

2003 No.

**CONSUMER PROTECTION
ENVIRONMENTAL PROTECTION**

THE CONTROLS ON AZODYES REGULATIONS 2003

<i>Made</i>	2003
<i>Laid before Parliament</i>	2003
<i>Coming into force</i>	
<i>For the purposes of</i>	
<i>regulation 4</i>	[...] 2003
<i>For the purposes of</i>	
<i>regulation 5</i>	30 June 2004

The Secretary of State for Environment, Food and Rural Affairs being a Minister designated^(a) for the purposes of section 2(2) of the European Communities Act 1972^(b) 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 on her by the said section 2(2)^(c), by section 11 of the Consumer Protection Act 1987¹ and of all other powers enabling her in that behalf hereby makes the following Regulations:

Citation, commencement and extent

1. (1) These Regulations may be cited as the Controls on Azodyes Regulations 2003.
(2) Regulation 4 and 8 and regulations 1, 2, 3 and 6 insofar as they relate to regulation 4 shall come into force on [. . . 2003].
(3) Regulation 5 and 7 and regulations 1, 2, 3 and 6 insofar as they relate to regulation 5 shall come into force on 30 June 2004.

^(a) S.I. 1992/1711.

^(b) 1972 c. 68.

^(c) 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.

¹ 1987 c.43.

(4) These Regulations extend to Great Britain. For the purposes of regulation 4 and regulations 1, 2, 3, 6, 7 and 8 insofar as they relate to regulation 4, these Regulations also extend to Northern Ireland.

Interpretation

2. (1) In these Regulations –

“the 1987 Act” means the Consumer Protection Act 1987^(d); and

“the 1995 Act” means the Environment Act 1995^(e).

(2) Expressions used in these Regulations which are also used in Council Directive 76/769/EC 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^(f), as last amended by European Parliament and Council Directive 2002/61/EC amending for the 19th time Council Directive 76/769/EC^(g) 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)^(h) shall have the meaning they bear in that Directive.

Scope

3. These Regulations do not apply to:

- (a) the placing on the market or use of dangerous substances or preparations for research and development or analysis purposes;
- (b) the carriage of dangerous substances or preparations by rail, road, inland waterway, sea or air;
- (c) dangerous substances or preparations exported to a country which is not a Member State of the European Community nor Norway, Iceland or Liechtenstein; and
- (d) dangerous substances or preparations in transit and subject to customs inspection, provided that they undergo no processing.

Prohibition on the placing on the market and use of azodyes

4. (1) Azodyes 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:

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags;
- footwear, gloves, wristwatch straps, handbags, purses or wallets, briefcases, chair covers, purses worn round 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.

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

(3) The textile and leather articles referred to in paragraph (1) of this regulation may not be placed on the market unless they conform to the requirements set out in that paragraph. By way of

^(d) 1987 c. 43.

^(e) 1995 c. 25.

^(f) O.J. No. L262, 27.9.1976, p. 201.

^(g) O.J. No. L243, 11.9.2002, p. 15.

^(h) O.J. No. L4, 9.1.2003, p. 12.

derogation, until 1 January 2005, this paragraph shall not apply to textile articles made of recycled fibres, 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. The azodyes listed in Schedule 2 to these Regulations may not be placed on the market or used for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0.1 % by mass.

Offences and penalties

6. (1) Any person who contravenes regulations 4 or 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 the statutory maximum or to imprisonment not exceeding six months.

(3) Where an offence under regulations 4 or 5 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 regulations 4 or 5 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 1, 2, 3, 6 and 8 insofar as they relate to regulation 4 shall be treated for the purposes of the 1987 Act, other than section 12 of that Act, as if they were safety regulations made under that Act.

Powers of enforcing authorities in relation to blue colourant

8. (1) 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 (2).

(2) The powers exercisable under paragraph (1) are the powers in paragraphs (a) to (m) of sub-section 4 of section 108 of the 1995 Act as modified by paragraph (3) of this regulation and subject to sub-sections (6) to (16) of that section.

(3) For the purposes of paragraph (2), 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 Azodyes 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 Azodyes 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.

(4) 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.

Minister of State

Department for Environment, Food and Rural Affairs

List of aromatic amines referred to in regulation 4

In this Schedule: -

“CAS number” means the number given in the 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⁽ⁱ⁾,

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

	CAS number	Index number	EC number	Substances
1	92-67-1	612-072-00-6	202-177-1	biphenyl-4-ylamine 4-aminobiphenyl xenyamine
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 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

⁽ⁱ⁾ O.J. No. P196, 16.8.67, p.1.

List of azodyes referred to in regulation 5

In this Schedule: -

“CAS number” means the number given in the 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^(j),

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

	CAS number	Index number	EC number	Substances
1	Not allocated Component 1: CAS-No.: 118685-33-9 $C_{39}H_{23}ClCrN_7O_{12}S_2Na$ Component 2: $C_{46}H_{30}CrN_{10}O_{20}S_2_3Na$	611-070-00-2	405-665-4	A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)

^(j) O.J. No. P196, 16.8.67, p.1.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations give effect to European Parliament and Council Directive 2002/61 on azocolourants, as amended by Commission Directive 2003/3 on blue colourants. The provisions relating to azodyes apply throughout the United Kingdom and come into force on []. The provisions relating to blue colourant apply to Great Britain only and come into force on 30 June 2004.

The Directive makes amendments to the regime established under Council Directive 76/769/EC 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. The Regulations apply from [...] in relation to azocolourants, from 30 June 2004 in relation to blue colourant.

Provisions of these Regulations relating to azodyes are made under the Consumer Protection Act 1987. Otherwise they are made under section 2 of the European Communities Act 1972.

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

Regulation 4 prohibits the use of azodyes 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. Such textile and leather articles may not be placed on the market unless they conform to the requirements set out in Regulation 5(1).

By way of derogation, until 1 January 2005, the prohibition on the placing on the market of textile and leather articles containing azodyes shall not apply to textile articles made of recycled fibres, provided specified conditions are met.

Regulation 5 prohibits the placing on the market and the use of certain azodyes (blue colourants) for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0.1 % by mass. The restricted azodyes are listed in Schedule 2.

Regulation 6 makes it a criminal offence to contravene regulations 4 or 5 and specifies the penalties for such an offence.

Regulation 7 provides that the provisions of these Regulations relating to azodyes should be treated as if they were safety regulations made under the Consumer Protection Act 1987 for the purposes of that Act.

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).