

# **LAW ON TECHNICAL REQUIREMENTS AND CONFORMITY ASSESSMENT OF PRODUCTS WITH**

## **I. GENERAL PROVISIONS**

### **Subject-matter of the Law Article 1**

This Law shall govern the manner of prescribing of technical requirements for products, procedures of conformity assessment of products with prescribed requirements (hereinafter referred to as the: conformity assessment), adoption of technical regulations, supervision of fulfillment of requirements referred to in technical regulations, validity of foreign documents on conformity and conformity marks.

### **Prescribing Technical Regulations Article 2**

By adopting technical regulations for products or groups of products, the following in particular shall be prescribed:

- 1) technical requirements that must be fulfilled by products placed into circulation or used;
- 2) rights and obligations of companies, other legal persons, entrepreneurs and natural persons that place products into circulation or use;
- 3) conformity assessment procedures;
- 4) requirements for the body that performs a conformity assessment;
- 5) documents accompanying products placed into circulation or use;
- 6) mark and manner of marking of products.

### **Placing in Circulation and Use of a Product Article 3**

Products subject to technical regulation shall be placed into circulation only if, in accordance with prescribed technical requirements, their conformity with such technical regulation has been assessed according to the prescribed procedure and if the product is marked in accordance with the regulation in force and if it is accompanied with prescribed documents.

### **Definitions Article 4**

The terms used in this Law shall have the following meaning:

- 1) **“product”** shall mean a result of a process (hardware, software, process material or a service) that was designed, manufactured or obtained in any other manner, regardless of the processing level and intended for placing in the circulation or use;

- 2) **“technical regulation”** shall mean a document that contains technical requirements, directly or by reference to Montenegrin standard, technical specification or the rules of the practice, or that includes the contents said documents, as well as conformity assessment procedures;
- 3) **“technical requirement”** shall prescribe characteristics of a product or a method of production or processing of such a product, including administrative provisions applicable to the product, that are by nature obligatory and compliance with which is mandatory. Technical requirement may also contain or to exclusively refer to terminology, symbols, requirements with respect to packaging, designating and indicating, if applicable to a product, method of production or processing.
- 4) **“technical specification”** shall mean a document that defines technical requirements that a product must fulfill;
- 5) **“placing a product into circulation”** shall mean for the first time selling, offering for sale, or entering into any other commercial transaction involving a product;
- 6) **“use”** shall mean the first use of a product by an end-user in the Republic of Montenegro (hereinafter referred to as: Montenegro)
- 7) **“supplier”** shall mean the manufacturer, its representative established in Montenegro, importer or any company, other legal person, entrepreneur or other natural person that places a product into circulation or makes it available for use;
- 8) **“conformity assessment”** shall mean any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled;
- 9) **“conformity assessment body”** shall mean an independent laboratory, certification body, control authority, or other authority that performs a conformity assessment;
- 10) **“certificate of conformity”** shall mean a declaration, test report, certificate or other document attesting to the conformity of a product with the relevant technical regulation;
- 11) **“conformity mark”** shall mean a mark or indication affixed to the product indicating compliance with a relevant technical regulation;
- 12) **“notification”** shall mean providing to the relevant international organizations the information required by international agreements ratified by Montenegro, and includes the notification requirement of the WTO Agreement on Technical Barriers to Trade;
- 13) **“interested parties”** shall have the meaning referred to in the law that regulates general administrative procedure and shall include exporters and officials of exporting countries, notably WTO Members.

**Justification for Technical Regulations**  
**Article 5**

Technical regulations shall be adopted only for the purpose of protecting human, animal and plant life, health and safety, environment protection, protection of property and protection of other public interests.

**Principles Applicable to Preparation, Adoption and Application  
Of Technical Regulations and Conformity Assessments Procedures**  
**Article 6**

- (1) Technical regulations and conformity assessment procedures shall not be prepared, adopted or applied so as to create unnecessary obstacles to international trade, nor have such effect, nor shall they be more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create.
- (2) Conformity assessment procedures shall be undertaken and completed as expeditiously as possible, and in a no less favorable order for products originating outside Montenegro as for domestic like products.
- (3) The standard processing period for each conformity assessment procedure shall be published, or the anticipated processing period shall be communicated to the applicant upon request.
- (4) Products originating from a country signatory of the relevant international agreement shall be accorded a treatment no less favorable than that accorded to like products of domestic origin or to like products originating from any other country
- (5) Where required by technical regulations and where relevant international standards exists or their adoption is in its final phase, such standards or the relevant parts thereof shall be used as a basis for technical regulation, except where they would be inefficient or inappropriate way to reach the legitimate goals envisaged.
- (6) Wherever appropriate, technical regulations shall specify product requirements in terms of performance rather than design or descriptive characteristics.
- (7) Technical regulation shall be revoked or amended if the circumstances or objectives giving rise to its adoption no longer exist or if changed circumstances or objectives can be addressed in a less trade-restrictive manner.
- (8) Upon request, the ministry responsible for the quality infrastructure (hereinafter referred to as: the Ministry) shall provide information to interested parties concerning the justification for any technical regulation that may have a significant impact on international trade

**Obligation to Inform and Notify**  
**Article 7**

- (1) The Ministry shall establish an enquiry point able to answer all reasonable enquiries from interested parties and to provide the relevant documents concerning:

- 1) any technical regulations or standards adopted or proposed in Montenegro;
  - 2) any conformity assessment procedures conducted within Montenegro;
  - 3) the participation of officials in Montenegro in international and regional standardizing bodies and conformity assessment systems, or in bilateral or multilateral arrangements relevant to technical regulations and standards; and
- (2) Any fees charged for providing the information referred to in paragraph 1 of this Article shall be identical to domestic and foreign parties, taking into consideration the real cost of delivery.
- (3) The Ministry shall administer the notification procedure with respect to technical regulations and conformity assessment procedures in accordance with the obligations arising from relevant international agreements.
- (4) The notification procedure shall be regulated by a separate regulation.

### **Preparation, Adoption and Application of Technical Regulations**

#### **Article 6**

Preparation, adoption and application of technical regulations and conformity assessment procedures shall be based on the following principles: .

- 1) With respect to technical regulations, imported products shall be accorded treatment no less favorable than that accorded to like products of domestic origin or to like products originating from any other country.
- 2) Technical regulations and conformity assessment procedures shall not be prepared, adopted or applied so as to create unnecessary obstacles to international trade, nor have such effect, nor shall they be more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create.
- 3) Technical regulation shall be revoked or amended if the circumstances or objectives giving rise to its adoption no longer exist or if changed circumstances or objectives can be addressed in a less trade-restrictive manner.
- 4) Technical regulations shall incorporate relevant international standards except where such international standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued.
- 5) Upon request, the Ministry shall provide information to interested parties concerning the justification for any technical regulation that may have a significant impact on international trade.
- 6) Wherever appropriate, technical regulations shall specify product requirements in terms of performance rather than design or descriptive characteristics.

## **Technical Regulations and International Standards**

### **Article 7**

- (1) Where a proposed technical regulations is not based on or is not in accord with an international standard, the Ministry shall:
  - 1) Publish a notice at an early stage of intent to introduce such a technical regulation;
  - 2) At an early appropriate stage, notify interested parties of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale;
  - 3) Upon request, provide copies of the proposed technical regulation, and where possible identify parts that in substance deviate from relevant international standards; and
  - 4) Without discrimination, allow reasonable time for interested parties to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.
- (2) Where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, requirements referred to in paragraph 1 of this Article may be disregarded, provided that the Ministry:
  - 1) upon adoption of a technical regulation dealing with such a problem, immediately notifies interested parties of the technical regulation and its objective and rationale, and the nature of the urgent problem;
  - 2) upon request, provides copies of the technical regulation; and
  - 3) without discrimination, allows interested parties to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account

## **II. PRESCRIBING TECHNICAL REQUIREMENTS**

### **Responsibility**

#### **Article 8**

- (1) Ministries responsible for the areas that have to be regulated by the technical regulation (hereinafter referred to as: responsible ministries) shall prepare and adopt technical regulations in accordance to principles established by Article 6 of this Law and in compliance with the obligations arising from bilateral and multilateral agreements on prevention or removal barriers to international trade when necessary to harmonize technical regulations with those of the European Union and technical regulations within the framework of international agreements binding on Montenegro.
- (2) Where a proposed technical regulation is not based on or is not in accord with an international standard, the responsible ministries shall:
  - 1) publish a notice at an early stage of intent to introduce such a technical regulation;
  - 2) at an early appropriate stage, notify interested parties of the products to be covered by the proposed technical regulation, together with an indication of its objective and rationale;

- 3) Upon request, provide copies of the proposed technical regulation, and where possible identify parts that in substance deviate from relevant international standards; and
  - 4) Without discrimination, allow reasonable time for interested parties to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.
- (3) The manner of preparation and adoption of technical regulations shall be regulated by a separate regulation.
  - (4) Technical regulations adopted under this Law shall be published in the “Official Gazette of the Republic of Montenegro”.
  - (5) The shall become effective not earlier than six months after its publication in the “Official Gazette of the Republic of Montenegro”.
  - (6) Where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, the time period referred to in paragraph 4 of this may be shortened, provide that the responsible ministry:
    - 1) upon adoption of a technical regulation or a conformity assessment procedure dealing with such a problem, immediately notifies interested parties of the technical regulation or a conformity assessment procedure and its objective and rationale, and the nature of the urgent problem;
    - 2) upon request of interested parties, provides copies of the technical regulation or a conformity assessment procedure ; and
    - 3) without discrimination, allows interested parties to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

### **Conformity of a Product with a Technical Regulation**

#### **Article 9**

- (1) A technical regulation may provide that a conformity of a product is assumed if it meets requirements of a standard referred to in the technical regulation.
- (2) A conformity of a product referred to in paragraph 1 of this Article may be established in any other manner.

#### **Article 10**

In the course of preparing a technical regulation, upon the request of responsible ministries the Institute for Standardization of Montenegro shall provide information as to whether an appropriate Montenegrin standard exists or is pending adoption, or whether European or international standard exist in the area to be governed by the technical regulation.

### **III. REGISTER OF TECHNICAL REGULATIONS**

#### **Article 11**

- (1) The Ministry shall maintain a Register of Technical Regulations as a public record.

- (2) The contents and the manner of maintaining the Register of Technical Regulations shall be prescribed in a separate regulation.

#### **IV. CONFORMITY ASSESSMENT PROCEDURES**

##### **Obligations of the Supplier Article 12**

- (1) Technical regulations shall specify the products for which a supplier shall, before placing them into circulation:
- 1) apply a conformity assessment procedure;
  - 2) issue or provide a certificate of conformity;
  - 3) maintain technical documentation in the prescribed volume, form and terms; and
  - 4) mark the products with prescribed conformity marks.
- (2) Conformity assessment procedures may be prescribed directly in technical regulations or indirectly in standards to which technical regulations refer or in technical specifications.
- (3) The manner of conformity assessment shall be prescribed by separate regulation

##### **Methods of Conformity Assessment Article 13**

- (1) A conformity assessment referred to in Article 12 of this Law may be accomplished by application of one procedure, a number of procedures or a combination of different conformity assessment procedures, including the following:
- 1) an independent conformity assessment of products by the producer;
  - 2) conformity assessment of products performed by a conformity assessment body on one or statistically chosen sample from the production process;
  - 3) a producer's quality management system; or
  - 4) supervision of a producer's quality management system by a conformity assessment body.
- (2) In any conformity assessment procedure, the conformity assessment body shall
- 1) promptly examine the completeness of the documentation and inform the applicant in a precise and complete manner of all deficiencies;
  - 2) transmit the results of the assessment to the applicant as soon as possible, in a precise and complete manner so that corrective action may be taken if necessary;
  - 3) even when the application has deficiencies, proceed as far as practical with the assessment if the applicant so requests;
  - 4) upon request, inform the applicant of the stage of the procedure, with any delay being explained.
  - 5) respect the confidentiality of information about products originating outside Montenegro arising from or supplied in connection with conformity assessment procedures in the same way as for domestic like products, and in such a manner that legitimate commercial interests are protected.

- (3) Details of procedures referred to in paragraph 1 of this Article shall be prescribed in a separate regulation.

**Changed Specifications**  
**Article 14**

Whenever the specifications of a product are changed subsequent to the determination of its conformity with an applicable technical regulation, the conformity assessment of the modified product shall be limited to determine whether the product still conforms to the applicable technical regulation.

**Conformity Mark**  
**Article 15**

- (1) A conformity mark shall be placed on products that conform with technical regulations as required by such regulations or a relevant conformity assessment procedure.
- (2) Form, content and appearance of the conformity mark shall be prescribed in a separate regulation.

**V. CONFORMITY ASSESSMENT BODY**

**Requirements for Conformity Assessment Body**  
**Article 16**

A technical regulation shall specify the conditions that must be fulfilled by a relevant conformity assessment body, notably:

- 1) professional competency of personnel;
- 2) equipment;
- 3) independence and impartiality in the conformity assessment procedure;
- 4) safeguard business secrets;
- 5) accountability for the tasks performed;
- 6) other conditions.

**Issuing of a Decision**  
**Article 17**

- (1) Ministers responsible for the areas subject to technical regulation (hereinafter referred to as: responsible ministers) shall issue a decision authorizing a conformity assessment body, which may be time limited.
- (2) The decision referred to in paragraph 1 of this Article shall be issued on the basis of an application submitted by the conformity assessment body.
- (3) In the course of issuing a decision on authorization referred to in paragraph 1 of this Article, the responsible minister shall determine whether the conformity assessment body fulfills the requirements for performing activities prescribed by this Law.



- (4) In assessing the fulfillment of the prescribed requirements referred to in paragraph 3 of this Article, the responsible minister may value the technical competence from the accreditation procedure or other equally significant procedure.
- (5) The decision referred to in paragraph 1 of this Article shall be final.

### **Article 18**

The manner of authorizing a conformity assessment body and determining the fulfillment of requirements referred to in Article 16 of this Law shall be prescribed in a separate regulation.

### **Register Article 19**

- (1) The Ministry shall maintain the Register of Authorized Conformity Assessment Bodies, as a public record.
- (2) The contents and the manner of maintaining the Register referred to in paragraph 1 of this Article shall be prescribed in a separate regulation.

### **Certificates of Conformity Article 20**

- (1) Certificates of conformity may be issued by a conformity assessment body or by a producer performing a conformity assessment in accordance with Article 13 of this Law, depending on the requirement of the technical regulation.
- (2) In the case of a certificate issued by a conformity assessment body, the certificates referred to in paragraph 1 of this Article shall be issued based on an application of the person placing the product into circulation.
- (3) The conformity assessment body and the person submitting the application referred to in paragraph 2 of this Article shall regulate by a contract their mutual rights and obligations with regard to the issuing of the certificate of conformity and maintenance of the conditions based on which the certificate of conformity has been issued.

## **VI. SUPERVISION**

### **Article 21**

Supervision of the implementation of this Law and regulations adopted pursuant to this Law shall be performed by the responsible ministries and inspection authorities, in accordance with the law.

## **VII. VALIDITY OF CONFORMITY ASSESSMENT PROCEDURES CONDUCTED ABROAD**

### **Validity Article 22**

- (1) The results of conformity assessment procedures conducted in other countries, including the resulting certificates of conformity and conformity marks, shall be valid in Montenegro if they are conducted in accordance with international agreements binding on Montenegro and provided that responsible ministries are satisfied that those procedures offer an assurance of conformity with applicable technical regulations equivalent to procedures applicable in Montenegro.
- (2) The Ministry shall keep a public record of types of valid certificates of conformity, conformity marks and conformity assessment bodies referred to in paragraph 1 of this Article
- (3) The contents and the manner of maintaining the Register referred to in paragraph 1 of this Article shall be prescribed in a separate regulation.

### **Equivalence of Technical Regulations Article 23**

- (1) Technical regulations of countries that are signatories to relevant international agreements, including the WTO Agreement on Technical Barriers to Trade, may be accepted as equivalent, even if these technical regulations differ from technical regulations of the Republic.
- (2) Details for the implementation of paragraph 1 of this Article shall be prescribed in a separate regulation.

## **VIII. PENAL PROVISIONS**

### **Article 24**

- (1) Any company, other legal person or an entrepreneur that:
  - 1) places into circulation a product that is not in conformity with the prescribed technical requirements, if the conformity of the product is not assessed in accordance with the prescribed procedure, or if it is not marked in accordance with regulations (Article 3);
  - 2) affixes a conformity mark or other mark similar to the prescribed conformity mark on a product that is not in conformity with relevant technical regulations, or on a product for which putting of conformity marks is not prescribed (Article 15).

shall be fined for the offence in the amount equal to 200 – 300 minimal wages in Montenegro.

- (2) The responsible person in a company or other legal person shall be fined for the offence referred to in paragraph 1 of this Article in the amount equal to 5-20 minimal wages in Montenegro.

**.Article 25**

- (1) A conformity assessment body that performs conformity assessment activities without authorization shall be fined for the offence in the amount equal to 150 – 200 minimal wages in Montenegro (Article 17, paragraph 1).
- (2) The responsible person in a conformity assessment body shall be fined for the offence referred to in paragraph 1 of this Article in the amount equal to 5-20 minimal wages in Montenegro.

**IX TRANSITIONAL AND FINAL PROVISIONS**

**Article 26**

- (1) Existing technical regulations must be brought into compliance with this Law within two years from the date this Law comes into force.
- (2) Technical regulations adopted and taken over on the basis of the Law on Standardization (“FRY Official Gazette”, No. 30/96, 59/98, 70/2001 and 8/2003) and the Law on Technical Requirements for Products and Assessment of Conformity of Products with Prescribed Requirements (“Official Gazette of Serbia and Montenegro”, No. 44/05) shall apply until the adoption of technical regulations in accordance with this Law

**Article 27**

Regulations for the implementation of this Law shall be adopted within two months of the date this Law comes into force.

**Article 28**

The provisions of the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (“Official Gazette of Serbia and Montenegro”, No.44/05) shall cease to apply on the date this Law has come into force.

**Article 29**

This Law shall come into force on the eighth day after being published in the "Official Gazette of Montenegro".