

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 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.

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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;

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- 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.