Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities.

2 This Regulation 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.

3 This Regulation provides a framework for controls on products from third countries.

4 This Regulation lays down the general principles of the CE marking.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. ‘making available on the market’ shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

2. ‘placing on the market’ shall mean the first making available of a product on the Community market;

3. ‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

4. ‘authorised representative’ shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Community legislation;

5. ‘importer’ shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

6. ‘distributor’ shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

7. ‘economic operators’ shall mean the manufacturer, the authorised representative, the importer and the distributor;

8. ‘technical specification’ shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;

9. ‘harmonised standard’ shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(1)] on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

10. ‘accreditation’ shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

11. ‘national accreditation body’ shall mean the sole body in a Member State that performs accreditation with authority derived from the State;

12. ‘conformity assessment’ shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

13. ‘conformity assessment body’ shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

14. ‘recall’ shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;

15. ‘withdrawal’ shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

16. ‘peer evaluation’ shall mean a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Regulation, and, where applicable, additional sectoral technical specifications;

17. ‘market surveillance’ shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

18. ‘market surveillance authority’ shall mean an authority of a Member State responsible for carrying out market surveillance on its territory;

19. ‘release for free circulation’ shall mean the procedure laid down in Article 79 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code[(2)];

20. ‘CE marking’ shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;

21. ‘Community harmonisation legislation’ shall mean any Community legislation harmonising the conditions for the marketing of products.

(**1**) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

(**2**) OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).