

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 technical requirements for products, procedures of conformity assessment of products with prescribed requirements (hereinafter referred to as the: conformity assessment), application 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 characteristic of a product or a method of production or processing of such product, including administrative provisions applicable to the product, that are by law obligatory and compliance with which is mandatory. Technical requirement may 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 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, report, certificate or other document attesting to the conformity of 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 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.

Principle

- 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, 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 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 descriptive characteristics.

- 3) Upon request, provide copies of the proposed technical regulation, and where possible identify parts that in substance deviate from irrelevant 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 no 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
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- (2) The contents and the manner of maintaining Register of Technical Regulations shall be prescribed in a separate regulation.

IV. CONFORMITY ASSESSMENT PROCEDURES

- (3) Details of procedures referred to in paragraph 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 3 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 to 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 the 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 minister 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 type 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 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

- (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 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 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 8/2002) 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 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".