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**Requirements regarding the organization and functioning of the sole Italian national body authorized to carry out accreditation activities in compliance with Regulation (EC) No 765/2008**

THE MINISTER

OF ECONOMIC DEVELOPMENT

IN COORDINATION WITH

MINISTERS OF INTERNAL AFFAIRS, OF AGRICULTURE, FOOD AND FORESTRY, OF THE ENVIRONMENT AND LAND AND MARITIME PROTECTION, OF INFRASTRUCTURES AND TRANSPORT, OF LABOR AND SOCIAL POLICIES, OF HEALTH, OF EDUCATION, UNIVERSITIES AND RESEARCH AND OF DEFENSE

Having regard to the Regulation (EC) No 765/2008 of the European Parliament and of the Council of July 9, 2008, which sets out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

Having regard to the Recital No 15 of the aforementioned Regulation (EC) No 765/2008;

Having regard to the Resolution No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products;

Having regard to the Law of July 23, 2009 No 99, setting out provisions for the development and internationalization of companies, as well as in the field of energy;

Having regard to the Article 4 of the aforementioned Law No 99 of 2009, and in particular the paragraph 1, according to which, in order to ensure the prompt application of Chapter II of the aforementioned Regulation (EC) No 765/2008, the Ministry of Economic Development, in coordination with the other Ministries, shall provide, within six months from the date of entry into force of the same Law, with one or more non-regulatory decrees, for the adoption of the provisions concerning the organization and the functioning of the sole national body authorized to carry out accreditation activities in compliance with the provisions of the Community legislation, for the definition of the criteria for setting up accreditation fees, also taking into account the similar price-related systems eventually adopted by other European countries, as well as for the regulation of the surveillance procedures of the body by the Ministries, also through the provision of the participation of the same Ministries' representatives to the relevant statutory bodies;

Having regard to the paragraph 3 of the same Article 4 of Law No 99 of 2009, according to which, for the accreditation of the organizations operating in the various sectors for which accreditation is required, the Ministry of Economic Development and the other Ministries shall regulate the procedures for participation in the body as per paragraph 1 of the accreditation bodies, already appointed for the areas of competence of the respective Ministries, and taking into consideration the specific competence assigned in this field also to public authorities such as the Superior Institute of Health for food safety and the National Institute of Metrological Research (INRIM) for calibration;

Having regard to paragraphs 2 and 4 of the same Article 4 of Law No 99 of 2009, which, among other things, provide that the Ministry of Economic Development, through the competent office, shall be the national reference authority for accreditation activities, the point of contact with the European Commission and shall assume functions as set out in Chapter II of the aforementioned Regulation not assigned to the national accreditation body, and that, moreover, from the implementation of the provisions of the same Article 4 must not derive new or greater obligations or less income for public finance and Ministries provide for this implementation with human, financial and instrumental resources available under current legislation;

With regard to the mandatory implementation of the aforementioned Article 4 of Law No 99 of 2009, except for further measures in the exercise of power conferred by the same Law;

DECREES:

**ARTICLE 1**

*Purposes*

1. This Decree regulates the organization and functioning of the sole national body, as well as the definition of the criteria for setting up accreditation fees, and the surveillance procedures of the body by the Ministries.

**ARTICLE 2**

*Definitions*

1. For the purposes of this Decree, it is meant that:

a) "Regulation", shall mean the Regulation (EC) No 765/2008 of the European Parliament and of the Council of July 9, 2008, which sets out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

b) "Law", shall mean the Law of July 23, 2009 No 99 setting out "Provisions for the development and internationalization of companies, as well as in the field of energy";

c) "accreditation", shall mean the attestation by a national accreditation body certifying that a given conformity assessment body meets the requirements set by harmonized standards and, where appropriate, any additional requirements including those set in relevant sectoral schemes, to carry out a specific conformity assessment activity;

d) "national accreditation body", shall mean the sole national body in a Member State that performs accreditation with authority derived from the State;

e) "conformity assessment", shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

f) "conformity assessment body", shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

g) "peer evaluation", shall mean a process for the assessment of a national accreditation body performed by other national accreditation bodies carried out in accordance with the requirements of the Regulation and, where applicable, additional sectoral technical specifications;

h) "market surveillance authority", shall mean an authority of a Member State responsible for carrying out market surveillance on its territory;

i) "CE marking", shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in EU's harmonization legislation providing for its affixing;

l) "EU's harmonization legislation", shall mean any Community legislation harmonizing the conditions for marketing products;

m) "Italian national accreditation body", shall mean the national accreditation body appointed by the Italian Government under the Law;

n) "Italian national accreditation authority", shall mean the competent office of the Ministry of Economic Development referent for accreditation activities and point of contact with the European Commission in accordance with Article 4, paragraph 2, of the Law.

### **ARTICLE 3**

#### *General provisions*

1. The Italian national accreditation body shall conform to the following principles and provisions:

a) it shall operate on a not-for-profit basis;

b) it shall be organized so as to ensure that accreditation, regardless of the use on a mandatory or voluntary basis, is carried out as an activity of public interest;

c) it shall not offer or provide any activities or services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body;

d) it shall have appropriate financial and personnel resources, and procedures for confidentiality and handling of complaints necessary to be a member of the European accreditation infrastructure as per Article 14 of the Regulation;

e) it shall establish and maintain appropriate structures to ensure the effective and balanced involvement of all interested parties within both its organization and the European accreditation infrastructure as per Article 14 of the Regulation;

f) it shall not compete with conformity assessment bodies;

g) it shall not compete with other national accreditation bodies.

### **ARTICLE 4**

#### *Requirements concerning the organization*

1. The Italian national accreditation body shall be a legal entity, have a statute, an organizational structure and management instruments so as to fulfil the following requirements:

a) it shall assume responsibilities, different from those of the other national authorities operating in the same sectors, related to the carrying out of voluntary accreditation tasks, as well

as being able to issue accreditation certificates for conformity assessments even in the area regulated by specific legislation, on behalf of the competent public administration according to the legislation in force and provided that the same public administration issues the provision of final authorization eventually provided for;

b) it shall ensure the independence of the conformity assessment bodies assessed by it;

c) it shall be free from commercial pressures;

d) it shall ensure that no conflicts of interest with conformity assessment bodies using accreditation occur;

e) it shall safeguard the objectivity and impartiality of its activities, also through the effective involvement of all interested parties within its organization, ensuring compliance with the standard UNI EN ISO 17011 as compatible with the Regulation;

f) it shall operate so that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;

g) it shall safeguard the confidentiality of the information obtained;

h) it shall identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to relevant Community or Italian legislation and standards;

i) it shall set up the procedures necessary to ensure efficient management and appropriate internal controls;

l) it shall have a number of competent personnel at its disposal sufficient for the proper performance of its tasks;

m) it shall document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;

n) it shall have, implement and maintain procedures for monitoring the performance and the competence of the personnel involved in accreditation activities;

o) it shall verify that conformity assessments are carried out in an appropriate manner, avoiding unnecessary burdens for companies and duly taking into account their size, sector and structure, and the degree of complexity of the product technology and the mass or serial nature of the production process;

p) it shall annually publish audited accounts prepared in accordance with accounting principles provided for by the legislation in force;

q) it shall, on a regular basis, subject itself to peer evaluation organized by the European accreditation infrastructure as per Article 14 of the Regulation;

2. For the accreditation of conformity assessment bodies operating in sectors for which, at the date of entry into force of this Decree, the specific current legislation provides for accreditation by one or more Ministries, or by public authorities monitored by them, or by accreditation bodies already identified for this purpose, the Italian national accreditation body, where mandated by the public administration in accordance with paragraph 1 letter a), provided what set out by Article 8, paragraph 1, shall have organizational instruments that enable appropriate participation to

accreditation activities by the aforementioned Ministries and by public authorities and bodies already appointed for this purpose by the competent Ministries; the procedures for participation, also in order to issue accreditation certificates, are arranged with an agreement, a memorandum of understanding or other similar bilateral documents and, in the absence of an agreement, are identified by the Ministry of Economic Development in coordination with the Ministry in question, once the parties have been consulted.

## **ARTICLE 5**

### *Requirements concerning the procedures*

1. Subject to the provisions of the Article 39 of the Regulation, the Italian national accreditation body shall evaluate the competence for carrying out a specific conformity assessment activity of conformity assessment bodies submitting the application and, if the evaluation is successful, it shall issue an accreditation certificate related to the specific conformity assessment activity. When a situation arises as set out in Article 4 paragraph 2 occurs, the accreditation certificate shall be accompanied by a reference to the accreditation body appointed before the entry into force of this Decree by the competent Ministry in accordance with the relevant sectoral legislation.

2. The Italian national accreditation body shall verify the conformity assessment bodies it issued an accreditation certificate to; when, as a result of a check, it ascertains that an accredited conformity assessment body is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, it shall take, following procedures made public, all the appropriate measures within sixty days to restrict, suspend or withdraw the accreditation certificate, promptly informing the Ministry of Economic Development and the Ministry or Ministries eventually involved.

3. The Italian national accreditation body shall inform the other national accreditation bodies of its conformity assessment activities in respect of which it operates accreditation and of any changes thereto and shall regularly make publicly available information concerning the results of its peer evaluation, the conformity assessment activities in respect of which it operates accreditation and any changes thereto.

## **ARTICLE 6**

### *Monitoring by the Government*

1. In order to ensure that the Italian national accreditation body fulfils permanently the requirements laid down in Article 8 of the Regulation and those in this Decree and its subsequent amendments and additions, regular monitoring is carried out on its structure and activity. In carrying out the monitoring, the results of peer evaluation as per Article 10 of the Regulation shall be particularly taken into account.

2. For an effective monitoring as per paragraph 1, a supervisory commission, composed of the Ministries' representatives, has been established within the Italian national accreditation authority, in accordance with Article 4, paragraph 2 of the Law. The commission is chaired by a member appointed by the Ministry of Economic Development who provides for organization, coordination and implementation of the surveillance plan. The secretarial functions are carried out by the staff of the competent office. The participation to the commission does not provide payments, emoluments, allowances or reimbursements.

3. The Ministries in question and public authorities specifically involved in the accreditation activity, shall appoint their representatives within the statutory bodies of the Italian national accreditation body and, in particular, they are represented as members of the Assembly and appoint their representatives within the governing bodies. The Ministry of Economic Development shall appoint also the chairman of the board of auditors or similar supervisory body and the Ministries or the public authorities more competent by subject shall appoint the chairmen of the sector accreditation committees, or similar bodies however named, to which is assigned the task to decide on accreditation in areas that the current national legislation attributes to the competence of these Ministries or accreditation bodies they have designated.

4. According to the surveillance plan developed by the commission as per paragraph 2, or on specific request of the same commission, the Italian national accreditation body shall provide documentation certifying the maintenance of compliance with the requirements referred to in paragraph 1. The Italian national accreditation body shall promptly provide information concerning the accreditation activity and assessment of conformity assessment bodies, the participation in peer evaluations, as well as documentation proving the compliance of the fees applied to the adequacy ratios as per Article 7.

5. Where the commission as per paragraph 2 ascertains that the Italian national accreditation body does not fulfil the requirements of the Regulation or does not comply with the obligations, it shall identify the measures to be taken and submit them for implementation to the national accreditation authority. The same authority shall ensure that the measure is taken and shall inform the European Commission thereof.

6. In order to handle complaints against decisions concerning accreditation or against the failure to implement such decisions, the Italian national accreditation body shall establish a specific commission, authoritative, impartial and competent in accordance with Article 9, paragraph 4 of the Regulation. The same body, in compliance with the Law on personal data protection, and with particular reference to the needs related to appeals through the aforementioned decisions or their failed implementation, shall guarantee to the commission as per paragraph 2 the examination of documentation in its possession according to the procedures established by the national accreditation authority.

## **ARTICLE 7**

### *Fee setting criteria*

1. The Italian national accreditation body shall set accreditation fees with a substantiated decision and with express reference to the recovery of the average costs incurred, also taking into account the similar price-systems implemented by the other European countries, and in compliance with the following principles:

a) it shall rigorously calculate costs according to criteria of efficiency, effectiveness and economy of the accreditation activity;

b) it shall differentiate fees according to criteria of adequacy and proportionality of the accreditation costs in relation to the conformity assessment activities for which accreditation is requested, in compliance with the requirements as per Article 4, paragraph 1, letter o);

c) it shall inform regarding each constituent element of the fee;

d) it shall inform regarding adequacy ratios of the fee;

e) it shall identify the periodic assessment and updating procedures.

2. The Italian national accreditation body shall communicate the measures as per paragraph 1 at least within thirty days before putting them into force to the commission as per Article 6, paragraph 2. Upon initial application, the Italian national accreditation body, within thirty days of its identification, shall in all cases set again the applied accreditation fees, on the basis of the criteria and according to the procedures as per paragraph 1, and shall communicate them within the following thirty days to the aforementioned commission. If the commission deems the fees do not comply with the criteria provided for, it shall notify the Italian national accreditation authority, which ensures that the Italian national accreditation body correctly sets the same fees, fixing a deadline where appropriate. As long as the resetting procedure is not concluded, the fees in force at the time of identification shall continue to apply.

## **ARTICLE 8**

### *Transitional and final provisions*

1. In order to avoid redoubling and waste of resources, the national accreditation body, in the first organization phase, before any initiative aimed at providing itself with new structures for the accreditation sectors in which it does not currently operate, or for the sectors for which, at the date of entry into force of this Decree, the specific current legislation provides for accreditation by one or more Ministries, or by public authorities by them monitored, or by accreditation bodies already identified for this purpose, shall set up the appropriate collaborations with public administrations and bodies already operating in each of the aforementioned sectors, in particular if already in possession of recognition as signatories of the EA MLA international mutual recognition agreements, giving them, also in order to issue accreditation certificates, through appropriate agreements, memoranda of understanding or similar legal documents, an adequate and significant role in their operative offices and using, according to mutually agreed procedures, the related personnel and offices.

2. The application of this Decree shall not affect the provisions set out by *lex specialis* to protect public interests in the matter of public security, public health and safety, environment and national defense.

3. New or greater obligations for public finance shall not derive from the implementation of this Decree. The public authorities shall provide for the implementation of this Decree with human, financial and instrumental resources available under current legislation.

4. This Decree shall be immediately effective.

This Decree will be published in the Official Journal of the Italian Republic.

Rome, December 22, 2009

*Minister of Economic Development*

SCAJOLA

*Minister of Internal Affairs*

MARONI

*Minister of Agriculture, Food and Forestry*

ZAIA

*Minister of the Environment and Land and Maritime Protection*

PRESTIGIACOMO

*Minister of Infrastructures and Transport*

MATTEOLI

*Minister of Labor and Social Policies*

SACCONI

*Minister of Health*

FAZIO

*Minister of Education, Universities and Research*

GELMINI

*Minister of Defense*

LA RUSSA

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