Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 09/07/2008 - Final act

PURPOSE: to establish requirements for accreditation and market surveillance for the marketing of products.

LEGISLATIVE ACT: Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

CONTENT: This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security. The Regulation provides a framework for controls on products from third countries and lays down the general principles of the CE marking.

Accreditation: accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements. The Regulation has developed comprehensive framework for accreditation and lays down at Community level the principles for its operation and organisation. Each Member State shall appoint a single national accreditation body. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect. The accreditation body must be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and ensure that no conflicts of interest with conformity assessment bodies occur.

Market surveillance: this must ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. National market surveillance infrastructures and programmes shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation. Market surveillance shall cover products assembled or manufactured for the manufacturer's own use where Community harmonisation legislation provides that its provisions shall apply to such products.

Products presenting a serious risk: Member States must ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay. The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other

products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

CE marking: the Regulation sets out the general principles of CE marking. The CE marking shall be affixed only by the manufacturer or his authorised representative, and it must be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation.

Review clause: not later than 5 years after the entry into force of the Regulation, the Commission shall submit a report on the application of the Regulation and Directive 2001/95/EC on General Product Safety and any other relevant Community instrument addressing market surveillance. In particular, the report shall analyse the coherence of Community rules in the field of market surveillance. If appropriate, the report shall be accompanied by proposals to amend and/or consolidate the instruments concerned. It will include an evaluation of the extension of the scope of Chapter III to all products. By 1 January 2013, and every five years thereafter, the Commission, in cooperation with the Member States, shall produce and submit to the European Parliament and to the Council a report on the implementation of this Regulation.

APPLICATION: from 1/01/2010.

ENTRY INTO FORCE: 02/09/2008.