

## **Translation from Finnish**

**Legally binding only in Finnish and Swedish**

**Ministry of Economic Affairs and Employment, Finland**

### **Act on Notified Bodies Concerning Certain Product Groups**

*(278/2016; amendments up to 1136/2016 included)*

By decision of Parliament, the following is enacted:

#### **Section 1 (1136/2016)**

##### **Scope of application**

This Act contains provisions on the approval of conformity assessment bodies for products falling within the scope of application of the Lift Safety Act (1134/2016), Measuring Instruments Act (707/2011), Pressure Equipment Act (1144/2016), Act on the Conformity of Pyrotechnic Articles (180/2015), Act on the Conformity of Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (1139/2016), Act on the Conformity of Explosives (1140/2016), Electrical Safety Act (1135/2016) and chapter 30 of the Information Society Code (917/2014) as notified bodies and on these bodies' operational obligations.

#### **Section 2 (1136/2016)**

##### **Relationship with other legislation**

Provisions on the national accreditation system for conformity assessment bodies are laid down in the Act on Verifying the Competence of Conformity Assessment Services (920/2005).

Provisions on the market surveillance of products falling within the scope of application of this Act are laid down in the Act on the Market Surveillance of Certain Products (1137/2016). Provisions on the market surveillance of radio equipment are laid down in chapter 30 of the Information Society Code.

#### **Section 3**

##### **Definitions**

For the purposes of this Act:

- 1) *notified body* means a body established in Finland which is designated by a Finnish public authority and notified to the European Commission and whose task is to offer product conformity assessment services when national legislation based on Union harmonisation legislation is applied;
- 2) *conformity assessment body* means a body that performs calibration, testing, certification and inspection or other conformity assessment activities;
- 3) *manufacturer* means any natural or legal person who manufactures a product or products, or has such a product designed or manufactured, and markets that product under his or her name or trademark;
- 4) *accreditation certificate* means 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;
- 5) *conformity assessment* means the process demonstrating whether the essential safety requirements relating to the product assessed have been fulfilled;
- 6) *Union harmonisation legislation* means any Union legislation harmonising the conditions for the marketing of products;
- 7) *authorised representative* means any natural or legal person established within the Union who has received a written mandate from the manufacturer to act on his or her behalf in relation to specified tasks.

## **Section 4**

### **Application for approval as a notified body**

A conformity assessment body established in Finland shall apply for approval as a notified body to a competent authority. The application shall be accompanied by information and evidence of compliance with the requirements set for the assessment body concerning the conformity

assessment activities, the conformity assessment module or modules and the product for which the body claims to be competent.

The assessment body may demonstrate its compliance with the requirements set by 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 with an accreditation certificate issued by the accreditation unit (FINAS Finnish Accreditation Service) of the Finnish Safety and Chemicals Agency, unless otherwise laid down elsewhere by law. Where the assessment body cannot provide an accreditation certificate, it shall provide the authority with the documentary evidence necessary for the authority's evaluation of the applicant's compliance with the requirements laid down on the basis of Union harmonisation legislation for approval as a notified body.

## **Section 5 (1136/2016)**

### **Competent authority**

The Ministry of Economic Affairs and Employment is the competent authority for applications concerning the designation as a notified body of conformity assessment bodies for products falling within the scope of application of the Lift Safety Act, Measuring Instruments Act, Pressure Equipment Act, Act on the Conformity of Pyrotechnic Articles, Act on the Conformity of Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres, Act on the Conformity of Explosives, and Electrical Safety Act.

The Finnish Communications Regulatory Authority is the competent authority for applications concerning the designation as a notified body of conformity assessment bodies for products falling within the scope of application of the Information Society Code.

The competent authorities monitor the notified bodies approved by them.

## **Section 6**

### **Approval as a notified body and revocation of approval**

The competent authority approves and designates a conformity assessment body as a notified body if the body fulfils the requirements for notified bodies based on Union harmonisation legislation laid down in sections 7–12 and notifies the body to the Commission and Member States

of the European Union. Any significant changes to the information notified shall also be notified to the Commission and Member States.

The approval decision determines the notified body's scope of accreditation, confirms the arrangements relating to the body's monitoring and, where applicable, sets requirements, restrictions and conditions concerning the body's activities to ensure the appropriate performance of tasks. The decision may be issued for a limited period.

Where a notified body no longer meets the requirements laid down or fails to comply with the conditions set in the approval decision or otherwise acts in material violation of provisions, the competent authority shall provide a sufficient period of time for the notified body to take remedial action. The competent authority shall revoke its approval if the notified body has not remedied the matter within the period of time provided.

Where a notified body has ceased its activity or its approval has been revoked, the competent authority shall take appropriate steps to ensure that the files of that body are processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

## **Section 7**

### **General requirements for a notified body**

A notified body shall fulfil the following requirements:

- 1) the body shall be a legal person registered in Finland;
- 2) the body shall be an external expert body independent of the organisation and the product it assesses;
- 3) the body's top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of products or substances which they assess, nor the authorised representative of any of those parties;
- 4) the body and its personnel shall have the requisite technical competence in the specific field;

5) the body shall be capable of carrying out all the conformity assessment tasks assigned to it and for which it has been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

## **Section 8**

### **Requirements for the activities of a notified body**

A notified body shall have at its disposal:

- 1) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- 2) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;
- 3) appropriate policies and procedures in place that distinguish between conformity assessment tasks it carries out as a notified body and other activities;
- 4) procedures for the performance of its activities which take due account 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.

A notified body shall have the capacities necessary to carry out the technical and administrative tasks required for the proper performance of conformity assessment tasks and shall have access to all necessary equipment and facilities.

## **Section 9**

### **Requirements for a notified body's assessment personnel**

The notified body's personnel responsible for carrying out conformity assessment tasks shall have the following:

- 1) sound technical and vocational training covering all the conformity assessment activities in relation to which the notified body has been notified;

2) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

3) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of European Union legislation and of its implementing regulations;

4) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

## **Section 10**

### **Impartiality of a notified body**

A notified body, its top level management and assessment personnel shall be impartial. The remuneration of the top level management and assessment personnel of a notified body shall not depend on the number of assessments carried out or on the results of those assessments.

## **Section 11**

### **A notified body's liability insurance**

A notified body shall have liability insurance that is sufficient taking into account the nature and extent of the activities.

## **Section 12**

### **Presumption of conformity**

Where a notified body demonstrates its conformity with the criteria laid down in the harmonised standards applied in assessment the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements laid down in this Act for a notified body in so far as the applicable standards cover those requirements.

## **Section 13**

### **Subcontracting of tasks or carrying out of tasks by a subsidiary**

Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set for approval as a notified body and shall inform the competent authority accordingly.

The notified body is responsible for the tasks performed by subcontractors or subsidiaries irrespective of their State of establishment.

Tasks may be subcontracted or carried out by a subsidiary only with the agreement of the client.

A notified body shall keep at the disposal of the competent authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the conformity assessment tasks carried out by them.

## **Section 14**

### **General obligations of a notified body and its subsidiary and subcontractor**

A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures provided in the acts referred to in section 1.

Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators and damage to economic operators' property. A notified body shall take account of the size of the undertaking in question, 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. Due care shall be exercised when carrying out conformity assessments.

When performing public administrative tasks referred to in this Act, a notified body or a subsidiary or subcontractor used by it shall comply with the provisions of the Act on the Openness of Government Activities (621/1999), the Act on Electronic Services and Communication in the Public Sector (13/2003), the Administrative Procedure Act (434/2003) and the Language Act (423/2003). Furthermore, provisions on criminal liability as a public official also apply to the personnel of a notified body or a subsidiary or subcontractor used by it when performing tasks referred to in this section. Provisions on liability for damages are laid down in the Tort Liability Act (412/1974).

## **Section 15**

### **A notified body's obligation to provide information to public authorities and other notified bodies**

Notwithstanding the provisions on secrecy of information, a notified body shall provide information to competent authorities about the body's activities and, at an authority's request, also about the activities performed by the body within the scope of application of its notification to the competent authority.

A notified body shall inform the competent authority of the following:

- 1) any refusal, restriction or revocation of an accreditation certificate issued to or approval of the body;
- 2) any circumstances affecting the scope of or conditions for approval of the notified body; and
- 3) any request for information which it has received from market surveillance authorities regarding conformity assessment activities.

A notified body shall provide the competent authority with information about any refusal and restriction of certificates of product conformity assessments issued by the body and any suspension or withdrawal of a previously issued certificate.

A notified body shall provide the other notified bodies carrying out similar conformity assessment activities covering the same products with relevant information on negative and, on request, also positive conformity assessment results.

## **Section 16**

### **A notified body's obligation to participate in standardisation activities and the coordination group's work**

A notified body shall participate in the relevant standardisation activities and the work of the notified body coordination group established under the Union harmonisation legislation. Where this is not possible, the body shall ensure that its assessment personnel are informed of the relevant standardisation activities and the coordination group's work.

## **Section 17**

### **Appeal**

Pursuant to the provisions of the Administrative Judicial Procedure Act (586/1996), an appeal against a decision referred to in this Act may be filed with the Administrative Court. An Administrative Court decision may be appealed against only if a leave to appeal is granted by the Supreme Administrative Court.

## **Section 18**

### **Entry into force**

This Act enters into force on 27 April 2016.