

01 Annex - Free movement of goods

**16. LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS
AND CONFORMITY ASSESSMENT OF PRODUCTS WITH
PRESCRIBED REQUIREMENTS**

16. LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY
ASSESSMENT OF PRODUCTS WITH PRESCRIBED REQUIREMENTS

Pursuant to the Article 95 paragraph 3 of the Constitution of the Republic of Montenegro, I hereby proclaim

**DECREE PROMULGATING THE
LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY ASSESSMENT
OF PRODUCTS WITH PRESCRIBED REQUIREMENTS**

(Official Gazette of the Republic of Montenegro 14/08 of 29 February 2008)

I promulgate the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements, adopted by the Parliament of the Republic of Montenegro at the second session of the extraordinary assembly in 2008, on 11 February 2008.

Number: 01-290/2

Podgorica, 21 February 2008

President of the Republic of Montenegro,

Filip Vujanović

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

GENERAL PROVISIONS

Article 1

This Law shall govern the following:

the manner of prescribing technical requirements for products, as well as the procedure of conformity assessment of products with prescribed requirements (hereinafter: conformity assessment);

- 1) adoption of technical regulations, which shall, for individual products or groups of products (hereinafter: products), prescribe in particular: register of technical regulations; supervision of fulfillment of requirements referred to in technical regulations, and validity of documents on conformity and conformity marks issued abroad.

Purpose and Content of Adoption of Technical Requirements

Article 2

- (1) Technical requirements shall be adopted for the purpose of prevention of the public interest, especially life, health and safety of people, animals and plants, protection of environment and protection of property.
- (2) Adoption of technical regulations for certain products, or groups of products, shall prescribe at least one of the following elements:
 - technical requirements product must fulfill in order to be put in trade or use;
 - rights and obligations of companies, other legal persons, entrepreneurs and natural persons that put the product in trade or use;
 - procedures of conformity assessments, including both regular and extraordinary controls of the products in use;
 - requirements that need to be fulfilled by the body that conducts conformity assessment;
 - certificates that are attached to the products put in trade or use;

- label and the manner of labeling the products.

Principles of Drafting, Adopting and Applying Technical Requirements and Procedures for Conformity Assessments

Article 3

- (1) Technical requirements and procedures for conformity assessment must not be drafted, adopted and applied in order to create unnecessary obstacles in international trade that limit the trade in the level greater than the necessary for achieving allowed purposes, depending on the risk that may be caused by non-conformity with the technical requirement.
- (2) Procedures for conformity assessment shall be taken and finished in the shortest possible time and in a manner that is not least favorable for products originating outside of Montenegro from the one applied for similar domestic products.
- (3) Duration of the procedure for conformity assessment shall be determined by the law or regulation adopted pursuant to the law, and at the request of the applicant, applicant shall be informed on duration of the procedure for conformity assessment.
- (4) Product, originating from the country signatory of one of the adequate international treaty, shall be treated in a manner that must not be less favorable than the treatment for similar domestic product, or similar product from other countries.
- (5) When drafting technical regulation for certain area in which adequate international standards exist or the adoption of standards is in its final phase, these standards or their adequate parts shall be used as a basis for technical regulation, unless they represent inefficient or inadequate mean for achieving allowed purpose.
- (6) Technical regulation shall primarily determine the requirements the product must fulfill in its application, rather than regarding its design or described characteristics.
- (7) When circumstances that lead to its adoption terminate, the technical regulation shall be put out of force. In the event that, due to the changed circumstances, the purpose of the regulation or some other document may be achieved with fewer restrictions for the trade, the technical regulation shall be altered.
- (8) The Ministry in competence for the quality infrastructure (hereinafter: Ministry) shall provide, to the interested parties, at their request, information regarding justifiability of the technical regulation that may have significant influence at the international trade.

Obligation to Provide Information

Article 4

- (1) The Ministry shall, through its information point, provide information at the request of interested parties and domestic and foreign legal and natural persons, as well as provide adequate documents regarding the following:
 - technical regulation adopted or proposed in Montenegro,
 - procedure for conformity assessment applied in Montenegro,
 - membership of Montenegro in international and regional systems for conformity assessment or in bilateral or multilateral treaties regarding technical regulations.
- (2) The fee amounting actual costs, that must be equal for domestic and foreign persons, shall be paid for submission of information and copies of documents referred to in the paragraph 1 of this Article.

Definition of Terms

Article 5

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

- 1) product is the result of a process (hardware, software, process material or service), designed, produced or otherwise derived, regardless of the processing level, and intended to be put in trade or use;
- 2) technical regulation is a regulation containing technical requirements directly, or referring to the Montenegrin standard, technical specification or rule of practice, or including the contents of the said documents, as well as the conformity assessment procedures;
- 3) technical requirement is document describing the characteristics of the product or production method and processing for such product, including administrative provisions that may be applied to the product, and which are obligatory in its character and with which the obligation is complied, and it may contain or it may refer solely to terminology, symbols, requirements regarding packing, marking or labeling if applied to the product, production method or processing method;
- 4) technical specification is part of the general document defining technical requirements that products must fulfill;
- 5) putting product in trade is selling, offering or participation in business transaction regarding the product for the first time;
- 6) use is the first use of the product in Montenegro by the end user;
- 7) supplier is the producer, his agent, with the seat in Montenegro, importer, that is, company, or other legal person, entrepreneur or other natural persons that put the product in trade or enabled its use;
- 8) conformity assessment is any activity directly or indirectly establishing whether the prescribed technical requirements for products have been fulfilled;
- 9) conformity assessment body is an independent laboratory, certification body, control authority, or other authority taking part in the conformity assessment procedure;
- 10) appointment is the procedure conducted by the competent Ministry in order to give competence to the laboratory, certification body, control authority, that is some other subject for conducting works of the conformity assessment for the needs of suppliers;
- 11) authorization is procedure conducted by the competent Ministry in order to give competence to the body for conformity assessment for conduct of works of the conformity assessment for the needs of state administration;
- 12) document on conformity is statement, report on research, certificate or other document that confirms conformity of the product with the adequate technical regulation;
- 13) conformity mark is the mark or label attached to the product and it shows its conformity with adequate technical regulation;
- 14) notification is provision to the adequate international organization information required regarding international treaty that is obligatory for Montenegro, including informing pursuant to the Treaty on Technical Obstacles in Trade of the World Trade Organization;
- 15) interested party is interested member, which is competent authority of the member of international organizations including the World Trade Organization, in compliance with the rules from international treaties.

II. PRESCRIBING TECHNICAL REQUIREMENTS

Competence

Article 6

The Ministry competent for adoption of technical regulation (hereinafter: competent Ministry) shall adopt technical regulation in compliance with the principles determined in the Article 3 of this Law and obligations taken on by bilateral and multilateral treaties on prevention and removal of obstacles in the international trade.

- (1) The manner of preparing and adopting technical regulations shall be prescribed in the regulation of the Government of the Republic of Montenegro (hereinafter: Government).
- (2) Technical regulations shall be published in the Official Gazette of the Republic of Montenegro, and they shall be applied not sooner than six months from the day of their publication.

Notification

Article 7

- (1) In the case when the technical regulation does not have the basis in the international standard or it is not complied with one, and it may have significant influence on the international trade, the competent Ministry shall do the following:
 - submit notification on preparation of the technical regulation to the interested parties in compliance with the rules set forth in the international treaty;
 - in preparing draft of the technical regulation, inform the interested parties on products the proposed technical regulation refers to, with the description of its goals and explanation;
 - at the request of interested parties, provides copies of the proposed technical regulation and, when possible, identify parts that are essentially different from the applicable international standard;
 - allow, without discrimination, to the interested parties to within reasonable time period submit their comments in written, discuss these comments at their request and consider these comments and the results of such discussions.
- (2) Provisions referred to in the paragraph 1 of this Article and the term referred to in the Article 6 paragraph 3 of this Law, shall not be applied when they act or there is a treat that they may act as danger for the safety and health of people, animals or plants or for the environment.
- (3) Competent Ministry, in the events referred to in the paragraph 2 of this Article, after adoption of the technical regulation, shall be obliged to do the following:
 - to immediately inform interested parties on technical regulation and its goals and purpose, as well as on the nature of the urgent problem;
 - to provide, at the request of the interested parties, copies of the technical regulation;
 - to allow, without discrimination, to the interested parties to submit comments in written, discuss these comments at their request and take into consideration comments and the results of such discussions.
- (4) Procedure for notification shall be governed in more detail by the regulation of the Government.

Putting the product in trade

Article 8

The product shall be put in trade or in use, that is, it shall be used only if it is complied with the proscribed technical regulation, if its conformity is assessed in compliance with the prescribed procedure and if the product is labeled in compliance with the regulations and if it has prescribed documents attached to it.

Compliance of the Product with the Technical Regulation

Article 9

- (1) A technical regulation may provide that a product is in conformity if it fulfills the requirements of a standard referred to in the technical regulation.
- (2) The conformity of the product referred to in paragraph 1 of this Article may be determined by other means as well.

Article 10

- (1) Technical regulation may determine the obligatory application of the technical specifications adopted and issued as separate publications by the competent ministries.
- (2) Technical specifications shall be prepared by expert commissions established by the competent Ministry.
- (3) List of adopted technical specifications, that is specifications that are out of use, shall be published in the Official Gazette of the Republic of Montenegro, and the publications shall be publicly available in the competent Ministry.
- (4) Manner of preparation and main content of the technical specifications shall be determined by the regulation of the Government.

Article 11

When preparing technical regulation, at the request of the competent Ministry, the Institute of Standardization of Montenegro shall be obliged to provide information if, in the area that should be regulated by the technical regulation, there is adequate Montenegrin standard or its adoption is expected, that is whether an appropriate European or international standard exists.

Protection Clause

Article 12

If it is determined that the products complied with technical regulations may endanger public interest, and especially safety of life and health of people, animals and plants, environment and property, the competent ministry shall take measures to withdraw such products from the market, that is it shall order prohibition or limitation of its putting in trade or its use.

III. REGISTER OF TECHNICAL REGULATIONS

Article 13

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

IV. CONFORMITY ASSESSMENT PROCEDURES

Obligation of Supplier

Article 14

- (1) Technical regulations shall determine the products for which the supplier is obliged, before putting them in trade or in use, to:
 - 1) apply a conformity assessment procedure;
 - 2) issue or provide a certificate on conformity;
 - 3) prepare and provide keeping of technical documentation in the prescribed volume, form and terms;
 - 4) provide labeling of the products with prescribed conformity marks.
- (2) Conformity assessment procedures shall be prescribed directly in technical regulations or indirectly in standards to which technical regulations refer or by technical specifications.
- (3) The manner of conformity assessment shall be prescribed by regulation of the Government.

Methods for Conformity Assessment

Article 15

- (1) For conformity assessment referred to in the Article 14, paragraph 2 of this Law, one procedure, several procedures or appropriate combination of different conformity assessment procedures shall apply, such as the following:
 - 1) independent conformity assessment of products by the producer;
 - 2) conformity assessment of products performed by the conformity assessment body on a sample or on a statistically chosen sample from the production process;
 - 3) producer's quality management system;
 - 4) conformity assessment and supervision of quality management system that is performed by the conformity assessment body.
- (2) During conformity assessment, conformity assessment body shall be obliged to do the following:
 - within shortest possible time, to examine completeness of the application and documents and to inform applicant fully and in a precise manner on all shortcomings;

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- within shortest possible time, completely and in a precise manner, submit to the applicant results of the conformity assessment, in order for him to conduct alterations, if necessary;
 - conduct assessment as far as it is possible even when the application has shortcomings, at the request of the applicant;
 - inform the applicant, at his request, on the phase of the procedure and with explanation in the event of delay in conformity assessment;
- (3) provide confidentiality of data acquired or gained regarding the conformity assessment of the product originating in Montenegro and in a manner that would protect legitimate business relations. Manner and procedure of conformity assessment shall be prescribed by regulation of the Government.

Change of Specification

Article 16

If the change of technical specification of the product occurs after determination of its conformity with applicable technical regulation, the procedure of conformity assessment shall be limited on assessing if the product still matches the technical regulation.

Conformity Mark

Article 17

- (1) Conformity mark shall be placed on products that are in conformity with technical regulations.
- (2) It shall be obligatory to put the conformity mark on the product for which obligation of putting conformity mark is prescribed.
- (3) Form, content and design of the conformity mark shall be prescribed in a separate regulation.

V. CONFORMITY ASSESSMENT BODY

Requirements that Must be Fulfilled by the Conformity Assessment Body

Article 18

A technical regulation shall specify the requirements that must be fulfilled by the conformity assessment body, in particular:

- 1) professional competency of personnel;
- 2) necessary equipment;
- 3) independence and impartiality in the conformity assessment procedure;
- 4) business secrecy;
- 5) accountability for the tasks performed;
- 6) other conditions, in compliance with the Law.

Adoption of Decision

Article 19

- (1) The competent ministry shall adopt decision on appointment, or on authorization of a conformity assessment body, that may be time limited.
- (2) The decision referred to in paragraph 1 of this Article shall be adopted on the basis of an application submitted by the legal person that fulfills requirements to conduct conformity assessment.
- (3) In the course of adopting the decision referred to in paragraph 1 of this Article, the competent Ministry shall determine whether the legal person referred to in paragraph 2 of this Article fulfills the requirements for conducting conformity assessment activities.
- (4) In assessing the fulfillment of the prescribed requirements referred to in paragraph 3 of this Article, the competent Ministry may estimate 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 no administrative procedure may be conducted against it.

Article 20

- (1) The manner of appointing and authorizing a conformity assessment body and of determining the fulfillment of requirements referred to in the Article 18 of this Law shall be prescribed in regulation of 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 regulation of the Ministry.

Certificate on Conformity

Article 22

- (1) Conformity certificate may be issued by the body appointed or authorized for conduct of conformity assessment, producer or importer that undertakes the procedure for conformity assessment referred to in the Article 15 of this Law, in compliance with the technical regulation.
- (2) In the case that the conformity assessment body issues the conformity certificate, the certificate referred to in the paragraph 1 of this Article shall be issued at the request of the person putting the product in trade.
- (3) The conformity assessment body and the person submitting the application referred to in paragraph 2 of this Article shall regulate, by contract, their mutual rights and obligations with regard to the issuing of certificate of conformity and maintaining 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 competent inspection authorities within prescribed competences.
- (2) Apart from the competences referred to in the paragraph 1 of this Article, the competent inspector may perform the following:
 - request from the suppliers all necessary information and insight into documents on conformity and technical documents;
 - conduct adequate review and examination of the product regarding its conformity with regulations when put on the market, that is when they are in use;
 - take samples of products and put them at the examination and conformity assessment;
 - determine correction of certain nonconformities;
 - request for the product to be properly labeled, that is removal of non-allowed marks;
 - prohibit putting at the market, limit putting into market or determine withdrawal of non-conformed products from the market and initiate additional measures that would enable this prohibition to be applied;
 - inform competent state authority that adopted the regulation regarding certain product to take actions determined by the regulation on mutual provision of information.
- (3) If the competent inspection authority does not have at its disposal professional knowledge or equipment necessary to perform review or examination referred to in the paragraph 2 of this Article, certain actions within inspection supervision may be conducted by competent institution.
- (4) Costs of the inspection supervision (costs of review and examination of conformity of the products and other costs regarding inspection supervision) occurred during the supervision shall be paid by the legal or natural person if it is determined that the product is not in conformity with important requirements.

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

Validity

Article 24

- (1) Certificates of conformity and conformity marks that are issued abroad shall be valid in Montenegro if the competent ministries estimate that the applied procedures for conformity assessment provide sufficient level of conformity with equivalent technical regulations applied 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 the paragraph 1 of this Article.
- (3) The content and the manner of keeping the record referred to in paragraph 2 of this Article shall be prescribed in regulation of the Government.

VIII. EQUIVALENCY OF TECHNICAL REGULATIONS

Equivalency

Article 25

- (1) Technical regulations of other countries that are signatories to relevant international agreements, including the Agreement on technical obstacles in trade of the World Trade Organization, may be applied as equivalent, even if these technical regulations differ from technical regulations in Montenegro.
- (2) Conditions for the implementation of paragraph 1 of this Article shall be prescribed in regulation of the Government.

IX PENALTY PROVISIONS

Article 26

- 1) Any company, other legal person or entrepreneur shall be punished by a fine amounting two-hundred-fold to three-hundred-fold of the minimal wage in Montenegro, if: put in trade 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 followed by the prescribed documents (Article 8);
- 2) places a conformity mark or other mark similar to the prescribed conformity marks on products that are not in conformity with relevant technical regulations, or on products for which placement of conformity marks is not prescribed (Article 17).

The responsible person in a company or other legal person shall be punished by a fine in the amount of five-fold to twenty-fold of the minimal wage in Montenegro offence referred to in paragraph 1 of this Article.

Article 27

- (1) State authority or legal person that participates in the procedure of conformity assessment shall be punished by a fine in the amount of two-hundred-fold to three-hundred-fold of the minimal wage in Montenegro if it performs conformity assessment activities without appointment or authorisation to do so (Article 19, paragraph 1).
- (2) The responsible person in the state authority or in the legal person that participates in the procedure of conformity assessment shall be punished by a fine in the amount of ten-fold to twenty-fold of the minimal wage in Montenegro for actions referred to in paragraph 1 of this Article.

IX TRANSITIONAL AND FINAL PROVISIONS

Article 28

16. LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY
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- (1) Technical regulations applicable at the day of the entry into force of this Law shall be complied with this Law within two years from the date this Law enters into force.
- (2) Technical regulations adopted and taken over on the basis of the Law on Standardization (Official Gazette of the Federal Republic of Yugoslavia 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 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 of the date this Law enters into force.
- (2) The provisions of the Law on Technical Requirements and Conformity Assessment of Products with Prescribed Requirements (Official Gazette of Serbia and Montenegro 44/05) shall apply until adoption of regulations referred to in the paragraph 1 of this Article, unless they are in contradiction with this Law.

Article 30

By the day of the entry into force of this Law the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (Official Gazette of Serbia and Montenegro 44/05), Regulation on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements (Official Gazette of the Republic of Montenegro 56/06) and the Decision on the Amount of Fine 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 52/06) shall cease to apply, in the part related to the measures prescribed by the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements.

Article 31

This Law shall enter into force on the eight day after its publication in the Official Gazette of and the Republic of Montenegro.

SU-SK Number 01-8/6

Podgorica, 11 February 2008

Parliament of the Republic of Montenegro

Speaker,

Ranko Krivokapić