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 5

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

Article 36

Union market surveillance and control of instruments entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to instruments covered by Article 1 of this Directive.

Article 37

Procedure for dealing with instruments presenting a risk at national level

Where the market surveillance authorities of one Member State have sufficient reason to believe that an 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 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 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 instrument into compliance with those requirements, to withdraw the 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.

- 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 instruments concerned that it has made available on the market throughout the Union.

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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 instrument's being made available on their national market, to withdraw the 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.

- 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 instrument, the origin of the 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 instrument to meet requirements relating to the aspects of public interest protection laid down in this Directive; or
 - b shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.
- 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 instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.
- 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 instrument from the market, are taken in respect of the instrument concerned without delay.

Article 38

Union safeguard procedure

Where, on completion of the procedure set out in Article 37(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.

If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant 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.

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Where the national measure is considered justified and the non-compliance of the instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 39

Compliant instruments which present a risk

- Where, having carried out an evaluation under Article 37(1), a Member State finds that although an 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 instrument concerned, when placed on the market, no longer presents that risk, to withdraw the 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 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 instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.
- 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 41(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 40

Formal non-compliance

- 1 Without prejudice to Article 37, 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 17 of this Directive;
 - b the CE marking or the supplementary metrology marking has not been affixed;
 - the inscriptions provided for in Article 6(5) have not been affixed or have been affixed in violation of Article 6(5);
 - d the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 17 or has not been affixed;
 - e the EU declaration of conformity has not been drawn up;

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- f the EU declaration of conformity has not been drawn up correctly;
- g technical documentation is either not available or not complete;
- the information referred to in Article 6(6) or 8(3) is absent, false or incomplete;
- i any other administrative requirement provided for in Article 6 or 8 is not fulfilled.
- Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.