding the total cost to British industry of testing imports of textiles and leather goods that may have been dyed using these azo dyes.


ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW

28. The enforcement arrangements and sanctions are set out in the Statutory Instrument. The implementing regulations will be monitored and reviewed in accordance with normal procedures - a review is likely once the implementing regulations have been in force for 2-3 years.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the balance between the cost and benefit is the right one in the circumstances.

Signed by the Minister responsible 
(Department for Environment, Food and Rural Affairs)

Signed by the Minister responsible 
(Parliamentary Under Secretary of State for Employment Relations, Competition and Consumers, Department of Trade and Industry)

17/12/03