Directive 2014/32/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 measuring instruments (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter

This Directive establishes the requirements that measuring instruments have to satisfy with a view to their being made available on the market and/or put into use for the measuring tasks referred to in Article 3(1).

Article 2

Scope

1 This Directive applies to the measuring instruments defined in the instrument-specific Annexes III to XII (hereinafter 'instrument-specific Annexes') concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), thermal energy meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

2 This Directive is a specific Directive in respect of requirements for electromagnetic immunity within the meaning of Article 2(3) of Directive 2014/30/EU of the European Parliament and of the Council[(1)]. That Directive continues to apply with regard to emission requirements.

Article 3

Optionality

1 Member States may prescribe the use of measuring instruments for measuring tasks, where they consider it justified for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading.

2 Where Member States do not prescribe such use, they shall communicate the reasons therefor to the Commission and the other Member States.

Article 4

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) ‘measuring instrument’ means any device or system with a measurement function that is covered by Article 2(1);

(2) ‘sub-assembly’ means a hardware device, mentioned as such in the instrument-specific annexes, that functions independently and makes up a measuring instrument together with other sub-assemblies with which it is compatible, or with a measuring instrument with which it is compatible;

(3) ‘legal metrological control’ means the control of the measurement tasks intended for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

(4) ‘normative document’ means a document containing technical specifications adopted by the International Organisation of Legal Metrology;

(5) ‘making available on the market’ means any supply of a measuring instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(6) ‘placing on the market’ means the first making available of a measuring instrument on the Union market;

(7) ‘putting into use’ means the first use of a measuring instrument intended for the end-user for the purposes for which it was intended;

(8) ‘manufacturer’ means any natural or legal person who manufactures a measuring instrument or has a measuring instrument designed or manufactured, and markets that measuring instrument under his name or trade mark or puts it into use for his own purposes;

(9) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(10) ‘importer’ means any natural or legal person established within the Union who places a measuring instrument from a third country on the Union market;

(11) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a measuring instrument available on the market;

(12) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(13) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a measuring instrument;

(14) ‘harmonised standard’ means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(15) ‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) no 765/2008;

(16) ‘national accreditation body’ means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) no 765/2008;

(17) ‘conformity assessment’ means the process demonstrating whether the essential requirements of this Directive relating to a measuring instrument have been fulfilled;

(18) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(19) ‘recall’ means any measure aimed at achieving the return of a measuring instrument that has already been made available to the end-user;

(20) ‘withdrawal’ means any measure aimed at preventing a measuring instrument in the supply chain from being made available on the market;

(21) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

(22) ‘CE marking’ means a marking by which the manufacturer indicates that the measuring instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 5

Applicability to sub-assemblies

Where instrument-specific annexes lay down the essential requirements for sub-assemblies, this Directive shall apply mutatis mutandis to such sub-assemblies.

Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing conformity.

Article 6

Essential requirements

A measuring instrument shall meet the essential requirements set out in Annex I and in the relevant instrument-specific Annex.

Member States may require, if it is needed for correct use of the instrument, the information referred to in point 9 of Annex I or in the relevant instrument-specific Annexes to be provided in a language which can be easily understood by end-users, as determined by the Member State in which the instrument is made available on the market.

Article 7

Making available on the market and putting into use

1 Member States shall not impede for reasons covered by this Directive the making available on the market and/or putting into use of any measuring instrument that satisfies the requirements of this Directive.

2 Member States shall take all appropriate measures to ensure that measuring instruments are made available on the market and/or put into use only if they satisfy the requirements of this Directive.

3 A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4 When different accuracy classes are defined for a measuring instrument:

a the instrument-specific Annexes under the heading ‘Putting into use’ may indicate the accuracy classes to be used for specific applications;

b in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

For the purposes of point (a) or point (b), measuring instruments of a better accuracy class may be used if the owner so chooses.

5 At trade fairs, exhibitions, demonstrations or similar events, Member States shall not prevent the showing of measuring instruments not in conformity with this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for making available on the market and/or putting into use until they are brought into conformity.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1 When placing their measuring instruments on the market and/or putting them into use, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

2 Manufacturers shall draw up the technical documentation referred to in Article 18 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure,

manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary metrology marking.

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the measuring instrument has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the performance of a measuring instrument, manufacturers shall carry out sample testing of measuring instruments made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that measuring instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the measuring instrument does not allow it, that the required information is provided in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I.

6 Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7 Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by a copy of the EU Declaration of conformity and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8 Manufacturers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Article 9

Authorised representatives

1 A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

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

b further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a measuring instrument;

c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by measuring instruments covered by their mandate.

Article 10

Obligations of importers

1 Importers shall place only compliant measuring instruments on the market.

2 Before placing a measuring instrument on the market and/or putting a measuring instrument into use importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears the CE marking and the supplementary metrology marking and is accompanied by a copy of the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not place the measuring instrument on the market or put it into use until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3 Importers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the measuring instrument is accompanied by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

6 When deemed appropriate with regard to the performance of a measuring instrument, importers shall carry out sample testing of measuring instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

7 Importers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 Importers shall, for 10 years after the measuring instrument has been 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.

9 Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Article 11

Obligations of distributors

1 When making a measuring instrument available on the market and/or putting it into use, distributors shall act with due care in relation to the requirements of this Directive.

2 Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the EU declaration of conformity, by the required documents and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not make the measuring instrument available on the market or put it into use, until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3 Distributors shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

4 Distributors who consider or have reason to believe that a measuring instrument which they have made available on the market or put into use is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the measuring instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have made available on the market.

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a measuring instrument on the market under his name or trade mark or modifies a measuring instrument already placed on the market in such a way that compliance with this Directive may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a measuring instrument;

(b) any economic operator to whom they have supplied a measuring instrument.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the measuring instrument and for 10 years after they have supplied the measuring instrument.

CHAPTER 3

CONFORMITY OF MEASURING INSTRUMENTS

Article 14

Presumption of conformity of measuring instruments

1 Measuring instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those standards or parts thereof.

2 Measuring instruments which are in conformity with parts of normative documents, the list of which has been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents.

3 A manufacturer may choose to use any technical solution that complies with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes. In addition, to benefit from the presumption of conformity, the manufacturer must correctly apply solutions mentioned either in the relevant harmonised standards or in the normative documents referred to in paragraphs 1 and 2.

4 Member States shall presume compliance with the appropriate tests mentioned in point (i) of Article 18(3) if the corresponding test programme has been performed in accordance with the relevant documents mentioned in paragraphs 1, 2 and 3 and if the test results ensure compliance with the essential requirements.

Article 15

Publication of the references of normative documents

On request by a Member State or in its own initiative, the Commission shall, where appropriate:

(a) identify normative documents and, in a list, indicate the parts thereof that satisfy the requirements which they cover and which are set out in Annex I and in the relevant instrument-specific Annexes;

(b) publish the reference of the normative documents and the list referred to in point (a) in the *Official Journal of the European Union*.

Article 16

Withdrawal of the references of normative documents

1 When a Member State or the Commission considers that a normative document whose reference has been published or is intended to be published in the *Official Journal of the European Union* does not entirely satisfy the essential requirements which it covers and which are set out in Annex I and in the relevant instrument-specific Annexes, the Commission shall decide:

a to publish, not to publish or to publish with restriction the references to the normative documents concerned in the *Official Journal of the European Union*;

b to maintain, to maintain with restrictions or to withdraw the references to the normative documents concerned in or from the *Official Journal of the European Union*.

2 The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

3 The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 46(3).

Article 17

Conformity assessment procedures

Conformity assessment of a measuring instrument with the applicable essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the relevant instrument-specific Annex.

The conformity assessment procedures are set out in Annex II.

Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

Article 18

Technical documentation

1 The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the applicable requirements of this Directive.

2 The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:

a the definition of the metrological characteristics;

b the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;

c the integrity of the measuring instrument.

3 The technical documentation shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

a a general description of the measuring instrument;

b conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.;

c manufacturing procedures to ensure consistent production;

d if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

e descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;

f a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the *Official Journal of the European Union*;

g descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;

h results of design calculations, examinations, etc.;

i the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:

— the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,

— the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;

j the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.

4 The manufacturer shall specify where seals and markings have been applied.

5 The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

Article 19

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex XIII, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall 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.

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

4 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the measuring instrument with the requirements laid down in this Directive.

Article 20

Conformity marking

The conformity of a measuring instrument with this Directive shall be indicated by the presence on it of the CE marking and the supplementary metrology marking as specified in Article 21.

Article 21

General principles of the CE marking and of the supplementary metrology marking

1 The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

2 The supplementary metrology marking shall consist of the capital letter ‘M’ and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.

3 The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, mutatis mutandis, to the supplementary metrology marking.

Article 22

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

1 The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate. Where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any.

2 When a measuring instrument consists of a set of devices, not being sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument’s main device.

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

4 The CE marking and the supplementary metrology marking may be affixed to the instrument during the fabrication process, if justified.

5 The supplementary metrology marking shall immediately follow the CE marking.

The CE marking and the supplementary metrology marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase as set out in Annex II.

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

The identification number of the notified body concerned shall be indelible or self destructive upon removal.

6 The CE marking, the supplementary metrology marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

7 Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 23

Notification

1 Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

2 If a Member State has not introduced national legislation for measuring tasks referred to in Article 3, it shall retain the right to notify a body for conformity assessment tasks relating to the measuring instrument concerned.

Article 24

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 29.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 25. In addition it shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 25

Requirements relating to notifying authorities

1 A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2 A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3 A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4 A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5 A notifying authority shall safeguard the confidentiality of the information it obtains.

6 A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 26

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 27

Requirements relating to notified bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established under national law of a Member State and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the measuring instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of measuring 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.

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

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those measuring instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

The second subparagraph does not, however, preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

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

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

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of measuring instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

b descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

c 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 measuring instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out conformity assessment tasks shall 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 essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;

d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

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

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall 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 relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 28

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 27 in so far as the applicable harmonised standards cover those requirements.

Article 29

Subsidiaries of and subcontracting by notified bodies

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 Article 27 and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility 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 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

Article 30

Accredited in-house bodies

1 An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in point 2 (Module A2) and point 5 (Module C2) of Annex II. That body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, production, supply, installation, use or maintenance of the measuring instruments it assesses.

2 An accredited in-house body shall meet the following requirements:

a it shall be accredited in accordance with Regulation (EC) No 765/2008;

b the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

c neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

d it shall supply its services exclusively to the undertaking of which it forms a part.

3 An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article 31

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the measuring instrument or measuring instruments for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27.

Article 32

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27.

2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include information on the kind(s) of measuring instrument(s) for which each body has been designated and, where relevant, the instrument accuracy classes, the measuring range, the measurement technology, and any other instrument characteristic limiting the scope of the notification. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and measuring instrument or measuring instruments concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate as referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with

documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6 The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 33

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2 The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 34

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 27, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall 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 notifying Member State 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.

Article 35

Challenge of the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

Article 36

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

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

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the measuring instrument with this Directive.

3 Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective 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 a measuring 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.

Article 37

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 38

Information obligation on notified bodies

1 Notified bodies shall 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 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 this Directive carrying out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 40

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or those groups, directly or by means of designated representatives.

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF MEASURING INSTRUMENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 41

Union market surveillance and control of measuring instruments entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to measuring instruments.

Article 42

Procedure for dealing with measuring instruments presenting a risk at national level

1 Where the market surveillance authorities of one Member State have sufficient reason to believe that a measuring instrument covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the measuring instrument concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the measuring instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the measuring instrument into compliance with those requirements, to withdraw the measuring instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2 Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the measuring instruments concerned that it has made available on the market throughout the Union.

4 Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the measuring instrument being made available on their national market, to withdraw the measuring instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5 The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant measuring instrument, the origin of the measuring instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

a failure of the measuring instrument to meet requirements relating to aspects of public interest protection laid down in this Directive; or

b shortcomings in the harmonised standards or normative documents referred to in Article 14 conferring a presumption of conformity.

6 Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the measuring instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7 Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8 Member States shall ensure that appropriate restrictive measures, such as withdrawal of the measuring instrument from the market, are taken in respect of the measuring instrument concerned, without delay.

Article 43

Union safeguard procedure

1 Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2 If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant measuring instrument is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3 Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 42(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

4 Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the normative documents referred to in point (b) of Article 42(5), the Commission shall apply the procedure provided for in Article 16.

Article 44

Compliant measuring instruments which present a risk

1 Where, having carried out an evaluation under Article 42(1), a Member State finds that although a measuring instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the measuring instrument concerned, when placed on the market, no longer presents that risk, to withdraw the measuring instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2 The economic operator shall ensure that corrective action is taken in respect of all the measuring instruments concerned that he has made available on the market throughout the Union.

3 The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the measuring instrument concerned, the origin and the supply chain of the measuring instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4 The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 46(3).

5 The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 45

Formal non-compliance

1 Without prejudice to Article 42, where a Member State makes one of the following findings, it shall 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 violation of Article 30 of Regulation (EC) No 765/2008 or of Article 22 of this Directive;

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

c the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 22 or has not been affixed;

d the EU declaration of conformity does not accompany the measuring instrument;

e the EU declaration of conformity has not been drawn up correctly;

f technical documentation is either not available or not complete.

g the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;

h any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2 Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the measuring instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 6

COMMITTEE AND DELEGATED ACTS

Article 46

Committee procedure

1 The Commission shall be assisted by the Committee on Measuring Instruments. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4 Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

5 The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

Article 47

Amendments of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 48 concerning the amendment of the instrument-specific Annexes, in relation to the following:

(a) maximum permissible errors (MPEs) and accuracy classes;

(b) rated operating conditions;

(c) critical change values;

(d) disturbances.

Article 48

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 47 shall be conferred on the Commission for a period of five years from 18 April 2014. The Commission shall draw up a

report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Article 47 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 47 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 49

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Article 50

Transitional provisions

1 Member States shall not impede the making available on the market and/or the putting into use of measuring instruments covered by Directive 2004/22/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued under Directive 2004/22/EC shall be valid under this Directive.

2 The effects of Article 23 of Directive 2004/22/EC shall continue until 30 October 2016.

Article 51

Transposition

1 Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 5 to 22 of Article 4, Articles 8 to 11, 13, 14, 19 and 21, Article 22(1), (3), (5) and (6), Articles 23 to 45, 49 and 50 and Annex II. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 52

Repeal

Without prejudice to Article 50, Directive 2004/22/EC as amended by the acts listed in Annex XIV, Part A, is repealed with effect from 20 April 2016 without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law and the dates of application of the Directives set out in Annex XIV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XV.

Article 53

Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 1, 2 and 3, points 1 to 4 of Article 4, Articles 5, 6, 7, 15 to 18 and 20, Article 22(2) and (4) and Annexes I and III to XII shall apply from 20 April 2016.

Article 54

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

(**1**) Directive 2014/30/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 electromagnetic compatibility (see page 79 of this Official Journal).