STATUTORY INSTRUMENTS

1994 No. 3080

ELECTROMAGNETIC COMPATIBILITY

The Electromagnetic Compatibility (Amendment) Regulations 1994

Made - - - - 2nd December 1994
Laid before Parliament 5th December 1994

Coming into force

Regulations 1, 2 and 6(1) 30th December 1994

Regulation 6(2) 1st May 1995

Remainder 1st January 1995

The Secretary of State, being a Minister designated(1) for the purposes of section 2(2) of the European Communities Act 1972(2) in relation to measures relating to apparatus which is liable to cause electromagnetic disturbance and to apparatus the performance of which is liable to be affected by such disturbance, in exercise of the powers conferred on him by that section and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation and commencement

- **1.** These Regulations may be cited as the Electromagnetic Compatibility (Amendment) Regulations 1994 and shall come into force as follows—
 - (a) regulations 1, 2 and 6(1), on 30th December 1994;
 - (b) regulation 6(2), on 1st May 1995; and
 - (c) the remainder, on 1st January 1995.

Interpretation

2. In these Regulations—

"the principal Regulations" means the Electromagnetic Compatibility Regulations 1992(3); and

⁽¹⁾ S.I.1989/2393.

^{(2) 1972} c. 68.

⁽³⁾ S.I. 1992/2372.

"the CE Marking Directive" means Council Directive 93/68/EEC(4).

Interpretation of the principal Regulations

- **3.** Regulation 3 of the principal Regulations is (in addition to the amendments made by regulation 4(a) below) hereby amended as follows—
 - (a) for paragraph (1) (definition of the EMC Directive) there shall be substituted the following paragraph—
 - "(1) In these Regulations, "the EMC Directive" means Council Directive 89/336/ EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility(5), as amended by—
 - (a) Article 9.4 of the Telecommunications Terminal Equipment Directive(6);
 - (b) Council Directive 92/31/EEC(7); and
 - (c) Article 5, 14.1 and 14.2 of the CE Marking Directive.";
 - (b) in paragraph (2)—
 - (i) before the definition of "the Commission" there shall be inserted the following definition—

""CE Marking Directive" means Council Directive 93/68/EEC;";

- (ii) in the definition of "the Community" the word "Economic" shall be omitted(8);
- (iii) for the definition of "educational electronic equipment" there shall be substituted the following—

""education and training equipment" has the meaning given by regulation 8(3) below:"

(iv) after the definition of "responsible person" there shall be inserted the following definitions—

""satellite earth station equipment" means satellite earth station equipment within the meaning of Article 1.2 of the Satellite Earth Station Equipment Directive;

"Satellite Earth Station Equipment Directive" means Council Directive 93/97/ EEC supplementing Directive 91/263/EEC in respect of satellite earth station equipment(9);"; and

- (v) to the definition of "Telecommunications Terminal Equipment Directive" there shall be added at the end the following—
 - "as amended by Article 11, 14.1 and 14.2 of the CE Marking Directive";
- (c) in regulation 3(5)(a) (definition of immediate electromagnetic environment), for the words "educational electronic equipment" there shall be substituted the words "education and training equipment"; and
- (d) after paragraph (6) there shall be inserted the following paragraph—

⁽⁴⁾ OJ No. L220, 30.8.93, p.1.

⁽⁵⁾ OJ No. L139, 23.5.89, p.19. Article 10.5 of the EMC Directive has been disapplied in relation to equipment falling within the scope of Telecommunications Terminal Equipment Directive and the Satellite Earth Station Equipment Directive by Article 8.3 of the latter Directive.

⁽⁶⁾ OJ No. L128, 23.5.91, p.1.

⁽⁷⁾ OJ No. L126, 12.5.92, p.11.

⁽⁸⁾ This change was effected by Title II, Article G.A. of the Treaty on European Union signed at Maastricht on 7th February 1992.

⁽⁹⁾ OJ No. L290, 24.11.93, p.1.

- "(7) In these Regulations, with respect to matters arising on and after 1st January 1994, a reference to the Community includes a reference to the EEA, and a reference to a member State includes a reference to an EEA State, and for the purposes of this paragraph—
 - (a) the "EEA" means the European Economic Area;
 - (b) an "EEA State" means a state which is a contracting party to the EEA Agreement but until the EEA Agreement comes into force in relation to Liechtenstein does not include the State of Liechtenstein; and
 - (c) the "EEA Agreement" means 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.".

Implementation of the CE Marking Directive

- 4. Subject to regulation 5 below, the principal Regulations are hereby amended as follows—
 - (a) in regulation 3(2)—
 - (i) for the definition of "affixed", there shall be substituted the following definition—
 - ""affixed" in relation to the CE marking, or any inscription which is liable to be confused therewith, or which is likely to deceive third parties as to the meaning and form thereof, means affixed to one of the items mentioned in regulation 33(2) below or to any other item such that it is referrable to any apparatus;"; and
 - (ii) for the definition of "CE mark" there shall be substituted the following definition—
 ""CE marking" and "CE conformity marking" shall be construed in accordance with regulation 33 below;";
 - (b) in regulation 30(c), for "CE mark" there shall be substituted "CE marking";
 - (c) for regulation 33, there shall be substituted the following regulation—

"The CE marking

- **33.**—(1) For the purposes of these Regulations, the CE marking shall be regarded as properly affixed in relation to relevant apparatus if the requirements of this regulation are complied with.
- (2) The CE marking shall be affixed in relation to any relevant apparatus by being affixed to one of the following—
 - (a) the apparatus; or
 - (b) the apparatus'—
 - (i) packaging;
 - (ii) instructions for use; or
 - (iii) guarantee certificate.
- (3) Subject to paragraph (4) below, where the apparatus is the subject of other Community Directives covering other aspects and which also provide for the CE conformity marking, the latter shall indicate that the apparatus is also presumed to conform to those other Directives.
- (4) Where one or more of the other Directives referred to in paragraph (3) above allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the

European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.

- (5) No person shall affix to relevant apparatus, its packaging, the instructions for use or the guarantee certificate any marking which is likely to deceive third parties as to the meaning and form of the CE marking. Any other marking may be affixed to the apparatus, its packaging, the instructions for use or the guarantee certificate provided that the visibility and legibility of the CE marking are not thereby reduced.
- (6) No person shall affix the CE marking, or any other inscription liable to be confused therewith, in relation to any relevant apparatus, unless—
 - (a) the apparatus complies with the protection requirements; and
 - (b) the conformity assessment requirements have been complied with.
- (7) Except as provided in paragraph (3) above, no person shall affix the CE marking, or any other inscription liable to be confused therewith, to any electrical apparatus other than relevant apparatus.
- (8) The CE marking shall comply with the form requirements set out in Schedule 4 to these Regulations.
- (9) In these Regulations, "CE marking" means the CE conformity marking, being a mark—
 - (a) consisting of the initials "CE";
 - (b) taking the form set out in paragraph 1 of Schedule 4 hereto; and
 - (c) which, when used in relation to the EMC Directive, indicates conformity to all the provisions of that Directive, including the conformity assessment requirements.";
- (d) after regulation 77, there shall be inserted the following regulation—

"Compliance notices

- **77A.**—(1) Subject to paragraph (4) below, in the relevant circumstances, no notice may be served pursuant to regulation 78 or 79 below, and no proceedings may be commenced pursuant to regulation 82, 85, 94 or 95 below, unless the requirements of this regulation are satisfied.
- (2) The relevant circumstances are that it is established that the CE mark or CE marking has been affixed unduly to electrical apparatus.
 - (3) The requirements of this regulation are that—
 - (a) there has been served upon the manufacturer or his authorized representative a notice in writing obliging the person on whom the notice is served to make the electrical apparatus conform as regards the provisions concerning the CE mark or CE marking and its due affixation and to end the infringement under conditions imposed in, or in relation to, the said notice; and
 - (b) the non-conformity continues after the period specified in, or in relation to, the said notice during which the infringement must be ended has expired.
- (4) Without prejudice to paragraph 3(a) and (b), a notice served pursuant to paragraph (1) above shall include, but not by way of limitation,
 - (a) a description of the electrical apparatus in respect of which the notice is served on the manufacturer or his authorised representative in a manner sufficient to identify it;

- (b) a statement that the CE mark or CE marking affixed to either the electrical apparatus or the apparatus' packaging, instructions for use or guarantee certificate is unduly affixed, or that the CE mark or CE marking is affixed to some other item accompanying the apparatus;
- (c) a statement of the grounds upon which it is established that the CE mark or CE marking has been or is being unduly affixed in relation to the electrical apparatus; and
- (d) an indication as to which of the following procedures cannot be commenced unless the requirements of this regulation are satisfied:—
 - (i) a notice pursuant to regulation 78 or 79 below; or
 - (ii) proceedings pursuant to regulation 82, 85, 94 or 95 below,

and may include such other information as may be considered expedient to enable the person to whom the notice is addressed to decide what action should be taken to end the particular infringement.

- (5) This regulation does not apply where it is found that apparatus bearing the CE mark or CE marking does not comply with the protection requirements.";
- (e) for regulation 85, there shall be substituted the following regulation—

"Misuse of the CE marking etc

- **85.**—(1) Any person who, in relation to any relevant apparatus, or any electrical apparatus other than relevant apparatus, affixes the CE marking or any other inscription or marking in contravention of regulation 33(5), (6) or (7) above, shall be guilty of an offence.
 - (2) Any person who issues an EC declaration of conformity in relation to—
 - (a) any relevant apparatus in contravention of regulation 34(3) above; or
- (b) any electrical apparatus in contravention of regulation 34(4) above, shall be guilty of an offence.";
- (f) in regulation 94(1), for sub-paragraph (b) of paragraph (1) there shall be substituted the following sub-paragraph—
 - "(b) electrical apparatus other than relevant apparatus, on the grounds that the CE marking, or an inscription liable to be confused therewith, is affixed in relation to it in contravention of regulation 33(7) above;";
- (g) in regulation 95(1), for sub-paragraph (b) of paragraph (1) there shall be substituted the following sub-paragraph—
 - "(b) electrical apparatus other than relevant apparatus, on the grounds that the CE marking, or an inscription liable to be confused therewith, is affixed in relation to it in contravention of regulation 33(7) above;"; and
- (h) for Schedule 4, there shall be substituted the following Schedule—

"SCHEDULE 4

Regulation 33

THE CE MARKING

1. In the CE marking, the initials CE shall take the following form



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

- **2.** If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- **3.** The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.".

Transitional provisions pursuant to Article 14.2 of the CE Marking Directive

- **5.**—(1) This regulation shall apply to make provision in respect of relevant apparatus—
 - (a) supplied before 1st January 1997; or
 - (b) taken into service before that date,

in relation to which the responsible person elects, pursuant to Article 14.2 of the CE Marking Directive, to affix the CE mark.

- (2) Where this regulation applies, the principal Regulations shall have effect as if the amendments made by regulation 4 above, save for paragraph (d), had not come into force.
- (3) Where the letters "CE" are affixed in relation to relevant apparatus but the requirements of regulation 33 and Schedule 4 of the principal Regulations as substituted by regulation 3 above are not complied with, then, unless the responsible person has demonstrated an intention to comply with those provisions as so substituted, he shall be presumed to have elected to affix the CE mark.

Disapplication of the principal Regulations pursuant to Article 2.2 of the EMC Directive

6.—(1) For regulation 22 of the principal Regulations there shall be substituted the following—

"Medical devices

- **22.**—(1) This regulation applies to medical devices first supplied in the Community on or after 30th December 1994 (hereinafter referred to as a "relevant medical device").
- (2) Subject to paragraph (3) below, on and before 13th June 1998, these Regulations apply to relevant medical devices.
 - (3) Paragraph (2) above shall not apply where either—
 - (a) both of the following conditions are satisfied—
 - (i) the manufacturer elects to comply with the Wireless Telegraphy (Control of Interference from Electro Medical Apparatus) Regulations 1963(10) if applicable; and
 - (ii) the relevant medical device
 - (aa) if required pursuant to any Community obligation other than the EMC Directive or the Medical Devices Directive to bear the CE mark or CE marking, neither bears nor is accompanied by any other indication,

- howsoever expressed, that it complies with either of those Directives; or
- (bb) where sub-paragraph (aa) above does not apply, bears neither the CE mark nor the CE marking, nor any inscription likely to be confused with such mark or marking; or
- (b) in relation to a device first supplied in the Community on or after 1st January 1995, the manufacturer elects to comply with the Medical Devices Directive and the device bears the CE marking.
- (4) In so far as the Wireless Telegraphy (Control of Interference from Electro Medical Apparatus) Regulations 1963 impose electromagnetic compatibility requirements which must be complied with if a relevant medical device is to be supplied, used or taken into service, those Regulations shaLl cease to apply except where paragraph (3)(a)(i) above applies.
 - (5) In—
 - (a) this regulation, "Medical Devices Directive" means Council Directive 93/42/EEC concerning medical devices(11); and
 - (b) this regulation and in regulations 3 and 11, "medical device" has the meaning given by Article 1.2(a) of the Medical Devices Directive.".
- (2) For regulation 27 of the principal Regulations there shall be substituted the following regulation—

"Telecommunications terminal equipment and satellite earth station equipment

- **27.**—(1) Nothing in these Regulations shall impose electromagnetic compatibility requirements in so far as such requirements are specific to any description of telecommunications terminal equipment or satellite earth station equipment.
- (2) For the purposes of paragraph (1) above, electromagnetic compatibility requirements shall be taken to be specific—
 - (a) to a description of telecommunications terminal equipment, if that equipment is required to satisfy those requirements pursuant to Article 4(c) of the Telecommunications Terminal Equipment Directive; and
 - (b) to a description of satellite earth station equipment, if that equipment is required to satisfy those requirements pursuant to Article 4(c) of the Telecommunications Terminal Equipment Directive as extended to such equipment by Article 4.4 of the Satellite Earth Station Equipment Directive.
- (3) In the application of these Regulations to telecommunications terminal equipment and satellite earth station equipment, these Regulations shall have effect as if—
 - (a) in regulation 31, paragraph (b) were omitted;
 - (b) in regulations 36 and 42, there were omitted in each case—
 - (i) from paragraph (1), the words "Subject to paragraph (2) below,"; and
 - (ii) the whole of paragraph (2) (the disapplication of the provisions of Parts IV and V to radiocommunication transmission apparatus); and
 - (c) the whole of Part VI (the EC type-examination route to compliance for radiocommunication transmission apparatus) were omitted.".

⁽¹¹⁾ OJ No. L169, 12.7.93, p.1. Article 22.4 provides for a transitional period until 13th June 1998 during which existing provisions may be complied with.

Other amendments to the principal Regulations

- 7. The principal Regulations are hereby amended as follows:—
 - (a) in regulation 3—
 - (i) in paragraph (2), there shall be added at the end of the definition of "kit" the following—
 - "and for the avoidance of doubt, it is hereby declared that for the purposes of the definition of "system" in this paragraph and of the application of regulation 7 below, a kit shall be considered to be a system with an intrinsic function intended for the end user notwithstanding that, when it is supplied, it is not yet assembled;"; and
 - (ii) in paragraph (6) after the words "person who imported it" there shall be inserted the words "from a country or territory other than a member State";
 - (b) for regulation 8 there shall be substituted the following regulation—

"Education and training equipment

- **8.**—(1) This regulation applies to education and training equipment which would not, except for the provisions of this regulation, conform with the protection requirements under normal conditions of use in its usual electromagnetic environment.
- (2) Education and training equipment to which this regulation applies shall be deemed to conform with the protection requirements if it satisfies the following conditions—
 - (a) in relation to supply, the apparatus is accompanied by a declaration in English stating that the use of the apparatus outside the classroom, laboratory, study area or similar such place invalidates conformity with the protection requirements of the Electromagnetic Compatibility Directive (89/336/EEC) and could lead to prosecution; and
 - (b) the equipment when operated does not cause electromagnetic disturbance to apparatus situated outside its immediate electromagnetic environment.
- (3) In these Regulations, "education and training equipment" means any relevant apparatus (including a kit)—
 - (a) supplied or possessed for supply to education or training establishments or manufactured in such an establishment for the purposes of experimentation, learning or practical training; and
 - (b) the usual electromagnetic environment of which is a classroom, laboratory, study area or similar such place.";
- (c) in regulation 11—
 - (i) for sub-paragraph (b)(ii)(aa) there shall be substituted the following—
 - "(aa) the supplier believes (with reasonable cause) will be used in that member State;" and
 - (ii) after sub-paragraph (b) there shall be added the following—
 - "Provided that this regulation shall not apply to medical devices.";
- (d) in regulation 23(2), for the symbol "H3" there shall be substituted the symbol "Hz";
- (e) in regulation 36(2), for "regulation 37" there shall be substituted "regulation 38"; and
- (f) in regulation 39, the words "by notice in the London, Edinburgh and Belfast Gazettes" shall, on each occasion that they occur, be omitted.

Amendments to other legislation

- **8.** Schedule 1 to the Provision and Use of Work Equipment Regulations 1992(12) is hereby amended as follows—
 - (a) for paragraph 28 there shall be substituted the following—
 - "28. Council Directive 89/336/EEC on the approximation of the laws of the member States relating to electromagnetic compatibility (OJNo. L139, 23.5.89, p.19); as amended by Council Directive 92/31/EEC (OJ No. L126, 12.5.92, p.11) and Article 5 of Council Directive 93/68/EEC (OJ No. L220, 30.8.93, p.1.);" and
 - (b) paragraph 35 shall be omitted.

Department of Trade and Industry 2nd December 1994

Ian Taylor
Parliamentary Under Secretary of State for Trade
and Technology,

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations implement Council Directive 93/68/EEC (the "CE Marking Directive") (regulation 4) as it amends Council Directive 89/336/EEC (the EMC Directive) by amending the Electromagnetic Compatibility Regulations 1992 (S. I. No. 2372; "the EMC Regulations"). Provision is made for the CE mark to continue to be applied until 31st December 1996 pursuant to the transitional period in Article 14.2 of the CE Marking Directive (regulation 5).

These Regulations also make certain updating and other changes to the EMC Regulations (regulation 4(d) and 6). The principal changes are as follows—

- (a) provision is made to recognise the extension of the EMC Directive to the European Economic Area (regulation 3(d));
- (b) the compliance notice procedure required by the CE Marking Directive in relation to the CE marking is also provided in relation to the CE mark (regulation 4(d));
- (c) with regard to the disapplication of the EMC Directive to particular products pursuant to Article 2.2 consequent upon the adoption of product specific directives—
 - (i) the disapplication is qualified in relation to medical devices and active implantable medical devices; the EMC Regulations are to apply until the transitional periods in the product specific directives expire, unless the manufacturer elects to apply the product specific directives;
 - (ii) the EMC Regulations cease to apply to EMC requirements specific to satellite earth station equipment where the product specific directive applies; in addition, Part VI of the EMC Regulations ceases to apply to both telecommunications terminal equipment and satellite earth station equipment where the product specific directives apply (but Parts IV and V will apply instead to the EMC requirements which are not specific to the equipment concerned);
- (d) the modification of the requirements of the EMC Regulations provided for educational electronic equipment by regulation 8 of those Regulations is replaced by a modification for a new category of education and training equipment (regulation 7(c)); and
- (e) the details of standards will no longer have to be published in the London, Edinburgh and Belfast Gazettes pursuant to regulation 39 of the EMC Regulations (regulation 7(f)); details will be published in other publications.