

# **REGULATION ON CONFORMITY ASSESSMENT BODIES AND NOTIFIED BODIES**

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## **CHAPTER I**

### **Objective, Legal Basis and Definitions**

#### **Objective**

**Article 1-** (1) The objective of this Regulation is to set out minimum qualifications, operational rules and procedures and notification -to the relevant parties in accordance with Turkey's international obligations- procedures of the conformity assessment bodies, including bodies notified among them, which examine and certify the conformity of a product to the relevant technical legislation by means of conformity assessment.

#### **Legal basis**

**Article 2-** (1) This Regulation is based on Article 14 of Law No. 4703 on the Preparation and Implementation of Technical Legislation on Products, dated 29/6/2001.

#### **Definitions**

**Article 3-**(1) For the purposes of this Regulation the following definitions shall apply:

- a) "Accreditation" shall mean an official 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 sectorial schemes, to carry out a specific conformity assessment activity.
- b) "Ministry" shall mean Ministry of Economy.
- c) "Peer evaluation" shall mean the evaluation process of a national accreditation body carried out by other national accreditation bodies which are signatories to an international agreement which the evaluated national accreditation body too is a signatory to or an applicant for being a party of, in accordance with the specified rules in context of that agreement.
- ç) "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.
- d) "Commission" shall mean the European Commission.
- e) "Module" shall mean each conformity assessment procedure specified in Annex 3 of the "Regulation on CE Marking" which was put into force by the Decision of the Council of Ministers of 16/12/2011 and No.2011/2588.
- f) "Notified bodies" shall mean the conformity assessment body established in Turkey, designated by the competent authority in accordance with this Regulation and relevant technical legislation to perform conformity assessment procedures laid down in a technical regulation, and notified to the Commission.

g) “Making available on the market” shall mean any supply of a product for distribution, consumption or use on domestic market in the course of a commercial activity, whether in return for payment or free of charge.

ğ) “Placing on the market” shall mean the first making available of a product on domestic market.

h) “Standard” shall mean any voluntary document adopted by a national or international standardisation body, aiming to provide an optimum level of order under the existing conditions, laying down -for common and repeated use- one or more of the characteristics, processing or production methods of a product or the related terminology, symbols, packaging, marking, labelling and conformity assessment procedures.

ı) “Technical regulation” shall mean any mandatory legislation laying down one or more of the characteristics or processing and production methods of a product or the related terminology, symbols, packaging, marking, labelling and the conformity assessment procedures.

ı) “Technical specification” shall mean any document that prescribes technical requirements to be fulfilled by a product, process or service.

j) “TÜRKAK” shall mean Turkish Accreditation Agency.

k) “Conformity assessment” shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

l) “Conformity assessment body” shall mean a body established in Turkey that performs conformity assessment activities including calibration, testing, certification and inspection.

m) “Harmonised standard” shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to the Regulation on the Notification of the Technical Legislation and Standards Between Turkey and the European Union published in Official Gazette, dated 3/4/2002 no. 24715.

n) “Harmonized national standard” shall mean a standard adopted by Turkish Standards Institute as a Turkish Standard to transpose a harmonised standard.

o) “Competent authority” shall mean a public body authorized by a law or a regulatory act to draw up or implement legislation concerning to a specific product or a product group or to inspect them.

ö) “Authorised representative” shall mean any natural or legal person established in Turkey who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

## **CHAPTER II**

### **General Principles Regarding Conformity Assessment Bodies**

#### **Conformity assessment bodies**

**Article 4-** (1) Without prejudice to the provisions of this Regulation, the minimum criteria regarding the competence of the bodies performing conformity assessment shall be specified in the relevant technical regulations and/or in the regulatory act concerning the designation.

(2) Conformity assessment bodies shall be responsible to the competent authority which designates them for the activities set out in the relevant technical regulation.

(3) Conformity assessment bodies shall;

a) carry out their activities, in accordance with the rules and procedures laid down in this Regulation and in the relevant technical regulations, in a transparent, independent and impartial manner without creating any discrimination and unnecessary burdens to their clients,

b) keep all documents and records concerning their activities for a period laid down in the relevant technical regulation, and in case that no such period is specified, for 10 years from the date that they are drawn up and submit them to the competent authorities upon their request.

(4) Competent authorities shall monitor and inspect conformity assessment bodies which they have designated to see whether they continue to maintain the qualifications, to fulfil obligations and to carry out activities in accordance with the requirements laid down in this Regulation and in the relevant technical regulation.

(5) In case of any non-compliances found out as a result of the monitoring and inspection specified in paragraph 4, the activities of the conformity assessment body within the context of the relevant technical regulation shall be temporarily restricted or suspended by the competent authority. If these non-compliances are not corrected within the period specified in the relevant technical regulation or in case that no such period is specified, in a period of minimum 20, maximum 60 working days, exact duration of which determined by the competent authority taking into account the criteria such as;

a) the gravity of the risks that the product assessed may present,

b) the proximity of the danger,

c) the characteristics of the users and consumers

the competent authority shall stop activities of the conformity assessment body temporarily or permanently. The decisions taken by the competent authority shall be notified to the Commission via the Ministry when it is required by national legislation or international obligations.

(6) Conformity assessment bodies of which activities have been stopped by the competent authority or by themselves shall hand over documents and records relating to the conformity

assessment activities they have performed to the competent authority to be transferred to another conformity assessment body operating in the same area. The responsibilities of these conformity assessment bodies relating to the documents and records concerned shall continue throughout the period laid down in the relevant technical regulation, and in case that no such period is specified, for 10 years starting from the date that these documents are drawn up. The competent authority shall take necessary measures to ensure that the conformity assessment body fulfils these responsibilities.

(7) Accreditation of the conformity assessment bodies established in Turkey shall be performed by TÜRKAK. Conformity assessment bodies may apply to the national accreditation bodies of the Member States of the European Union which have successfully undergone peer evaluation in case TÜRKAK does not perform accreditation or its peer evaluation has not been finalized or has not undergone successfully regarding the conformity assessment procedure for which accreditation is sought.

(8) Where TÜRKAK receives a request from a conformity assessment body established in a Member State of the European Union pursuant to paragraph 7, TÜRKAK shall inform the national accreditation body of the Member States of the European Union in which the requesting conformity assessment body is established. In such cases, the latter national accreditation body may participate in the accreditation procedure carried out by TÜRKAK as an observer, without prejudice to the principle of reciprocity.

(9) TÜRKAK may request from a national accreditation body of a Member State of the European Union which has successfully undergone peer evaluation to carry out part of the assessment activity within the accreditation it performs. In such a case, the accreditation certificate shall be issued by TÜRKAK.

(10) The competent authorities, without prejudice to the principle of reciprocity, recognise the equivalence of the services delivered by the national accreditation bodies of the Member States of the European Union which have successfully undergone peer evaluation and accept the accreditation certificates of those bodies and attestations issued by the conformity assessment bodies, established in the Member States of the European Union, accredited by them.

## **CHAPTER III**

### **Special Provisions for Notified Bodies**

#### **Requirements for the competent authorities notifying conformity assessment bodies**

**Article 5-** (1) Where a relevant technical regulation requires, competent authorities shall designate an appropriate number of bodies among the conformity assessment bodies which are established in Turkey and which have applied for being designated, in accordance with the rules and procedures laid down in this Regulation, in the relevant technical regulation and if any, in the regulatory act concerning the designation.

(2) The competent authorities which designate, monitor and inspect notified bodies shall take all necessary measures and make arrangements to ensure following requirements are met;

a) All administrators and personnel of the notifying authority shall have no conflict of interest with the candidate notified bodies.

b) Each decision relating to the designation of a notified body shall be taken by the competent personnel different from those who have carried out the assessment of that notified body.

c) None of the units, administrators and personnel of the notifying authority involving the assessment or the notifying process of the notified bodies shall not offer or provide any activities –particularly consultancy services- that conformity assessment bodies perform on a commercial or competitive basis.

ç) All administrators and relevant personnel of the notifying authority shall safeguard the confidentiality of the information they obtain.

d) All administrators and personnel of the notifying authority shall have sufficient competency and qualifications and shall be in a sufficient number to carry out properly their task of monitoring of the notified bodies they have designated.

(3) The procedures followed by the competent authorities for the assessment, designation and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto shall be notified to the European Commission through the Ministry.

#### **Application for notification**

**Article 6 –** (1) The application of a conformity assessment body established in Turkey to the competent authority to be a notified body shall be accompanied by a description of the conformity assessment activities, module or modules, the product or products for which that body claims to be competent and as well as by an accreditation certificate where one exists, issued as referred to in Article 4(7) indicating that the conformity assessment body meets the requirements laid down in Article 7.

(2) The conformity assessment bodies which do not have accreditation certificate as referred to in Article 4(7) shall submit documentary evidence which demonstrates that they meet the requirements for the notified bodies as laid down in Article 7 and which enables regular monitoring of their compliance to these requirements, when they apply to competent authorities to be notified.

#### **Requirements relating to notified bodies**

**Article 7-** (1) Without prejudice to the provisions of relevant technical regulation, a conformity assessment body designated for the purposes of notification shall meet the following requirements:

a) A conformity assessment body shall be established under national legislation and have legal personality.

b) A conformity assessment body must be a third-party body independent of the undertaking or the product it assesses. A body belonging to a party or chamber of industry, commerce or profession or a professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

c) A conformity assessment body;

1) itself, its top level management and the personnel shall not be the designer, manufacturer, supplier, purchaser, owner, -without prejudice to the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes- user or maintainer of the products which they assess, nor the authorised representative of any of those parties;

2) itself, its top level management and the personnel shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity, particularly consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

3) shall take all necessary measures to ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

ç) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons with an interest in the results of those activities.

d) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the relevant technical regulation and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary;

1) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

2) descriptions of procedures followed in the conformity assessment to ensure the transparency and the ability of reproduction of those procedures;

3) appropriate policies and procedures to distinguish between the tasks it carries out as a notified body and other activities;

4) procedures for the performance of activities which take due account of the size of an undertaking which requests conformity assessment, 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.

e) The conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

f) The personnel responsible for carrying out conformity assessment activities shall have the following qualifications;

1) Sound technical and vocational training covering all conformity assessment activities in relation to which the conformity assessment 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 and adequate knowledge and understanding of the essential requirements and the relevant provisions of technical regulations and of the applicable harmonised national standards;

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

g) Provided that it covers the conformity assessment activities that the notified body carries out and unless the liability is assumed by the state finance; a notified body shall take out liability insurance of which the coverage amount is determined by the competent authority which takes due account of such criteria as the risks that the product assessed has due to its nature and may present in a duration of its normal use, and the characteristics of the conformity assessment activity, the users and consumers concerned and the size of the sector.

ğ) The conformity assessment body shall guarantee the impartiality of itself, its top level management and of the assessment personnel. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

h) The personnel of a conformity assessment body shall protect professional secrecy and intellectual property rights with regard to all information obtained in carrying out their tasks under relevant technical regulation except where providing information and documents to the competent authorities is required by legislation.

ı) Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established by the European Union under the relevant harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

(2) Where a conformity assessment body demonstrates its conformity with the harmonised national standards meeting the requirements specified in this article, it shall be presumed to comply with the requirements set out in this article.

### **Preference for accreditation**

**Article 8-** (1) Competent authorities shall prefer the conformity assessment bodies accredited as in Article 4(7) when they designate notified bodies. Competent authorities shall designate conformity assessment bodies which are not accredited in accordance with Article 4(7) for the notification purposes only when documentary evidence referred to in Article 6(2) and valid reasons exist.

### **Notification procedure and designation**

**Article 9-** (1) The requisite documentary evidence relevant to candidate notified body shall be sent to the Commission through the Ministry. The notification includes all details about the relevant conformity assessment activities, module or modules, product or products assessed and the competence of the body. When a competent authority designate a conformity assessment body which is not accredited in line with Article 4(7) as a notified body, the competent authority shall send documentary evidence which make available the verification of the competence of the body in the context of the relevant technical regulation, together with an official statement demonstrating valid reasons taken into account in the designation to the Ministry to transfer them to the Commission when necessary.

(2) Within two weeks of a notification to the Commission where an accreditation certificate is used for the assessment of the competence of the candidate notified body and within two months where an accreditation certificate is not used, the Commission and the Member States of the European Union may request additional information about or raise an objection to the competence of the body notified.

(3) The competent authorities may contact with the Ministry for their requests for additional information about or objection to the competence of the candidate notified body designated by a Member State of the European Union, which then be communicated to the Commission in the period referred to in the second paragraph.

(4) After an identification number to the notified conformity assessment body is allocated by the Commission, the competent authority shall designate this body as a notified body. The decision on the designation shall be published in the Official Gazette as soon as possible.

(5) Any changes in the activities and qualifications of the conformity assessment bodies in relation to its notification shall be notified to the Commission through the Ministry.

### **Obligations of notified bodies**

**Article 10-** (1) In addition to the obligations of conformity assessment bodies laid down in Article 4, notified bodies shall fulfil the following obligations;

a) Where a notified body finds that requirements laid down in the relevant technical regulation or harmonised national standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer take appropriate corrective measures and shall not issue a conformity certificate.

b) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall, in proportion to the non-compliance, suspend or withdraw the certificate if necessary.



c) Where corrective measures in relation to the non-compliance referred to in subparagraph (b) are not taken or do not have the required effect, the notified body shall, in proportion to the non-compliance, restrict the scope or validity period of the certificate or suspend or withdraw the certificate.

ç) Notified bodies shall inform the notifying authority of any refusal, restriction, suspension or withdrawal of a certificate; any circumstances affecting the scope of and conditions for notification; any request for information which they have received from market surveillance authorities regarding conformity assessment activities; on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including activities outside Turkey and subcontracting.

d) Notified bodies shall provide the other bodies notified under the same technical regulation carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

e) Notified bodies shall fulfil other obligations laid down in the relevant technical regulation.

#### **Sanctions for non-compliant notified bodies**

**ARTICLE 11-** (1) Where any non-compliance is found as a result of monitoring and inspection referred to in Article 4(4), the competent authority shall restrict or suspend the activities of the notified bodies. If these non-compliances are not corrected within the period specified in the relevant technical regulation or in case that no such period is specified in a period of minimum 20, maximum 60 working days, exact duration of which determined by the competent authority taking into account the criteria such as;

- a) the gravity of the risks that the product assessed may present,
- b) the proximity of the danger,
- c) the characteristics of the users and consumers,

the competent authority shall withdraw the notification of these bodies within the context of the relevant technical regulation.

(2) Decisions taken by competent authorities concerning restriction, suspension and withdrawal of the notifications of conformity assessment bodies shall be published in the Official Gazette. The Commission shall be informed of these decisions through the Ministry.

(3) A notified body of which activities have been restricted or suspended or notification has been withdrawn or of which activities have ceased by its own consent shall hand over documents and records relating to the conformity assessment activities it has performed to the competent authority to be transferred to another notified body operating in the same area. However, the responsibility of the former notified body for keeping and submitting of the documents and records concerned to the competent authority upon its requests shall continue throughout the period as laid down in subparagraph (b) of Article 4(3). The competent authority shall take all necessary measures to ensure that the notified body has fulfilled these obligations.

(4) Where the Commission or a Member State of the European Union requests any verification of the technical competency and the conformity to the relevant technical regulation of a notified body which Turkey has designated, the procedure laid down in Article 4 of the Turkey-EU Association Council Decision, no. 1/2006, shall be followed. Competent authorities shall provide all necessary information and documents to the Ministry, ensure cooperation with other parties and take all necessary measures.

#### **Coordination and cooperation of notified bodies**

**Article 12** – (1) Competent authorities may assemble the conformity assessment bodies they have notified, to discuss the problems that these bodies have faced during the conformity assessment activities they performed and to find out their solutions. The findings of these meetings shall be communicated to the Ministry and other competent authorities, when necessary.

### **CHAPTER IV**

#### **Subsidiaries, Subcontractors and Accredited In-house Bodies**

##### **Subsidiaries and subcontractors**

**Article 13** – (1) 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 out in Article 7 and shall inform the notifying competent authority accordingly.

(2) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. The certificates issued as a result of the conformity assessment activities in which subcontractors or subsidiaries are involved shall be issued by the contracting notified body itself.

(3) Conformity assessment activities may be carried out by a subsidiary or a subcontractor only with the agreement of the client.

(4) Notified bodies shall keep at the disposal of the notifying competent authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the relevant technical regulation in a period as laid down in subparagraph (b) of Article 4(3).

(5) Competent authorities may withdraw the notification due to the non-compliances of the subcontractor or the subsidiary of a notified body.

##### **Foreign notified bodies' subsidiaries and subcontractors in Turkey**

**Article 14-** (1) Competent authorities, in the scope of their jurisdiction, shall inspect the entities such as subsidiaries and subcontractors which operate in Turkey, on behalf and under the responsibility of the notified bodies established abroad, based on the relevant provisions laid down in this Regulation and in the relevant technical legislation upon complaint or its own initiative. In this inspection, competent authorities shall examine the contracts relating to the devolution of authority and division of tasks between the notified body established abroad and the subsidiaries and subcontractors of this body which perform conformity assessment activity in Turkey, when necessary.

(2) It shall be presumed that the subsidiaries and subcontractors referred to in the first paragraph have the requisite technical competence; where these entities are accredited in line with Article 4(7) to cover their activities or where the notified body established abroad has an accreditation certificate issued by a national accreditation body of a Member State of the European Union which has successfully undergone peer evaluation and this certificate covers its subsidiaries and subcontractors established in Turkey as well.

(3) The competent authority shall not perform any inspection on the technical competency, in case the accreditation certificates referred to in the second paragraph are present. This provision, however, shall not preclude the competent authority to carry out inspection anyway where serious findings and evidences about non-compliances of the subsidiaries and subcontractors referred to in the first paragraph exist.

(4) When the competent authority finds out a non-compliance of the subsidiaries and subcontractors concerned as a result of the inspection specified in the first paragraph or market surveillance the authority performed, it may request the competent authorities of the Member State which notified the conformity assessment body to verify technical competence of this notified body and its subsidiaries or subcontractors operating in Turkey, through the Ministry, providing documentary evidence as set out in Article 4 of the Turkey-EU Association Council Decision, no.1/2006. Where the accreditation certificates referred to in the second paragraph are present, the competent authority shall inform the relevant accreditation body as well, through the Ministry.

(5) In case that these non-compliances are not corrected in a reasonable period, the procedure laid down in Article 4 of the Turkey-EU Association Council Decision, no. 1/2006 shall be followed.

#### **Accredited in-house bodies**

**Article 15-** (1) An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in A1, A2, C1 and C2 modules, provided that it constitutes a completely separate part of the undertaking and does not participate in the design, production, supply, installation, use or maintenance of the products it assesses.

(2) An accredited in-house body shall meet the following requirements;

a) it shall be accredited in accordance with Article 4(7);

b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess nor shall they engage in any activity that might conflict with their independence of judgement or integrity in relation to their assessment activities;

ç) the body shall supply its services exclusively to the undertaking of which it forms a part.

(3) An accredited in-house body shall not be notified to the Commission or the Member States of the European Union, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the competent authority, upon request.

(4) The competent authorities may inspect accredited in-house bodies, when necessary. The activities of the accredited in-house bodies which do not meet the requirements referred to paragraph 2, shall be ceased by the competent authority.

## **CHAPTER V**

### **Miscellaneous Provisions**

#### **The Equivalence of the foreign notified bodies**

**Article 16-** (1) The notified bodies established in a Member State of the European Union are accepted equivalent to the ones established in Turkey, without prejudice to the principle of reciprocity.

(2) Those notified bodies established outside Turkey and the European Union shall be deemed equivalent to the ones established in Turkey, where a mutual recognition agreement between the European Union and the third country in which the notified body established exists and a parallel agreement between Turkey and that third country has been concluded and entered into force.

#### **Application**

**Article 17-** (1) The provisions of this Regulation shall be implemented together with the relevant technical regulations.

#### **Penalties**

**Article 18-** (1) For the persons who infringed the provisions of this Regulation, fines laid down in Law no 4703 shall be applied.

#### **Repealed legislation**

**Article 19-** (1) The Regulation on Conformity Assessment Bodies and Notified Bodies, which was put into force by the Decision of Council of Ministers of 13/11/2001 and No.2001/3531, shall be repealed. References to the repealed Regulation shall be construed as references to this Regulation.

#### **The existing accreditation certificates**

##### **PROVISIONAL ARTICLE – 1**

The accreditation certificates of the conformity assessment bodies issued before this Regulation entered into force shall remain valid until the date of their expiry, but no later than 31 December 2014. The provisions of this Regulation shall, however, be applied in the case of their extension or renewal.

#### **Entry into force**

**Article 20-** (1) This Regulation shall enter into force on the date of its publication.

#### **Implementation**

**Article 21 -** (1) This Regulation shall be implemented by the Council of Ministers.