

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

## **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, register of technical regulations, supervision of fulfillment of requirements prescribed in technical regulations, validity of foreign documents on conformity and conformity marks.

### **Purpose and Content of Technical Regulations Article 2**

- (1) Technical regulations shall be adopted for the purpose of protecting public interest, most notably protection of life, health and safety of humans, animals and plants, protection of environment and protection of property.
- (2) By adopting technical regulations for certain products or groups of products, at least one of the following shall be prescribed:
  - technical requirements that must be fulfilled by products placed into circulation or use;
  - rights and obligations of companies, other legal persons, entrepreneurs and natural persons that place products into circulation or use;
  - conformity assessment procedures, including regular and special control of products in use;
  - requirements for the body that performs conformity assessment;
  - documents accompanying products placed into circulation or use;
  - mark and manner of marking of products.

### **Principles for Preparation, Adoption and Application of Technical Regulations and Conformity Assessments Procedures Article 3**

- (1) Technical regulations and conformity assessment procedures shall not be prepared, adopted or applied so as to create unnecessary obstacles to international trade, nor shall they be more trade restrictive than necessary to fulfill a legitimate objective, taking account risks non-fulfillment would create.
- (2) Conformity assessment procedures shall be undertaken and completed as expeditiously as possible, in a manner that is no less favorable for products originating outside Montenegro than the one applicable to domestic like products.

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- (3) The standard processing period for each conformity assessment procedure shall be established by the law or a sub-legal act, and upon request, the applicant shall be informed of the anticipated processing period.
- (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) When preparing technical regulations in the area where relevant international standards exist 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 if the circumstances giving rise to its adoption no longer exist. Where, due to changed circumstances, objectives of the technical regulation or other act can be addressed in a less trade-restrictive manner, the technical regulation shall be amended.
- (8) Upon request of an interested party, 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** **Article 4**

- (1) The Ministry shall, through an enquiry point, answer all reasonable enquiries from interested parties, domestic and foreign legal and natural persons, and provide the relevant documents concerning:
  - any technical regulations adopted or proposed in Montenegro;
  - any conformity assessment procedures conducted within Montenegro;
  - membership of Montenegro in international and regional conformity assessment systems, or in bilateral or multilateral arrangements related to technical regulations.
- (2) Any fees charged for providing the information and copies of documents referred to in paragraph 1 of this Article shall reflect the real costs, which must be identical for domestic and foreign persons.

#### **Definitions** **Article 5**

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 is intended for placing in the circulation or use;
- 2) **“Technical regulation”** shall mean a regulation that contains technical requirements, directly or by reference to Montenegrin standard, technical specification or the rules of practice, or a document that includes their contents, as well as conformity assessment procedures;
- 3) **“Technical Requirement”** shall mean document that prescribes characteristics of a product or a method of production or processing of such a product, including administrative provisions applicable to the product, that are obligatory and compliance with which is mandatory. Technical requirement may contain or exclusively refer to terminology, symbols, requirements with respect to packaging, marking or labeling, if applicable to a product, method of production or processing;
- 4) **“Technical Specification”** shall mean a part of the general act that defines technical requirements that products 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 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 prescribed requirements for products are fulfilled;
- 9) **“Conformity Assessment Body”** shall mean an independent laboratory, certification body, control authority, administration authority or other authority that performs a conformity assessment;
- 10) **“Appointing”** shall mean a procedure administered by the responsible ministry, for the purpose of assigning responsibility to a laboratory, certification body, control authority or any other subject to perform activities of conformity assessment for suppliers;
- 11) **“Authorizing”** shall mean a procedure administered by the responsible ministry, for the purpose of assigning responsibility to a conformity assessment body to perform activities of conformity assessment for the needs of state administration;

- 12) **“Certificate of Conformity”** shall mean a declaration, testing report, certificate or any other document attesting to the conformity of a product with the relevant technical regulation;
- 13) **“Conformity Mark”** shall mean a mark or indication affixed to a product indicating its compliance with a relevant technical regulation;
- 14) **“Notification”** shall mean providing to the relevant international organization the information required by international agreements binding on Montenegro, including the notification under the World Trade Organization Agreement on Technical Barriers to Trade;
- 15) **“Interested Parties”** shall be an interested member or the responsible authority of the member of international organizations, including the World Trade Organization, in accordance with the rules of international agreements.

## **II. PRESCRIBING TECHNICAL REQUIREMENTS**

### **Responsibility**

#### **Article 6**

- (1) The ministry responsible for adoption of the technical regulation (hereinafter referred to as: responsible ministry) shall adopt technical regulation in accordance with the principles established by Article 3 of this Law and in compliance with the obligations arising from bilateral and multilateral agreements on preventing and eliminating barriers to international trade.
- (2) The manner of preparation and adoption of technical regulations shall be governed by a regulation issued by the Government of Montenegro (hereinafter referred to as: the Government).
- (3) Technical regulations shall be published in the “Official Gazette of Montenegro” and shall become effective not earlier than six months after their publication.

### **Notification**

#### **Article 7**

- (1) Where a proposed technical regulation is not based on or is not in accordance with an international standard, and where such technical regulation may have a significant impact on international trade, the responsible ministry shall:
  - Notify interested parties of commencement of preparation of such a technical regulation, in accordance with the rules of international agreements;
  - 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 objectives and rationale;

- Upon request of interested parties, provide copies of the proposed technical regulation, and where possible identify parts that in substance deviate from relevant international standard;
  - Without discrimination, allow reasonable time for interested parties to submit comments in writing, discuss these comments upon request, and take comments and the results of discussions into account.
- (2) Where urgent problems of safety, health of humans, animals and plants or environment arise or threaten to arise, provisions of paragraph 1 of this Article and the time period referred to in Article 6, paragraph 3 of this Law shall not apply.
- (3) In the cases referred to in paragraph 2 of this Article, following the adoption of the technical regulation, the responsible ministry shall:
- immediately notify interested parties of the technical regulation and its objectives and rationale, and the nature of the urgent problem;
  - upon request of interested parties, provide the copy of the technical regulation;
  - without discrimination, allow interested parties to submit comments in writing, discuss these comments upon request, and take comments and the results of discussions into account.
- (4) The notification procedure shall be governed by a regulation issued by the Government.

### **Placing the Product into Circulation and Its Use**

#### **Article 8**

Product shall be placed into circulation or use only if, in accordance with prescribed technical requirements, its conformity has been assessed according to the prescribed procedure and if the product is marked in accordance with regulations and if it is accompanied with prescribed documents.

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

#### **Article 9**

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

#### **Article 10**

- (1) Technical regulation may prescribe mandatory application of technical specifications, which responsible ministries issue and publish as separate publications.
- (2) Technical specifications shall be prepared by expert commissions established by the responsible ministry.

- (3) The list of adopted technical specifications and the list of specifications that have ceased to apply shall be published in the „Official Gazette of Montenegro“, and the publications shall be available at the responsible ministry.
- (4) The manner of preparation and the basic content of technical specifications shall be prescribed in the regulation issued by the Government.

#### **Article 11**

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

#### **Protective Clause Article 12**

Where it is determined that products conforming with technical regulations may jeopardize public interest, notably the safety of life, health of humans, animals and plants, environment and property, the responsible ministry shall undertake measures for withdrawing of such products from the market or order prohibition or restriction of their placing on the market and their use, as the case may be.

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

#### **Article 13**

- (1) The Ministry shall maintain the Register of Technical Regulations as a public record.
- (2) The contents and the manner of maintaining the Register of Technical Regulations shall be governed by a regulation issued by the Government.

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

#### **Obligations of the Supplier Article 14**

- (1) Technical regulations shall specify the products for which a supplier shall, before placing them into circulation or use:
  - 1) Ensure application of a conformity assessment procedure;
  - 2) Issue or provide a certificate of conformity;
  - 3) Prepare and maintain technical documentation in the prescribed volume, form and deadlines;
  - 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 governed by a regulation issued by the Government.

### **Methods of Conformity Assessment** **Article 15**

- (1) A conformity assessment referred to in Article 14, paragraph 2 of this Law may be accomplished by application of one procedure, a number of procedures or appropriate 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 sample or statistically chosen sample from the production process;
  - 3) A producer's quality management system;
  - 4) Conformity assessment and supervision of quality management system, performed by the conformity assessment body.
- (2) When conducting conformity assessment, the conformity assessment body shall:
  - promptly examine the completeness of the application and the documentation and inform the applicant in a precise and complete manner of all deficiencies;
  - transmit the results of the conformity assessment to the applicant as soon as possible, in a precise and complete manner so that corrective action may be taken if necessary;
  - even when the application has deficiencies, proceed as far as practical with the assessment if the applicant so requests;
  - upon request, inform the applicant of the stage of the procedure, with any delay being explained.
  - respect the confidentiality of information arising from or supplied in connection with conformity assessment of products originating outside Montenegro in the same way as for products originating in Montenegro, and in such a manner that legitimate commercial interests are protected.
- (3) Manner and procedures of conformity assessment of products shall be governed by a regulation issued by the Government.

### **Change of Specification** **Article 16**

Whenever the technical specification of a product is changed subsequent to the determination of its conformity with an applicable technical regulation, the conformity assessment procedure for the modified product shall be limited to determining whether the product still conforms to the technical regulation.

**Conformity Mark**  
**Article 17**

- (1) A conformity mark may be placed on products that conform to technical regulations.
- (2) Conformity marks must be placed on product for which an obligation of placing conformity mark has been prescribed.
- (3) Form, content and appearance of the conformity mark shall be governed by a regulation issued by the Government.

**V. CONFORMITY ASSESSMENT BODY**

**Requirements for Conformity Assessment Body**  
**Article 18**

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 of commercial secrets;
- 5) accountability for the tasks performed;
- 6) other conditions, in accordance with law.

**Issuing of a Decision**  
**Article 19**

- (1) Responsible ministry shall issue a decision on appointing or 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 legal person that meets the requirements specified in the technical regulation for performing conformity assessment.
- (3) In the course of issuing a decision referred to in paragraph 1 of this Article, the responsible ministry shall determine whether the legal person referred to in paragraph 2 of this Article meets the requirements for performing conformity assessment.
- (4) In assessing the fulfillment of the prescribed requirements referred to in paragraph 3 of this Article, the responsible ministry shall also evaluate 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, and administrative dispute proceedings may be initiated against such a decision.



## **Article 20**

The manner of appointing and authorizing a conformity assessment body and determining the fulfillment of conditions referred to in Article 18 of this Law shall be governed by a regulation issued by the Government.

## **Register Article 21**

- (1) The Ministry shall maintain the Register of Appointed and 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 issued by the Ministry.

## **Certificates of Conformity Article 22**

- (1) Certificates of conformity may be issued by a body appointed or authorized for conformity assessment, a producer or importer performing conformity assessment procedure referred to in Article 15 of this Law, in accordance with the technical regulation.
- (2) In the case certificate of conformity has been issued by a conformity assessment body, the certificate referred to in paragraph 1 of this Article shall be issued upon the 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 23**

- (1) Supervision of the implementation of this Law shall be performed by the inspection authorities within the limits of their prescribed responsibilities.
- (2) In addition to the powers referred to in paragraph 1 of this Article, the responsible inspector may:
  - request from the supplier all the necessary information and insight into documents on conformity and technical documentation;
  - perform the appropriate inspection and testing of products with respect to conformity to regulations once they are placed on the market or use;
  - take samples of products and have them tested and assessed for conformity;

- order rectifying of determined deficiencies;
  - request marking of products with prescribed marks, or removal of illegal marks, as the case may be;
  - prohibit or restrict placing on the market or order removal from the market of non-conforming products and ensure that such prohibition is abided by;
  - inform the responsible state authority that has adopted the regulation applicable to specific product to take action in accordance with the regulation on mutual information;
  - order destruction of non-conforming products if it is necessary to protect human health and safety.
- (3) If the responsible inspection authority does not have necessary expertise and equipment to perform inspection and testing referred to in paragraph 2 of this Article, some of the activities of inspectorial supervision may be entrusted to the institution which is capable of performing them.
- (4) The costs of inspectorial supervision (costs of testing and assessment of conformity of products and other costs related to inspectorial supervision) incurred in connection with supervision shall be borne by natural or legal person, if it is demonstrated that the product was not in conformity with essential requirements.

## **VII. VALIDITY OF CERTIFICATES OF CONFORMITY AND CONFORMITY MARKS ISSUED ABROAD**

### **Validity Article 24**

- (1) Certificates of conformity and conformity marks issued abroad shall be valid in Montenegro if responsible ministries are satisfied that applied conformity assessment procedures offer an adequate level of conformity with equivalent technical regulations 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 record referred to in paragraph 2 of this Article shall be prescribed by a regulation issued by the Government.

## **VIII. EQUIVALENCE OF TECHNICAL REGULATIONS**

**Equivalence**  
**Article 25**

- (1) Technical regulations of countries that are signatories to relevant international agreements, including the World Trade Organization Agreement on Technical Barriers to Trade, may be accepted as equivalent, even if these technical regulations differ from technical regulations of Montenegro.
- (2) Conditions for application of technical regulations referred to in paragraph 1 of this Article shall be prescribed by a regulation issued by the Government.

**IX. PENAL PROVISIONS**

**Article 26**

- (1) Any company, other legal person or 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, or not accompanied by prescribed documents (Article 8);
  - 2) affixes a conformity mark or any 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 17);

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

**Article 27**

- (1) A state administration authority or a legal person that performs conformity assessment activities without being appointed or authorized shall be fined for the offence in the amount equal to 200 – 300 times the amount of minimal wages in Montenegro (Article 19, paragraph 1).
- (2) The responsible person in state administration authority or in a legal person who performs conformity assessment activities shall be fined for the offence referred to in paragraph 1 of this Article in the amount equal to 10-20 times the amount of minimal wages in Montenegro.

**X. TRANSITIONAL AND FINAL PROVISIONS**

### **Article 28**

- (1) Technical regulations valid on the day this Law comes into force shall 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, 70/01 and 8/03) and 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 apply until the adoption of technical regulations in accordance with this Law or other laws.

### **Article 29**

- (1) Regulations for the implementation of this Law shall be adopted within four months as of the date this Law comes into force.
- (2) Until the enactment of regulations referred to in paragraph 1 of this Article, regulations issued under 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 apply, if they are not in contravention to this Law.

### **Article 30**

On the date this Law becomes effective, the following shall cease to apply: Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (“Official Gazette of Serbia and Montenegro”, No.44/05), Regulation on Determining Authorities that Assume Responsibilities from the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (“Official Gazette of the Republic of Montenegro”, No.56/06) and the Regulation on Fines Prescribed by the Law on Metrology and the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (“Official Gazette of the Republic of Montenegro”, No.52/06), in part related to measures prescribed by the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements.

### **Article 31**

This Law shall come into force on the eighth day after the day of its publication in the “Official Gazette of Montenegro”.