Electromagnetic compatibility. Recast. 'Goods package'

2011/0351(COD) - 26/02/2014 - Final act

PURPOSE: to align Directive 2004/108/EC on the harmonisation of the laws of the Member States relating to electromagnetic compatibility with the new legislative framework, which established a common framework for the marketing of products (Goods Package).

LEGISLATIVE ACT: Directive 2014/30/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

CONTENT: the Directive is part of a package aiming to recast **eight directives** in order to adapt them to the EU's new legislative framework on sectoral product harmonisation.

The recast seeks to further harmonise and simplify national laws applicable to:

- explosives for civil uses
- simple pressure vessels
- **electromagnetic compatibility**
- non-automatic weighing instruments
- measuring instruments
- lifts and safety components for lifts
- equipment for use in potentially explosive atmospheres
- electrical equipment designed for use within certain voltage limits.

The EU's "new legislative framework", which was adopted in 2008, is a general measure of the internal market with the objective of strengthening the effectiveness of the Union’s legislation on product safety and its implementation mechanisms. It aims to **strengthen the safety of products** available on the market, and ensures a better functioning internal market for instance through equal treatment of economic operators on the market.

It is made up of **two complementary texts**: regulation 765/2008 outlining the requirements concerning accreditation and surveillance for the marketing of products, and decision 768/2008/EC relating to a common framework for the marketing of products.

The main elements of the new Directive are as follows:

Purpose and scope: this Directive **regulates the electromagnetic compatibility of equipment**. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility. It covers **products which are new to the Union market** when they are placed on the market; that is to say they are either new products made by a manufacturer established in the

Union or products, whether new or second-hand, imported from a third country. This Directive should apply to all forms of supply, including distance selling.

This Directive shall not apply to:

- radio equipment and telecommunications terminal equipment since they are already regulated by Directive 1999/5/EC;

- aircraft or equipment intended to be fitted into aircraft, since they are already subject to special Union or international rules governing electromagnetic compatibility.

- custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

Obligations of economic operators and traceability requirements: the Directive clarifies the obligations of manufacturers and introduces obligations for importers and distributors:

- When placing on the market their apparatus, **manufacturers** shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I. Apparatus which they have placed on the market must bear a type and serial or batch identification allowing their identification. Where the size or nature of the apparatus does not allow it, the required information shall be placed on the packaging or in a document accompanying the apparatus.

- Before placing apparatus on the market, **importers** shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the CE marking and that it is accompanied by the required documents and by instructions and **safety information**.

- Manufacturers and importers shall indicate on the apparatus 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. The instructions and safety information should be in a **language which can be easily understood by end-users**, as determined by the Member State concerned.

Manufacturers who consider or have reason to believe that apparatus which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate.

EU declaration of conformity: the EU declaration of conformity shall have the model structure set out in Annex IV. In order to reduce the **administrative burden** on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

CE marking: the Directive states that the CE marking and the inscriptions shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. It shall be affixed before the apparatus is placed on the market. As requested by the European Parliament, 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.

Notified bodies: the Directive **reinforces the notification criteria** for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements

for notifying authorities are introduced, and the procedure for notification of notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. A conformity assessment body shall be a third-party body independent of the organisation or the apparatus it assesses. 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.

Market surveillance and the safeguard clause procedure: the Directive revises the existing safeguard clause procedure. It introduces a **phase of information exchange** between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant article is found. Member States should take all appropriate measures to ensure that apparatus may be placed on the market only if, when **properly stored** and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons.

Restrictive measures in case of non-compliance: appropriate restrictive measures, such as **withdrawal of the apparatus** concerned from the market should be taken in respect of the apparatus concerned without delay.

Rules on **penalties** applicable to infringements by economic operators could include criminal penalties for serious infringements. The penalties provided for should be effective, proportionate and dissuasive.

Transitional provisions/products in stock: distributors should therefore be able to supply apparatus that has been placed on the market, namely stock that is already in the distribution chain, before the 20 April 2016.

ENTRY INTO FORCE: 18/04/2014.

TRANSPOSITION: 19/04/2016. Measures shall apply from 20.04.2016.