STATUTORY INSTRUMENTS.

S.I. No. 47 of 2018

EUROPEAN UNION (NON-AUTOMATIC WEIGHING INSTRUMENTS) REGULATIONS 2018

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I, HEATHER HUMPHREYS, Minister for Business, Enterprise, and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2014/31/EU of the European Parliament and of the Council of 26 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 (recast), hereby make the following regulations—

PART 1

General Provisions

Citation and commencement

1. (1) These Regulations may be cited as the European Union (Non-Automatic Weighing Instruments) Regulations 2018.

(2) These Regulations come into operation on 6 March 2018.

Interpretation

2. (1) In these Regulations—

"Annex" means an Annex to the Directive;

“appeal panel” means a panel established by the Minister under Regulation 27;

“authorised officer” means a person appointed under Regulation 34;

"authorised representative" means an authorised representative appointed under Regulation 9;

“Commission” means the European Commission;

"competent authority " means—

(*a*) in relation to the State, the Director, and

(*b*) in relation to another Member State, the competent authority under the Directive, of that State;

"Directive" means Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014[1] on the harmonisation of the laws of the Member

[1]OJ No. L 96, 29.3.2014, p. 107.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 6*th March*, 2018.

States relating to the making available on the market of non-automatic weighing instruments (recast);

"Director" means the Director of Legal Metrology;

"EC Regulation" means Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008[2] setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

"mandate" has the meaning assigned to it by Regulation 9(1);

"Minister" means the Minister for Business, Enterprise and Innovation;

"Regulations of 1992" means the European Communities (Non-Automatic Weighing Instruments) Regulations 1992 (S.I. No. 424 of 1992).

(2) A word or expression which is used in these Regulations and is also used in the Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Directive.

(3) For the purposes of these Regulations, the Director of Legal Metrology is the market surveillance authority in the State.

Application

3. These Regulations shall apply to 2 categories of instruments:

(*a*) instruments used for the determination of mass for the following applications:

(i) commercial transactions;

(ii) the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

(iii) the application of laws or regulations or expert opinion given in court proceedings;

(iv) in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;

(v) making up medicines on prescription in a pharmacy and analyses carried out in medical and pharmaceutical laboratories;

(vi) pricing on the basis of mass for the purposes of direct sales to the public and the making up of prepackages;

(*b*) instruments for all applications other than those referred to in paragraph (*a*).

[2]OJ No. L 218, 13.8.2008, p.30.

Making available on the market and putting into service of instruments

4. A person shall not make available, or cause to be made available, on the market or put into service any non-automatic weighing instrument unless the instrument satisfies the requirements of these Regulations.

Essential requirements

5. (1) Instruments used or intended to be used for the applications referred to in Regulation 3 (*a*) shall satisfy the essential requirements set out in Annex 1.

(2) If an instrument includes or is connected to devices which are not used for applications listed in Regulation 3 (*a*), the devices shall not be subject to the essential requirements referred in paragraph (1).

Free movement of instruments

6. (1) A person shall not impede, within the State, the making available on the market of an instrument unless the instrument satisfies the requirements of these Regulations.

(2) A public body or a private body acting as a public undertaking, or acting as a public body on the basis of a monopoly position or under a public mandate, shall not make, impose or enforce any rules or conditions relating to the use of instruments which would have the effect of impeding making available on the market or the putting into service of such instruments, where those instruments meet the requirements of these Regulations.

(3) Nothing in the Metrology Act 1996 (No. 27 of 1996) or any other enactment or rule of law shall impede the making available on the market or putting into service for the applications referred to in Regulation 3(*a*) of an instrument where such instrument complies with the Directive.

PART 2

Obligations of Economic Operators

Obligations of manufacturers

7. (1) A manufacturer shall ensure that instruments, intended to be used for the applications referred to in Regulation 3(*a*), placed on the market have been designed and manufactured in accordance with the essential requirements set out in Annex I.

(2) Before placing an instrument intended to be used for the applications referred to in Regulation 3(*a*) on the market, the manufacturer of the instrument shall:

(*a*) draw up the technical documentation referred to in Annex II;

(*b*) carry out or have carried out the relevant conformity assessment in accordance with Regulation 15;

(3) Where compliance of an instrument intended to be used for the applications referred to in Regulation 3(*a*) with the applicable requirements has been demonstrated by the conformity assessment procedure, the manufacturer shall—

(*a*) draw up an EU declaration of conformity in accordance with Regulation 16,

(*b*) affix a CE marking and the supplementary metrology marking to the instrument in accordance with Regulation 19,

(*c*) retain the technical documentation and EU declaration of conformity for 10 years after the instrument has been placed on the market,

(*d*) when deemed appropriate with regard to the performance of an instrument—

(i) carry out sample testing of instruments made available on the market,

(ii) investigate and, if necessary, keep a register of complaints of non-conforming instruments and instrument recalls, and

(iii) keep distributors informed of any such monitoring;

(*e*) mark the instrument in accordance with Regulation 8, as appropriate;

(*f*) ensure that an instrument is accompanied by clear, understandable and intelligible instructions and information, including labelling, in the English language.

(4) A manufacturer shall ensure that procedures are in place for series production to remain in conformity with these Regulations, having regard to any changes in instrument design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of an instrument is declared.

(5) A manufacturer who considers or has reason to believe that an instrument which he or she has placed on the market is not in conformity with these Regulations shall immediately take any corrective measures necessary to—

(*a*) bring the instrument into conformity;

(*b*) withdraw the instrument, or

(*c*) recall the instrument.

(6) A manufacturer shall inform the competent authorities of the Member States in which he or she made the instrument available on the market, of the non-compliance and of any corrective measures taken.

(7) (*a*) A manufacturer shall, further to a reasoned request from a competent authority, provide it with all the information and documentation in

paper or electronic form necessary to demonstrate the conformity of the instrument with these Regulations, in English or in a language which can be easily understood by that authority; and

(*b*) A manufacturer shall co-operate with the competent authority in the State or a competent authority in another Member State, at its request, on any action taken to eliminate the risk posed by instruments which the manufacturer has placed on the market.

Marking of instruments

8. (1) A manufacturer shall ensure that the following marks have been affixed to instruments which they have placed on the market—

(*a*) a type, batch or serial number or other element allowing their identification as set out in Annex III,

(*b*) where the instrument is intended to be used for the applications referred to in Regulation 3(*a*), the inscriptions provided for in point 1 of Annex III,

(*c*) where the instrument is not intended to be used for the applications referred to in Regulation 3(*a*), the inscriptions provided for in point 2 of Annex III.

(2) A manufacturer shall indicate on the instrument the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted or, where that is not possible, on its packaging or a document accompanying the instrument, and—

(*a*) the address shall indicate a single point at which the manufacturer can be contacted, and

(*b*) the contact details shall be in a language that is easily understood by end users and market surveillance authorities;

(3) Where an instrument which is intended to be used for an application referred to in Regulation 3(*a*) includes, or is connected to, a device which is not used or intended to be used for any of the applications referred to in that Regulation, the manufacturer shall affix to each of those devices the restrictive use symbol in accordance with Regulation 20 and point 3 of Annex III.

Authorised representatives

9. (1) Subject to paragraphs (2) and (3), a manufacturer may, by a written mandate (in this Regulation referred to as a "mandate"), appoint an authorised representative.

(2) The obligations laid down in Regulation 7(1) and the obligation to draw up technical documentation referred to in Regulation 7(2) (*a*) shall not be included in the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in a mandate received from the manufacturer.

(4) The mandate shall allow the authorised representative to—

(*a*) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the instrument has been placed on the market,

(*b*) further to a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an instrument,

(*c*) cooperate with each such competent authority at its request, on any action taken to eliminate the risks posed by instruments covered by their mandate, and

(*d*) such other matter as is provided for in a mandate.

(5) An authorised representative shall provide the Director with a copy of the mandate, if requested to do so.

Obligations of importers

10. (1) An importer shall not place instruments on the market unless those instruments comply with these Regulations.

(2) Before placing an instrument on the market intended to be used for the applications referred to in Regulation 3(*a*), an importer shall ensure that the appropriate conformity assessment procedure referred to in Regulation 15 has been carried out by the manufacturer.

(3) An importer of instruments intended to be used for the applications referred to in Regulation 3(*a*) shall also ensure that—

(*a*) the manufacturer has drawn up the technical documentation,

(*b*) the instrument bears the CE marking and the supplementary metrology marking,

(*c*) is accompanied by a copy of the EU declaration of conformity,

(*d*) is accompanied by the required documents, and

(*e*) the manufacturer has complied with the requirements set out in Regulation 8 as appropriate.

(4) Where an importer considers or has reason to believe that an instrument intended to be used for the applications referred to in Regulation 3(*a*) is not in conformity with the essential requirements set out in Annex 1, the importer shall not place the instrument on the market or put it into use until it has been brought into conformity.

(5) Where the instrument intended to be used for the applications referred to in Regulation 3(*a*) presents a risk, the importer shall inform the manufacturer and the market surveillance authorities of that risk.

(6) Before placing an instrument on the market that is not intended to be used for the applications referred to in Regulation 3(*a*), an importer shall ensure that the manufacturer has complied with the requirements set out in Regulation 8 (1)(*a*) and (*c*) and Regulation 8(2) and (3).

(7) An importer of instruments intended to be used for any application referred to in Regulation 3 shall indicate on the instrument—

(*a*) their name, registered trade name or registered trade mark, and

(*b*) a postal address at which they can be contacted.

(8) The information referred to in paragraph (7) shall be in a language easily understood by end-users and the market surveillance authority in the Member State in which it is to be made available to end-users.

(9) Where it is not possible to indicate the information specified in paragraph (7) on the instrument, the importer shall indicate the information—

(*a*) on the packaging, or

(*b*) in a document accompanying the instrument.

(10) An importer shall ensure that the instrument intended to be used for an application referred to in Regulation 3(*a*) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned.

(11) An importer shall ensure that, while he or she is responsible for an instrument intended to be used for an application referred to in Regulation 3(*a*), its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex 1.

(12) When deemed appropriate with regard to the performance of an instrument intended to be used for an application referred to in Regulation 3(*a*), an importer shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

(13) An importer who considers or has reason to believe that an instrument intended to be used for any application set out in Regulation 3 which he or she has placed on the market is not in conformity with these Regulations shall immediately take the corrective measures necessary to—

(*a*) bring the instrument into conformity,

(*b*) withdraw the instrument, or

(*c*) where appropriate, recall the instrument.

(14) Where an instrument intended to be used for any application referred to in Regulation 3 presents a risk, an importer shall immediately inform the competent authorities of the Member States in which they made the instrument available on the market to that effect, giving details of—

(*a*) the respect in which the instrument is considered to be non-compliant, and

(*b*) any corrective measures taken.

(15) An importer shall, for 10 years after an instrument intended to be used for the applications referred to in Regulation 3(*a*) has been placed on the market—

(*a*) keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities, and

(*b*) ensure that the technical documentation can be made available to those authorities, upon request.

(16) An importer of an instrument used for any of the applications referred to in Regulation 3 shall, further to a reasoned request from the Director or a competent authority in another Member State, provide the Director or the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an instrument in a language which can be easily understood by that authority.

(17) An importer shall cooperate with the Director or a competent authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

Obligations of distributors

11. (1) A distributor shall not make an instrument available on the market without acting with due care in relation to the requirements of these Regulations.

(2) Before making an instrument available on the market a distributor shall verify that—

(*a*) where the instrument is intended to be used for the applications referred to in Regulation 3(*a*), it—

(i) bears the CE marking and the supplementary metrology marking,

(ii) is accompanied by the EU declaration of conformity,

(iii) is accompanied by the required documents,

(iv) is accompanied by instructions and information in a language which can be easily understood by end-users in the Member State in which the instrument is to be made available on the market,

(*b*) where the instrument is intended to be used for any of the applications referred to in Regulation 3—

(i) the manufacturer of an instrument has complied with the requirements set out in Regulations 7 and 8 as appropriate, and

(ii) the importer has complied with the requirements set out in Regulation 10 (7), (8) and (9).

(3) Where a distributor considers, or has reason to believe, that an instrument intended to be used for the applications referred to in Regulation 3(*a*) is not in conformity with the essential requirements set out in Annex 1, the distributor—

(*a*) shall not make the instrument available on the market until it has been brought into conformity, and

(*b*) where the instrument presents a risk, shall inform the manufacturer or the importer as well as the market surveillance authority of that risk.

(4) A distributor shall ensure that, while an instrument intended to be used for the applications set out in Regulation 3(*a*) is under the responsibility of the distributor, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex 1.

(5) A distributor who considers or has reason to believe that an instrument, which the distributor has made available on the market, is not in conformity with these Regulations shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken.

(6) Where the instrument presents a risk, the distributor shall immediately inform the competent authorities of the Member States in which the distributor made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(7) A distributor shall, further to a reasoned request from a competent authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an instrument with these Regulations.

(8) A distributor shall cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by an instrument which the distributor has made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors

12. An importer or distributor shall be considered a manufacturer for the purposes of these Regulations, and shall be subject to the obligations of the

manufacturer under Regulations 7 and 8, where he or she places an instrument on the market under his or her name or trade mark or modifies an instrument already placed on the market in such a way that compliance with these Regulations may be affected.

Identification of economic operators

13. (1) Where an instrument is intended to be used for any of the applications referred to in Regulation 3(*a*), an economic operator shall, on request, identify to the Director or the market surveillance authority of another Member State—

(*a*) any other economic operator who has supplied the operator with an instrument, or

(*b*) any other economic operator to whom the operator has supplied an instrument.

(2) An economic operator to whom this Regulation applies shall ensure that he or she is able to present—

(*a*) the information referred to in paragraph (1)(*a*) for a period of 10 years after the operator has been supplied with an instrument, and

(*b*) the information referred to in paragraph (1)(*b*) for a period of 10 years after the operator supplied the instrument.

PART 3

Conformity of Instruments

Presumption of conformity of instruments

14. An instrument which is in conformity with harmonised standards (or part of such a standard) the references to which have been published in the Official Journal of the Union shall be presumed to be in conformity with the essential requirements referred to in Annex I covered by that standard (or part of that standard).

Conformity assessment procedures

15. (1) The conformity assessment of an instrument with the applicable essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the following conformity assessment procedures with reference to the Modules specified in Annex II:

(*a*) Module B, followed by either Module D or by Module F, or

(*b*) Module G.

(2) Module B is not compulsory for instruments which do not use electronic devices and the load-bearing device of which does not use a spring to balance the load.

(3) Where a manufacturer does not refer an instrument to Module B as permitted under paragraph (2) Module D1 or Module F1 shall be applied.

(4) Records and correspondence relating to conformity assessment procedures shall be in the English language.

EU declaration of conformity

16. (1) An EU declaration of conformity shall—

(*a*) state that the fulfilment of the essential requirements set out in Annex I has been demonstrated in respect of the instrument,

(*b*) have the model structure as set out in Annex IV,

(*c*) contain the elements specified in the relevant modules set out in Annex II,

(*d*) be continuously updated, and

(*e*) be translated into the language, or languages, required by the Member State in which the measuring instrument is placed or made available on the market.

(2) Where an instrument is subject to more than one European act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such European acts. That declaration shall contain the identification of the European acts concerned including their publication references.

(3) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the instrument with the requirements laid down in these Regulations.

(4) In this Regulation—

"Act of 1972" means the European Communities Act 1972;

"European act" means—

(*a*) a provision of the treaties governing the European Union, or

(*b*) an act adopted by an institution of the European Union, an institution of the European Communities or any other body competent under those treaties;

"European Communities" has the same meaning as it has in the Act of 1972;

"European Union" has the same meaning as it has in the Act of 1972;

"treaties governing the European Union" has the same meaning as it has in the Act of 1972.

Conformity marking

17. The conformity of an instrument intended to be used for the applications referred to in Regulation 3(*a*) with these Regulations shall be indicated by the presence of the CE marking and the supplementary metrology marking on it as specified by Regulation 18.

General principles of CE marking and supplementary metrology marking

18. (1) The CE marking and supplementary metrology marking shall be subject to the general principles set out in Article 30 of the EC Regulation.

(2) The supplementary metrology marking shall consist of the capital letter "M" and the last 2 digits of the year of its affixing, surrounded by a rectangle.

(3) The height of the rectangle referred to in paragraph (2) shall be equal to the height of the CE marking.

Rules and conditions for affixing the CE marking and the supplementary metrology marking

19. (1) A person who affixes the CE marking or the supplementary metrology marking to a measuring instrument shall comply with this Regulation.

(2) The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the instrument or to its data plate.

(3) The CE marking and the supplementary metrology marking shall be affixed before the instrument is placed on the market.

(4) The supplementary metrology marking shall immediately follow the CE marking.

(5) The CE marking and the supplementary metrology marking shall be followed by the identification number or numbers of the notified body or bodies, where such body or bodies is or are involved in the production control phase as set out in Annex II.

(6) The identification number of the notified body shall be affixed by the body itself, or under its instructions, by the manufacturer or the authorised representative.

(7) The CE marking, the supplementary metrology marking and, where applicable, the identification number or numbers of the notified body or bodies (as the case may be) may be followed by any other mark indicating a special risk or use.

(8) A person shall not affix a CE marking or the supplementary metrology marking to an instrument which does not conform with these Regulations.

(9) A person shall not affix to any measuring instrument, a marking or inscription which may lead to confusion as to the meaning and form of the CE marking or the supplementary metrology marking.

Restrictive use symbol

20. The symbol referred to in Regulation 8(3) and specified in point 3 of Annex III shall be affixed to the devices concerned in a clearly visible and indelible form.

PART 4

Notification of Conformity Assessment Bodies

Designation of Minister as notifying authority

21. The Minister is designated as the notifying authority in the State for the purposes of Article 20 of the Directive.

Requirements relating to notified bodies

22. (1) Subject to paragraph (2), a conformity assessment body shall meet the requirements of Article 23 of the Directive for the purposes of notification.

(2) Where a notified body subcontracts specific tasks connected with conformity assessment, it shall comply with Article 23 of the Directive.

(3) Application for notification by a conformity assessment body shall be in accordance with Article 26 of the Directive.

(4) The Minister may where—

(*a*) a conformity assessment body has made an application in accordance with Article 26 of the Directive, and

(*b*) he or she is satisfied that the conformity assessment body meets the requirements set out in Article 23 of the Directive,

notify the conformity assessment body concerned to the Commission and the other Member States.

(5) The Irish National Accreditation Board shall carry out the following activities on behalf of the Minister:

(*a*) the setting up and carrying out the necessary procedures for the assessment and accreditation of conformity assessment bodies;

(*b*) the monitoring of such notified bodies, including compliance with Regulation 24.

(6) Where the Minister has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23 of the Directive or that it is failing to fulfil its obligations under Regulation 26, the Minister shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(7) The Minister shall—

(*a*) inform the notified body concerned in writing of his or her decision and allow the body an opportunity to make representation to him or her, and

(*b*) immediately inform the Commission and other Member States accordingly.

(8) Where a notifying body has restricted, suspended or withdrawn notifications in accordance with paragraph (6) or where the notified body has ceased its activity, the Minister shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Presumption of conformity of notified bodies

23. Where a notified body demonstrates its conformity with the criteria laid down in the relevant harmonised standards (or part of such a standard), the reference to which has been published in the Official Journal of the Union, it shall be presumed to comply with the requirements set out in Article 23 of the Directive in so far as the relevant harmonised standards cover those requirements.

Subsidiaries of and subcontracting by notified bodies

24. (1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Regulation 22 and shall inform the Minister accordingly.

(2) The notified body shall be responsible for the tasks performed by subcontractors or subsidiaries wherever these are established.

(3) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(4) The notified body shall keep at the disposal of the Minister the relevant documents concerning the assessment of the qualifications of a subcontractor or a subsidiary and the work carried out by them under Annex II to the Directive.

Changes to notifications

25. (1) Where the Minister has ascertained or has been informed that a notified body no longer meets the requirements laid down in Regulation 22, or that it is otherwise failing to fulfil its obligations, the Minister shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations and immediately inform the Commission and the other Member States accordingly.

(2) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Minister shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Operational obligations of notified bodies

26. (1) A notified body shall carry out a conformity assessment in accordance with the conformity assessment procedure provided for in Annex II to the Directive.

(2) A notified body shall perform its activities taking due account of—

(*a*) the size of the undertaking,

(*b*) the sector in which it operates,

(*c*) the structure of the undertaking,

(*d*) the degree of complexity of the instrument technology, and

(*e*) the mass or serial nature of the production process.

(3) Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate measures and shall 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 an instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

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

(6) A manufacturer whose certificate has been restricted, suspended or withdrawn under paragraph (5), may appeal the decision of the notified body to an appeal panel established under Regulation 27 not later than 21 days, or such longer period as the Minister may, for good and sufficient reason, determine.

Appeal panel

27. (1) This Regulation applies to—

(*a*) an economic operator aggrieved by a decision by a notified body pursuant to Regulation 26 which affects the economic operator, and

(*b*) a notified body aggrieved by a decision of the Minister pursuant to Regulation 22.

(2) The Minister shall, upon a request in writing from a person to whom this Regulation applies who is aggrieved by a decision referred to in subparagraph (*a*) or (*b*) of paragraph (1), establish a panel ("appeal panel") to consider an appeal by that person against the decision concerned.

(3) The Minister may establish more than one appeal panel to consider one or more appeals.

(4) An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the Minister one of whom shall be designated by the Minister to be the chairperson of the panel.

(5) An appeal panel shall determine its own procedure.

(6) Upon appeal—

(*a*) under Regulation 26, an appeal panel may—

(i) affirm or vary the refusal, restriction, suspension or withdrawal of a certificate, as the case may be, or

(ii) quash the decision of the notified body and direct the notified body, for stated reasons, to reconsider its decision,

(*b*) under Regulation 22, an appeal panel may—

(i) affirm or vary the restriction, suspension or withdrawal of notification, as the case may be, or

(ii) quash the decision of the notifying authority and direct the notifying authority, for stated reasons, to reconsider its decision.

(7) An appeal panel shall notify the person who made the request under paragraph (2) of its determination under subparagraph (*a*) or (*b*) as the case may be, of paragraph (6).

(8) The notifying authority or a notified body, as the case may be, shall comply with a determination of an appeal panel under this Regulation.

(9) A party to an appeal under this Regulation may, not later than 21 days after service on the party concerned of the determination of the appeal panel, appeal that determination to the High Court on a specified question of law.

(10) A decision of the High Court under this Regulation shall be final, save that, by leave of the court an appeal from the decision shall lie to the Court of Appeal on a specified question of law.

(11) All expenses reasonably incurred by the appellant under this Regulation in relation to an appeal before an appeal panel, the High Court or the Court of Appeal, as the case may be, shall be borne by the appellant where the appeal panel, the High Court or the Court of Appeal, as the case may be, affirms the decision of the notifying authority or notified body concerned.

(12) The notifying authority or notified body concerned, as the case may be, may recover the expenses referred to in paragraph (11) as a simple contract debt in any court of competent jurisdiction.

Information obligation on notified bodies

28. (1) Notified bodies shall inform the Minister 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 activities;

(*d*) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) Notified bodies shall provide the other bodies notified under the Directive carrying out similar conformity assessment activities covering the same instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

PART 5

Union Market Surveillance, Control of Instruments Entering the Union Safeguard Procedure

Union market surveillance and control of instruments entering the Union market

29. (1) Articles 16 to 29 of the EC Regulation shall apply to non-automatic weighing instruments.

(2) For the purposes of Article 19 of the EC Regulation, where pursuant to that Article, the Director considers it is necessary to do so, the Director may destroy or otherwise render inoperable a measuring instrument presenting a serious risk referred to in that said Article.

(3) Where a measuring instrument is destroyed, or rendered inoperable under paragraph (2), the costs of such destruction or the rendering inoperable of the measuring instrument may be charged to the economic operator or any other person making the instrument available on the market.

Procedure for dealing with instruments presenting a risk at national level

30. (1) Where the Director has sufficient reason to believe that an instrument presents a risk to aspects of public interest protection covered by these Regulations, he or she shall carry out an evaluation in relation to the instrument concerned covering all relevant requirements laid down in these Regulations.

(2) The relevant economic operators shall cooperate as necessary with the Director in carrying out an evaluation under paragraph (1).

(3) Where, in the course of the evaluation referred to in paragraph (1), the Director finds that the instrument does not comply with the requirements laid down in these Regulations, he or she shall without delay require the relevant economic operator by notice in writing ("a risk compliance notice")—

(*a*) to take all appropriate corrective actions to bring the instrument into compliance with those requirements,

(*b*) to withdraw the instrument from the market, or

(*c*) to recall it

within a reasonable period stated in the notification commensurate with the nature of the risk, as the Director decides.

(4) Article 21 of the EC Regulation shall apply to the measures referred to in paragraph (3) and Regulation 37 shall apply to the notice.

(5) The Director shall inform the relevant notified body accordingly of the matters referred to in paragraph (3).

(6) Where the Director considers that non-compliance of the instrument is not restricted to the territory of the State, the Director shall inform the Commission and the other Member States of the result of the evaluation referred to in paragraph (1) and of the actions which he or she has required the economic operator to take.

(7) The economic operator shall ensure that corrective action is taken in respect of all instruments that are found to be non-compliant under paragraph (3) which that operator has made available on the market throughout the Union.

(8) Where the relevant economic operator does not take adequate corrective action as required under paragraph (3) within the period referred to in that notice, the Director shall take all appropriate provisional measures to—

(*a*) prohibit or restrict the instrument being made available on the market in the State,

(*b*) withdraw the instrument from that market or

(*c*) recall the instrument.

(9) Where, pursuant to paragraph (8), the Director takes a measure specified in that paragraph, the Director shall notify the economic operator of the measure concerned, by notice in writing, and Regulation 37 shall apply to that notice.

(10) An economic operator shall comply with measures taken under paragraph (8) unless the notice in which they are specified is withdrawn or amended under Regulation 35(5) or annulled under Regulation 38 (5).

(11) The Director shall inform the Commission and the other Member States in writing without delay, of those measures taken under paragraph (8) with all available details in particular:

(*a*) the data necessary for the identification of the non-compliant 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 national measures taken;

(*e*) the arguments put forward by the relevant economic operator.

(12) The Director shall indicate in addition to the matters referred to in paragraph (11), whether the non-compliance is due to—

(*a*) the failure of the instrument to meet requirements relating to aspects of public interest laid down in these Regulations, or

(*b*) shortcomings in the harmonised standards referred to in Regulation 14 conferring a presumption of conformity.

(13) Where another Member State has initiated the procedure under Article 37 of the Directive—

(*a*) the Director shall without delay inform the Commission and the other Member States of—

(i) any national measure adopted, and

(ii) any additional information at their disposal relating to the non-compliance of the instrument concerned and

(*b*) where the Director disagrees with the adopted national measure, the objections of the Director.

(14) Where, within 3 months of receipt of the information referred to in paragraph 13, no objection has been raised by—

(*a*) another Member State, or

(*b*) the Commission

in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

(15) The Director shall ensure that appropriate restrictive measures are taken in respect of an instrument which has been subject to restrictive measures by the market surveillance authorities of another Member State, such as withdrawal of the instrument from the market in the State, without delay.

Union safeguard procedure

31. Where, pursuant to Article 38 of the Directive, a national measure of a Member State

(*a*) is considered justified, the Director shall—

(i) take the necessary measures to ensure that the non-compliant measuring instrument is withdrawn from the market in the State, and

(ii) inform the Commission accordingly, or

(*b*) is considered unjustified, the Director shall withdraw that measure.

Formal non-compliance

32. (1) Without prejudice to Regulation 30, where the Director makes one of the following findings, the Director shall, by notice in writing (a "formal non-compliance notice"), require the relevant economic operator to put an end to the non-compliance concerned:

(*a*) the CE marking or the supplementary metrology marking has been affixed in contravention of Article 30 of the EC Regulation or Regulation 19;

(*b*) the CE marking or the supplementary metrology marking has not been affixed;

(*c*) the inscriptions provided for in Regulation 8 have not been affixed or have been affixed in contravention of that Regulation;

(*d*) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in contravention of Regulation 19 or has not been affixed;

(*e*) the EU declaration of conformity has not been drawn up;

(*f*) the EU declaration of conformity has not been drawn up correctly;

(*g*) technical documentation is either not available or not complete;

(*h*) the information referred to in Regulation 8(2) or Regulation 10 (6), (7) or (8) is absent, false or incomplete;

(*i*) any other administrative requirement provided for in Regulations 7, 8 10 or 11 is not fulfilled.

(2) For the purposes of paragraph (1)—

(*a*) the Director, in a formal non-compliance notice, shall specify the measures to be taken to end the non-compliance concerned, and

(*b*) Regulation 37 shall apply to that notice.

(3) Where the non-compliance referred to in paragraph (1) persists, the Director shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

(4) Where, pursuant to paragraph (3), the Director takes a measure specified in that paragraph—

(*a*) the Director shall notify the economic operator of the measure concerned, by notice in writing, and

(*b*) Regulation 37 shall apply to that notice.

(5) A person to whom a formal non-compliance notice, or a notice under paragraph (4), is given shall comply with the notice unless the notice concerned is withdrawn or amended under Regulation 35(5) or is annulled under Regulation 38 (6).

Compliant instruments which present a risk

33. (1) Where, having carried out an evaluation under Regulation 30(1), the Director finds that although an instrument is in compliance with these Regulations, it presents a risk to aspects of public interest protection covered by these Regulations, he or she shall require the relevant economic operator by a notice in writing—

(*a*) to take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk,

(*b*) to withdraw the instrument from the market, or

(*c*) to recall it,

within a reasonable period commensurate with the nature of the risk, as the Director decides.

(2) An economic operator shall ensure that the corrective action required under paragraph (1) is taken in respect of all the instruments concerned that he or she has made available on the market throughout the Union.

(3) The Director shall immediately inform the Commission and other Member States of the matters referred to in paragraph (1) and shall include all available details including—

(*a*) the data necessary for the identification of the instrument,

(*b*) the origin and the supply chain of the instrument,

(*c*) the nature of the risk involved, and

(*d*) the nature and duration of the national measures taken.

(4) Regulation 37 applies to the service of notices under this Regulation.

PART 6

Enforcement

Authorised officers

34. (1) The Director may appoint such and so many persons as he or she thinks fit to be authorised officers for the purposes of ensuring compliance with such of these Regulations as the Director may specify in the warrant referred to in paragraph (2).

(2) An authorised officer shall be furnished with a warrant of his or her appointment and when exercising any power conferred on him or her under these Regulations an authorised officer shall, if requested by any person thereby affected, produce the warrant or a copy of it to that person for inspection.

(3) Subject to paragraph (7), an authorised officer may for the purpose of ensuring that these Regulations and the Directive are being complied with—

(*a*) at all reasonable times enter any premises or a place, at which there are reasonable grounds to believe that instruments to which these Regulations apply, are or likely to be found, made available or placed on the market, put into service or in service or that books, documents or records relating to the instrument are kept, and search and inspect the premises or place and any product or record found therein,

(*b*) secure for later inspection any premises or place or part of it in which such instruments or records are kept or there are reasonable grounds for believing that such instruments or books, documents or records are kept,

(*c*) require any person in charge of or employed in such premises or place to produce to the officer such books, documents or records (and in the case of such information in a non-legible form to reproduce it in a permanent legible form) that are in the person's power or control or to give to the officer such information as the officer may reasonably require in relation to any entries in such records,

(*d*) inspect, and take copies of or extracts from, any such books, documents or records (including in the case of information in non-legible form a copy of or extract from such information in a permanent legible form),

(*e*) remove and detain, where the officer has reasonable cause to suspect that there has been a contravention of these Regulations, the instrument or records for such period as may be reasonable for further examination or until the conclusion of any legal proceedings,

(*f*) in or at the premises, seize any equipment or part thereof or any books, records or other documents relating to equipment that the officer may reasonably require,

(*g*) as regards any instrument or any article or device, part or component used in the manufacture of an instrument the officer finds at or in a premises, require any person in charge of the premises, or any person who appears to the officer to be in possession of the instrument or the article or device, part or component, to supply without payment, for test, examination or analysis sufficient samples thereof,

(*h*) require any person to afford the officer such facilities and assistance within the person's control or responsibilities as are reasonably necessary to enable the officer to exercise any of the powers conferred on an authorised officer under this Regulation,

(*i*) examine any procedure connected with the manufacture, importation or distribution of an instrument, and

(*j*) request the person in charge of a vehicle or vessel to bring that vehicle or vessel to the nearest appropriate test facility at which an inspection may be carried out.

(4) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (7) authorising such entry.

(5) Where an authorised officer in the exercise of the officer's powers under this Regulation is prevented from entering any premises, an application may be made to the District Court under paragraph (7) for a warrant authorising such entry.

(6) An authorised officer, where he or she considers it necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorised officer under this Regulation.

(7) If a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that there is information required by an authorised officer under this Regulation held on any premises or any part of any premises or there is an instrument or article, device, part or component of an instrument which an authorised officer requires to inspect for the purposes of these Regulations or that such inspection is likely to disclose evidence of a contravention of these Regulations, the judge may issue a warrant authorising an authorised officer, accompanied by either or both authorised officers and members of the Garda Síochána, at any time or times within one month from the date of issue of the warrant, on production if so requested of the warrant, to enter, if need be by reasonable force, the premises and exercise all or any of the powers conferred on an authorised officer under this Regulation.

(8) An application under paragraph (7) shall be made to the judge of the District Court in whose District Court district the premises is situated.

(9) A person shall not—

(*a*) obstruct or interfere with an authorised officer in the exercise of the officer's powers under this Regulation,

(*b*) without reasonable excuse, fail to comply with a request from an authorised officer under this Regulation, or

(*c*) make a statement to such officer which the person knows is false or misleading.

(10) An inspector appointed under section 9 (1) of the Metrology Act 1996 for the purposes of that Act who immediately before the making of these Regulations held office as such an officer continues to be an authorised officer under this Regulation.

(11) In this Regulation, premises or place includes a vehicle or vessel.

Measures entailing prohibition or restriction

35. (1) Where the Director takes a measure referred to in Regulation 30, 31, 32 and 33, he or she shall follow the procedures set out in this Regulation.

(2) A measure referred to in paragraph (1) shall be notified without delay to the person concerned, and the notification shall—

(*a*) state the exact grounds on which the measure is based, and

(*b*) inform the person concerned of his or her right to make representations under paragraph (3) and of his or her right of appeal under Regulation 38, and

(*c*) explain the measures, and any time limits associated with them, that must be taken in order to remove the necessity for the prohibition or restriction.

(3) Subject to paragraph (4), a person concerned by a measure referred to in paragraph (1) shall have the opportunity to make representations to the Director in advance of the measure being taken.

(4) Where, due to the urgency of the measure referred to in paragraph (1), it is not possible to give the person concerned the opportunity to make representations in advance of the measure being taken, the Director shall give such opportunity, as soon as may be, thereafter.

(5) The Director may, where he or she considers it appropriate to do so, withdraw, or amend by a further notification in writing any notification given under this Regulation.

(6) Without prejudice to paragraph (5), the Director shall, where he or she is satisfied that the economic operator concerned has taken effective action, amend or withdraw the notice concerned.

(7) A notification under this Regulation may require that the measures concerned be undertaken—

(*a*) immediately, because of the urgency of the matter,

(*b*) from a specified date,

(*c*) by a specified date, or

(*d*) between specified dates.

(8) The Director shall cause the Commission to be notified of any relevant notification or other measures taken pursuant to paragraph (1).

(9) A person shall comply with a notification under this Regulation, or a requirement of a notification, unless and until the notification is annulled under Regulation 38 (6).

(10) Where a person fails to comply with a notification under this Regulation or a requirement of a notification, the Director may institute, in a court of competent jurisdiction, proceedings for an order requiring the person to comply with the terms of the notification.

Compliance Notice

36. (1) Where an authorised officer is satisfied that a person has contravened Regulation 4, 6, 7, 8, 9, 10, 11, 13, or 32, the authorised officer may serve a notice (in these Regulations referred to as a "compliance notice") on the person.

(2) A compliance notice shall—

(*a*) state the grounds for the authorised officer being satisfied that there has been a contravention referred to in paragraph (1),

(*b*) for the purpose of ensuring compliance by the person concerned with any provision of these Regulations, require the person to do or refrain from doing such act or acts as is or are specified in the notice by such date as is so specified, and

(*c*) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(*b*) that falls on or before the date by which an appeal under paragraph (5) shall be brought.

(4) An authorised officer may—

(*a*) withdraw a compliance notice at any time, as he or she considers appropriate, or

(*b*) where no appeal is brought under this Regulation, specify a date extending the period specified in the notice for the purposes of paragraph (2)(*b*), and notify the person in writing accordingly.

(5) A person may appeal a compliance notice served on him or her to the District Court not later than 21 days after the service of the compliance notice concerned.

(6) The authorised officer and the appellant concerned shall be entitled to be heard and to adduce evidence at the hearing of an appeal under this Regulation.

(7) The District Court shall, upon an appeal under this Regulation, do one of the following:

(*a*) affirm the compliance notice concerned;

(*b*) direct the authorised officer to withdraw the compliance notice concerned.

(8) An authorised officer shall comply with a direction under paragraph (7).

(9) A person shall comply with a compliance notice on or before the specified date.

(10) This Regulation shall not operate to prevent or restrict—

(*a*) the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations by a person, or

(*b*) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(11) In this Regulation "specified date" means, in relation to a compliance notice—

(*a*) the date specified in the notice in accordance with paragraph (2)(*b*), where no appeal against the notice is brought under this Regulation,

or

(*b*) the day falling immediately after the expiration of the period of 7 days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (7)(*a*).

Service of Notifications

37. (1) Subject to paragraph (2), a notification under Regulations 30, 31, 32, 33 and 36 shall be addressed to the person concerned by name and may be given to the person in one of the following ways—

(*a*) by delivering it to the person,

(*b*) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address, or

(*c*) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address.

(2) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Right of appeal against notifications or other measures

38. (1) A person aggrieved by a notification or other measure taken under Regulation 30, 31, 32 or 33 may appeal to the appropriate court against the giving of the direction or taking of the measure.

(2) An appeal under this Regulation shall state the grounds on which the appeal is made and be made by written notice, which shall be lodged with the appropriate office of the court by the appellant not later than 14 days from the date upon which the notification concerned was given to him or her or the measure was taken.

(3) Where a person appeals a notice referred to in paragraph (1) he or she shall—

(*a*) give the Director a copy of the notice of appeal at the same time he or she lodges the notice of appeal in accordance with paragraph (2), and

(*b*) notify the Director in writing of the grounds of the appeal.

(4) The Director shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(5) Where an appeal is made under paragraph (1) the notification shall remain in force until the appeal is determined or withdrawn, subject to any decision to the contrary by the High Court.

(6) On the hearing of an appeal under this Regulation the appropriate court may, as it thinks fit, confirm the notification or measure concerned or annul the notification or measure and make any other such order as it considers appropriate.

(7) In this Regulation "appropriate court" means—

(*a*) in case the estimated value of the measuring instrument concerned does not exceed €15,000, or such other amount as may stand specified

for the time being by law as that Court's jurisdiction in tort, the District Court,

(*b*) in case the estimated value of the measuring instrument concerned does not exceed €75,000, or such other amount as may stand specified for the time being by law as that Court's jurisdiction in tort, the Circuit Court, and

(*c*) in any case, the High Court.

(8) If, in relation to an appeal under this Regulation to the District Court, that court becomes of opinion during the hearing of the appeal that the value of the measuring instrument, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to its opinion of the value of the measuring instrument.

(9) If, in relation to an appeal under this Regulation to the Circuit Court, that court becomes of opinion during the hearing of the appeal that the value of the measuring instrument, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the High Court.

(10) Paragraphs (8) and (9) are without prejudice to the jurisdiction of a court (being either the District Court or the Circuit Court) to determine an appeal under this Regulation in relation to which it was, at the time of the hearing of the appeal, the appropriate court.

(11) An appeal under this Regulation to the District Court shall be determined by the judge of the District Court for the District Court district in which the measuring instrument concerned were made available on the market or the appellant ordinarily resides.

(12) An appeal under this Regulation to the Circuit Court shall be determined by the judge of the Circuit Court for the circuit in which the measuring instrument concerned was made available on the market or the appellant ordinarily resides.

Offences

39. (1) A person who contravenes a provision or requirement of this Regulation or Regulation 4, 6, 7, 8, 9, 10, 11, 13, 19, 30, 32, 33, 34, 35, 36, 40, 46, 53 or 59 commits an offence.

(2) A person who—

(*a*) forges or counterfeits the CE marking or supplementary metrology marking or any document required for the purposes of these Regulations,

(*b*) applies to any instrument a marking which he or she knows to be forged or counterfeit,

(*c*) knowingly makes available, places on the market or puts into use any instrument with such forged or counterfeit mark, or any mark liable to be confused with the marks authorised under these Regulations, or

(*d*) fails to comply with Regulation 19,

commits an offence.

(3) A person who knowingly alters a measuring instrument, device, part or component of a measuring instrument so as to affect its accuracy, commits an offence.

(4) A person who knowingly makes available on the market, places on the market or puts into use any instrument so altered commits an offence.

(5) Without prejudice to paragraph (3) a person who alters, adjusts or repairs an instrument so as to bring it into conformity with the Regulations does not commit an offence.

(6) Where a person is convicted of an offence under these Regulations, the court may order the forfeiture to the Director of any measuring instrument to which the offence relates.

(7) Summary proceedings for an offence under these Regulations may be brought and prosecuted by the Director.

Offence of providing false or misleading information

40. A person who provides to the Director information which the person knows or ought reasonably to know to be false or misleading (whether on the person's own behalf or on behalf of another person) in purported compliance with a requirement imposed by these Regulations, commits an offence.

Penalties

41. A person convicted of an offence under these Regulations is liable—

(*a*) on summary conviction to a class B fine, or imprisonment for a term not exceeding 12 months, or to both, or

(*b*) on conviction on indictment to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

Offences by bodies corporate

42. (1) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any wilful neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Time limit for bringing proceedings

43. Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under these Regulations may be instituted at any time within 12 months from the date on which the offence was committed or alleged to have been committed.

Costs

44. Where a person is convicted of an offence under these Regulations the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the prosecutor the costs and expenses, measured by the court, reasonably incurred by the prosecutor in relation to the investigation, detection and prosecution of the offence, including costs incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers.

PART 7

Instruments in Service

Definitions

45. In this Part—

"authorised person" means a person designated by a special body to undertake verification of non-automatic weighing instruments in accordance with Regulation 50;

"non-conformity mark" means the non-conformity mark prescribed under the Legal Metrology (Marks) Regulations 2008 (S.I. No. 296 of 2008);

“prescribed mark” means a mark prescribed under the Legal Metrology (Marks) Regulations 2008 (S.I. No. 296 of 2008);

“security mark” means a mark prescribed under the Legal Metrology (Marks) Regulations 2008 (S.I. No. 296 of 2008);

"special body" means a body authorised under Regulation 48,

"user" means the person or organisation responsible for use of the instrument for the applications referred to in Regulation 3(*a*);

"verification mark" means the verification mark prescribed under the Legal Metrology (Marks) Regulations 2008 (S.I. No. 296 of 2008).

Control In-Service

46. (1) A person who uses or has in his or her possession for use an instrument to which Regulation 3(*a*) applies shall ensure the instrument continues to conform to the requirements of the Directive in accordance with the procedures and requirements set down set down in this Part.

(2) A person who knowingly fails or neglects to comply with paragraph (1) commits an offence.

Inspection in-service

47. (1) An instrument when in use for the applications referred to in Regulation 3 (*a*) shall be inspected in accordance with this Part at least every 2 years.

(2) Notwithstanding paragraph (1), the Director may extend or reduce the in-service inspection interval specified in that paragraph for a particular geographical region or for a particular trade or for a particular type or category of instrument or for any other reason the Director considers necessary for the purposes of the proper application of this Regulation.

Special Bodies

48. (1) The Director, with the consent of the Minister, and subject to conditions as are considered appropriate, may authorise such bodies as the Director thinks fit to carry out the verification of non-automatic weighing instruments.

(2) The Director shall ensure that bodies so authorised continue to meet the conditions laid down in accordance with paragraph (1).

(3) The Director shall withdraw the authorisation in respect of any authorised body where that body fails to meet the conditions stipulated under paragraph (1).

(4) Subject to the provisions of paragraphs (1), (2) and (3), neither the Minister nor the National Standards Authority of Ireland shall incur any liability for any act or default in the discharge or purported discharge of the function referred to in paragraph (1) by a body authorised under this Regulation.

Continuation in use

49. (1) Upon inspection in-service an authorised officer may allow any instrument to continue in use unless he or she finds—

(*a*) subject to subparagraph (*b*) the instrument no longer complies with the essential requirements or certificate granted by a notified body for its putting into service,

(*b*) the maximum permissible errors set down in Regulation 51(2) are exceeded,

(*c*) the instrument has been repaired, altered or adjusted, including where evidence of such repair, alteration or adjustment is by way of interference with or tampering with or removal of any prescribed mark or any security device or seal,

(*d*) the instrument has been broken or damaged to an extent which may affect its accuracy,

(*e*) the instrument is in use for a particular purpose for which it was not intended,

(*f*) the instrument is erected in such a manner as not to facilitate testing,

(*g*) the instrument bears a mark that is not prescribed, or

(*h*) the manner of use of the instrument is contrary to the requirements of Regulation 54.

(2) Where an authorised officer determines—

(*a*) that an instrument exceeds the maximum permissible error set down in Regulation 51(2) by not more than 10%, or

(*b*) that the degree of non-compliance with the requirements of these Regulations is such that the instrument should not immediately be taken out of service,

the authorised officer shall issue to the user a notice in writing giving reasons for his or her decision and directing the user to rectify the matter within a period not exceeding 20 working-days.

(3) Should the user fail to comply with the direction issued under paragraph (2) by the date given in the notice, the authorised officer shall affix the non-conformity mark to the instrument.

(4) Except where provided for in paragraph (2) an authorised officer shall immediately affix the non-conformity mark to any instrument found not to be allowed to continue in use for one or more reasons set out in paragraph (1).

(5) An instrument referred to in paragraphs (3) or (4) shall thereafter be submitted for verification in accordance with Regulation 50 in order to be used for the purposes set down in Regulation 3 (*a*).

Verification

50. An authorised officer or authorised person shall affix the verification mark to any instrument that has been repaired, altered or adjusted or otherwise brought into conformance since it was put into service or last verified where he or she finds that the instrument complies with—

(*a*) the essential requirements for its first placing on the market and any relevant certificate granted by a notified body for its putting into service,

(*b*) the maximum permissible errors referred to in Regulation 51 (1),

(*c*) the manner of use requirements set down in Regulation 54.

Maximum permissible errors

51. (1) The maximum permissible errors applicable upon verification of non-automatic weighing instruments are set out in the Table to this Regulation.

(2) The maximum permissible errors applicable upon inspection in-service of non-automatic weighing instruments are twice the values set down in the Table to this Regulation.

Table

mpe	**for loads m expressed in verification scale intervals e**			
	Class I	**Class II**	**Class III**	**Class IIII**
$\pm$ 0.5 e	$0 \leq m \leq 50\,000$	$0 \leq m \leq 5\,000$	$0 \leq m \leq 500$	$0 \leq m \leq 50$
$\pm$ 1 e	$50\,000 < m \leq 200\,000$	$5\,000 < m \leq 20\,000$	$500 < m \leq 2\,000$	$50 < m \leq 200$
$\pm$ 1.5 e	$200\,000 < m$	$20\,000 < m \leq 100\,000$	$2\,000 < m \leq 10\,000$	$200 < m \leq 1\,000$

Sealing and securing

52. (1) Upon verification an instrument shall be secured in such a manner as to enable an adjustment to be detected in so far as possible.

(2) Facilities for providing such securing where not already present on the instrument shall be provided by the user.

(3) Interference with or tampering with or removal of any prescribed mark or any security device or seal shall be deemed to invalidate any previous verification.

Affixation of prescribed marks

53. (1) Without prejudice to the circumstances provided for in Regulation 52 (3), the affixation of a verification or non-conformity mark under these Regulations shall be deemed to invalidate all previously affixed prescribed marks and shall continue in effect until such time as the instrument has affixed a verification mark or non-conformity mark as the case may be.

(2) Where a verification mark is affixed subsequent to a non-conformity mark it shall be affixed in such a position that it obliterates any non-conformity mark in so far as possible.

(3) Any non-conformity mark required to be affixed under these Regulations shall be affixed in such a position that it obliterates any verification mark in so far as possible.

(4) It shall be an offence to use an instrument for the applications referred to in Regulation 3(*a*) where—

(*a*) such instrument bears a non-conformity mark affixed in accordance with Regulation 51, or

(*b*) the verification of such instrument has been deemed invalid under Regulation 52(3).

Manner of use

54. (1) A person shall use an instrument for the applications referred to in Regulation 3(*a*)—

(*a*) within the environmental conditions for which it is intended,

(*b*) in the manner for which it is intended, and

(*c*) in accordance with any inscription signifying the manner and purpose of use;

(2) The user of an instrument for the applications referred to in Regulation 3(*a*) shall ensure—

(*a*) the instrument is not installed in conditions that could prevent the instrument from operating consistently or accurately and such conditions are not likely prematurely to degrade the instrument performance,

(*b*) no inscription or article is placed on an instrument where if it be so placed as to obscure or interfere with the placement of any prescribed mark or inscription.

Re-installation

55. In the case of an instrument which is required to be calibrated in-situ, if following its first placing into service it is thereafter dismantled and reinstalled, whether in the same or another location, it shall not be used for any of the applications referred to in Regulation 3(*a*) until it has been verified in accordance with Regulation 50.

Printers

56. A person shall not use an instrument fitted with a printing device unless the device produces a legible and durable printout.

Testing procedures

57. (1) The technical and metrological test procedures required to establish compliance with the provisions in this Part shall be identified by the Director.

Appeals

58. (1) Any person aggrieved by the decision made by an authorised officer or by a special body in relation to Part 7 of these Regulations may, within seven days, appeal to the Director in writing.

(2) An appeal under paragraph (1) shall set out specifically any manner in which it is claimed that the authorised officer or special body misapplied any provision of Part 7 of these Regulations.

(3) The Director shall not decide the appeal until he or she has—

(*a*) received a report on the matter from the authorised officer or special body concerned, and

(*b*) afforded the person aggrieved and the authorised officer or special body an opportunity to make submissions to him or her, and

(*c*) where he or she considers it necessary or desirable, received the result of any other test or examination of the instrument performed on his or her behalf by any other person for that purpose.

(4) In deciding the appeal, the Director may—

(*a*) reject the appeal and confirm the performance of any operation by the authorised officer or special body concerned, or

(*b*) allow the appeal and direct the authorised officer or special body concerned to perform the operation concerned in a manner specified in that direction.

(5) A decision by the Director on an appeal under this Regulation shall be final and binding and no further appeal shall lie under these Regulations.

Removal of seals or marks

59. (1) Subject to paragraph (2), every person who removes, defaces or obliterates any marking or tag or wilfully breaks any seal or device that has been placed on or attached to an instrument that is or is to be used for an application referred to in Regulation 3(*a*) is guilty of an offence if that marking, tag, seal or device has been placed on or attached to the instrument by an authorised officer or by an authorised person.

(2) No person is guilty of an offence under paragraph(1) if he or she removes any marking or tag or breaks any seal or device referred to in that subsection for the purpose of altering, adjusting or repairing an instrument, and so informs the user.

(3) The user of the instrument shall, as soon as practicable after being so informed, arrange to have the instrument verified in accordance with Regulation 50.

Fees

60. (1) The Director, with the approval of the Minister, may charge a fee for carrying out or causing to be carried out any function related to verification under Part 7 of these Regulations.

(2) A notified body may charge a fee which shall be equal to the amount which the notified body estimates it will incur in, or in connection with, carrying out or causing to be carried out the functions referred to in these Regulations in respect of the application concerned.

(3) A fee charged pursuant to paragraph (1) or (2) shall—

(*a*) be reasonable, proportionate and commensurate with the costs incurred in respect of the particular function or service,

(*b*) not exceed the real cost of the function or service provided, and

(*c*) in the case of a flat-rate fee, be justified by reference to the average cost of the function or service provided.

PART 8

General

Repeal and Revocations

61. (1) Section 10 (6) of the Metrology Act 1996 (N0. 27 of 1996) is repealed.

(2) The Legal Metrology (General) Regulations 2008 (S.I. No. 323 of 2008) are amended—

(*a*) in Regulation 2 (1)—

(i) by the deletion of the definition of "Directive 90/384/ EEC",

(ii) by the deletion of "(or in the case of non-automatic weighing instruments taking out of use for any purpose prescribed by Regulation 4 (*a*) of the 1992 Regulations" in the definition of "taking out of service",

(iii) the deletion of the definition of "1992 Regulations",

(*b*) in Regulation 2(2), by the deletion of "Directive 90/384/ EEC",

(*c*) by the revocation of Regulation 3 (2),

(*d*) by the revocation Regulation 3(5) (*a*),

(*e*) in Regulation 8(2) (*b*), by the deletion of clause (iii)

(*f*) in Regulation 9 (*a*), by the deletion of clause (iii),

(*g*) in Regulation 68 (*a*), by the deletion of "of Directive 90/384/EEC or".

(3) Regulation 2(1) of the Legal Metrology (Marks) Regulations 2008 (S.I. No.296 of 2008) are amended—

(*a*) by the deletion of the definition of the definition of "1992 Regulations", and,

(*b*) by inserting the following definition:

"2018 Regulations' means the European Union (Non-automatic Weighing Instruments) Regulations 2018 (S.I. No. 47 of 2018).

(4) The European Communities (Non-automatic Weighing Instruments) Regulations 1992 (S.I. No. 424 of 1992) are revoked.

Transitional

62. (1) Instruments which are in conformity with the Regulations of 1992 and which were placed or made available on the market or put into service before the coming into operation of these Regulations may continue to be made available on the market and where in use may be inspected in-service in accordance with Part 7 of these Regulations.

(2) Certificates issued under the Regulations of 1992 shall be valid under these Regulations.

(3) References to Directive 2009/23/EC in any Act or statutory instrument shall be construed as references to the Directive.

L.S.

GIVEN under my Official Seal,
5 March 2018.

HEATHER HUMPHREYS,
Minister for Business, Enterprise and Innovation.

EXPLANATORY NOTE

(This note is not part of the Regulations and does not purport to be a legal interpretation)

These Regulations give effect to Directive 2014/31/EU of the European Parliament and of the Council of 26 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 (recast).

The Regulations provide for the *free movement* within the Community of non-automatic weighing instruments and set out *essential requirements*, which must be met for instruments intended for certain specified uses.

Part 1 deals with the *General Provisions* of the Regulations and contains *definitions, application to the instruments* as defined in Annexes 1 to VI of the Directive.

Part 2 of the Regulations sets out the *Obligations of Economic Operators (authorised representatives, manufacturers, importers and distributors)* in relation to the marking of, and the indication of regulated instruments in the State, and, in particular to ensure that they meet the essential requirements applicable to those instruments.

Part 3 of the Regulations deals with the *Conformity of Instruments*. An instrument which is in conformity with harmonised standards (or part of such a standard) the references to which have been published in the Official Journal of the Union shall be presumed to be in conformity with the essential requirements referred to in Annex I of the Directive, covered by that standard (or part of that standard).

Part 4 of the Regulations deals with *Notification of Conformity Assessment Bodies*. The Regulations provide for the appointment of a Notifying Authority and Notified Bodies to carry out the various functions such as type-approval, verification and quality system approval and sets out the obligations on manufacturers and the conditions under which they may issue a declaration of conformity.

Part 5 of the Regulations deals with *Union Market Surveillance*, and *Control of Instruments entering the Union Market and Union Safeguard Procedures* for dealing with Instruments presenting a risk at national level.

Part 6 of the Regulations deals with *Enforcement*. The Regulations provide for an Appeals Procedure, market surveillance, powers of inspectors and authorised officers and penalties for Offences.

Part 7 deals with *Instruments in Service*. A person who uses or has in his or her possession for use an instrument to which Regulation 3(a) applies, shall ensure that the instrument continues to conform to the requirements of the Regulations and the Directive in accordance with the procedures and requirements set down in this Part. A person who knowingly fails or neglects to comply

with the above, commits an offence. Any person aggrieved by a decision made under Part 7, can appeal to the Director of Legal Metrology.

Part 8 deals with Repeal and Revocations and Transitional Provisions. Under the Regulations:

(1) Section 10 (6) of the Metrology Act 1996 (No. 27 of 1996) is repealed.

(2) The Legal Metrology (General) Regulations 2008 (S.I. No. 323 of 2008) are either amended or revoked as follows: in Regulations 2(1), 2(2), 3(2), 3(5)(a), 8(2)(b)(iii), Regulation 9(a)(iii), and Regulation 68(a).

(3) Legal Metrology (General) Regulations 2008 (S.I. No. 323 of 2008) are amended.

(4) Regulation 2(1) of the Legal Metrology (Marks) Regulations 2008 (S.I. No.296 of 2008 is amended.

(5) The European Communities (Non-Automatic Weighing Instruments) Regulations 1992 (S.I. No. 424 of 1992) are revoked.

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