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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) It is necessary to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules. Provision should, therefore, be made for rules on accreditation, market surveillance, controls of products from third countries and the CE marking.

(2) It is necessary to establish an overall framework of rules and principles in relation to accreditation and market surveillance. That framework should not affect the substantive rules of existing legislation setting out the provisions to be observed for the purpose of protecting public interests such as health, safety and protection of consumers and of the environment, but should aim at enhancing their operation.

(3) This Regulation should be seen as complementary to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products[(3)].

(4) It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of

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a horizontal nature to deal with such products, to cover lacunae, in particular pending revision of existing specific legislation, and to complement provisions in existing or future specific legislation, in particular with a view to ensuring a high level of protection of health, safety, the environment and consumers, as required by Article 95 of the Treaty.

(5) The framework for market surveillance established by this Regulation should complement and strengthen existing provisions in Community harmonisation legislation relating to market surveillance and the enforcement of such provisions. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation. Examples can be found in the following sectors: drug precursors, medical devices, medicinal products for human and veterinary use, motor vehicles and aviation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions.

(6) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[(4)] established rules to ensure the safety of consumer products. Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive.

(7) However, in order to achieve a higher level of safety for consumer products, the market surveillance mechanisms provided for in Directive 2001/95/EC should be reinforced as regards products presenting a serious risk, in accordance with the principles established by this Regulation. Directive 2001/95/EC should therefore be amended accordingly.

(8) Accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements.

(9) The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

(10) Accreditation, though so far not regulated at Community level, is carried out in all Member States. The lack of common rules for that activity has resulted in different approaches and differing systems throughout the Community, with the result that the degree of rigour applied in the performance of accreditation has varied between Member States. It is therefore necessary to develop a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organisation.

(11) The establishment of a uniform national accreditation body should be without prejudice to the allocation of functions within Member States.

(12) Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in this Regulation, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Community the preferred means of demonstrating the technical competence of those bodies. However,

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national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(13) A system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them. It thereby enhances the principle of mutual recognition and therefore the provisions of this Regulation on accreditation should apply in relation to bodies carrying out conformity assessments in both the regulated and the non-regulated areas. The issue at stake is the quality of certificates and test reports irrespective of whether they fall within the regulated or the non-regulated area, and no distinction should therefore be made between those areas.

(14) For the purposes of this Regulation, not-for-profit operation by a national accreditation body should be understood as an activity that is not intended to add any gain to the resources of the body's owners or members. While national accreditation bodies do not have the objective of maximising or distributing profits, they may provide services in return for payment, or receive income. Any excess revenue that results from such services may be used for investment to develop their activities further, as long as it is in line with their main activities. It should accordingly be emphasised that the primary objective of national accreditation bodies should be to support or engage actively in activities that are not intended to produce any gain.

(15) Since the purpose of accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities, Member States should not maintain more than one national accreditation body and should ensure that that body is organised in such a way as to safeguard the objectivity and impartiality of its activities. Such national accreditation bodies should operate independently of commercial conformity assessment activities. It is therefore appropriate to provide that Member States ensure that, in the performance of their tasks, national accreditation bodies are deemed to exercise public authority, irrespective of their legal status.

(16) For the assessment and continued monitoring of the competence of a conformity assessment body, it is essential to determine its technological knowledge and experience and its ability to carry out assessment. It is therefore necessary that the national accreditation body possess the relevant knowledge, competence and means for the proper performance of its tasks.

(17) Accreditation should in principle be operated as a self-supporting activity. Member States should ensure that financial support exists for the fulfilment of special tasks.

(18) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national accreditation body, that Member State should have recourse to the national accreditation body of another Member State and should be encouraged to have such recourse to the fullest extent possible.

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(19) Competition between national accreditation bodies could lead to the commercialisation of their activity, which would be incompatible with their role as the last level of control in the conformity assessment chain. The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value. National accreditation bodies may find themselves in competition on the markets of third countries, but that must have no effect on their activities inside the Community, or on the cooperation and peer evaluation activities organised by the body recognised under this Regulation.

(20) In order to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies, conformity assessment bodies should request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body is able to request accreditation in another Member State in the event that there is no national accreditation body in its own Member State or where the national accreditation body is not competent to provide the accreditation services requested. In such cases, appropriate cooperation and exchange of information between national accreditation bodies should be established.

(21) In order to ensure that national accreditation bodies fulfil the requirements and obligations provided for in this Regulation, it is important that Member States support the proper functioning of the accreditation system, monitor their national accreditation bodies regularly and take appropriate corrective measures within a reasonable timeframe where necessary.

(22) In order to ensure the equivalence of the level of competence of conformity assessment bodies, to facilitate mutual recognition and to promote the overall acceptance of accreditation certificates and conformity assessment results issued by accredited bodies, it is necessary that national accreditation bodies operate a rigorous and transparent peer evaluation system and regularly undergo such evaluation.

(23) This Regulation should provide for the recognition of a single organisation at European level in respect of certain functions in the field of accreditation. The European cooperation for Accreditation (the EA), whose main mission is to promote a transparent and quality-led system for the evaluation of the competence of conformity assessment bodies throughout Europe, manages a peer evaluation system among national accreditation bodies from the Member States and other European countries. That system has proved to be efficient and to provide mutual confidence. The EA should, therefore, be the first body recognised under this Regulation and Member States should ensure that their national accreditation bodies seek and maintain membership of the EA for as long as it is so recognised. At the same time, the possibility of changing the relevant body recognised under this Regulation should be provided for, in case there is a need for it in the future.

(24) Effective cooperation among national accreditation bodies is essential for the proper implementation of peer evaluation and with regard to cross-border accreditation. In

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the interests of transparency, it is, therefore, necessary to provide for an obligation on national accreditation bodies to exchange information among themselves and to provide the national authorities and the Commission with relevant information. Updated and accurate information concerning the availability of accreditation activities operated by national accreditation bodies should also be made public and, therefore, accessible, in particular to conformity assessment bodies.

(25) Sectoral accreditation schemes should cover the fields of activity where general requirements for the competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety-related requirements are imposed. Given the fact that the EA has at its disposal a broad range of technical expertise, it should be requested to develop such schemes, especially for areas covered by Community legislation.

(26) For the purpose of ensuring the equivalent and consistent enforcement of Community harmonisation legislation, this Regulation introduces a Community market surveillance framework, defining minimum requirements against the background of the objectives to be achieved by Member States and a framework for administrative cooperation including the exchange of information among Member States.

(27) In the case of economic operators in possession of test reports or certificates attesting conformity issued by an accredited conformity assessment body, where the relevant Community harmonisation legislation does not require such reports or certificates, market surveillance authorities should take due account of them when performing checks on product characteristics.

(28) Cooperation between competent authorities at national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation, even before the placing on the market of dangerous products, by reinforcing measures to identify them, mainly in seaports, is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market. National consumer protection authorities should cooperate, at national level, with national market surveillance authorities and should exchange information with them relating to products which they suspect present a risk.

(29) Risk assessment should take all relevant data into account, including, where available, data on risks that have materialised with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks.

(30) Situations of serious risk posed by a product require rapid intervention, which may entail the withdrawal of the product, its recall or the prohibition of its being made available on the market. In those situations it is necessary to have access to a system of rapid exchange of information between Member States and the Commission. The system provided for in Article 12 of Directive 2001/95/EC has proved its effectiveness and efficiency in the field of consumer products. To avoid unnecessary duplication, that system should be used for the purposes of this Regulation. Moreover, coherent market surveillance throughout the Community requires a comprehensive exchange of information on national activities in this context which goes beyond this system.