

# The European Regulation on Accreditation and its Impact on Greek Labs

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**REGULATION (EC) No 765/2008**  
**OF THE EUROPEAN PARLIAMENT AND OF THE**  
**COUNCIL**  
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**setting out the requirements for  
accreditation and market surveillance  
relating to the marketing of  
products and repealing Regulation (EEC)  
No 339/93**

## *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.

## *General principles*

- Each Member State shall appoint a single national accreditation body.
- The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities.
- The national accreditation body shall operate on a not-for-profit basis.

- The national accreditation body 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.
- Each Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks, including the fulfillment of special tasks, such as activities for European and international accreditation cooperation and activities that are required to support public policy and which are not self-financing.
- The national accreditation body shall be a member of the European Cooperation for Accreditation (EA).

## *Operation of accreditation*

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.

- National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate.
- Where a national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, that accreditation body shall take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate.

## *Requirements for national accreditation bodies*

A national accreditation body shall fulfill the following requirements:

1. it shall be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur;
2. it shall be organised and operated so as to safeguard the **objectivity** and **impartiality** of its activities;
3. it shall ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;

4. it shall have adequate arrangements to safeguard the confidentiality of the information obtained;

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

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

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

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

9. it shall establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;

10. it shall verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;

11. it shall publish audited annual accounts prepared in accordance with generally accepted accounting principles.

# Status in Greece

Labs as Notified bodies for the implementation of the 89/106/EC Directive (Construction Products Directive)

# Requirements for notified bodies

## ➤ Legal and contractual matters

*A notified body shall be established under national law and have legal personality*

# Requirements for notified bodies

## ➤ Management of impartiality

*The notified body must have documented procedures for the identification, review and resolution of all cases where a conflict of interest is suspected or proven.*

*If threats to impartiality are identified, the conformity assessment body shall document and be able to demonstrate how it eliminates or minimizes such threats.*

# Requirements for notified bodies

*The impartiality requirements do not preclude the possibility of the national authorities responsible for market surveillance to use in given situations the facilities and/or the expertise of a notified body. However, to safeguard impartiality it is important to make a clear distinction between conformity assessment and market surveillance. Therefore, it is to be considered as inappropriate for notified bodies to be responsible for market surveillance.*

*If a notified body and a market surveillance authority come under the same superior authority, the lines of responsibility shall be so organised that there is no conflict of interest between these activities*

# Requirements for notified bodies

## ➤ Liability and financing

*Notified bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.*

*The scope and overall financial value of the liability insurance shall correspond to the level of risks associated with the activities of the notified body. The notified body is expected to be able to show what factors have been taken into account when determining the necessary level of the contracted insurance.*

# Requirements for notified bodies

## ➤ Identification number of notified bodies

*The notified body, as proprietor of its identification number that is intended for use in combination with the CE marking, shall have a policy governing its protection and use.*

# Requirements for notified bodies

## ➤ Structural requirements

- *Role as notified body*
- *Cooperation with other bodies*

# Requirements for notified bodies

- **Resource requirements**
  - Personnel
  - Monitoring
  - Equipment
  - Outsourcing (subcontracting)

# Requirements for notified bodies

➤ **Information requirements and confidentiality**

➤ ***Operational obligations for notified bodies***

*Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonisation legislation.*

# Requirements for notified bodies

- **Assessment criteria**
- **Preparation for assessment and contract review**
- **Assessment**
- **Decision on conformity and assessment report**
- **Records**
- **Management system requirements**