

2016 No. XXXX

ELECTROMAGNETIC COMPATIBILITY

The Electromagnetic Compatibility Regulations 2016

Made - - - - - ***
Laid before Parliament ***
Coming into force - - - 20th April 2016

CONTENTS

PART 1

PRELIMINARY

1.	Citation and commencement	4
2.	Interpretation	4
3.	Application	6
4.	Exemptions	6
5.	Application of other Union Legislation	6
6.	Measuring Instruments Directive	6
7.	Application of safety legislation	7
8.	Exhibition at trade fairs	7

PART 2

PLACING APPARATUS ON THE UNION MARKET

9.	Essential requirements	7
10.	Making available or putting into service	7
	MANUFACTURERS	
11.	Duty to ensure apparatus complies with the essential requirements	7
12.	Technical documentation and conformity assessment	7
13.	EU declaration of conformity and CE marking	8
14.	Manufacturer's duty to retain technical documentation and EU declaration of conformity	8
15.	Compliance procedures for series production	8
16.	Manufacturers duty to ensure apparatus is marked	8
17.	Duty to provide information	8
18.	Instructions and safety information	9
19.	Duty to take action in respect of apparatus placed on the market which are considered not to be in conformity	9

20.	Provision of information and co-operation	9
	IMPORTERS	
21.	Prohibition on placing apparatus on the market	9
22.	Requirements that must be satisfied before an importer places apparatus on the market	9
23.	Duty not to place apparatus on the market where the importer suspects that it is not in conformity	10
24.	Importers duty to ensure that apparatus is marked	10
25.	Instructions and safety information	10
26.	Storage and transport: importers	10
27.	Duty to take action in respect of apparatus placed on the market which are considered not to be in conformity	11
28.	Importers duty to retain technical documentation and EU declaration of conformity	11
29.	Provision of information and co-operation	11
	DISTRIBUTORS	
30.	Duty to act with due care	11
31.	Making available on the market	11
32.	Duty not to place apparatus on the market where the distributor suspects that it is not in conformity	12
33.	Storage and transport: distributors	12
34.	Duty to take action in respect of apparatus placed on the market or made available on the market which is considered not to be in conformity	12
35.	Provision of information and co-operation	12
36.	Cases in which the obligations of manufacturers apply to importers and distributors	13
37.	Prohibition on improper use of CE marking	13
38.	Identification of economic operators	13
	PART 3	
	AUTHORISED REPRESENTATIVES	
39.	Authorised representatives	13
	PART 4	
	CONFORMITY OF THE APPARATUS AND CONFORMITY ASSESSMENT PROCEDURES	
40.	Presumption of conformity	14
41.	Applicable conformity assessment procedures	14
42.	EU declaration of conformity	14
43.	CE marking	14
44.	Information concerning the use of apparatus	15
45.	Fixed installations	15
	PART 5	
	NOTIFICATION OF CONFORMITY ASSESSMENT BODIES	
46.	Notified bodies	16
47.	Right to perform the activities of a notified body	16
48.	Designation of notified bodies	16
49.	Application for designation as a notified body	16
50.	Presumption of conformity of notified bodies	17

51.	Notification	17
52.	Monitoring of notified bodies	17
53.	Delegation to the United Kingdom Accreditation Service	17
54.	Changes to notifications	17
55.	Operational obligations of notified bodies	18
56.	Subsidiaries and contractors	18
57.	Appeal against a change to a notification	18
58.	Information to be provided by a notified body to the Secretary of State	19

PART 6 MARKET SURVEILLANCE AND ENFORCEMENT

59.	Market surveillance and enforcement authorities	19
60.	Market Surveillance	20
61.	Enforcement powers	20
62.	Evaluation of apparatus presenting a risk	21
63.	Enforcement action in respect of apparatus that are not in conformity and which present a risk	21
64.	EU Safeguard procedure	22
65.	Enforcement action in respect of formal non-compliance	23
66.	Offences	23
67.	Defence of due diligence	25
68.	Liability of persons other than the principal offender	26
69.	Extension of time for bringing summary proceedings	26
70.	Interference of condition of equipment at the time of placing on the market or putting into service	27
71.	Power of the court to require a matter to be remedied	27
72.	Penalties	27
73.	Commencement of proceedings	27

PART 7 MISCELLANEOUS

74.	Fees	28
75.	Service of documents	28
76.	Duty of enforcement authorities to inform the Secretary of State of action taken	28
77.	Savings for certain privileges	28
78.	Savings for action taken under other enactments	29
79.	Amendment to the Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Specification) Order 2004	29
80.	Amendment to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007	29
81.	Amendment to the Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order	29
82.	Review	29
83.	Transitional provisions	30
84.	Revocations and savings	30

SCHEDULES

SCHEDULE 1 — Essential Requirements	30
SCHEDULE 2 — Module A: internal production control	31
SCHEDULE 3 — Applicable conformity assessment procedures	32
SCHEDULE 4 — EU declaration of conformity	35
SCHEDULE 5 — Time-limit for transposition into national law and date of application	35
SCHEDULE 6 — Requirements relating to a notified body	36
SCHEDULE 7 — Operational requirements of notified bodies	37
SCHEDULE 8 — Enforcement powers conferred on enforcement authorities	38
SCHEDULE 9 — Powers conferred on market surveillance authorities	41

The Secretary of State is a Minister designated^(a) for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to apparatus which is liable to cause electromagnetic disturbance and to apparatus the performance of which could be affected by such disturbance.

The Secretary of State, in exercise of the powers conferred upon him by Section 2(2) of that Act, makes the following Regulations.

PART 1

PRELIMINARY

Citation and commencement

1.— These Regulations may be cited as the Electromagnetic Compatibility Regulations 2016 and will come into force on 20th April 2016.

Interpretation

2.—(1) In these Regulations,

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

“accreditation” means accreditation as defined in paragraph 10 of Article 2 of RAMS;

“apparatus” means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

“authorised representative” means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to certain tasks;

“CE marking” means a marking by which the manufacturer indicates that the apparatus is in conformity with the applicable requirements set out in Union harmonisation providing for its affixing;

“conformity assessment” means the process demonstrating whether the essential requirements of the Directive relating to apparatus have been fulfilled;

(a) S.I. 1989/2393.

(b) c. 43

“conformity assessment body” means a body that performs conformity assessment activities including calibration, testing, certification and inspection.

“the Directive” means Directive 2014/30/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of laws of the Member States relating to electromagnetic compatibility (recast)(a);

“distributor” means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market;

“economic operators” means the manufacturer, the authorised representative, the importer and the distributor;

“electromagnetic compatibility” means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;

“electromagnetic disturbance” means any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

“electromagnetic environment” means all electromagnetic phenomena observable in a given location;

“essential requirements” means the requirements set out in Schedule 1;

“fixed installation” means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently, at a predefined location;

“harmonised standard” means harmonised standard as defined in sub-paragraph (c) of paragraph 1 of Article 2 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25th October 2012 on European Standardisation(b);

“importer” means any natural or legal person established within the Union who places apparatus from a third country on the Union market;

“immunity” means the ability of equipment to perform as intended without degradation in the presence of electromagnetic disturbance;

“making available on the market” means any supply of apparatus for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

“manufacturer” means any natural or legal person who manufactures apparatus or has apparatus designed or manufactured, and markets that apparatus under his name or trade mark;

“national accreditation body” means national accreditation body as defined in paragraph 11 of Article of RAMS;

“placing on the market” means the first making available of apparatus on the Union market;

“recall” means any measure aimed at achieving the return of apparatus that has already been made available to the end-user;

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9th July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of apparatus(c);

“safety purposes” means the purposes of safeguarding human life or property;

“technical specification” means a document that prescribes technical requirements to be fulfilled by the equipment;

“Union harmonisation legislation” means any Union legislation harmonising the conditions for the marketing of apparatus;

(a) OJ L 96, 29.3.2014, p. 79.

(b) OJ L 316, 14.11.2012, p. 12.

(c) OJ L 218, 13.8.2008, p. 30.

“withdrawal” means any measure aimed at preventing apparatus in the supply chain from being made available on the market.

Application

3. Subject to regulation 4, these Regulations apply to all equipment.

Exemptions

4.—(1) These Regulations will not apply to equipment—

- (a) to which Directive 1999/5/EC of the European Parliament and of the Council of 9th March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (a) applies;
- (b) aeronautical apparatus, parts and appliances as referred to in Regulation (EC) 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC(b);
- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union(c);
- (d) equipment the inherent nature and physical characteristics of which is such that—
 - (i) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
 - (ii) it operates without an unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
- (e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

(2) These Regulations will not apply to kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs.

Application of other Union Legislation

5. In respect of equipment to which the Directive applies, if the essential requirements set out in Schedule 1 of these Regulations are subsequently wholly or partly laid down in more detail in another piece of Union legislation then, the Schedule 1 will not apply, or will cease to apply to that equipment from the date on which that Union legislation is implemented.

Measuring Instruments Directive

6.—(1) These Regulations do not apply to a measuring instrument or sub-assembly covered by Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments which have—

- (a) a CE marking;
- (b) an M marking; and
- (c) the identification number of the notified body responsible for carrying out the conformity assessment of the instrument or sub-assembly

(a) OJ L 91, 7.4.1999, p. 10.

(b) OJ L 79, 19.3.2008, p. 1.

(c) Constitution and Convention of the International Telecommunications Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994)

in accordance with the requirements of that Directive, as regards the immunity of such instruments and sub-assemblies.

(2) For the purpose of this regulation—

- (a) “measuring instrument” and “sub-assembly” have the meanings defined in that Directive, and
- (b) “notified body” means the body designated under paragraph 1 of Article 11 of that Directive.

Application of safety legislation

7. Nothing in these Regulations will affect the application of Union or national legislation regulating the safety of equipment.

Exhibition at trade fairs

8. Nothing in these Regulations prevents the showing of apparatus which does not comply with the Directive at a trade fair, exhibition or demonstration, provided that a visible sign clearly indicates that the apparatus is not in conformity with the Directive and will not be made available on the market or be put into service until it has been brought into conformity with the Directive.

PART 2

PLACING APPARATUS ON THE UNION MARKET

Essential requirements

9. No person will make apparatus available on the market or put it into service unless it complies with the essential requirements set out in Schedule 1.

Making available or putting into service

10.—(1) Nothing in these Regulations prevents the making available or putting into service in the United Kingdom of any apparatus complying with the essential requirements of the Directive, when properly installed, maintained and used for its intended purpose.

(2) Nothing in these Regulations prevents the application of the following measures in relation to the putting into service or use of apparatus in the United Kingdom—

- (a) measures to overcome an existing or predicted electromagnetic compatibility problem at a specific site;
- (b) measures taken for safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

MANUFACTURERS

Duty to ensure apparatus complies with the essential requirements

11. Before placing apparatus on the market, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential requirements.

Technical documentation and conformity assessment

12. Before placing apparatus in the market a manufacturer must—

- (a) have a relevant conformity assessment procedure carried out; and
- (b) draw up the technical documentation referred to—

- (i) in Schedule 2 or Schedule 3, and;
- (ii) any other technical documentation required as part of the relevant conformity assessment procedure to demonstrate the means used by the manufacturer to ensure that the apparatus complies with the essential requirements.

EU declaration of conformity and CE marking

13.—(1) Where the conformity of apparatus with the essential requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the apparatus on the market—

- (a) draw up the EU declaration of conformity in accordance with regulation 42 (EU declaration of conformity); and
- (b) affix the CE marking to the apparatus in accordance with regulation 43 (CE marking).

(2) The manufacturer must ensure that the EU declaration of conformity is translated into the language or languages required by the Member State in which the apparatus is placed or made available on the market.

(3) The manufacturer must keep the EU declaration of conformity up-to-date.

(4) Where apparatus is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which—

- (a) identifies all of the EU instruments; and
- (b) includes references to the publication of those EU instruments in the Official Journal of the European Union.

Manufacturer's duty to retain technical documentation and EU declaration of conformity

14. A manufacturer must keep the technical documentation and the EU declaration of conformity drawn up in respect of apparatus for a period of 10 years beginning with the day on which the apparatus is placed on the market.

Compliance procedures for series production

15.—(1) A manufacturer of apparatus which is manufactured by series production must ensure that, before placing apparatus on the market, procedures are in place to ensure that any apparatus so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

- (a) any changes in the design or characteristics of apparatus; and
- (b) any changes in the harmonised standard or in another technical specification by reference to which the EU declaration of conformity of apparatus was drawn up.

Manufacturers duty to ensure apparatus is marked

16.—(1) Before placing apparatus onto the market a manufacturer must ensure that it bears—

- (a) a type, batch or serial number; or
- (b) another element which identifies them as the manufacturer of the apparatus.

(2) Where the size and nature of apparatus or any component of apparatus does not allow it to bear the information referred to in paragraph (1), that information must be provided on the packaging or in a document accompanying the apparatus or component.

Duty to provide information

17.—(1) Before placing apparatus on the market, a manufacturer must ensure that the apparatus is marked with—

- (a) their name;
- (b) their registered trade name or registered trade mark; and
- (c) an address, which is the single point at which they can be contacted.

(2) Where it is not possible to provide the information referred to in paragraph (1) on the apparatus that information must be provided on the packaging or a document accompanying the apparatus.

Instructions and safety information

18.—(1) When placing apparatus on the market a manufacturer must ensure that the apparatus is accompanied by instructions and safety information in the owner's manual in a language that can be easily understood by consumers and other end-users.

(2) Where apparatus is placed on the market in the United Kingdom, the instructions and safety information in the owner's manual must be in English.

Duty to take action in respect of apparatus placed on the market which are considered not to be in conformity

19.—(1) A manufacturer who considers or has reason to believe that apparatus that they have placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring the apparatus into conformity;
- (b) to withdraw the apparatus from the Union market; or
- (c) recall it.

(2) Where the apparatus presents a risk, the manufacturer must immediately inform the competent authorities of any member State in which the manufacturer has made the apparatus available on the market of the risk, giving details of—

- (a) the reason or reasons why the apparatus is not considered to be in conformity with Part 2; and
- (b) any corrective measures taken.

Provision of information and co-operation

20.—(1) A manufacturer must, following a reasoned request from an enforcement authority, provide it with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) The information and documentation referred to in paragraph (1) must be in a language that can be easily understood by the enforcement authority.

(3) The manufacturer must, at the request of the enforcement authority, co-operate with the authority on any action taken to eliminate the risks posed by apparatus that the manufacturer or importer has placed on the market.

IMPORTERS

Prohibition on placing apparatus on the market

21. An importer must not place apparatus on the market unless it is in conformity with the essential requirements.

Requirements that must be satisfied before an importer places apparatus on the market

22.—(1) Before placing apparatus on the market an importer must ensure that—

- (a) A relevant conformity assessment has been carried out by the manufacturer;

- (b) The manufacturer has drawn up the technical documentation;
 - (c) The apparatus—
 - (i) bears the CE marking; and
 - (ii) is accompanied by the required documents and;
 - (d) manufacturer has complied with the requirements of regulations 11(duty to ensure apparatus complies with the essential requirements) and 12 (technical documentation and conformity assessment).
- (2) In paragraph (1)(c)(ii) “required documents” means—
- (a) the European Declaration of conformity referred to in regulation 42 (EU declaration of conformity); and

Duty not to place apparatus on the market where the importer suspects that it is not in conformity

23.—(1) Where an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements, the distributor must not place the apparatus on to the market.

(2) Where apparatus presents a risk, the importer must inform the manufacturer and the market surveillance authorities of that risk.

Importers duty to ensure that apparatus is marked

24.—(1) Before placing apparatus on the market, an importer must indicate on the apparatus—

- (a) their name, registered trade name or registered trade mark; and
- (b) the address at which they can be contacted.

(2) The information specified in paragraph (1) must in in a language that can be easily understood by end-users and the market surveillance authority in the Member state in which it is made available to end-users.

(3) Where, in the case of components for use in apparatus, it is not possible indicate the information specified in paragraph (1) on the component, the importer must indicate that information—

- (a) on the packaging; or
- (b) a document accompanying the component.

Instructions and safety information

25.—(1) When placing apparatus on the market an importer must ensure that the apparatus is accompanied instructions and safety information in the owner’s manual in a language that can be easily understood by consumers and other end-users.

(2) In this regulation, “safety information” means—

information about any specific precautions that must be taken when the apparatus is installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with Part 1 of Schedule 1.

Storage and transport: importers

26. An importer must ensure that while apparatus is under their responsibility, its storage or transport conditions do not jeopardise the conformity of the apparatus with the essential requirements.

Duty to take action in respect of apparatus placed on the market which are considered not to be in conformity

27.—(1) An importer who considers or has reason to believe that apparatus that they have placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring the apparatus into conformity;
- (b) to withdraw the apparatus from the Union market; or
- (c) recall the apparatus.

(2) Where the apparatus presents a risk, the importer must immediately inform the competent authorities of any member State in which the importer has made the apparatus available on the market of the risk, giving details of—

- (a) the reason or reasons why the apparatus is not considered to be in conformity with Part 2; and
- (b) any corrective measures taken.

Importers duty to retain technical documentation and EU declaration of conformity

28. An importer must, for the period of 10 years beginning on the day on which the apparatus is placed on the market—

- (a) keep a copy of the EU declaration of conformity at the disposal of the enforcing authorities; and
- (b) ensure that the technical documentation relating to that apparatus can be made available to the enforcing authorities upon request.

Provision of information and co-operation

29.—(1) An importer must, following a reasoned request from an enforcement authority, provide it with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) The information and documentation referred to in paragraph (1) must be in a language that can be easily understood by the enforcement authority.

(3) The importer must, at the request of the enforcement authority, co-operate with the authority on any action taken to eliminate the risks posed by apparatus that the manufacturer or importer has placed on the market.

DISTRIBUTORS

Duty to act with due care

30. When making apparatus available on the market, a distributor must act with due care to ensure the conformity of that apparatus with Part 2.

Making available on the market

31.—(1) Before making apparatus available on the market, a distributor must verify that—

- (a) the apparatus—
 - (i) bears the CE marking;
 - (ii) is accompanied by the required documents;
 - (iii) is accompanied by the instructions and safety information referred to in regulation 25
- (b) the manufacturer has complied with the requirements of—
 - (i) regulation 11 (duty to ensure that apparatus complies with the essential requirements);

- (ii) regulation 12 (technical documentation and conformity assessment)
 - (iii) regulation 15 (compliance procedures for series production);
 - (iv) regulation 16 (manufacturers duty to ensure that apparatus is marked); and
 - (v) regulation 25 (instructions and safety information).
- (c) that the importer has complied with the requirements of—
- (i) regulation 21 (prohibition on placing on the market); and
 - (ii) regulation 23 (duty not to place apparatus in the market where the importer suspects that the apparatus is not in conformity)

(2) For the purposes of this regulation “required documents” has the same meaning as in regulation 22.

Duty not to place apparatus on the market where the distributor suspects that it is not in conformity

32.—(1) Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements, the distributor must not place the apparatus on to the market.

(2) Where apparatus presents a risk, the distributor must inform the manufacturer and the market surveillance authorities of that risk.

Storage and transport: distributors

33. A distributor must ensure that while apparatus is under their responsibility, its storage or transport conditions do not jeopardise the conformity of the apparatus with the essential requirements.

Duty to take action in respect of apparatus placed on the market or made available on the market which is considered not to be in conformity

34.—(1) A distributor who considers or has reason to believe that apparatus that they have placed on the market or made available on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring the apparatus into conformity;
- (b) to withdraw the apparatus from the **Union market**; or
- (c) recall the apparatus.

(2) Where the apparatus presents a risk, the distributor must immediately inform the competent authorities of any **other member State** in which the distributor has made the apparatus available on the market or the manufacturer or importer to of that apparatus, of the risk, giving details of—

- (a) the reason or reasons why the apparatus is not considered to be in conformity with Part 2; and
- (b) any corrective measures taken.

Provision of information and co-operation

35.—(1) A distributor must, following a reasoned request from an enforcement authority, provide it with all of the information and documentation necessary to demonstrate the conformity of the apparatus with Part 2.

(2) The information and documentation referred to in paragraph (1) must be in a language that can be easily understood by the enforcement authority.

(3) The distributor must, at the request of the enforcement authority, co-operate with the authority on any action taken to eliminate the risks posed by apparatus that the distributor has placed on the market.

Cases in which the obligations of manufacturers apply to importers and distributors

36. An importer or a distributor who—

- (a) places apparatus on the market under their own trademark; or
- (b) modifies apparatus already placed on the market in such a way that it may affect whether the apparatus is in conformity with Part 2;
- (c) will be treated as the manufacturer of that apparatus for the purposes of these Regulations and they will need to comply with the obligations of a manufacturer set out in this Part.

Prohibition on improper use of CE marking

37.—(1) An economic operator must not affix the CE marking to apparatus unless—

- (a) that economic operator is the manufacturer; and
- (b) the conformity of apparatus with the essential requirements has been demonstrated by a relevant conformity procedure.

(2) An economic operator must not affix a marking to apparatus which is not the CE marking but, which purports to attest to the conformity of the apparatus with the essential requirements.

(3) An economic operator must not affix to apparatus any marking, sign or inscription which is likely to mislead any person as to the meaning or form of the CE marking.

(4) An economic operator must not affix to apparatus any other marking if, as a result of affixing that marking, the visibility, legibility and meaning of the CE marking would be impaired.

Identification of economic operators

38.—(1) Economic operators must, on request, provide information to the market surveillance authorities concerning—

- (a) any economic operator who has supplied them with apparatus; and
- (b) any economic operator to whom they have supplied apparatus.

(2) Economic operators must be able to provide the information referred to in paragraph (1) to the market surveillance authorities for a period of 10 years after they have been supplied with, or supplied the apparatus.

PART 3

AUTHORISED REPRESENTATIVES

Authorised representatives

39.—(1) A manufacturer may choose to appoint an authorised representative.

(2) Where a manufacturer chooses to appoint an authorised representative, the authorised representative must be appointed by way of written mandate.

(3) An authorised representative must perform the tasks specified in the written mandate provided by the manufacturer under paragraph (2).

(4) The tasks specified in the written mandate must include, as a minimum, a duty on behalf of the manufacturer, to—

- (a) keep a copy of—
 - (i) the EU declaration of conformity; and
 - (ii) the technical documentation
- (b) at the disposal of the enforcing authorities, for a period of 10 years beginning on the day on which the apparatus is placed on the market;

- (c) provide to the national competent authority, following a reasoned request from them, all of the information and documentation necessary to demonstrate the conformity of apparatus with the essential requirements; and
- (d) co-operate with the competent national authorities, upon their request, on any action to eliminate the risks posed by apparatus covered by their mandate.

(5) A manufacturer must not delegate the performance of their obligations under regulation 11 (duty to ensure that apparatus complies with the essential requirements) and regulation 12 (technical documentation and conformity assessment) of these Regulations to an authorised representative.

PART 4

CONFORMITY OF THE APPARATUS AND CONFORMITY ASSESSMENT PROCEDURES

Presumption of conformity

40. Apparatus which is in conformity with a harmonised standard or part of a harmonised standard, the reference to which has been published in the *Official Journal of the European Union*, is to be presumed to be in conformity with the applicable essential requirements covered by that standard or parts thereof and these Regulations.

Applicable conformity assessment procedures

41.—(1) The manufacturer must demonstrate the conformity of the apparatus with the requirements in Schedule 1 by means of either—

- (a) internal production control set out in Schedule 2; or
- (b) EU type examination that is followed by conformity to type based on internal production control set in Schedule 3.

(2) The manufacturer may choose to use the procedure set out in paragraph (1)(b) to demonstrate that the apparatus complies with some of the essential requirements set out in Schedule 1 provided that, the procedure referred to in paragraph (1)(a) can be used to demonstrate conformity with the remaining requirements, not assessed using the procedure in paragraph (1)(b).

EU declaration of conformity

42. The EU declaration of conformity for apparatus must—

- (a) state that the apparatus complies with the essential requirements of the Directive
- (b) contain the elements specified in the relevant conformity procedure followed in respect of the apparatus; and
- (c) have the model structure set out in Schedule 4.

CE marking

43.—(1) Any person who places apparatus on the market must ensure that the CE marking is affixed visibly, legibly and indelibly to the apparatus.

(2) Where it is not possible or warranted, on account of the nature of a component to affix the CE marking in accordance with paragraph (1), the person who places the apparatus on the market must ensure that the CE marking must be affixed to—

- (a) the packaging; and
- (b) the accompanying documents.

(3) The **CE marking** must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the apparatus where that body is involved in the production control phase.

(4) The identification number of the notified body must be affixed—

- (a) by the notified body itself; or
- (b) under the instructions of the notified body by the manufacturer.

Information concerning the use of apparatus

44.—(1) Any person who places apparatus on the market which emits electromagnetic interference at a level which causes or is likely to cause interference with electromagnetic apparatus operating in residential areas must ensure that the apparatus is accompanied by information clearly setting out the nature and extent of the restrictions upon the use of this apparatus in residential areas.

(2) Where possible, given the size of the apparatus, the person who places the apparatus on the market must ensure that the information referred to in paragraph (1) is included on the packaging for that apparatus.

(3) Any person who places apparatus on the market must ensure that the information required to enable apparatus to be used in accordance with its intended purpose is included in the instructions that accompany the apparatus.

Fixed installations

45.—(1) Apparatus that has been made available on the market and which can be incorporated into a fixed installation will be subject to all relevant provisions for apparatus set out in these Regulations.

(2) The requirements of Part 2 and regulations 39 (identification of economic operators) to 42 (**EU declaration of conformity**) will not be compulsory in respect of apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market.

(3) Any person who places apparatus of the type referred to in paragraph (2) on the market must ensure that that apparatus is accompanied by documentation that—

- (a) identifies the fixed installation in which it is to be incorporated the electromagnetic compatibility characteristics of that fixed installation
- (b) sets out the precautions to be taken when the apparatus is incorporated into the fixed installation in order not to compromise the conformity of the installation
- (c) includes the information referred to in—
 - (i) regulation 15 (compliance procedures for series production);
 - (ii) regulation 16 (manufacturers duty to ensure apparatus is marked), and;
 - (iii) regulation 23 (duty not to place apparatus on the market where the importer suspects that it is not in conformity).

(4) The good engineering practices referred to in paragraph 2 of Part 1 of Schedule 1 will be documented and the documentation will be held by the person who installs the fixed installation at the disposal of the relevant national authorities for inspection for as long as the fixed installation into which the apparatus referred to in paragraph (2) is in operation.

(5) Where the enforcement authority has received complaints about disturbances being generated by the installation or, has reason to believe that a fixed installation is not in compliance with these Regulations that authority may request evidence of compliance of the fixed installation, and, initiate an evaluation of the installation where appropriate.

(6) Where the evaluation referred to in paragraph (5) establishes that the fixed installation is not in compliance with these Regulations, the enforcement authority must impose appropriate

measures to bring the fixed installation into compliance with the essential requirements set out in Part 2 of Schedule 1.

(7) A person who installs a fixed installation is responsible for ensuring that the installation complies with the essential requirements set out in Part 2 of Schedule 1.

PART 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Notified bodies

46. For the purposes of this Part, a notified body is a conformity assessment body which the Secretary of State has designated as a notified body in accordance with regulation 46 (designation of authorised bodies) and notified to the European Commission and the other member States as a notified body in accordance regulation 49 (notification)

Right to perform the activities of a notified body

47. A notified body that has been notified to the European Commission and the other member States in accordance with regulation 51 (notification) will be able to perform the activities of a notified body provided that no objections are raised by the European Commission or the other Member States—

- (i) within two weeks of a notification being made, where an accreditation certificate is used; or
- (ii) within two months of a notification, where accreditation is not use.

Designation of notified bodies

48. The Secretary of State may designate a conformity assessment body as an authorised body if—

- (a) The conformity assessment body has submitted an application in accordance with regulation 49 (application for designation as an authorised body); and
- (b) The Secretary of State is satisfied that the conformity assessment body meets the notified body notified body requirements set out in Schedule 6.

Application for designation as a notified body

49. When making a an application to the Secretary of State for designation as an authorised body, a conformity assessment body must ensure that the application is accompanied by—

- (a) a description of —
 - (i) the conformity assessment activities;
 - (ii) the conformity assessment modules; and
 - (iii) the types of apparatusin relation to which that conformity assessment body claims to be competent;
- (b) an accreditation certificate issued by the United Kingdom Accreditation Service attesting that the conformity assessment body fulfils the requirements in Schedule 6; or, where an accreditation certificate is not available
- (c) documentary evidence necessary to allow the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified requirements.

Presumption of conformity of notified bodies

50. Where a conformity assessment body that is a notified body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* the Secretary of State will presume that, the conformity assessment body meets the notified body requirements covered by that standard or part of that standard.

Notification

51.—(1) The Secretary of State must notify the European Commission and the other member States of any conformity assessment body that is designated as a notified body in accordance with regulation 49 (application for designation as a notified body).

(2) A notification under paragraph (1) must include—

- (a) details of—
 - (i) the conformity assessment activities;
 - (ii) the conformity assessment modules; and
 - (iii) each apparatus
in relation to which that conformity assessment body claims to be competent;
- (b) an accreditation certificate issued by the United Kingdom Accreditation Service attesting that the conformity assessment body fulfils the requirements in Schedule 6; or, where a certificate is not available
- (c) documentary evidence which attests to—
 - (i) the conformity assessment body's competence; and
 - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly to ensure that it continues to satisfy the requirements in Schedule 6.

Monitoring of notified bodies

52. The Secretary of State must monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) complies with any condition to which its designation as a notified body by the Secretary of State is subject; and
- (c) carries out its functions in accordance with these Regulations.

Delegation to the United Kingdom Accreditation Service

53. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

- (a) assessing applications for designation as a notified body; and
- (b) monitoring notified bodies.

Changes to notifications

54.—(1) Where the Secretary of State determines that a notified body no longer meets the requirements in Schedule 6 or that it is failing to fulfil its obligations under these Regulations, the Secretary of State must, as appropriate, restrict, suspend or withdraw the notification in respect of that notified body.

(2) When deciding whether to restrict, suspend or withdraw a notification under paragraph (1), the Secretary of State must have regard to the seriousness of the failure of the notified body to meet the notified body requirements or to fulfil its obligations under these Regulations.

(3) Where the Secretary of State takes action under paragraph (1), the Secretary of State must immediately inform the Commission and the other Member States.

(4) Where the Secretary of State has taken action under paragraph (1), or where the notified body has ceased its activity, the notified body must—

- (a) on the request of the Secretary of State, transfer its files (including the register which it maintains under paragraph 5 of Schedule 7 (operational obligations of notified bodies)) to another notified body or to the Secretary of State; or
- (b) ensure that its files are kept available for the Secretary of State and enforcing authorities for a period equal to that specified in paragraphs 5 and 6 of Schedule 7.

Operational obligations of notified bodies

55. When a notified body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 7 (operational obligations of notified bodies).

Subsidiaries and contractors

56.—(1) Where a notified body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the tasks are only to be treated as having been carried out by a notified body for the purposes of regulations 34 to 44 where the conditions in paragraphs (2) and (3) are satisfied.

(2) The notified body must—

- (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
- (b) inform the Secretary of State accordingly.

(3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the notified body must for a period of 10 years beginning on the day on which the tasks are carried out, keep at the disposal of the Secretary of State the documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring a notified body in accordance with regulation 50, the Secretary of State is to treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

Appeal against a change to a notification

57.—(1) Where the Secretary of State intends to restrict, suspend or withdraw a notification in accordance with regulation 52 (changes to notifications) the Secretary of State must give notice in writing to the notified body concerned that its notification will be restricted, suspended or withdrawn.

(2) A written notice provided in accordance with paragraph (1) must contain—

- (a) the date on which the notice is issued;
- (b) a statement of the reasons why the notification is being restricted, suspended or withdrawn;
- (c) the date on which the restriction, suspension or withdrawal of the notification is to take effect;

- (d) where a notification has been restricted or suspended, state what the effect of that restriction or suspension upon the notified body;
- (e) inform the notified body of their right to make representations to the Secretary of State, in writing, within 14 days of the date on the notice, against this decision.

(3) Where a notified body submits written representations to the Secretary of State, the Secretary of State will respond to those representations within 21 days of the date on which those representations are received, stating whether, having considered those representations, the notice issued under paragraph (1) will be modified or withdrawn.

Information to be provided by a notified body to the Secretary of State

58.—(1) A notified body must inform the Secretary of State in writing of—

- (a) any refusal, restriction, suspension or withdrawal of a conformity assessment certificate;
- (b) any circumstances affecting the scope of and conditions for notification; and
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities.

(2) A notified body must, following a request from the Secretary of State, inform the Secretary of State in writing of any conformity assessment activities performed within the scope of their notification provided under paragraph (1) and any other activity performed, including cross-border activities and subcontracting.

(3) A notified body will provide to other bodies notified under the Directive that carry out similar conformity assessment activities covering the same apparatus any relevant information on issues relating to negative and, on request, positive conformity assessment results.

PART 6

MARKET SURVEILLANCE AND ENFORCEMENT

Market surveillance and enforcement authorities

59.—(1) For the purpose of these Regulations, the market surveillance authority will be—

- (a) within their area in Great Britain, weights and measures authorities; and
- (b) in Northern Ireland, every district council.

(2) For the purpose of these Regulations, the enforcement authority in Great Britain will be—

- (a) OFCOM insofar as action taken to enforce these Regulations relates to the protection and management of spectrum; and
- (b) local weights and measures authorities within their area^(a).

(3) For the purpose of these Regulations, the enforcement authority in Northern Ireland will be—

- (a) OFCOM insofar as action taken to enforce these Regulations relates to the protection and management of spectrum; and
- (b) the Department of Enterprise, Trade and Investment.

(4) Except in relation to the descriptions of apparatus mentioned in paragraph (3), the Secretary of State may enforce these Regulations.

(5) These Regulations may be enforced in relation to electricity meters other than these which are wireless telegraphy apparatus—

(a) For the investigatory powers available to an enforcement authority for the purposes of the duty imposed by this regulation, see Schedule 5 to the Consumer Rights Act 2015 (c.15)

- (a) in Great Britain, by the Gas and Electricity Markets Authority;
- (b) in Northern Ireland by the Northern Ireland Authority for Energy Regulation; and
- (c) by any person designated to act on behalf of the Gas and Electricity Markets Authority of the Northern Ireland Authority for Energy Regulation.

(6) These Regulations will apply to OFCOM as if they were listed as a domestic enforcer for the purposes of Schedule 5 of the Consumer Rights Act 2015(a).

(7) In Scotland, only the Lord Advocate may commence proceedings for an offence.

Market Surveillance

60.—(1) For the purpose of providing for the carrying out of the market surveillance activities provided for in these Regulations the market surveillance authority has the same duty to enforce these Regulations as it has in relation to the Directive(b).

(2) For the purpose of providing for the enforcement of the market surveillance obligations in these Regulations, Schedule 9 will apply.

Enforcement powers

61.—(1) For the purposes of enforcing these Regulations, Schedule 8 (enforcement powers conferred upon enforcement authorities) will apply.

(2) Where the market surveillance authority has reasonable grounds to suspect that the CE marking has been affixed to apparatus which does not satisfy the essential requirements of these Regulations, it may serve a compliance notice on—

- (a) the manufacturer or their authorised representative in the United Kingdom; or
- (b) where the manufacturer is established outside the EU and—
 - (i) does not have an authorised representative established in the United Kingdom; or
 - (ii) their authorised representative who is established in the United Kingdom is not the person who places the apparatus on the market,

the person who places the apparatus on the market in the United Kingdom.

(3) Where a compliance notice is served in accordance with paragraph (4), no other notice as referred to in Part 2 of Schedule 8 can be issued and no proceedings pursuant to regulation 65 can be brought, until the compliance notice has been served and the person on whom that notice has been served has failed to comply with its requirements.

(4) A compliance notice must—

- (a) state that the enforcement authority suspects that the CE marking has been affixed to apparatus in circumstances where that apparatus does not comply with the requirements of these Regulations;
- (b) state the reasons for that suspicion;
- (c) identify the essential requirements with which it is suspected that the apparatus does not comply;
- (d) specify a date by which any necessary action to remedy non-compliance must have been taken;
- (e) require the person on whom the notice is served to—
 - (i) take the necessary action to ensure that the apparatus to which the notice relates conforms with the requirements of these Regulations and RAMS concerning the CE marking and, to end the infringement by the date specified in the notice; or

(a) c.15

(b) For the investigatory powers available to an enforcement authority for the purposes of the duty imposed by this regulation, see Schedule 5 to the Consumer Rights Act 2015 (c.15)

- (ii) to provide evidence, by the date specified in the notice, that demonstrates to the satisfaction of the enforcement authority, that all provisions of the Regulations, which apply to the apparatus have been complied with; and
 - (f) warn the person on whom the notice is served that if the apparatus does not comply with the essential requirements of the Regulations by the date specified in the notice, further enforcement action may be taken under these Regulations in respect of the apparatus referred to in the notice or any apparatus of the same type placed on the market by that person.
- (5) A compliance notice may include directions as to the measures to be taken by the person upon whom it is served in order ensure that the apparatus complies with the requirements of these Regulations which apply to it, by the date specified in the notice.

(6) In this regulation—
“enforcement officer” means—

- (a) an officer of an enforcement authority who is authorised in writing by that authority to act as an enforcement officer for the purposes of this Part; and
- (b) a person appointed by the Secretary of State who is authorised in writing by the Secretary of State to act as an enforcement officer for the purposes of this Part.

Evaluation of apparatus presenting a risk

62.—(1) Where the market surveillance authority has sufficient reason to believe that apparatus presents a risk, that authority must carry out an evaluation of that apparatus in order to determine whether the apparatus satisfies the requirements of Part 2.

(2) Where the enforcement authority has sufficient reason to believe that apparatus presents a risk, that authority may carry out an evaluation of that apparatus in order to determine whether the apparatus satisfies the requirements of Part 2.

Enforcement action in respect of apparatus that are not in conformity and which present a risk

63.—(1) Where in the course of the evaluation referred to in regulation 62 (evaluation of apparatus presenting a risk) the enforcement authority finds that the apparatus does not comply with the requirements of Part 2 of these Regulations it must, without delay, require a relevant economic operator to—

- (a) take the appropriate corrective action to bring the apparatus into conformity with those requirements within a proscribed period;
- (b) withdraw the apparatus within such a period as the enforcement authority will prescribe; or
- (c) recall the apparatus within the prescribed period.

(2) The enforcement authority must inform the notified body that carried out the conformity assessment procedure in relation to the apparatus of—

- (a) the respect in which the apparatus is not in conformity with Part 2; and
- (b) the actions which the enforcement authority is requiring the relevant economic operator to take to bring the apparatus into conformity with Part 2;

(3) Where the enforcement authority considers that the failure of apparatus to conform with the requirements of Part 2 referred to in paragraph (1) is not restricted to apparatus that have been placed or made available on the market in the United Kingdom, it must notify the Secretary of State of—

- (a) the results of the evaluation; and
- (b) the actions which it has required the economic operator to take in accordance with paragraph (2)(b).

(4) Where the Secretary of State receives notice from an enforcement authority under paragraph (3), or otherwise considers that the failure of apparatus to conform with the requirements of Part 2 referred to in paragraph (1) is not restricted in the United Kingdom, the Secretary of State must inform the European Commission and the other member States of—

- (a) the results of the evaluation; and
- (b) the actions which the enforcement authority has required the economic operator to take in accordance with paragraph (2)(b)

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the enforcement authority must take appropriate measures to—

- (a) prohibit or restrict the apparatus being made available on the market in the United Kingdom;
- (b) withdraw the apparatus from the United Kingdom market; or
- (c) recall the apparatus.

(6) Where the enforcement authority takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

(7) Where the Secretary of State receives a notice under paragraph (6), or takes measures under paragraph (5), the Secretary of State must notify the European Commission and the other member States without delay.

(8) The notices referred to in paragraphs (6) and (7) must include details about the apparatus and, in particular—

- (a) the information necessary to identify the apparatus that is not in conformity with Part 2;
- (b) the origin of the apparatus;
- (c) the nature of—
 - (i) the failure of the apparatus to conform with the requirements of Part 2; and
 - (ii) the alleged risk
- (iii) the corrective measures taken and their duration
- (d) the arguments put forward by the economic operator;
- (e) whether the failure of the apparatus to conform with the requirements of Part 2 is due to—
 - (i) the failure of the apparatus to meet the requirements of that Part relating to risk; or
 - (ii) shortcomings in the harmonised standards referred to in regulation 40 (presumption of conformity) which confer a presumption of conformity.

(9) In this regulation, “prescribed period” means a period which is—

- (a) prescribed by the enforcement authority; and
- (b) reasonable and commensurate with the nature of the risk presented by the apparatus.

EU Safeguard procedure

64.—(1) Where the procedure referred to in paragraphs (3) to (7) of regulation 63 (enforcement action in respect of apparatus that is not in conformity and which presents a risk), has been completed and—

- (a) an objection has been raised against a measure taken by a member State; or
- (b) the Commission considers the national measure to be contrary to Union legislation; the relevant economic operators will co-operate with the Commission to evaluate the measure.

Enforcement action in respect of formal non-compliance

65.—(1) Where an enforcement authority makes one of the following findings relating to apparatus—

- (a) the CE marking, has been affixed in violation of regulation 37 (prohibition on improper use of CE marking) and regulation 43 (CE marking);
- (b) the CE marking referred to in regulation 43 has not been affixed;
- (c) the EU declaration of conformity referred to in regulation 13 (EU declaration of conformity and CE marking) or the declaration referred to in Schedule 4—
 - (i) has not been drawn up; or
 - (ii) has not been drawn up correctly;
- (d) the technical documentation referred to in regulation 12 (technical documentation and conformity assessment) and Schedule 4 (EU declaration of conformity) is either not available or not complete;
- (e) the information set out in regulation 17 (duty to provide information) and regulation 16 (manufacturers duty to ensure apparatus are marked) is absent, false or incomplete;
- (f) any other administrative requirement referred to in regulations 9 to 29 has not been complied with;

it will require the relevant economic operator to put an end to the non-compliance concerned.

(2) Where an economic operator does not remedy any non-compliance falling with paragraph (1), the enforcement authority will take all appropriate measures to restrict or prohibit the apparatus being made available on the market or ensure that the apparatus is recalled or withdrawn from the market, or in the case of apparatus imported their own use, that that apparatus is prohibited or restricted.

Offences

66.—(1) It is an offence for a person to contravene or fail to comply with any requirement of—

- (a) regulation 8 (exhibition at trade fairs);
- (b) regulation 9 (essential requirements); and
- (c) regulation 10 (making available or putting into service);
- (d) regulation 44 (information concerning the use of apparatus); and
- (e) regulation 45 (fixed installations).

of these Regulations;

(2) It is an offence for a manufacturer to contravene or fail to comply with any requirement of—

- (a) regulation 11 (duty to ensure apparatus comply with the essential requirements);
- (b) regulation 12 (technical documentation and conformity assessment);
- (c) regulation 13 (EU declaration of conformity and CE marking);
- (d) regulation 14 (manufacturers duty to retain technical documentation and EU declaration of conformity);
- (e) regulation 15 (compliance procedures for series production);
- (f) regulation 16 (manufacturers duty to ensure that apparatus are marked);
- (g) regulation 17 (duty to provide information);
- (h) regulation 18 (instructions and safety information);
- (i) regulation 19 (duty not to take action in respect of apparatus placed on the market which are considered not to suspects that it is not in conformity);
- (j) regulation 20 (provision of information and co-operation);

(3) It is an offence for an importer to contravene or fail to comply with any requirement of—

- (a) regulation 21 (prohibition on placing apparatus on the market);
- (b) regulation 22 (requirements that must be satisfied before an importer places apparatus on the market);
- (c) regulation 23 (duty not to place apparatus on the market where the importer suspects that it is not in conformity)
- (d) regulation 24 (importers duty to ensure that apparatus is marked);
- (e) regulation 25 (instructions and safety information);
- (f) regulation 26 (storage and transport);
- (g) regulation 27 (duty to take action in respect of apparatus placed on the market which are considered not to be in conformity);
- (h) regulation 28 (importers duty to retain technical documentation and EU declaration of conformity);
- (i) regulation 29 (provision of information and co-operation);
- (j) regulation 36 (cases in which the obligations of manufacturers apply to importers and distributors);
- (k) regulation 41 (applicable conformity assessment procedures).

(4) It is an offence for a distributor to contravene or fail to comply with any requirement of—

- (a) regulation 30 (duty to act with due care);
- (b) regulation 31 (making available on the market);
- (c) regulation 32 (duty not to place apparatus on the market where an importer suspects that it is not in conformity);
- (d) regulation 33 (storage and transport);
- (e) regulation 34 (duty to take action in respect of apparatus placed on the market or made available on the market which are considered not to be in conformity);
- (f) regulation 35 (provision of information and co-operation); and
- (g) regulation 36 (cases in which the obligations of manufacturers apply to importers and distributors);

of these Regulations.

(5) It is an offence for an authorised representative who, has been appointed by way of written mandate to act as an authorised representative on behalf of a manufacturer, to contravene or fail to comply with regulation 39 (authorised representatives).

(6) It is an offence for an economic operator to contravene or fail to comply with any requirement of—

- (a) regulation 37 (prohibition on improper use of CE marking)
- (b) regulation 38 (identification of economic operators); and
- (c) regulation 43 (CE marking)

of these Regulations.

(7) It is an offence for any notified body to contravene or fail to comply with any requirement of—

- (a) regulation 55 (operational obligations of notified bodies);
- (b) regulation 56 (subsidiaries and contractors); and
- (c) regulation 58 (information to be provided to by the notified body to the Secretary of State)

of these Regulations.

(8) Any person who contravenes any notice in Part 2 of Schedule 8 is guilty of an offence.

(9) Any person who fails to retain documentation as required by—

- (a) regulation 38 (identification of economic operators);
- (b) regulation 39 (authorised representatives); and
- (c) regulation 56 (subsidiaries and contractors).

is guilty of an offence.

(10) If an offence under these Regulations committed by a body corporate is shown—

- (a) to have been committed with the consent or connivance of an officer, or
- (b) to be attributable to any neglect on the part of the officer,
- (c) the officer as well as the body corporate is guilty of the offence and liable to be proceeded against and punished accordingly.

(11) If the affairs of a body corporate are managed by its members, paragraph (10) applies in relation to the acts and defaults of a member in connection with the functions of management of that member as if the member were a director of the body.

(12) If an offence under these Regulations committed by a partnership is shown—

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

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

(13) If an offence under these Regulations committed by an unincorporated body, other than a partnership, is shown—

- (a) to have been committed with the consent or connivance of an officer of the body; or
- (b) a member of its governing body, or
- (c) to be attributable to any neglect on the part of such an officer or member,

that officer or member as well as the body is guilty of the offence and liable to be proceeded against and punished accordingly.

(14) In this regulation—

- (a) “officer”, in relation to a body corporate, means a director, member of the committee of management, chief executive, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity;
- (b) “partner” includes a person purporting to act as a partner; and
- (c) “body corporate” includes references to a partnership in Scotland and, in relation to such a partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

(15) Where an offence under these Regulations is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of, or have been attributable to neglect on the part of, any partner or a person who was purporting to act as such, that person as well as the partnership will be guilty of that offence and will be liable to be proceeded against and punished accordingly.

Defence of due diligence

67.—(1) Subject to the following provisions of this regulation, in proceedings against any person for an offence contrary to regulation 66 (offences) of these Regulations, it will be a defence for that person to show that they took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where in any proceedings against any person for such an offence the defence provided by paragraph (1) above involves an allegation that the commission of the offence was due—

- (a) to the act or default of another; or
- (b) to reliance on information given by another,

that person will not, without leave of the court, be entitled to rely on the defence unless, not less than seven clear days before the hearing of the proceedings (or in Scotland the trial diet), he has served a notice under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph must give such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time they serve it.

(4) A person will not be entitled to rely on the defence provided by paragraph (1) by reason of their reliance on information supplied by another, unless they show that it was reasonable in all the circumstances for him to have relied on the information, having particular regard to—

- (a) the steps which they took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) whether he had any reason to disbelieve the information.

Liability of persons other than the principal offender

68.—(1) Where the commission by any person of any offence under these Regulations or any other applicable legislation^(a) is due to the act or default committed by some other person in the course of any business of his, the other person will be guilty of an offence and may be proceeded against and punished whether or not proceedings are taken against the first person.

(2) Where a body corporate is guilty of an offence under these Regulations and it is proved that the offence was committed—

- (a) with the consent or connivance of an officer of the body corporate; or
- (b) as a result of the negligence of an officer of the body corporate,

the officer, as well as the body corporate, will be guilty of an offence.

(3) In paragraph (2), a reference to an officer of a body corporate includes a reference to—

- (a) a director, manager secretary or other similar officer of the body corporate;
- (b) a person purporting to act as a director, manager or secretary or other similar officer; and
- (c) if the affairs of the body corporate are arranged by its members, a member.

(4) In this regulation, “body corporate” has the same meaning as in regulation 66 (offences).

Extension of time for bringing summary proceedings

69. Notwithstanding section 127 of the Magistrates’ Courts Act 1980 and section 136 of the Criminal Procedure (Scotland) Act 1995, proceedings for an offence contrary to regulation 66 (offences) may be commenced at any time within three years of the date of the offence, or one year from the date on which there comes to the knowledge of the prosecutor evidence sufficient to justify a prosecution for that offence, whichever is the earlier; and for the purposes of this regulation—

- (a) a certificate of the prosecutor stating that such evidence came to his knowledge on a specified date will be conclusive evidence of that fact; and
- (b) a document purporting to be such a certificate and to be signed by or on behalf of the prosecutor in question will be presumed to be such a certificate unless the contrary is proved.

(a) Schedule 5 of the Consumer Rights Act 2015 (c.15) sets out the investigatory powers that are conferred upon the enforcement authorities identified in regulation 59 for the purpose of enforcing these Regulations. Paragraph 36 of schedule 5 makes it an offence for any person to obstruct an officer who is enforcing these Regulations or, to make a false or misleading statement to that officer.

Interference of condition of equipment at the time of placing on the market or putting into service

70. In any proceedings in which it is in issue whether any apparatus complied with the essential requirements or the requirements of Part 2 or Part 3 or regulation 45 (fixed installations) at the time when it was placed on the market or put into service, a court may infer that such equipment did not so comply at that time if—

- (a) it is proved that it does not so comply or did not so comply or did not so comply at a time subsequent to its having been placed on the market or put into service.
- (b) having regard to all the circumstances of the case, it appears to the court that the failure of the apparatus to comply at the time referred to in paragraph (a) above is not attributable to any cause arising subsequent to its having been supplied or put into service.

Power of the court to require a matter to be remedied

71.—(1) Where a person is convicted of an offence in relation to the contravention or failure to comply with a requirement of under Part 2 or Part 3 or regulation 45 (fixed installations) of these Regulations in respect of any matters that appear to the court to be matters which it is within that person's power to remedy, the court may, in addition to or instead of imposing any punishment, order that person within such time as may be specified in that order, to take such steps as may be specified in the order for remedy the said matters.

(2) The time specified in an order made under paragraph (1) may be extended or further extended by order of the court on an application made before the end of the time that was originally specified in that order or extended under this paragraph, as the case may be.

(3) Where a person is ordered under paragraph (1) to remedy any matters, that person will not be guilty of an offence under these Regulations insofar as those offences continued until the date specified in the order under paragraph (1) or the date to which the period specified in that order is extended under paragraph (2).

Penalties

72.—(1) Any person who is guilty of an offence under regulation 66 (offences) is liable on summary conviction—

- (a) in England and Wales—
 - (i) to imprisonment for a term not exceeding 3 months; or
 - (ii) a fine; or
 - (iii) to both.
- (b) in Scotland and Northern Ireland—
 - (i) to imprisonment for a term not exceeding 3 months; or
 - (ii) a fine not exceeding level 5 on the standard scale; or
 - (iii) to both.

Commencement of proceedings

73.—(1) In England and Wales a magistrates' court may try an information, and in Northern Ireland a magistrates' court may try a complaint, in relation to an offence under these Regulations if the information is laid or if the complaint is made within twelve months from the time when the offence is committed.

(2) In Scotland proceedings in relation to any offence which under these Regulations is triable only by way of summary proceedings, may be begun at any time within twelve months from the time when the offence is committed.

(3) [In Scotland, only the Lord Advocate may commence proceedings in relation to an offence committed under these regulations].

PART 7

MISCELLANEOUS

Service of documents

74.—(1) Any document required or authorised by these Regulations to be served on a person may be so served—

- (a) by delivering it to him or by leaving it at his proper address or by sending it to him by post at that address;
- (b) if these person is a body corporate, by serving it in accordance with sub-paragraph (a) on the secretary or clerk of that body; or
- (c) if the person is a partnership, by serving it in accordance with sub-paragraph (a) on a partner or on a person having control or management of the partnership business; or
- (d) if the person is an unincorporated body, by serving it in accordance with sub-paragraph (a) on a person having control or management of that body.

(2) For the purposes of paragraph (1), and for the purposes of section 7 of the Interpretation Act 1978 (which relates to the service of documents by post) in its application to that paragraph, the proper address of any person on whom a document is to be served by virtue of these Regulations will be known as his last known address except that—

- (a) in the case of service on a partnership or a partner or a person having the control or management of a partnership business, it will be the principal place of business in the United Kingdom of the partnership;
- (b) in the service on a body registered in the United Kingdom , or its secretary or clerk, it will be the address of the registered office or the principal place of business in the United Kingdom of that body; and
- (c) in the case of service on a body that is not registered in the United Kingdom, it will be the address of the principal place of business in the United Kingdom of that body.

Duty of enforcement authorities to inform the Secretary of State of action taken

75. An enforcement authority must, where action has been taken by it to prohibit or restrict the supply or taking into service (whether under these Regulations or otherwise) of any apparatus, immediately inform the Secretary of State of the action taken, and the reasons for it.

Savings for certain privileges

76.—(1) Nothing in these Regulations will require a person to produce any documents or records if they would be entitled to refuse to produce those documents or records in any proceedings in any court on the grounds that they are subject of legal professional privilege or, in Scotland, that they contain a confidential communication made by or to an advocate or solicitor [acting]in that capacity, or as authorising any person to take possession of any documents or records which are in the possession of a person who would be so entitled.

(2) Nothing in these Regulations is to be construed as requiring a person to answer any question or give any information if to do so would incriminate that person or that person's spouse or civil partner.

(3) Sub-section (1) of section 14 of the Civil Evidence Act 1968 (which relates to the privilege against self-incrimination) will apply to the right conferred by paragraph (2) as it applies to the right described in sub-section (1) of that section; but this paragraph does not extend to Scotland.

(4) In Northern Ireland sub-section (1) of section 10 of the Civil Evidence Act (Northern Ireland) 1971 will apply to the right conferred by paragraph (2) as it applies to the right described in that sub-section.

Savings for action taken under other enactments

77. Nothing in these Regulations shall be construed as preventing the taking of any action in respect of any apparatus under the provisions of any other enactment.

Amendment to the Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Specification) Order 2004

78.—(1) The Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information)(Specification) Order 2004(a) is amended as follows.

(2) In Schedule 1, for the words “The Electromagnetic Compatibility Regulations 2006” substitute “The Electromagnetic Compatibility Regulations 2016”.

Amendment to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007

79.—(1) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007(b) is amended as follows.

(2) In Part 3 of the Schedule, under the heading “consumer and business protection” for the entry “The Electromagnetic Compatibility Regulations 2006” substitute “The Electromagnetic Compatibility Regulations 2016”.

Amendment to the Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order

80.—(1) The Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order(c) is amended as follows.

(2) In Part 4 of Schedule 1, for the entry “The Electromagnetic Compatibility Regulations 2006” substitute “The Electromagnetic Compatibility Regulations 2016”.

Review

81.—(1) The Secretary of State must from time to time—

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other member States.

(3) The report must, in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published on or before 20th April 2021.

(5) Reports under this regulation will be published at intervals not exceeding 5 years from the date in subsection (4).

(a) S.I. 2004/693.
(b) S.I. 2007/3544.
(c) S.I. 2009/699.

Transitional provisions

82. Nothing in these Regulations prevents the making available on the market of apparatus which—

- (a) is in conformity with the requirements of Directive 2004/104/EC on the approximation of laws, regulations and administrative provisions of the Member States relating to electromagnetic compatibility^(a) and;
- (b) was placed on the market before 20th April 2016.

Revocations and savings

83.—(1) Subject to paragraph (2), the Electromagnetic Compatibility Regulations 2006^(b) are revoked save as regard their application to —

- (a) any apparatus that was placed on the market or put into service prior to 20th April 2015; and
- (b) the appointment or termination of appointment of any notified body for the purposes of those Regulations.

(2) The following provisions of the Electromagnetic Compatibility Regulations 2006 will continue in force—

- (a) section 2(2) (revocation and disapplication) and;
 - (b) Schedule 1 (regulations made under section 10 of the Wireless Telegraphy Act 1949).
- (3) The Electromagnetic Compatibility (Amendment) Regulations 2006^(c) are revoked.

SCHEDULES

SCHEDULE 1

Essential Requirements

PART 1

General requirements

1. Equipment must be so designed and manufactured, having regard to the state of the art, as to ensure that—

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended
- (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation to its intended use.

PART 2

Specific requirements for fixed installations

2. Installations and intended use of components

(a) OJ L 390, 31.12.2004, p. 24.
(b) S.I. 2006/3418
(c) S.I. 2006/1449.

3.A fixed installation must be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in Part 1 of this Schedule.

SCHEDULE 2

Module A: internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 to 5 of this annex, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of these Regulations that apply to it.

Electromagnetic compatibility assessment

2. The manufacturer must perform an Electromagnetic Compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in paragraph 1 of Schedule 1.

3. The electromagnetic compatibility assessment will take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment must confirm whether the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1 in all the possible configurations identified by the manufacturer as representative of its intended use.

Technical documentation

4. The manufacturer will establish the technical documentation. The documentation must make it possible to assess the conformity of the apparatus to the relevant requirements, and will include an adequate analysis and assessment of the risks.

5. The technical documentation must specify the applicable requirements and cover as far as relevant for the assessment, the design manufacture and operation of the apparatus. The technical documentation will, wherever applicable, contain at least the following elements—

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where the harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation will specify the parts of the standard that have been applied;
- (e) results of design calculations made, examinations carried out, etc.
- (f) test reports.

Manufacturing

6. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the compliance of the manufactured apparatus with the technical documentation referred to in paragraph 3 of this Schedule and the essential requirements set out in paragraph 1 of Schedule 1.

CE marking and EU declaration of conformity

7. The manufacturer must affix the **CE marking** to each individual apparatus and satisfies the applicable requirements of the Regulations,

8. The manufacturer must draw up a written EU declaration of conformity for apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity must identify the apparatus for which it has been drawn up.

Authorised Representative

9. The manufacturer's obligations set out in paragraph 5 may be fulfilled by the authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE 3

Applicable conformity assessment procedures

PART 1

Module B: EU-type Examination

1. **EU-type examination** is the part of a conformity assessment procedure in which a notified body examines the technical design of apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1.

2. **EU-type examination** will be carried out by an assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in paragraph 3 without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative.

3. The manufacturer must lodge an application **for EU-type examination** with a single notified body of his choice. The application will specify the aspects of the essential requirements for which examination is requested and will include—

- (a) the name and address of the manufacturer or, if the application is lodged by an authorised representative, the name and address of the authorised representative and of the manufacturer;
- (b) a written declaration that the same application has not been lodged with another notified body;
- (c) the technical documentation.

4. The technical documentation referred to in paragraph 3(c) of this Schedule must make it possible to assess the apparatus conforming with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risks posed by the apparatus. The technical documentation must specify and cover, as far as is relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation will contain at least the following elements, where applicable—

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where the harmonised

standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation will specify the parts of the standard that have been applied;

- (e) results of design calculations made, examinations carried out, etc.
- (f) test reports.

5. The notified body will examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is required.

6. The notified body must draw up an evaluation report which records the activities undertaken in accordance with paragraph 5 and their outcomes. Without prejudice to its obligations to the notifying authorities, the notified body will release the content of that report, in full or in part, only with the agreement of the manufacturer.

7. Where the type meets the requirements of these Regulations that apply to the apparatus concerned, the notified body will issue an EU-type examination certificate to the manufacturer.

8. The EU-type examination certificate, which may be accompanied by one or more annexes, will contain—

- (a) the name and address of the manufacturer;
- (b) the conclusions of the examination of the apparatus;
- (c) the aspects of the essential requirements covered by the examination;
- (d) the conditions (if any) for the validity of the certificate, and;
- (e) the necessary data for the identification of the approved type.

9. The EU-type examination certificate and any annexes to that certificate must contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

10. Where the type does not satisfy the applicable requirements of these Regulations, the notified body must refuse to issue the EU-type examination certificate and will inform the applicant accordingly, giving detailed reasons for its refusal.

11.—(1) The notified body will keep apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations and will determine whether such changes require further investigation. If so, the notified body must inform the manufacturer accordingly.

12. The manufacturer must inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of these Regulations of the conditions for validity of that certificate. Such modifications will require additional approval in the form of an addition to the EU-type examination certificate.

13. Each notified body must inform its notifying authority of any EU-type examination certificates or any additions thereto, which it has issued or withdrawn and, must periodically or upon request, make available to its notifying authority a list of such certificates and additions thereto that it has refused, suspended or otherwise restricted.

14. Each notified body must inform the other notified bodies [operating in the European Union] of any EU-type examination certificates or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted. Upon request from another notified body, a notified body must inform the requesting body of the EU-type examination certificates that it has issued.

15. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificate and any additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the

results of the examination carried out by the notified body. The notified body must keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

16. The manufacturer must keep a copy of the EU-type examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

17. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 12 and 16 of this Schedule, provided that they are specified in the authorised representative's written mandate.

PART 2

Module C: conformity to type based on internal production control

18. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations set out in paragraphs 19 and 20 of this Schedule and ensures and declares that the apparatus concerned are in conformity with the type described in the EU-type Examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

19. The manufacturer must take all measures necessary to ensure that the manufacturing process and the monitoring of that process ensure the conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of these Regulations that apply to them.

CE marking and EU declaration of conformity

20. The manufacturer must affix the CE marking to each individual apparatus that is in conformity with the type described on the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

21. The manufacturer must draw up a written EU declaration of conformity for each apparatus and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity must identify the apparatus model for which it has been drawn up.

22.A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

Authorised representative

23. The manufacturer's obligations set out in paragraphs 20 to 22 of this Schedule may be fulfilled by an authorised representative on behalf of the manufacturer and under the responsibility of the manufacturer provided that these responsibilities are set out in the authorised representative's written mandate.

SCHEDULE 4

EU declaration of conformity

EU declaration of conformity (No xxxx)(a)

1. Apparatus model (apparatus, type, batch or serial number):
2. Name and address of manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification in relation to which conformity is declared:
7. Where applicable, the notified body... (name, number) performed... (description of intervention) and issued the certificate:
8. Additional information:
Signed for and on behalf of:
(place and date of issue):
(name, function) (signature):

SCHEDULE 5

Time-limit for transposition into national law and date of application

[Table to be inserted. Corresponding annex of the Directive will be copied out]

(a) It is optional for the manufacturer to assign a number to the declaration of conformity.

SCHEDULE 6

Requirements relating to a notified body

1. A conformity assessment body must be established under national law and have legal personality.

2. A conformity assessment body must be a third-party body independent of the organisation or the apparatus it assesses.

3. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment must not be the—

- (a) designer;
- (b) manufacturer;
- (c) supplier;
- (d) installer;
- (e) purchaser;
- (f) owner;
- (g) user; or
- (h) maintainer

of the apparatus which the conformity assessment body assesses, nor the representative body of any of these persons.

5. Nothing in paragraph 4 of this schedule will preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment must not be directly involved in the—

- (a) design or manufacture;
- (b) marketing;
- (c) installation;
- (d) use of maintenance

of the apparatus, or represent the persons engaged in those activities.

7. A conformity assessment body must not engage in any activity, including consultancy services that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified.

8. Conformity assessment bodies will ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

9. Conformity assessment bodies and their personnel will carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and will be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

10. A conformity assessment body must be capable of carrying out the conformity assessment tasks assigned to it by regulation 41 (applicable conformity assessment procedures) and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

11. At all times and for each conformity assessment procedure and each kind or category of apparatus in relation to which it has been notified, a conformity assessment body must have at its disposal, the necessary—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures;
- (c) policies and procedures in place to distinguish between tasks that it carries out as a notified body and other activities;
- (d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the apparatus in question and the mass or serial nature of the production process; and
- (e) means to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment and facilities to perform these activities.

12. The personnel responsible for carrying out the conformity assessment activities must have—

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments that they carry out and adequate authority to carry out those assessments

SCHEDULE 7

Operational requirements of notified bodies

1. Notified bodies must carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule 3 of these Regulations.

2. Conformity assessments must be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies must perform their activities taking due account of the size of [an undertaking] the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

3. Conformity assessment bodies must respect the degree of rigour and level of protection required for the compliance of the apparatus with the Directive

4. Where a notified body finds that the requirements of regulation 9 and Schedule 1 or the corresponding harmonised standards have not been met by the manufacturer, that body will require that manufacturer to take appropriate corrective measures and will not issue a conformity assessment certificate until the appropriate corrective measures have been taken.

5. Where, in the course of the monitoring of the conformity of the apparatus following the issue of a conformity assessment certificate, a notified body finds that apparatus is no longer in compliance, it will require the manufacturer to take appropriate corrective measures and will suspend or withdraw the conformity assessment certificate if necessary.

6. Where corrective measures are not taken or do not have the required corrective effect, the notified body will restrict, suspend or withdraw any conformity assessment certificates as appropriate.

SCHEDULE 8

Enforcement powers conferred on enforcement authorities

PART 1

POWERS

Enforcement powers under the 1987 Act

1. For the purposes of enforcing these Regulations, the sections of the 1987 Act listed in paragraph 2 will apply, subject to paragraph 3 of this Schedule.

2. The following provisions of the 1987 Act will be conferred upon the enforcement authorities—

- (a) section 14 (suspension notices);
- (b) section 15 (appeals against suspension notices);
- (c) section 16 (forfeiture: England, Wales and Northern Ireland);
- (d) section 17 (forfeiture: Scotland); and
- (e) section 18 (power to obtain information);

3. For the purpose of paragraph 2(a) of this Schedule the words “three months” are substituted for the words “six months” in section 14(6) of the 1987 Act.

4. For the purpose of paragraph 2(b) of this Schedule, section 15 will apply with the following modification—

After subsection (1) insert—

“(2) In Scotland, the appropriate court for the purposes of this section is the sheriff of a sheriff court district in which a notice has been served on an economic operator.”

PART 2

NOTICES

Compliance notice

5. An enforcement authority may serve a compliance notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that there is non-compliance.

6. A compliance notice must—

- (a) require the relevant economic operator on which it is served to—
 - (i) end the non-compliance within such period as may be specified in the notice; or
 - (ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcement authority that the non-compliance has not in fact occurred; and
- (b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice,

further action may be taken in respect of the apparatus or any apparatus of the same type made available on the market by that relevant economic operator.

7. A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

8. Subject to paragraph (5), an enforcement authority may revoke or vary a compliance notice by serving a notification on the economic operator.

9. An enforcement authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Withdrawal notice

10. An enforcement authority may serve a withdrawal notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that—

- (a) the apparatus has been made available on the market; and
- (b) there is non-compliance.

11. A withdrawal notice must prohibit the relevant economic operator from making the apparatus available on the market without the consent of the enforcement authority.

12. A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the apparatus.

13. A withdrawal notice may require the relevant economic operator to keep the enforcement authority informed of the whereabouts of any apparatus referred to in the notice.

14. A consent given by the enforcement authority pursuant to a withdrawal notice, may impose such conditions on the making available on the market as the enforcement authority considers appropriate.

15. Subject to paragraph (7), an enforcement authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

16. An enforcement authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Recall notice

17. The enforcement authority may serve a recall notice on a relevant economic operator in respect of apparatus if the authority has reasonable grounds for believing that—

- (a) the apparatus has been made available to end-users; and
- (b) there is non-compliance.

18. A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the apparatus from end-users to the relevant economic operator or another person specified in the notice.

19. A recall notice may—

- (a) require the recall to be effected in accordance with a code of practice;
- (b) require the relevant economic operator to—
 - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;
 - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the apparatus poses and the fact of the recall; or
 - (iii) make arrangements for the collection or return of the apparatus from end-users or its disposal; or

- (c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the apparatus.

20. In determining what requirements to include in a recall notice, the enforcement authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

21. A recall notice may only be issued by the enforcement authority where—

- (a) other action which it may require under these Regulations would not suffice to address the non-compliance;
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance;
- (c) the enforcement authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice; and
- (d) the enforcement authority has taken account of any advice obtained under sub-paragraph (6).

22. A relevant economic operator which has received notice from the enforcement authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—

- (a) whether there is non-compliance; and
- (b) whether the issue of a recall notice would be proportionate.

23. Sub-paragraphs (5)(b), (c) and (d) do not apply in the case of apparatus presenting a serious risk requiring, in the view of the enforcement authority, urgent action.

24. Where a relevant economic operator requires the enforcement authority to seek advice under sub-paragraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcement authority.

25. In this regulation, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

26. A recall notice served by the enforcement authority may require the relevant economic operator to keep the authority informed of the whereabouts of apparatus to which the recall notice relates, so far as the relevant economic operator is able to do so.

27. Subject to paragraph (12), an enforcement authority may revoke or vary a recall notice by serving a notification on the economic operator.

28. An enforcement authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Interpretation

29. In this Schedule, “non-compliance” means that the apparatus—

- (a) presents a risk; or
- (b) is not in conformity with Part 2 or RAMS (in its application to apparatus).

SCHEDULE 9

Powers conferred on market surveillance authorities

1. Subject to paragraph 2, a market surveillance authority has the same duty to enforce these Regulations as it has in relation to the following sections of the 1987(a) Act—

- (a) section 13 (prohibition notices and notices to warn);
- (b) section 14 (suspension notices);
- (c) section 16 (forfeiture: England, Wales and Northern Ireland);
- (d) section 17 (forfeiture: Scotland);
- (e) section 18 (power to obtain information);
- (f) section 35 (recovery of expenses of enforcement);
- (g) section 37 (power of the Commissioners for Revenue and Customs to disclose information), and;
- (h) sub-sections (3) and (4) of section 42 (Reports, etc)(b);

2. The powers listed in paragraph 1 apply with the following modification—

- (a) section 13 of the 1987 Act (prohibition notices and notices to warn) will apply, to the extent that it does not already do so, to any apparatus falling within the scope of these Regulations as it applies to consumer goods under that section, as if the words “3 months” were substituted for the words “6 months” in section 13(4).

-
- (a) The sections listed in this paragraph apply subject to the modifications made by Schedule 6 of the Consumer Rights Act 2015 (c.15).
 - (b) Subsection 42(3) provides that any person under an obligation under section 27(2) of the 1987 Act to enforce safety provisions will, whenever the Secretary of State directs, make a report to the Secretary of State on the exercise of the functions exercisable by them by virtue of any such regulations. Subsection 42(4) provides that a report provided in accordance with subsection 42(3) will take the format and contain such particulars as are specified by the Secretary of State.