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) (Text with EEA relevance)

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6

Obligations of manufacturers

1 When placing on the market their instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall draw up the technical documentation referred to in Annex II and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with the applicable requirements 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 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the 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 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 shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers 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.

5 Manufacturers shall ensure that instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, as set out in Annex III.

For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 1 of Annex III.

For the instruments not intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 2 of Annex III.

Where an instrument which is intended to be used for any of the applications listed in points (a) to (f) of Article 1(2) includes, or is connected to, devices which are not used or intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix to each of those devices the restrictive use symbol as provided for in Article 18 and in point 3 of Annex III.

6 Manufacturers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. 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 instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information 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 an 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 instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the 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 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 instruments which they have placed on the market.

Article 7

Authorised representatives

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

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(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 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 an instrument;

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

Article 8

Obligations of importers

1 Importers shall place only compliant instruments on the market.

2 Before placing on the market an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the instrument bears the CE marking and the supplementary metrology marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not place the instrument on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) importers shall ensure that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3 Importers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6 When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers 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.

7 Importers who consider or have reason to believe that an 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 instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made

the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall, for 10 years after the 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 an 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 instruments which they have placed on the market.

Article 9

Obligations of distributors

1 When making an instrument available on the market distributors shall act with due care in relation to the requirements of this Directive.

2 Before making an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the instrument bears the CE marking, and the supplementary metrology marking, that it is accompanied by the required documents and 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, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not make the instrument available on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

3 Distributors shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4 Distributors who consider or have reason to believe that an instrument which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the 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 an instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have made available on the market.

Article 10

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 6, where he places an instrument on the market under his name or trade mark or modifies an instrument already placed on the market in such a way that compliance with this Directive may be affected.

Article 11

Identification of economic operators

For instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), economic operators shall, on request, identify the following to the market surveillance authorities:

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

(b) any economic operator to whom they have supplied an 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 instrument and for 10 years after they have supplied the instrument.