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STATUTORY INSTRUMENTS

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**2003 No. 3310**

**CONSUMER PROTECTION  
ENVIRONMENTAL PROTECTION**

**The Controls on Certain Azo Dyes and  
“Blue Colourant” Regulations 2003**

<i>Made</i>	- - - -	<i>17th December 2003</i>
<i>Laid before Parliament</i>		<i>18th December 2003</i>
<i>Coming into force</i>		
	<i>Regulations 1 to 4 and 7</i>	<i>8th January 2004</i>
	<i>Remainder</i>	<i>30th June 2004</i>

The Secretary of State, being a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to measures relating to restrictions on the marketing and use of certain dangerous substances and preparations, having consulted such organisations as appear to her to be representative of interests substantially affected by these regulations, such other persons as she considers appropriate, and the Health and Safety Commission, in exercise of the powers conferred upon her by section 2(2) of the 1972 Act<sup>(3)</sup>, and by section 11 of the Consumer Protection Act 1987<sup>(4)</sup> makes the following Regulations:

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Controls on Certain Azo Dyes and “Blue Colourant” Regulations 2003.

(2) Regulations 1 to 4 and 7 shall come into force on 8th January 2004.

(3) Regulations 5, 6 and 8 shall come into force on 30th June 2004.

(4) These Regulations extend to Great Britain. Regulations 4 and 7 and regulations 2 and 3 insofar as they relate to regulation 4 also extend to Northern Ireland.

**Interpretation**

2.—(1) In these Regulations—

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(1) S.I.1992/1711.

(2) 1972 c. 68.

(3) The power of the Minister to make regulations in relation to matters in or as regards Scotland is preserved by section 57(1) of the Scotland Act 1998.

(4) 1987 c. 43.

“Member State” means a member state of the European Community or a State which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;

“supply” has the meaning given by section 46 of the 1987 Act;

“the 1987 Act” means the Consumer Protection Act 1987;

“the 1995 Act” means the Environment Act 1995<sup>(5)</sup>;

(2) Expressions used in these Regulations which are also used in Council Directive [76/769/EEC](#) on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations<sup>(6)</sup>, as last amended by European Parliament and Council Directive [2002/61/EC](#) amending for the 19th time Council Directive [76/769/EEC](#)<sup>(7)</sup> and Commission Directive [2003/3/EC](#) relating to restrictions on the marketing and use of “blue colourant” (twelfth adaptation to technical progress of Council Directive [76/769/EEC](#))<sup>(8)</sup> shall have the meaning they bear in that Directive.

### Scope

3.—(1) These Regulations do not apply to—

- (a) the placing on the market or use of azo dyes or “blue colourant” for research and development or analysis purposes;
- (b) the carriage of azo dyes or “blue colourant” by rail, road, inland waterway, sea or air;
- (c) azo dyes or “blue colourant” exported to a country which is not a Member State; and
- (d) azo dyes or “blue colourant” in transit and subject to customs inspection, provided that they undergo no processing.

(2) In this regulation “azo dyes” means those azo dyes referred to in regulation 4(1) and “blue colourant” means the colourant referred to in regulation 5.

### Prohibition on the placing on the market and use of azo dyes

4.—(1) Azo dyes which, by reductive cleavage of one or more azo groups, may release in detectable concentrations one or more of the aromatic amines listed in Schedule 1 to these Regulations may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, including—

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

(2) For the purposes of this regulation “detectable concentrations” means concentrations of aromatic amines above 30 ppm in the finished articles or in the dyed parts thereof.

(3) No person shall supply, offer or agree to supply, expose or possess for supply any textile and leather articles referred to in paragraph (1) of this regulation unless they conform to the requirements set out in that paragraph.

(4) The prohibition in paragraph (3) shall not apply to—

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<sup>(5)</sup> [1995 c. 25](#).

<sup>(6)</sup> O.J. No. L262, 27.9.1976, p. 201.

<sup>(7)</sup> O.J. No. L243, 11.9.2002, p. 15.

<sup>(8)</sup> O.J. No. L4, 9.1.2003, p. 12.

- (a) textile and leather articles placed on the market in a Member State before 11th September 2003; and
- (b) textile articles made of recycled fibres placed on the market in a Member State before 1st January 2005 provided that—
  - (i) the amines are released by residues deriving from previous dyeing of the same fibres; and
  - (ii) the amines referred to in paragraph (1) are released in concentrations below 70 ppm.

### **Prohibition on the placing on the market and use of “blue colourant”**

5.—(1) No person shall supply, offer or agree to supply, expose or possess for supply, or use for colouring textile and leather articles, the “blue colourant” defined in Schedule 2 to these Regulations as a substance or constituent of preparations in concentrations higher than 0.1% by mass.

(2) Paragraph (1) shall not prohibit a person from supplying, offering or agreeing to supply, exposing or possessing for supply “blue colourant” placed on the market in a Member State before 30th June 2004.

### **Offences and penalties**

6.—(1) Any person who contravenes regulation 5, or causes or permits another person to contravene that regulation, shall be guilty of an offence.

(2) Any person guilty of an offence under paragraph (1) shall be liable, on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months and, on conviction on indictment, to a fine not exceeding £5,000 or to imprisonment not exceeding six months.

(3) Where an offence under paragraph (1) committed by a body corporate is proved—

- (a) to have been committed with the consent or connivance of an officer, or
- (b) to be attributable to any neglect on his part,

the officer as well as the body corporate shall be guilty of that offence and liable to be proceeded against and punished accordingly.

(4) In paragraph (3) “officer”, in relation to a body corporate, means a director, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity.

(5) If the affairs of a body corporate are managed by its members, paragraph (3) shall apply in relation to the acts or defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(6) Where an offence under paragraph (1) committed by a partnership in Scotland is proved—

- (a) to have been committed with the consent or connivance of a partner, or
- (b) to be attributable to any neglect on his part,

the partner as well as the partnership shall be guilty of that offence and liable to be proceeded against and punished accordingly.

(7) In paragraph (6) “partner” includes a person purporting to act as a partner.

### **Regulations to be treated as safety regulations within the meaning of the 1987 Act**

7. Regulation 4 and regulations 2 and 3 insofar as they relate to regulation 4 are safety regulations made under section 11 of the 1987 Act.

### **Powers of enforcing authorities in relation to “blue colourant”**

8.—(1) This regulation applies to regulation 5.

(2) For the purposes of this regulation, “enforcing authority” means—

- (a) in relation to England and Wales, the Environment Agency; and
- (b) in relation to Scotland, the Scottish Environment Protection Agency.

(3) Any person who appears suitable to an enforcing authority may be authorised in writing by that enforcing authority, for the purpose of determining whether regulation 5 is being, or has been, complied with, to exercise any of the powers specified in paragraph (4).

(4) The powers exercisable under paragraph (3) are the powers in paragraphs (a) to (m) of sub-section (4) of section 108 of the 1995 Act as modified by paragraph (5) of this regulation and subject to sub-sections (6) to (16) of that section.

(5) For the purposes of paragraph (4), section 108 shall apply as if—

- (a) in paragraph (g), for the words “have caused or to be likely to cause pollution of the environment or harm to human health” there were substituted the words “be or contain a substance referred to in regulation 5 of the Controls on Certain Azo Dyes and “Blue Colourant” Regulations 2003”;
- (b) in paragraph (h), for the words in sub-paragraph (iii) there were substituted the words “to ensure that it is available for use as evidence in any proceedings for an offence under regulation 6 of the Controls on Certain Azo Dyes and “Blue Colourant” Regulations 2003”;
- (c) in paragraph (k), sub-paragraph (i) was omitted;
- (d) in paragraph (m), sub-paragraph (ii) was omitted;
- (e) in paragraph (15), the term “authorised person” included a person authorised under paragraph (1) of this regulation.

*Gerry Sutcliffe,*  
Parliamentary Under Secretary of State for  
Employment Relations, Competition and  
Consumers, Department of Trade and Industry

17th December 2003

## SCHEDULE 1

Regulation 4

## LIST OF AROMATIC AMINES REFERRED TO IN REGULATION 4

In this Schedule—

“CAS number” means the number given in the CAS Registry Handbook, ISSN 0093-058X,  
 “Index number” means the identification code given to the substance in amended Annex I of  
 Directive [67/548/EEC](#) on the approximation of laws, regulations and administrative provisions  
 relating to the classification, packaging and labelling of dangerous substances<sup>(9)</sup>,  
 “EC number” means the identification code given to the substance and published in the  
 European Inventory of Existing Commercial Chemical Substances (Einecs).

	<i>CAS number</i>	<i>Index number</i>	<i>EC number</i>	<i>Substances</i>
1	92-67-1	612-072-00-6	202-177-1	biphenyl-4- ylamine  4-aminobiphenyl  xenylamine
2	92-87-5	612-042-00-2	202-199-1	benzidine
3	95-69-2		202-441-6	4-chloro-o- toluidine
4	91-59-8	612-022-00-3	202-080-4	2-naphthylamine
5	97-56-3	611-006-00-3	202-591-2	o- aminoazotoluene  4-amino-2',3- dimethylazobenzene  4-o-tolylazo-o- toluidine
6	99-55-8		202-765-8	5-nitro-o- toluidine
7	106-47-8	612-137-00-9	203-401-0	4-chloroaniline
8	615-05-4		210-406-1	4-methoxy-m- phenylenediamine
9	101-77-9	612-051-00-1	202-947-4	4,4'- methylenedianiline  4,4'- diaminodiphenylmethane
10	91-94-1	612-068-00-4	202-109-0	3,3'- dichlorobenzidine

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(9) O.J. P196, 16.8.1967, p. 1.

**Status:** This is the original version (as it was originally made). UK  
Statutory Instruments are not carried in their revised form on this site.

	<i>CAS number</i>	<i>Index number</i>	<i>EC number</i>	<i>Substances</i>
				3,3'-dichlorobiphenyl-4,4'-ylenediamine
11	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine
				o-dianisidine
12	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine
				4,4'-bi-o-toluidine
13	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o-toluidine
14	120-71-8		204-419-1	6-methoxy-m-toluidine
				p-cresidine
15	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis-(2-chloro-aniline)
				2,2'-dichloro-4,4'-methylene-dianiline
16	101-80-4		202-977-0	4,4'-oxydianiline
17	139-65-1		205-370-9	4,4'-thiodianiline
18	95-53-4	612-091-00-X	202-429-0	o-toluidine
				2-aminotoluene
19	95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenediamine
20	137-17-7		205-282-0	2,4,5-trimethylaniline
21	90-04-0	612-035-00-4	201-963-1	o-anisidine
				2-methoxyaniline
22	60-09-3	612-008-00-4	200-453-6	4-amino azobenzene

## SCHEDULE 2

Regulation 5

## “BLUE COLOURANT” REFERRED TO IN REGULATION 5

In this Schedule—

“CAS number” means the number given in in the CAS Registry Handbook, ISSN 0093-058X,

“Index number” means the identification code given to the substance in amended Annex I of Directive [67/548/EEC](#) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(10),

“EC number” means the identification code given to the substance and published in the European Inventory of Existing Commercial Chemical Substances (Einecs).

	<i>CAS number</i>	<i>Index number</i>	<i>EC number</i>	<i>Substances</i>
1	Not allocated	611-070-00-2	405-665-4	A mixture of:
	Component 1:			disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)
	CAS-No.:			(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-);
	118685-33-9			and
	$C_{39}H_{23}ClCrN_7O_{12}S_2Na$			trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)
	Component 2:			
	$C_{46}H_{30}CrN_{10}O_{20}S_2.3Na$			

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations give effect to European Parliament and Council Directive [2002/61/EC](#) on azocolourants, as amended by Commission Directive [2003/3/EC](#) on “blue colourant”. To the extent that the Regulations apply to azocolourants, they also apply to Northern Ireland.

Both Directives make amendments to the regime established under Council Directive [76/769/EEC](#) 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.

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(10) O.J. P196, 16.8.1967, p.1 .

The Regulations apply from 8th January 2004 in relation to azocolourants and from 30th June 2004 in relation to “blue colourant”.

Regulation 3 sets out exclusions from the scope of the Regulations.

Regulation 4 provides that azo dyes may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity where such substances, by reductive cleavage of one or more azo groups, may release in detectable concentrations one or more of the aromatic amines listed in Schedule 1. The supply of textile and leather articles which do not comply with regulation 4(1) is prohibited by regulation 4(3).

Regulation 4(4) contains transitional provisions permitting the supply of leather and textile articles placed on the market in a Member State before 11th September 2003 and articles made of recycled fibres placed on the market before 1st January 2005.

Regulation 5 prohibits the supply and the use of “blue colourant” defined in Schedule 2 for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0.1% by mass. The prohibition on supply does not apply to “blue colourant” which is placed on the market before 30th June 2004 (regulation 5(2)).

Regulation 6 makes it an offence to contravene regulation 5 and specifies the penalties for such an offence. By virtue of regulation 7, regulation 4 and other regulations insofar as they relate to regulation 4, are safety regulations made under the Consumer Protection Act 1987. This Act makes the supply of goods in contravention of safety regulations an offence and makes other provisions for the enforcement of safety regulations.

Regulation 8 specifies the powers of the Environment Agency, in England and Wales, and the Scottish Environment Protection Agency, in Scotland, to enforce regulation 5.

In these Regulations, the substances in Schedules 1 and 2 are identified by reference to their CAS Numbers, Index Numbers and EC Numbers. The CAS Number is given in the CAS Registry Handbook, ISSN 0093-058X, which may be inspected at the Royal Society of Chemistry, Burlington House, Piccadilly, London W1V 0BN. The Index Number is the identification code given to the substance in amended Annex I of Directive [67/548/EEC](#) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (O.J. No. P196, 16.8.67, p. 1) and published in the European List of Notified Chemical Substances (Elincs). The EC Number is the identification code given to the substance and published in the European Inventory of Existing Commercial Chemical Substances (Einecs).

A Regulatory Impact Assessment and a Transposition Note in relation to these Regulations have been prepared and placed in the library of each House of Parliament. Copies of either of these documents can be obtained from Defra, Chemicals and GM Policy Division, Ashdown House, 123 Victoria Street, London SW1E 6DE or from Department of Trade and Industry, Bay 432, 1 Victoria Street, London SW1H 0ET.