

2016 No. 1152

WEIGHTS AND MEASURES

The Non-automatic Weighing Instruments Regulations 2016

Made - - - - 29th November 2016

Laid before Parliament 6th December 2016

Coming into force - - 28th December 2016

The Secretary of State is a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to, and for purposes ancillary to, the regulation of specifications, construction, placing on the market and use of articles, instruments, containers or other equipment intended for weighing, measuring or testing.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A(c) of Schedule 2 to, that Act and, in relation to Part 7 of the Regulations (and any other provisions of these Regulations to the extent that they apply to, or give effect to, Part 7), under powers conferred by sections 15(1) and 86(1) of the Weights and Measures Act 1985(d).

PART 1

INTRODUCTORY

Citation commencement and extent

1.—(1) These Regulations may be cited as the Non-automatic Weighing Instruments Regulations 2016.

(2) These Regulations come into force on 28th December 2016.

(3) These Regulations extend to Northern Ireland except for Part 7.

(a) S.I. 1975/427.

(b) 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1) and the European Union (Amendment) Act 2008 (c.7), Schedule, Part 1.

(c) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and amended by the European Union (Amendment) Act 2008, Schedule, Part 1.

(d) 1985 c.72.

Interpretation

2.—(1) In these Regulations—

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

“accreditation certificate” means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body as defined in point 11 of Article 2 of RAMS in another EEA state, attesting that a conformity assessment body meets the notified body requirements;

“authorised representative” means any person established within the European Economic Area who has received a written mandate from a manufacturer to act on the manufacturer’s behalf in relation to specified tasks;

“CE marking” means a marking which takes the form set out in Annex II of RAMS;

“commencement date” means the date referred to in regulation 1(2);

“Commission” means the Commission of the European Union;

“competent authority” means a person who is, pursuant to regulation 62 (competent authorities and enforcement proceedings), authorised to enforce these Regulations ;

“compliance notice” means a notice served in accordance with regulation 63(2);

“conformity assessment” means the process demonstrating whether the essential requirements relating to a regulated non-automatic weighing instrument have been met;

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

“the Directive” means Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments^(a) and references to the Directive (or a specific provision of it) are references to the Directive (or that provision) as from time to time amended;

“disqualification mark” means a mark or sticker the design of which is published by the Secretary of State^(b) and which may be affixed to a regulated non-automatic weighing instrument in accordance with regulation 67 (disqualification);

“distributor” means any person in the supply chain, other than a manufacturer or an importer, who makes a non-automatic weighing instrument available on the market;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“enforcement notice” means a notice served in accordance with regulation 64(2);

“enforcement officer” means—

(a) an inspector; or

(b) a person appointed by the Secretary of State to act on the Secretary of State’s behalf to enforce these Regulations;

“essential requirements” means, in relation to a regulated non-automatic weighing instrument (or a class of that instrument), the requirements specified as being applicable in relation to that regulated non-automatic weighing instrument (or that class of instrument) in Annex I to the Directive;

“EU declaration of conformity” means a declaration of conformity required to be drawn up in accordance with Chapter 2 of Part 3;

(a) OJ L 96, 29.3.2014 p. 107.

(b) The design of the disqualification mark is published on page 66 of “Weights and Measures, the Non-automatic Weighing Instruments Regulations 2000 (S.I. 2000 No. 3236) as amended by the Non-automatic Weighing Instruments (Amendment) Regulations 2008 (S.I. 2008/738, Guidance on Regulation, December 2015, Version 6,” published by the Secretary of State which is available on the gov.uk website. Paper copies are available from the Regulatory Delivery Directorate, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET.

“EU-type examination certificate” means an EU-type examination certificate issued by a notified body in accordance with Module B of Annex II to the Directive;

“harmonised standard” has the meaning set out in point 1(c) of Article 2 of Regulation (EU) No. 1025/2012 of the European Parliament and of the Council on European standardisation^(a) (as amended from time to time);

“importer” means any person who—

- (a) is established within the European Economic Area ; and
- (b) places a non-automatic weighing instrument from a third country on the European Economic Area market;

“in writing” includes text that is—

- (a) transmitted by electronic means;
- (b) received in legible form; and
- (c) capable of being used for subsequent reference.

“M marking” means a marking applied to a regulated non-automatic weighing instrument which consists of the capital letter ‘M’ and the last two digits of the year of its affixing surrounded by a rectangle, the height of which is equal to that of the CE marking applied to that instrument;

“make available on the market” means any supply of a non-automatic weighing instrument for distribution or use on the European Economic Area market in the course of a commercial activity, whether in return for payment or free of charge and related expressions are to be construed accordingly;

“manufacturer” means any person who—

- (a) manufactures a non-automatic weighing instrument or has a non-automatic weighing instrument designed or manufactured and markets that instrument under their name or trademark; or
- (b) is to be treated as a manufacturer by virtue of regulation 5(2);

“market surveillance authority” means the Secretary of State acting in the capacity of market surveillance authority pursuant to the designation made by regulation 57 (the market surveillance authority), and, where the context requires, a market surveillance authority in another EEA state;

“national accreditation body” means the national accreditation body as defined in point 11 of Article 2 of RAMS;

“non-automatic weighing instrument” means a weighing instrument that—

- (a) serves to determine the mass of a body by using the action of gravity on that body and which may also serve to determine other mass-related magnitudes, quantities, parameters and characteristics; and
- (b) requires the intervention of an operator during weighing;

“notified body” means a conformity assessment body that has been notified to the Commission in accordance with Part 5 and includes, where the context so requires, a notified body designated as such in another EEA state in accordance with the Directive;

“notified body requirements” means the requirements set out in Schedule 3 (requirements related to notified bodies)

“notifying authority” means the notifying authority within the meaning of regulation 48 (the notifying authority);

“place on the market” means the first making available of a non-automatic weighing instrument on the market in the European Economic Area and related expressions are to be construed accordingly;

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

“RAMS” means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93(a) (as amended from time to time);

“recall” means any measure aimed at achieving the return of a regulated non-automatic weighing instrument that has already been made available to the end-user and related expressions are to be construed accordingly;

“regulated non-automatic weighing instrument” means a non-automatic weighing instrument which is intended to be used to perform one of the functions referred to in regulation 3(2);

“relevant economic operator” means, in relation to a non-automatic weighing instrument, an economic operator with obligations in respect of that non-automatic weighing instrument under Part 2;

“re-qualification mark” means a mark or sticker the design of which is published by the Secretary of State(b) and which is affixed to a regulated non-automatic weighing instrument in accordance with regulation 68 (re-qualification);

“technical documentation” means the documentation which meets the requirements of Annex II to the Directive;

“technical specification” means a document that prescribes technical requirements to be fulfilled by a regulated non-automatic weighing instrument;

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

“United Kingdom Accreditation Service” means the company limited by guarantee incorporated in England and Wales under number 3076190;

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985;

“withdraw” when used in relation to a regulated non-automatic weighing instrument means taking any measure aimed at preventing an instrument in the supply chain from being made available on the market and related expressions are to be construed accordingly.

(2) A non-automatic weighing instrument that meets the requirements of the Directive by virtue of the laws of another EEA state is to be treated as meeting the requirements of these Regulations (except any requirement of these Regulations for anything to be written in English) and references to a non-automatic weighing instruments being in conformity with these Regulations are to be construed accordingly.

(3) Other expressions used in these Regulations have in relation to the application of these Regulations to—

- (a) Great Britain, the same meanings as in the Weights and Measures Act 1985(c); and
- (b) Northern Ireland, the same meanings as in the Weights and Measures (Northern Ireland) Order 1981(d).

Application of these Regulations

3.—(1) Subject to regulation 4 (revocations and transitional and consequential provisions), these Regulations apply to non-automatic weighing instruments.

(2) These Regulations, except Part 4, apply to an instrument (referred to in these Regulations as a “regulated non-automatic weighing instrument”) for use for any of the following purposes—

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- (a) OJ L 218, 13.8.2008, p. 30.
 - (b) The design of the disqualification mark is published on page 66 of “Weights and Measures, the Non-automatic Weighing Instruments Regulations 2000 (SI 2000 No.3236) as amended by the Non-automatic Weighing Instruments (Amendment) Regulations 2008 (SI 2008/738, Guidance on Regulation, December 2015, Version 6,” published by the Secretary of which is available on the gov.uk website. Paper copies are available from the Regulatory Delivery Directorate, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET.
 - (c) 1985 c.72.
 - (d) S.I. 1981/231 (N.I. 10).

- (a) the determination of mass for commercial transactions;
 - (b) the determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
 - (c) the determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;
 - (d) the determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
 - (e) the determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories; and
 - (f) the determination of price on the basis of mass for the purposes of direct sales to the public and the making up of prepackages.
- (3) Part 4 applies to a non-automatic weighing instrument that is not a regulated instrument.

Revocations and transitional and consequential provisions

4.—(1) The Non-automatic Weighing Instruments Regulations 2000^(a) and the Non-automatic Weighing Instruments (Amendment) Regulations 2008^(b) are revoked.

(2) In this regulation, “the former law” means the Regulations referred to in paragraph (1).

(3) This paragraph applies to a regulated non-automatic weighing instrument placed on the market before the commencement date which was required by any provision of the former law to meet the essential requirements.

(4) A regulated non-automatic weighing instrument to which paragraph (3) applies which meets the requirements of the former law applicable to it is to be treated as meeting the requirements of these Regulations.

(5) Where a regulated non-automatic weighing instrument to which paragraph (3) applies does not meet the requirements of the former law, these Regulations apply to that instrument as they apply to a regulated instrument placed on the market or put into service after the commencement date which does not comply with the requirements of these Regulations.

(6) Part 7 (use for trade of regulated non-automatic weighing instruments for the purposes listed in regulation 3(2)) applies to regulated non-automatic weighing instruments to which paragraph (3) applies as it applies to a regulated instrument placed on the market or put into service after the commencement date.

(7) A certificate granted under any provision of the former law has effect as if granted under the corresponding provision of these Regulations.

(8) In the list in paragraph 10 in Schedule 5 to the Consumer Rights Act 2015^(c), insert at the appropriate place the following entry—

“regulation 62 of the Non-automatic Weighing Instruments Regulations 2016 (S.I. 2016/1152)”.

(9) In the table in paragraph 11 of Schedule 5 to the Consumer Rights Act 2015, omit the entry relating to the Non-automatic Weighing Instruments Regulations 2000.

(10) An application to be a recognised as a notified body which is made before the commencement date is to be treated as having been made under these Regulations if it meets the requirements of these Regulations.

(11) Except in a case where paragraph (10) applies, a requirement of these Regulations (“the relevant requirement”) is to be treated as having been satisfied by anything done on or after 20th April 2016 but before the commencement date where that thing—

(a) S.I. 2000/3236.
 (b) S.I. 2008/738.
 (c) 2015 c.15.

- (a) was done for the purposes of complying with a requirement of the Directive; and
- (b) if it had been done on or after the commencement date it would have met the relevant requirement.

PART 2

REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS – OBLIGATIONS OF ECONOMIC OPERATORS

CHAPTER 1

OBLIGATIONS OF MANUFACTURERS AND PERSONS TO BE TREATED AS MANUFACTURERS

Introductory

5.—(1) This Chapter applies in relation to the placing on the market of a regulated non-automatic weighing instrument by a manufacturer.

(2) The obligations in this Chapter also apply to an importer or distributor who—

- (a) places a regulated non-automatic weighing instrument on the market under the name or trade mark of that importer or distributor; or
- (b) modifies a regulated non-automatic weighing instrument already placed on the market in such a way that compliance with these Regulations may be affected,

and the expression “manufacturer” is to be construed accordingly.

Manufacturers’ responsibilities – design, conformity assessment and marking of regulated non-automatic weighing instruments

6. A manufacturer must not place on the market a regulated non-automatic weighing instrument unless the manufacturer has—

- (a) designed and manufactured the instrument in accordance with the essential requirements;
- (b) drawn up technical documentation in relation to the instrument;
- (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
- (d) drawn up an EU declaration of conformity; and
- (e) affixed to the instrument—
 - (i) the CE marking; and
 - (ii) the M marking.

Manufacturers’ obligations in respect of records

7. A manufacturer must keep the technical documentation and the EU declaration of conformity for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument to which it relates has been placed on the market.

Manufacturers’ obligations to ensure continuing conformity with the essential requirements

8.—(1) Manufacturers must have procedures in place for series production of regulated non-automatic weighing instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.

(2) These procedures must adequately take into account changes in—

- (a) regulated non-automatic weighing instrument design or characteristics; and

- (b) changes in the harmonised standards or in other technical specifications by reference to which the conformity of the regulated non-automatic weighing instrument is declared.
- (3) When deemed appropriate with regard to the risks presented by the use of a regulated non-automatic weighing instrument, a manufacturer must—
 - (a) carry out sample testing of regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (b) investigate complaints about regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated non-automatic weighing instruments; and
 - (iii) regulated non-automatic weighing instrument recalls; and
 - (d) keep distributors informed of any monitoring action the manufacturer has undertaken.

Manufacturers’ obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.

9.—(1) A manufacturer must ensure that a regulated non-automatic weighing instrument, which that manufacturer has placed on the market, bears a type, batch, serial number or other element allowing identification of the instrument.

(2) A manufacturer must ensure that a regulated non-automatic weighing instrument is marked with the information specified in Schedule 1 (information to be marked on regulated non-automatic weighing instruments) and in the manner required by that Schedule.

(3) Where a regulated non-automatic measuring instruments includes or is attached to devices which are not used or intended to be used for any of the purposes listed in regulation 3(2), the manufacturer must affix to those devices a symbol constituted by a capital letter (M) printed in black on a red background at least 25mm x 25mm square with two intersecting diagonals forming a cross.

(4) The symbol referred to in paragraph (3) must be affixed in a clearly visible and indelible form.

Manufacturers to mark contact details on regulated non-automatic weighing instruments

10.—(1) A manufacturer must indicate on every regulated non-automatic weighing instruments manufactured by that manufacturer, the manufacturer’s name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.

(2) The address required by these Regulations must indicate a single point at which the manufacturer can be contacted.

(3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities and in the case of regulated non-automatic weighing instruments made available in the United Kingdom, they must be in English.

Documentation to accompany regulated non-automatic weighing instruments

11.—(1) A manufacturer must ensure that regulated non-automatic weighing instruments manufactured by that manufacturer are accompanied by instructions and information easily understood by end-users.

(2) Where end-users are in the United Kingdom, those instructions and information must be in English.

(3) Such instructions and information and any labelling relating to a regulated non-automatic weighing instrument must be clear, understandable and intelligible.

Action to be taken where regulated non-automatic weighing instruments placed on the market are not in conformity with the essential requirements

12.—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated non-automatic weighing instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.

(2) The manufacturer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the regulated non-automatic weighing instrument presents a risk, the manufacturer must immediately inform the competent national authorities of the EEA states in which the instrument has been made available on the market to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

Provision of information to the competent authority

13.—(1) A manufacturer must, further to a reasoned request from a competent authority, provide that authority, with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a regulated non-automatic weighing instrument manufactured by that manufacturer with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A manufacturer must co-operate with a competent authority, at the request of that authority, on any action to eliminate the risks posed by regulated non-automatic weighing instruments that the manufacturer has placed on the market.

Use of authorised representatives by manufacturers

14.—(1) A manufacturer may, by written mandate, appoint an authorised representative to discharge the responsibilities of that manufacturer under these Regulations in relation to the placing on the market of a regulated non-automatic weighing instrument.

(2) The authorised representative does not have the power to discharge the manufacturer's obligations under regulations 6(a) and 6(b).

(3) The authorised representative must be treated as authorised to—

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years beginning with the day after the day on which a regulated non-automatic weighing instrument has been placed on the market;
- (b) provide a competent authority further to a reasoned request from that authority with all the information and documentation necessary to demonstrate the conformity of a regulated non-automatic weighing instrument; and
- (c) co-operate with a competent authority, at its request, on any action taken to eliminate the risks posed by regulated non-automatic weighing instruments covered by its mandate.

CHAPTER 2

OBLIGATIONS OF IMPORTERS

Introductory

15. This Chapter applies to the placing on the market of a regulated non-automatic weighing instrument that is imported into the United Kingdom from a country outside the European Economic Area.

Ensuring compliance of regulated non-automatic weighing instruments

16.—(1) An importer must only place compliant regulated non-automatic weighing instruments on the market.

(2) An importer must ensure that—

- (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated non-automatic weighing instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 5(2));
- (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 5(2));
- (c) the regulated non-automatic weighing instrument bears the CE marking and the M marking;
- (d) the manufacturer (or the importer where he is treated as the manufacturer under regulation 5(2)) has complied with the requirements of regulations 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.) and 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments).

Importers duty to notify manufacturer and market surveillance authorities of non-compliant regulated non-automatic weighing instruments that present a risk

17. Where an importer considers, or has reason to believe, that the regulated non-automatic weighing instrument is not in conformity with the essential requirements and presents a risk, the importer must inform the manufacturer and the market surveillance authority.

Requirements to mark importers' details on regulated non-automatic weighing instruments

18.—(1) An importer must indicate on any regulated non-automatic weighing instrument imported by that importer, the importer's name, registered trade name or trademark, and the postal address at which the importer can be contacted.

(2) Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument.

(3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities, and in the case of regulated non-automatic weighing instruments made available in the United Kingdom, they must be in English.

Importers' duty to ensure that regulated non-automatic weighing instruments are accompanied by relevant documentation.

19.—(1) An importer must ensure that regulated non-automatic weighing instruments imported by the importer are accompanied by instructions and information in a language easily understood by end users

(2) Where end users are in the United Kingdom, the instructions and information referred to in paragraph (1) must be in English.

Duty of importers to ensure proper conditions of storage and transport

20. An importer must, in respect of regulated non-automatic weighing instruments under the importer's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Duties of importers with regard to monitoring etc.

21.—(1) When deemed appropriate with regard to the performance of a regulated non-automatic weighing instrument imported by an importer, the importer must—

- (a) carry out a sample testing of regulated non-automatic weighing instruments made available on the market by the importer;
- (b) investigate complaints about regulated non-automatic weighing instruments imported by them; and
- (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated non-automatic weighing instruments;
 - (iii) regulated non-automatic weighing instrument recalls; and
- (d) where the importer is not also the distributor of the regulated non-automatic weighing instrument, keep distributors, to whom he has supplied an instrument, informed of any monitoring undertaken by that importer.

Action to be taken by importers where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

22.—(1) This regulation applies where an importer considers, or has reason to believe, that a regulated non-automatic weighing instrument placed on the market by the importer is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the importer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the non-automatic weighing instrument presents a risk, the importer must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

Requirement for importer to keep copy of EU declaration of conformity

23. The importer must, for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument is placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

Provision of information to a competent authority

24.—(1) The importer must, further to a reasoned request from a competent authority, provide the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) An importer must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the importer has placed on the market.

CHAPTER 3

OBLIGATIONS OF DISTRIBUTORS

Introductory

25. This Chapter applies in relation to the making available on the market of a regulated non-automatic weighing instrument by a distributor.

Distributors – duty to act with due care

26. Before making the regulated non-automatic instrument available on the market, the distributor must act with due care in relation to the requirements of these Regulations.

Distributors – verification obligations

27.—(1) The distributor must verify that the regulated non-automatic weighing instrument bears the CE marking and the M marking.

(2) The distributor must verify that the regulated non-automatic weighing instrument, it is accompanied by instructions and information easily understood by end users.

(3) Instructions and information supplied in accordance with this regulation must be in a language that is easily understood by end users and where those users are in the United Kingdom must be in English.

(4) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.), regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) and regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments).

Distributors not to make non-conforming non-automatic weighing instruments available on the market etc.

28.—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument is not in conformity with the essential requirements.

(2) Where this regulation applies, the distributor must not make the regulated non-automatic weighing instrument available on the market until it has been brought into conformity.

(3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform—

- (a) the manufacturer;
- (b) the importer (where the distributor is not also the manufacturer or importer); and
- (c) the market surveillance authority,

to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Duty of distributors to ensure proper conditions of storage and transport

29. A distributor must, in respect of regulated non-automatic weighing instruments under that distributor's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Action to be taken by distributors where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

30.—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument placed on the market by that distributor is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the distributor must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Provision of information to the competent authority

31.—(1) The distributor must, further to a reasoned request from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A distributor must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the distributor has placed on the market.

CHAPTER 4

IDENTIFICATION OF ECONOMIC OPERATORS

32.—(1) Economic operators must, on request, identify to the market surveillance authorities—

- (a) any economic operator who has supplied them with a regulated non-automatic weighing instrument; and
- (b) any economic operator to whom they have supplied a regulated non-automatic weighing instrument.

(2) Economic operators must be able to present the information referred to in paragraph (1) for 10 years beginning with the day on which they have been supplied with the regulated non-automatic weighing instrument and for 10 years beginning with the day after the day on which they have supplied the instrument.

(3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with an obligation imposed by this regulation.

(4) Schedule 5 has effect in relation to the imposition of a monetary penalty under paragraph (3).

PART 3

CONFORMITY OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory

33. This Chapter applies for the purposes of establishing whether a regulated non-automatic weighing instrument complies with the essential requirements.

Methods of establishing conformity with the essential requirements

34. Conformity with the essential requirements may be established in relation to a regulated non-automatic weighing instrument—

- (a) through conformity with harmonised standards (or parts of those standards) covering the essential requirements where the harmonised standards have been published in the Official Journal of the European Union; or
- (b) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

Presumptions of conformity of regulated non-automatic weighing instruments

35. Regulated non-automatic weighing instruments which are in conformity with harmonised standards (or parts of those standards) shall be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

Conformity assessment procedures

36.—(1) The conformity of regulated non-automatic weighing instruments to the essential requirements may, subject to paragraph (2), be established by either of the following conformity assessment procedures as selected by the manufacturer—

(a) Module B as set out in point 1 of Annex II to the Directive followed by either—

(i) Module D as set out in point 2 of Annex II; or

(ii) Module F as set out in point 4 of Annex II; or

(b) Module G as set out in point 6 of Annex II.

(2) Module B is compulsory for instruments—

(a) which use electronic devices; and

(b) the load measuring device of which uses a spring to balance the load.

(3) Where an instrument is not submitted to Module B, either of the following modules must be applied—

(a) Module D1 as set out in point 3 of Annex II; or

(b) Module F1 as set out in point 5 of Annex II.

(4) A notified body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 2.

(5) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation, and which are carried out in the United Kingdom, must be drawn up in English.

(6) In this regulation a reference to a module other than Module B includes the common provisions as set out in point 7 of Annex II to the Directive.

Subsidiaries and contractors

37.—(1) This regulation applies where—

(a) a notified body subcontracts specific conformity assessment activities, or

(b) has such activities carried out by a subsidiary.

(2) The activities are only to be treated as having been carried out by a notified body for the purposes of regulation 36 (conformity assessment procedures) where the conditions in paragraphs (3) and (4) are met.

(3) The notified body must—

(a) ensure that the subcontractor or subsidiary meets the notified body requirements; and

(b) inform the Secretary of State accordingly.

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

(5) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years beginning on the day after the activities 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.

(6) When monitoring a notified body in accordance with regulation 52 (monitoring), the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

Fees

38.—(1) A United Kingdom notified body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.

(2) The fees referred to in paragraph (1) must not exceed the following—

- (a) the costs incurred or to be incurred by the United Kingdom notified body in performing the relevant function; and
- (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.

(4) Where any fees payable to a United Kingdom notified body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment of the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.

(5) This regulation does not apply to the Secretary of State.

CHAPTER 2

REQUIREMENTS RELATING TO EU DECLARATIONS OF CONFORMITY

Application of Chapter

39. This Chapter applies in relation to EU declarations of conformity made in relation to a regulated non-automatic weighing instrument for the purposes of these Regulations.

Form and contents of EU declaration of conformity etc.

40.—(1) The EU declaration of conformity must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the regulated non-automatic weighing instrument;
- (b) have the model structure set out in Annex IV to the Directive; and
- (c) contain the elements specified in the relevant modules set out in Annex II to the Directive and must be updated when appropriate.

(2) Where a regulated non-automatic weighing instrument is placed or made available on the market in the United Kingdom, the EU declaration of conformity in relation to the instrument must be in English.

Regulated instruments that require more than one declaration of conformity

41.—(1) This regulation applies where a regulated non-automatic weighing instrument is subject to a requirement of European Union legislation for an EU declaration of conformity otherwise than by virtue of these Regulations.

(2) Where this regulation applies, a single EU declaration of conformity must be drawn up covering all applicable requirements which identifies the Union acts concerned including their publication references.

Responsibility of manufacturer that draws up declaration of conformity

42. A manufacturer, who draws up an EU declaration of conformity in relation to a regulated non-automatic weighing instrument, is responsible for compliance of that instrument with the requirements of these Regulations.

CHAPTER 3

CONFORMITY MARKING

Conformity with Directive requirements to be indicated by the CE marking

43. The conformity of a regulated non-automatic weighing instrument with the requirements of these Regulations must be indicated by the presence on it of the CE marking and the M marking.

General principles relating to the M marking

44. The general principles set out in article 30 of RAMS apply to the M marking with such modifications as are necessary in the circumstances.

Rules and conditions for affixing the CE marking and the M marking etc.

45.—(1) The CE marking and M marking (“the markings”) must be affixed to a regulated non-automatic weighing instrument in accordance with the provisions of this regulation.

(2) The markings must be affixed visibly, legibly and indelibly to the regulated non-automatic weighing instrument or its data plate.

(3) The markings must be affixed before the regulated non-automatic weighing instrument is placed on the market.

(4) The M marking must immediately follow the CE marking.

(5) The markings must immediately be followed by the identification of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive.

(6) The identification number of the notified body which carried out the conformity assessment procedure must be affixed by the body itself, or under its instructions by the manufacturer or the manufacturer’s authorised representative.

(7) The markings and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

PART 4

REQUIREMENTS FOR NON-REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

46.—(1) This regulation applies to a non-automatic weighing instrument which is not a regulated non-automatic weighing instrument.

(2) A manufacturer must not place on the market a non-automatic weighing instrument to which this regulation applies unless it is marked legibly and indelibly with the following information—

- (a) the manufacturer’s name, registered trade name or registered trade mark; and
- (b) the maximum capacity of the instrument, in the form “Max.....”.
- (c) the postal address at which they can be contacted, indicating a single point of contact.

(3) Before placing on the market a non-automatic weighing instrument to which this regulation applies, an importer must ensure that—

- (a) the manufacturer has marked the instrument in the manner referred to in paragraph (2) with the information referred to in that paragraph;
- (b) the importer has indicated on the instrument their name or registered trade mark and the postal address at which they can be contacted.

(4) Where compliance with paragraph (3)(b) would require the packaging to be opened, the information required by that paragraph may be given on the packaging and in a document accompanying the non-automatic weighing instrument.

(5) Before making available on the market a non-automatic weighing instrument to which this regulation applies, a distributor must verify that—

- (a) the manufacturer has marked the instrument in the manner referred to in paragraph (2) with the information referred to in that paragraph;
- (b) the importer of the instrument has complied with paragraph (3).

PART 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Introductory

47.—(1) This Part applies to the notification to the Commission and other EEA states of the bodies authorised to carry out conformity assessment procedures in the United Kingdom in relation to regulated non-automatic weighing instruments.

(2) For the purposes of this Part, a notified body is a conformity assessment body—

- (a) which has been notified to the Commission and to other EEA states in accordance with the Directive; and
- (b) in respect of which no objections are raised by the Commission or other EEA states—
 - (i) within 2 weeks of a notification, where an accreditation certificate is used; or
 - (ii) within 2 months of a notification, where accreditation is not used.

(3) Paragraph (2) has effect subject to regulation 54 (changes to notifications).

The notifying authority

48.—(1) The notifying authority for the purposes of these Regulations is the Secretary of State.

(2) The functions of the notifying authority are—

- (a) to assess whether applicants for recognition as conformity assessment bodies meet the requirements for recognition as such;
- (b) where an assessment that a body is qualified to act as a conformity assessment body is made, to notify the Commission of that fact; and
- (c) to carry out such monitoring of bodies notified to the Commission to ensure continuing compliance with the requirements of these Regulations.

(3) The notifying authority may delegate the performance of its functions to a body that meets the requirements of Articles 20(3) and 21 of the Directive but in the event of such a delegation the notifying authority remains fully responsible for the performance of those functions.

(4) The notifying authority must supply such information as the Commission may request in relation to a body notified by it.

Notification

49.—(1) The Secretary of State may notify to the Commission and the other EEA states only those conformity assessment bodies that qualify for notification.

(2) A conformity assessment body qualifies for notification if the first and the second conditions below are met.

(3) The first condition is that the conformity assessment body makes an application to the Secretary of State for notification and that application is accompanied by—

- (a) a description of—
 - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
 - (ii) the conformity assessment module for which the conformity assessment body claims to be competent; and
 - (iii) the regulated non-automatic weighing instrument in respect of which the conformity assessment body claims to be competent; and
- (b) an accreditation certificate or the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the requirements of Schedule 3 (“the notified body requirements”).

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the notified body requirements.

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the Commission and the other member States, the Secretary of State may—

- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
- (b) set conditions that the conformity assessment body must meet.

(7) The Secretary of State must inform the Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies, and any changes to those procedures.

Presumption of conformity of notified bodies

50.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal of the European Union, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Contents of notification

51. A notification under regulation 49 (notification) must include—

- (a) details of—
 - (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
 - (ii) the conformity assessment module in respect of which the conformity assessment body has made its application for notification;
 - (iii) the regulated non-automatic weighing instrument in respect of which the conformity assessment body has made its application for notification; and
- (b) either or both of the following—

- (i) an accreditation certificate; or
- (ii) documentary evidence which attests to—
 - (aa) the conformity assessment body’s competence; and
 - (bb) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

Monitoring

52.—(1) 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) meets any conditions set in accordance with regulation 49(6)(b) ; and
- (c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must inform the Commission of the United Kingdom’s procedures for the monitoring of notified bodies, and any changes to those procedures.

Delegation to the United Kingdom Accreditation Service

53.—(1) 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 whether a conformity assessment body meets the notified body requirements; and
- (b) monitoring notified bodies.

(2) Where the Secretary of State authorises the United Kingdom Accreditation Service pursuant to paragraph (1), the Secretary of State remains fully responsible for anything done pursuant to that authorisation.

Changes to notifications

54.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 49(6)(b), the Secretary of State must restrict, suspend or withdraw the body’s status as a notified body under regulation 49 (notification).

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 49(6)(b), the Secretary of State may restrict, suspend or withdraw the body’s status as a notified body under regulation 49 (notification).

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the failure.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing that the Secretary of State intends to take such action and the reasons for taking such action; and
- (b) give the notified body an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other EEA states.

(6) Where the Secretary of State has taken action in respect of a notified body under paragraph (1) or (2), or where a notified body has ceased its activity, the body must—

- (a) on the request of the Secretary of State, transfer its files to another notified body or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), ensure that its files are kept available for the Secretary of State and each enforcing authority for such period as the Secretary of State may specify.

(7) The Secretary of State may impose a monetary penalty on a United Kingdom notified body that fails to comply with any requirement imposed by or under paragraph (6).

(8) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (7).

PART 6

PUTTING INTO SERVICE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS FOR THE PURPOSES LISTED IN REGULATION 3(2)

55. No person shall put into service a regulated non-automatic weighing instrument for any of the uses listed in regulation 3(2) or have such an instrument in his possession for such use unless prior to placing the instrument on the market it has been established by the application of the appropriate conformity assessment procedure that the essential requirements are met in relation to the instrument.

PART 7

USE FOR TRADE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS IN GREAT BRITAIN

56. Schedule 4 applies to the use for trade of regulated non-automatic weighing instruments in Great Britain.

PART 8

MARKET SURVEILLANCE AND ENFORCEMENT

CHAPTER 1

MARKET SURVEILLANCE

The market surveillance authority

57. The Secretary of State is the market surveillance authority for the purposes of these Regulations and RAMS.

Regulated non-automatic weighing instruments presenting a risk

58.—(1) This regulation applies where the market surveillance authority has sufficient reason to believe that a regulated non-automatic weighing instrument presents a risk in relation to any of the purposes set out in regulation 3(2).

(2) Where this regulation applies the market surveillance authority must carry out an evaluation of the regulated non-automatic weighing instrument covering all relevant requirements of these Regulations which apply to that instrument.

(3) The relevant economic operators in relation to the non-automatic weighing instrument must co-operate as necessary with the market surveillance authority for that purpose.

(4) Where, in the course of the evaluation referred to in paragraph (2), the market surveillance authority finds that that the regulated non-automatic weighing instrument does not comply with the essential requirements applicable to it, it must without delay issue a direction which requires the relevant economic operator to—

(a) take all appropriate corrective actions;

- (b) withdraw the regulated non-automatic weighing instrument from the market; or
- (c) recall it within a reasonable period commensurate with the nature of the risk.

(5) Where the market surveillance authority acts under paragraph (4) it must without delay inform the notified body that carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument of—

- (a) the respect in which the regulated non-automatic weighing instrument is not in conformity with the requirements of these Regulations; and
- (b) the actions that the authority is requiring the relevant economic operator to take.

(6) Where the market surveillance authority considers that non-compliance is not restricted to the United Kingdom, it must inform the Commission and the other EEA states of the results of the evaluation and of the actions which they have required the economic operator to take.

(7) The economic operator must ensure that all appropriate corrective action is taken in respect of all the regulated non-automatic weighing instruments concerned that it has made available on the market throughout the European Economic Area.

(8) Where the relevant economic operator does not take adequate corrective action within a reasonable period, the market surveillance authority must take all provisional measures to prohibit or restrict the regulated non-automatic weighing instrument being made available on the market, to withdraw the instrument from that market or to recall it.

(9) Where the market surveillance authority takes measures under paragraph (8), the market surveillance authority must notify the Commission and the other EEA states of those measures without delay.

(10) A notification under paragraph (9) must include all available details, in particular—

- (a) the data necessary for the identification of the non-compliant regulated measuring instrument;
- (b) the origin of the instrument;
- (c) the nature of the non-compliance alleged and the risk involved;
- (d) the nature and duration of the measures taken;
- (e) the arguments put forward by the relevant economic operator; and
- (f) whether the non-compliance is due to either of the following—
 - (i) failure of the regulated measuring instrument to meet the requirements relating to a risk; or
 - (ii) shortcomings in the harmonised standards referred to in regulation 34(a).

EU safeguard procedure

59.—(1) Where another EEA state has initiated the procedure under Article 37 of the Directive, the market surveillance authority must without delay, inform the Commission and the other EEA states of—

- (a) any measures taken by competent authority in respect of the regulated non-automatic weighing instrument;
- (b) any additional information which the market surveillance authority has at its disposal relating to the lack of conformity of the regulated non-automatic weighing instrument; and
- (c) any objections that the market surveillance authority may have to the measure taken by the EEA state initiating the procedure;

(2) Where a measure taken by another EEA state in respect of a regulated non-automatic weighing instrument is considered justified under Article 37(7) of the Directive, the market surveillance authority must ensure that appropriate measures to withdraw the instrument are taken in respect of the regulated non-automatic weighing instrument without delay.

(3) If, pursuant to Article 38 of the Directive, the Commission considers a direction given pursuant to regulation 58(4) is unjustified, the market surveillance authority must forthwith withdraw it and notify other competent authorities and economic operators affected accordingly.

Compliant regulated non-automatic weighing instruments which present a risk

60.—(1) This regulation applies where, having carried out an evaluation under regulation 58 (regulated non-automatic weighing instruments presenting a risk), the market surveillance authority finds that although a regulated non-automatic weighing instrument is in compliance with the requirements of these Regulations, it presents a risk in relation to its use in relation to any activity referred to in regulation 3(2).

(2) Where this regulation applies, the market surveillance authority must issue a direction requiring the economic operator to—

- (a) take all appropriate measures to ensure that the non-automatic weighing instrument concerned, when placed on the market, no longer presents that risk;
- (b) withdraw the non-automatic weighing instrument from the market; or
- (c) recall it within a reasonable period, commensurate with the nature of the risk as it may prescribe.

(3) Where this regulation applies, the market surveillance authority must immediately inform the Commission and the other EEA states of all available details including—

- (a) the data necessary for the identification of the regulated non-automatic weighing instrument concerned;
- (b) the origin and supply chain of the regulated non-automatic weighing instrument;
- (c) the nature of the risk involved; and
- (d) the nature and duration of the national measures taken.

Provisions as to directions under regulations 58 and 60

61.—(1) This regulation applies in relation to directions given under regulations 58 (regulated non-automatic weighing instruments presenting a risk) and 60 (compliant regulated non-automatic weighing instruments which present a risk).

(2) A direction must—

- (a) be in writing;
- (b) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
- (c) specify the risk identified by the market surveillance authority; and
- (d) specify the steps that the economic operator must take (including the time period within which they must be taken).

(3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with a direction given under regulation 58 or 60.

(4) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (3).

CHAPTER 2

ENFORCEMENT PROCEDURES

Competent authorities and enforcement proceedings

62.—(1) In Great Britain, it is the duty of every local weights and measures authority to enforce these Regulations within its area.

(2) In Northern Ireland, it is the duty of the Department for the Economy to enforce these Regulations (other than Part 7).

(3) The Secretary of State—

- (a) must enforce these Regulations when required to do so in the capacity of the market surveillance authority; and
- (b) may otherwise than in the capacity of market surveillance authority enforce these Regulations and for that purpose may appoint any person to act on his behalf.

(4) No proceedings for an offence under these Regulations may be instituted in England and Wales except by or on behalf of a competent authority.

(5) Nothing in these Regulations authorises a competent authority to bring proceedings in Scotland for an offence.

(6) No proceedings shall be instituted in Northern Ireland for an offence under these Regulations in respect of a regulated non-automatic weighing instrument except—

- (a) by or on behalf of a competent authority which has responsibility for enforcing these Regulations in respect of that regulated non-automatic weighing instrument; or
- (b) the Director of Public Prosecutions for Northern Ireland.

Compliance notice procedure

63.—(1) This regulation applies where a competent authority has reasonable grounds for considering that one or more of the following breaches applies in relation to a regulated non-automatic weighing instrument that has been placed on the market—

- (a) the CE marking or the M marking has been affixed in violation of Article 30 of the RAMS Regulation or the requirements of these Regulations;
- (b) the CE marking or the M marking has not been affixed;
- (c) the identification number of the notified body, where the body is involved in the production control phase has—
 - (i) been affixed otherwise than in accordance with the requirements of these Regulations; or
 - (ii) not been affixed;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) the technical documentation is either not available or is not complete;
- (f) the information referred to in regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) or regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments) is absent, false or incomplete; or
- (g) any other failure—
 - (i) by a manufacturer to comply with the requirements of Chapter 1 of Part 2; or
 - (ii) by an importer to comply with the requirements of Chapter 2 of Part 2.

(2) The competent authority may serve a notice in writing (“a compliance notice”) on the economic operator it considers is responsible for the breach which must—

- (a) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
- (b) specify which of the circumstances in paragraph (1) applies in relation to the regulated non-automatic weighing instrument;
- (c) require the economic operator on whom the notice is served to take steps specified in the notice to remedy the matters referred to in sub-paragraph (b);
- (d) specify the date, being not less than 21 days from the date of the notice, by which the steps specified in it must be taken; and
- (e) warn that person that, where the non-conformity continues beyond the date specified in sub-paragraph (d), the competent authority may take further action under regulation 64

(enforcement notice procedure) in respect of that regulated non-automatic weighing instrument.

(3) Where a compliance notice is served by a competent authority other than the Secretary of State, it must, at the same time as it serves that notice, send a copy to the Secretary of State.

Enforcement notice procedure

64.—(1) This regulation applies where a competent authority has reasonable grounds for considering that an economic operator on whom a compliance notice has been served by the competent authority has failed to comply with that notice.

(2) The competent authority may serve a notice (“an enforcement notice”) on the economic operator which must—

- (a) be in writing;
- (b) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
- (c) specify, with reasons, the respects in which, in the opinion of the competent authority, the compliance notice has not been complied with;
- (d) specify the steps that the economic operator must take to comply with the compliance notice; and
- (e) specify the date, being not less than 21 days from the date of the notice, by which the economic operator is required to take the steps specified in it.

(3) An enforcement notice may impose either or both of the following requirements where appropriate—

- (a) that the regulated non-automatic weighing instrument is to be withdrawn from the market unless the steps referred to in paragraph (2)(d) are taken; or
- (b) that the placing on the market or making available on the market of the regulated non-automatic weighing instrument is to be prohibited or restricted unless the steps referred to in paragraph (2)(d) are taken.

(4) Where an enforcement notice is served by an competent authority other than the Secretary of State, it must at the same time as it serves that notice send a copy of the notice to the Secretary of State.

(5) If the Secretary of State is of the opinion that consideration ought to be given as to whether a certificate or notification which is granted by a United Kingdom notified body should be withdrawn, the Secretary of State must inform that notified body of that fact.

(6) If the Secretary of State is of the opinion that consideration ought to be given as to whether a certificate or notification which is granted by a notified body in another EEA state should be withdrawn, the Secretary of State must inform the market surveillance authority in that state of that fact.

Review of decisions of a competent authorities

65.—(1) Where a notice is served under regulation 63 (compliance notice procedure) or 64 (enforcement notice procedure) by a competent authority other than the Secretary of State, an economic operator who is aggrieved by the decision to serve that notice may, in accordance with paragraphs (2) and (3) apply to the Secretary of State to review the decision and on such application the Secretary of State may—

- (a) hold an inquiry in connection with the decision; and
- (b) appoint an assessor for the purposes of assisting him with his review or any such inquiry.

(2) An application for a review of a decision under paragraph (1) must be made by notice in writing to the Secretary of State before the end of the period of 21 days beginning with the day on which the notice is served on the economic operator by the competent authority under regulation 63 or 64

(3) A notice of application for review under this regulation must state the grounds on which the application is made.

(4) The Secretary of State must, within a reasonable time, inform the economic operator and the authority referred to in paragraph (1) in writing of the Secretary of State's decision whether to uphold the decision of that authority and—

- (a) in a case where the Secretary of State upholds that decision, must also state the grounds for the Secretary of State's decision; and
- (b) in a case where the Secretary of State does not uphold that decision, may—
 - (i) where the review relates to regulation 63, give instructions for the withdrawal of the notice given under paragraph (2) of that regulation; or
 - (ii) where the review relates to regulation 64, give instructions for the withdrawal of the notice given under paragraph (2) of that regulation.

Offence of failing to comply with an enforcement notice

66.—(1) This paragraph applies where an enforcement notice has been served pursuant to regulation 64 (enforcement notice procedure) on an economic operator by a competent authority other than the Secretary of State and either—

- (a) the time for making an application for a review pursuant to regulation 65 (review of decisions of competent authorities) has expired without such an application having been made; or
- (b) an application has been made by the economic operator and determined without an instruction for the withdrawal of the notice being given and a period of 21 days has elapsed beginning with the day after notice of the outcome of the review has been served on the economic operator.

(2) Where this paragraph (1) applies, if the economic operator on whom the compliance notice has been served, fails to comply with the requirements of that notice, that economic operator is guilty of an offence.

(3) An economic operator that fails to comply with an enforcement notice served on the economic operator by the Secretary of State is guilty of an offence.

Disqualification

67.—(1) Where the circumstances in paragraph (2) apply, an inspector may affix a disqualification mark to a regulated non-automatic weighing instrument which bears the—

- (a) CE marking;
- (b) M marking; and
- (c) identification number of the notified body which carried out the conformity assessment procedure in respect of the instrument

(2) The circumstances referred to in paragraph (1) are that the instrument is used for any of the purposes listed in regulation 3(2) in circumstances where—

- (a) the instrument does not conform to the essential requirements;
- (b) the instrument does not conform to any EU-type examination certificate issued in relation to it;
- (c) by reason of any adjustment, alteration, addition, repair or replacement it is likely that the instrument has ceased to be compliant with the essential requirements; or
- (d) any requirements applicable to the instrument by virtue of Part 7 are not met.

(3) Where one or more of the markings and identification requirements referred to in paragraph (1) is not affixed to a regulated non-automatic weighing instrument, the inspector may affix a disqualification mark to the instrument.

(4) Where it appears to the inspector that the nature or degree of non-compliance of the regulated non-automatic weighing instrument under paragraph (1) is not such that a disqualification mark should be immediately affixed to it, the inspector may give to any person in possession of the instrument a notice requiring the person to ensure that the instrument is made to comply with the essential requirements before the expiry of 21 days from the date of the notice or such longer period as may be specified in the notice.

(5) If a notice given under paragraph (4) is not complied with, the inspector must affix a disqualification mark to the regulated non-automatic weighing instrument.

(6) Any disqualification mark which is affixed to a regulated non-automatic weighing instrument under this regulation must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.

(7) A person is guilty of an offence if that person uses for any of the purposes mentioned in regulation 3(2) a regulated non-automatic weighing instrument to which there is affixed a disqualification mark, unless a re-qualification mark has been affixed to it in accordance with regulation 68 (re-qualification).

Re-qualification

68.—(1) This regulation applies where—

- (a) a disqualification mark has been affixed to a regulated non-automatic weighing instrument in accordance with regulation 67 (disqualification);
- (b) a notice has been served under regulation 67(4); or
- (c) a regulated non-automatic weighing instrument intended to be used for any of the purposes mentioned in regulation 3(2) in the circumstances referred to in regulation 67(2)(a) to (iv) or (2) but a disqualification mark has not been affixed to the instrument.

(2) A person requiring a re-qualification mark to be affixed to the regulated non-automatic weighing instrument must submit it, in such manner as may be directed, to a re-qualification authority and provide such assistance as the requalification authority may reasonably require.

(3) For the purposes of this regulation, a requalification authority is—

- (a) an inspector;
- (b) an approved verifier;
- (c) a UK approved notified body for module F or F1 in Annex II to the Directive; or
- (d) a manufacturer whose quality system has been approved by a UK notified body under module D or D1 of Annex II to the Directive for the purposes of re-qualification.

(4) A requalification authority may affix a re-qualification mark to that regulated non-automatic weighing instrument if satisfied that the instrument is compliant with—

- (a) the essential requirements;
- (b) any EU-type examination certificate which applies to it; and
- (c) where it is intended that the instrument is to be used for trade any requirements applicable to that instrument by virtue of Schedule 4.

(5) For the purposes of being satisfied that a re-qualification mark may be affixed to a regulated non-automatic weighing instrument, a requalification authority may take such steps as the requalification authority considers appropriate, including testing the instrument by means of such test equipment as the requalification authority considers appropriate and suitable for the purpose.

(6) There may be charged in respect of any steps taken under paragraph (5) such fees as are reasonable in the circumstances.

(7) The requalification authority must keep a record of any test carried out under paragraph (5).

(8) Where a re-qualification mark is affixed to a regulated non-automatic weighing instrument pursuant to paragraph (4), it must be affixed in such a position that it obliterates as far as possible any disqualification mark.

Testing of regulated non-automatic weighing instruments

69.—(1) Where an inspector considers that a test of a regulated non-automatic weighing instrument is necessary, otherwise than for the purposes of regulation 68 (re-qualification), the inspector may require the person who has control of the instrument, or whom the inspector has reasonable cause to believe has control of the instrument, to provide to the inspector such equipment, test liquid, materials, qualified personnel or other assistance as the inspector may reasonably require.

(2) Every instrument submitted for testing must be in a clean condition.

Unsuitable use of regulated non-automatic weighing instruments

70.—(1) This regulation applies to a regulated non-automatic weighing instrument.

(2) If it appears to an inspector that a regulated non-automatic weighing instrument used for a purpose mentioned in regulation 3(2)—

- (a) for a purpose for which it is unsuitable; or
- (b) in circumstances where it is subject to any extraordinary environmental or operating conditions which—
 - (i) may prevent it operating consistently or accurately; or
 - (ii) are likely prematurely to degrade its metrological characteristics,

the inspector may affix a disqualification mark to the instrument; and any such mark must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.

PART 9 OFFENCES

Unauthorised application of authorised marks

71.—(1) Subject to paragraph (2), a person is guilty of an offence if, that person—

- (a) affixes an authorised mark to a regulated non-automatic weighing instrument otherwise than in accordance with these Regulations;
- (b) alters or defaces an authorised mark affixed to a regulated non-automatic weighing instrument (otherwise than as authorised by any provision of these Regulations);
- (c) removes an authorised mark affixed to a regulated non-automatic weighing instrument; or
- (d) affixes any other marking to a regulated non-automatic weighing instrument which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.

(2) Where the alteration, defacement or removal of an authorised mark is occasioned solely—

- (a) in the course of the adjustment or repair of a regulated non-automatic weighing instrument by a person regularly engaged in the business of repair of such instruments, or by that person's authorised agent; or
- (b) by an enforcement officer or approved verifier in the carrying out of any of their functions under these Regulations,

that person or that person's authorised agent, enforcement officer or approved verifier is not guilty of an offence under paragraph (1)(b) or (1)(c).

(3) A person is guilty of an offence if that person places on the market, puts into service or uses for a purpose mentioned in regulation 3(2) a regulated non-automatic weighing instrument—

- (a) from which, to that person's knowledge, an authorised mark has been removed; or
- (b) which to that person's knowledge, bears—

- (i) an authorised mark affixed otherwise than in accordance with these Regulations;
- (ii) an authorised mark that has been altered or defaced otherwise than in the circumstances referred to in paragraph (2); or
- (iii) any marking which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.

(4) A regulated non-automatic weighing instrument in respect of which an offence under this regulation has been committed and any implement used in the commissioning of the offence shall be liable to be forfeited.

(5) In this regulation, “authorised mark” means

- (a) the CE marking,
- (b) the M marking,
- (c) the identification number of the notified body which carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument,
- (d) a disqualification mark or
- (e) a re-qualification mark.

Offences by economic operators etc.

72.—(1) In this regulation, “event of default” means—

- (a) The placing on the market of a regulated non-automatic weighing instrument which—
 - (i) does not meet the essential requirements applicable to it;
 - (ii) has not been the subject of an applicable conformity assessment procedure;
 - (iii) does not bear the markings or inscriptions required by these Regulations; or
 - (iv) is not accompanied by the documents and information required by these Regulations;
- (b) any failure to—
 - (i) create or maintain any records required to be created or maintained under these Regulations;
 - (ii) provide to a competent authority documents or information pursuant to a requirement imposed by or under these Regulations; or
 - (iii) co-operate with the market surveillance authority under regulation 58(3);
- (c) any failure to comply with regulation 46 (requirements for non-regulated non-automatic weighing instruments);
- (d) any failure to comply with regulation 55 (putting into service of regulated non-automatic weighing instruments for the purposes listed in regulation 3(2)); or
- (e) any failure to comply with obligations arising under regulation 69 (testing of regulated non-automatic weighing instruments).

(2) Where an event of default of a kind mentioned in paragraph (1)(a), (1)(b) or (1)(c) occurs as a result of the failure of an economic operator to comply with an obligation imposed on that economic operator by any provision of these Regulations, that economic operator is guilty of an offence.

(3) Where an event of default of a kind mentioned in paragraph (1)(d) or (1)(e) occurs, the person responsible for that event of default is guilty of an offence.

Penalties for offences

73. A person guilty of an offence under any provision of these Regulations is liable, on summary conviction—

- (a) in England and Wales to a fine; and
- (b) in Scotland or Northern Ireland to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

74.—(1) In proceedings against a person for an offence under these Regulations (other than regulation 71(3)), it shall be a defence for that person to show that that person took all reasonable steps and exercised all due diligence to avoid committing the offence.

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

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

that person shall not, without the 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), that person has served a notice in accordance with paragraph (3) on the person bringing the proceedings.

(3) A notice under this regulation 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 that person serves it.

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

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

Liability of persons other than the principal offender

75.—(1) Where the commission by a person (“A”) of an offence under these Regulations is due to the act or default of another person (“B”) in the course of any business of A, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.

(2) Where a body corporate commits an offence 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, is guilty of the 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, secretary or other similar officer; and
- (c) if the affairs of the body corporate are managed by its members, a member.

(4) In this regulation, references to a “body corporate” include references to a partnership in Scotland, and in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

PART 10

MISCELLANEOUS AND SUPPLEMENTAL

Service of documents etc.

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

- (a) by delivering it to that person or by leaving it at that person's proper address or by sending it by post to that person at that address;
- (b) if the person is a body corporate, by serving it in accordance with sub-paragraph (a) on the secretary or clerk of that body corporate; 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.

(2) For the purposes of paragraph (1), and for the purposes of section 7 of the Interpretation Act 1978^(a) (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 in accordance with these Regulations shall be that person's last known address except that—

- (a) in the case of service on a body corporate or its secretary or clerk, it shall be the address of the registered or principal office of the body corporate; and
- (b) in the case of service on a partnership or a partner or a person having the control or management of a partnership business, it shall be the principal office of the partnership,

and for the purposes of this paragraph the principal office of a company registered outside the United Kingdom or of a partnership carrying on business outside the United Kingdom is its principal office within the United Kingdom.

Review

77.—(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 EEA 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 no later than 5 years after the date of the coming into force of these Regulations.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Margot James

Parliamentary Under Secretary of State

Minister for Small Business, Consumers and Corporate Responsibility

Department for Business, Energy and Industrial Strategy

29th November 2016

(a) 1978 c.30.

SCHEDULE 1

Regulation 9(2)

INFORMATION TO BE MARKED ON REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

1. The number of the EU-type examination certificate, where appropriate.
2. The manufacturer's name, registered trade name or registered trade mark.
3. The accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles.
4. Maximum capacity, in the form "Max".
5. Minimum capacity, in the form "Min".
6. Verification scale interval in the form "e =....."
7. Type, batch and serial number
8. When applicable the following:
 - (a) for instruments consisting of separate but associated units, the identification mark on each unit;
 - (b) scale interval if different from e, in the form "d =....";
 - (c) maximum additive tare effect, in the form "T = +.....";
 - (d) maximum subtractive tare effect if it is different from Max, in the form "T = -...";
 - (e) tare interval if it is different from d, in the form "d_T =";
 - (f) maximum safe load if it is different from "Max....", in the form "Lim....";
 - (g) the special temperature limits, in the form "...°C/...°C"; and
 - (h) ratio between load receptor and load.
9. The requirements of points 1.2 to 1.5 of the Annex III to the Directive must be complied with.

SCHEDULE 2

Regulation 36(4)

OPERATIONAL OBLIGATIONS OF NOTIFIED BODIES

1. Conformity assessment must be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.
2. Conformity assessment bodies must perform their activities taking due account of—
 - (a) the size of an undertaking;
 - (b) the sector in which it operates and its structure;
 - (c) the degree of complexity of the of the regulated non-automatic weighing instrument technology in question; and
 - (d) the mass or serial nature of the production process,but respecting the degree of rigour and the level of protection required for compliance of the regulated non-automatic weighing instrument with these Regulations.
3. Where a notified body finds that the essential requirements have not been met by a manufacturer, it—
 - (a) must require that manufacturer to take appropriate corrective measures; and
 - (b) must not issue a certificate of conformity.

4. Where in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a regulated non-automatic weighing instrument no longer complies, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body must restrict, suspend or withdraw any certificates, as appropriate.

6. Where a person is aggrieved at a decision taken by a notified body in relation to the conformity assessment of a regulated non-automatic weighing instrument, the notified body must have appropriate arrangements for the review of that decision by a person who was not involved in the taking of that decision.

7. Notified bodies must inform the notifying authority of the following—

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment; and
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

8. Notified bodies must provide other bodies notified under this Directive carrying out similar conformity assessment activities covering the same regulated non-automatic weighing instruments with relevant information on issues relating to negative and, on request positive conformity assessment results.

9. Notified bodies must—

- (a) when requested by the Secretary of State, nominate a representative to attend a group convened by the Commission pursuant to Article 35 of the Directive; and
- (b) ensure attendance of that representative at meetings of the group.

SCHEDULE 3

Regulation 49(4)

REQUIREMENTS RELATING TO NOTIFIED BODIES

1. A conformity assessment body must be established under the national law of an EEA state and have legal personality.

2. A conformity assessment body must be a third party body independent of the organisation or the regulated non-automatic weighing instrument 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 regulated non-automatic weighing instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body of a kind referred to in paragraph 2.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the regulated non-automatic weighing instruments that they assess, nor the representative of any of those parties. This provision shall not preclude the use of assessed regulated non-automatic weighing instruments that are necessary for the operations of the conformity assessment body or the use of such regulated non-automatic weighing instruments for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks—

- (a) must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those regulated non-automatic weighing instruments, or represent the parties engaged in those activities.
- (b) must not engage in any activity (including consultancy services) that may conflict with their independent of judgement or integrity in relation to the conformity assessment activities for which they are notified.

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

7. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free all pressures and inducements, particularly financial, which might influence their judgment 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.

8. A conformity assessment body must be capable of carrying out all the conformity assessment tasks assigned to it by Annex II to the Directive 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 under its responsibility.

9. At all times and for each conformity assessment procedure and each kind or category of regulated non-automatic weighing instruments 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 task;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;
- (c) appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; and
- (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 instrument technology in question, and the mass or serial nature of the production process.

10. A conformity assessment body must have the means necessary 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 or facilities.

11. The personnel responsible for carrying out conformity assessment tasks must have the following—

- (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 they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the requirements set out in Annex I to the Directive, of the applicable harmonised standards, and of the relevant provisions of European Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

12. Conformity assessment bodies, their top-level management and the personal responsible for carrying out conformity assessment tasks must be impartial in the execution of their functions.

13. The remuneration of the top-level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body must not depend on the number of assessments carried out or on the results of those assessments.

14. A conformity assessment body must satisfy the Secretary of State that it has adequate civil liability insurance.

15. The personnel of a conformity assessment body must observe professional secrecy with regard to all information obtained in carry out their tasks under Annex II, except as regards the Secretary of State. Proprietary rights must be protected.

16. Conformity assessment bodies must participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the European Union harmonisation legislation and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 4

Regulation 56

USE FOR TRADE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS IN GREAT BRITAIN

Restrictions on use of instruments for trade

1.—(1) An instrument marked with a weighing range may be used for trade for determining the weight of any item by ascertaining the difference between two weights (both of which fall within the weighing range).

(2) Save in accordance with paragraph (1) above, a person must not use for trade regulated non-automatic weighing instrument marked with a weighing range for determining a weight outside that range in relation to—

- (a) articles made from, gold, silver, platinum or palladium;
- (b) precious stones or pearls; or
- (c) drugs or other pharmaceutical products.

(3) A person must not use for trade any regulated non-automatic weighing instrument other than an instrument of accuracy classification Class I or Class II within the meaning of paragraph 2 of Annex I to the Directive in any transaction relating—

- (a) to, or to articles made from, gold, silver, platinum or palladium;
- (b) to precious stones or pearls.

(4) Where a regulated non-automatic weighing instrument bears a mark which signifies the manner and purpose of use, it must not be used for trade in a manner or for a purpose which does not accord with that marking.

(5) A person must not use a Class III regulated non-automatic weighing instrument (within the meaning of paragraph 2 of Annex I to the Directive) for trade for any purpose other than for weighing—

- (a) any of the materials to which the expression “ballast” applies in Schedule 4 to the Weights and Measures 1985 Act;
- (b) any material the disposal of which constitutes a landfill disposal as defined in paragraph (2) of section 70 of the Finance Act 1996^(a), whether or not the disposal amounts to a taxable disposal as defined in section 40 of that Act; or
- (c) waste not falling within paragraph (b).

(a) 1996 c.8.

(6) A person must not use for trade any regulated non-automatic weighing instrument for the purpose of multiple weighing, that is to say, determining the mass of a load by totalling the results of more than one static weighing operation during each of which the load is only partially supported by the load receptor.

(7) For the purposes of this paragraph, “waste” means any substance that its holder, discards, or intends or is required to discard, including any waste disposed of for reprocessing or recycling purposes.

Manner of erection of regulated non-automatic weighing instruments

2. Where a regulated non-automatic weighing instrument is fitted with one or more level-indicating devices, a person must not use the instrument for trade unless each such device indicates that it has been set to its reference position.

Regulated non-automatic weighing instruments marked with temperature range

3. Where a regulated non-automatic weighing instrument is marked with a temperature range, a person must not use the instrument for trade at temperatures outside that range.

Regulated non-automatic weighing instruments marked with manner of use

4. Where a regulated non-automatic weighing instrument is marked with the manner of use, a person must not use the instrument for trade in a manner which does not accord with the marking.

Regulated non-automatic weighing instruments fitted with printing devices

5. Where a regulated non-automatic weighing instrument is fitted with a printing device, a person must not use the instrument for trade unless the printing device produces a legible and durable printout.

Load receptors

6.—(1) A person must not use a regulated non-automatic weighing instrument for trade unless it is erected and used in such a manner that, during a weighing operation, the load being weighed is stationary relative to the load receptor and supported only by the load receptor.

(2) A person must not use for trade a regulated non-automatic weighing instrument for the purpose of sales by retail—

- (a) unless—
 - (i) the load receptor is not less than 10 mm above any adjacent surface; or
 - (ii) where the load receptor is less than 10 mm above any adjacent surface, the boundary of the top surface of all adjacent surfaces is durably marked in a distinctive and contrasting manner with a band at least 15 mm in width; or
- (b) if the load receptor is below the level of any adjacent surface.

Operation of regulated non-automatic weighing instrument

7. A person must not use a regulated non-automatic weighing instrument for trade unless it is erected in such a manner that the operator can, readily take up a single position from which he can—

- (a) see directly or with the aid of mirrors, closed-circuit television or other permanently installed facilities, the whole of the unladen load receptor;
- (b) operate the instrument’s controls; and
- (c) obtain a weight reading from the instrument.

Regulated non-automatic weighing instruments to be set to zero or to be balanced before use

8.—(1) A person must not use a regulated non-automatic weighing instrument for trade unless it is properly balanced or set to zero immediately prior to use.

(2) Paragraph (1) does not apply in the case of a regulated non-automatic weighing instrument if it is designed so as not to balance when unloaded.

SCHEDULE 5

Regulations 32(4),
54(8) and 61(4)

MONETARY PENALTIES

Introduction

1. This Schedule applies in relation to the imposition by the Secretary of State of a monetary penalty under these Regulations.

Procedure

2.—(1) Before imposing a monetary penalty under these Regulations, the Secretary of State must notify the person on whom the penalty is to be imposed of the Secretary of State's intention to do so.

(2) The notice must—

- (a) specify the proposed amount of the penalty (which must not exceed £50,000),
- (b) specify the Secretary of State's reasons for proposing to impose the penalty,
- (c) specify the period during which the person on whom the penalty is to be imposed may make representations about the proposal ("the specified period"), and
- (d) specify the way in which those representatives may be made.

(3) The specified period must not be less than 28 days beginning with the date on which the notice is received.

(4) The Secretary of State must have regard to any representations made by the person during the specified period in deciding whether to impose a monetary penalty on it.

(5) Having decided whether or not to impose a monetary penalty, the Secretary of State must notify the person of the Secretary of State's decision.

(6) Where the decision is to impose a monetary penalty, the notice must specify—

- (a) the amount of the penalty, and
- (b) the period within which the penalty must be paid or the periods within which different portions of the penalty must be paid.

(7) The notice must also contain information as to—

- (a) the grounds for imposing the penalty,
- (b) how payment may be made,
- (c) rights of appeal,
- (d) the period within which an appeal may be made, and
- (e) the consequences of non-payment.

(8) The requirement to pay the penalty is suspended at any time when an appeal could be brought in respect of the penalty or such an appeal is pending.

(9) But sub-paragraph (8) does not prevent the requirement to pay taking effect if the person notifies the Secretary of State that it does not intend to appeal.

Appeals

3.—(1) A person on whom a monetary penalty is imposed, may appeal to the First-tier Tribunal against—

- (a) a decision under these Regulations to impose a monetary penalty on the person;
- (b) a decision as to the amount of the penalty.

(2) An appeal under this paragraph may be made on the grounds—

- (a) that the decision was based on an error of fact;
- (b) that the decision was wrong in law;
- (c) that the decision was unreasonable.

(3) On an appeal under this paragraph the Tribunal may—

- (a) withdraw the requirement to pay the penalty;
- (b) confirm that requirement;
- (c) vary that requirement;
- (d) remit the decision whether to confirm the requirement to pay the penalty, or any matter relating to that decision, to the Secretary of State.

Interest and recovery

4.—(1) This paragraph applies if all or part of a monetary penalty imposed under these Regulations is unpaid by the time when it is required to be paid.

(2) The unpaid amount of the penalty for the time being—

- (a) carries interest at the rate for the time being specified in section 17 of the Judgments Act 1838(a), and
- (b) does not also carry interest as a judgment debt under that section.

(3) The total amount of interest imposed under sub-paragraph (2) must not exceed the amount of the penalty.

(4) The Secretary of State may recover from the person on whom it is imposed, as a civil debt, the unpaid amount of the penalty and any unpaid interest.

(5) Any sums received by the Secretary of State by way of a penalty imposed under these Regulations or interest under this paragraph must be paid into the Consolidated Fund.

EXPLANATORY NOTE

(This note is not part of these Regulations)

These Regulations implement Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of Member States relating to the making available on the market of non-automatic weighing instruments. These Regulations replace and revoke the Non-automatic Weighing Instruments Regulations 2000 and the Non-automatic Weighing Instruments (Amendment) Regulations 2008. Non-automatic weighing instruments are defined as instruments which require the intervention of an operator to determine mass and other things related to mass by the use of gravity. The Regulations impose requirements in relation to the manufacture of non-automatic weighing instruments which are used for determining mass for:

- (a) commercial transactions;
- (b) the determination of the amount of certain payments such as tolls or taxes;
- (c) the purposes of court proceedings and legal requirements;

(a) 1838 c.110.

- (d) the weighing of patients for medical purposes;
- (e) making up medicines and other medical and pharmaceutical laboratory purposes;
- (f) direct sales to the public and the making up of pre-packages.

and the determination of price on the basis of mass.

These instruments are referred to in the Regulations as “regulated non-automatic weighing instruments”.

The Regulations set out what are referred to as “the essential requirements” which must be met by regulated non-automatic weighing instruments. The essential requirements are defined in regulation 2(1) as the requirements relating to non-automatic weighing instruments set out in Annex I to the Directive.

Part 1 of the Regulation contains definitions, revocations and transitional provisions.

Part 2 of the Regulations sets out the obligations of economic operators (manufacturers (and their authorised representatives), importers and distributors) in connection with ensuring that instruments placed on the market meet the essential requirements and the other requirements of the Regulations.

Part 3 of the Regulations makes provision for establishing conformity with the essential requirements. Regulation 40 sets out the conformity assessment procedures that must be used to ensure conformity with the essential requirements and the requirements to be followed and the use of notified bodies.

Part 4 contains requirements as to markings to be placed on instruments that are not required to meet the essential requirements. Part 5 contains the requirements relating to the notification by the United Kingdom of conformity assessment bodies.

Part 6 contains provisions prohibiting the use of non-automatic weighing instruments for the purposes listed in regulation 3(2) unless they have been subject to the appropriate conformity assessment procedures. Part 7 imposes certain requirements for the use for trade of regulated non-automatic weighing instruments.

Part 8 makes provision in relation to market surveillance and enforcement of the Regulations; Part 9 makes provision about the unauthorised application of marks to regulated non-automatic weighing instruments and also makes provision in relation to penalties for offences and defences.

Part 10 contains miscellaneous and supplemental provisions. A draft of these Regulations was notified to the European Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p.37) as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p.18).

A transposition note and an impact assessment of the effect that this instrument will have on the costs of business, the public sector and voluntary sector is available from the Regulatory Delivery Directorate, 1 Victoria Street, London SW1 0ET. They are also available with the explanatory memorandum alongside this instrument on www.legislation.gov.uk.

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UK2016120124 12/2016 19585

<http://www.legislation.gov.uk/id/uksi/2016/1152>