

Draft Act for prescribing technical requirements for products and conformity assessment

Article 1

This Act regulates the method of prescribing technical requirements the products should meet before placed on the market or put into service on another way (hereinafter referred to as “products”), procedures for conformity assessment of products according prescribed technical requirements, surveillance of fulfillment of the requirements prescribed by regulations and validation of certificates and marks of conformity of foreign origin, if not stipulated differently by other act for specify products.

Products may only be placed on the market or put into service when they confirm to prescribed technical requirements, when their conformity with technical requirements has been assessed according prescribed procedure, when they are marked on prescribed manner and when are followed with documents specified in technical regulations.

Article 2

Technical regulations for prescribing technical requirements shall be issued when this is necessary for the protection of public interest, especially for defence and safety of country, protection of human life and health and life and health of animals and plants, protection and development of environment and nature, protection of consumers and other users of products and protection of property.

Technical regulations shall be issued by the Minister in charge of Ministry responsible by Act with tasks concerning products production, marketing and putting into service.

Technical regulations shall be issued for particular products or groups of products, procedures and methods of production concerning these products and compulsory should content one or more of elements as:

1. technical requirements the products should have to meet;

2. procedure, method and state of affairs for evaluation the assessment of conformity according technical requirements;
3. requirements that the bodies involved in the procedure of assessment of conformity should meet (hereinafter: conformity assessment bodies);
4. documents that should accompany a product when placed on the market or put into service and
5. obligation for marking and method of marking the product.

During preparation of technical regulations, the last state of the art scientific and professional achievements shall be used, taking in consideration the needs and possibilities of the economy of the Republic of Macedonia, as well as the obligations arising from ratified international treaties, binding on the Republic of Macedonia.

Article 3

Some of the terms used in this Act, shall mean as follows:

1. "Product" shall mean any product as a result of specified processing activities;
2. "Technical regulation" shall mean a regulation laying down the characteristics of a product or its related production procedure and method. In this respect it may also comprise or treat exclusively terms, symbols, packaging, declaration and marking;
3. "Technical specification" shall mean a document that prescribes the technical requirements to be fulfilled by a product, and when appropriate, also the procedures for determination that the given requirements have been fulfilled;
4. "Placing on the market" shall mean the initial action of making a product available, for payment or free of charge, on the market of the Republic of Macedonia;
5. "Putting into service" shall mean first use of a product by the final user in the Republic of Macedonia;

6. "Supplier" shall mean the manufacturer, his authorized representative based in the Republic of Macedonia, the importer or any other natural or legal person who had placed the product on the market or ensured its putting into service;
7. "Conformity assessment procedure" shall mean any procedure applied, directly or indirectly, to determine that the specified requirements are fulfilled;
8. "Conformity assessment body" shall mean a laboratory independent of the supplier, a certification body, an inspection body or any other body involved in conformity assessment procedure;
9. "Conformity certificate" shall mean a document issued in compliance with the rules of the certification system, which provides confidence that the identified process, product or service is in compliance with specified standard or other normative document;
10. "Certification mark" shall mean mark of conformity, used or issued in compliance with rules of certification system, which shows provided confidence that a product, process or service is in compliance with specified standard or other normative document;
11. "Accreditation" shall mean expert procedure performed by Macedonian Accreditation Institute, on the base of established criteria, of determination if specified natural or legal person fulfills necessary conditions for granting an accreditation certificate, as a formal recognition of competence, to carry out specified tasks in the field of conformity assessment.

Article 4

It may be specified by a technical regulation that a product is presumed to be in conformity with the technical requirements, when it complies with the requirements of the standards adopted by Macedonian Standardization Institute.

In the cases concerning preceding paragraph, in technical regulation shall be declared a list of standards, on which base shall be assessed conformity of product with technical requirements.

Technical regulation of paragraph 1 of this Article shall be issued by the Minister responsible for issuing a particular regulation, in agreement with the Minister of Economy.

Article 5

Mandatory use of technical specifications may be prescribed by technical regulations. Technical specifications shall be issued by the Minister responsible for issuing technical regulations, on the basis of proposal of the committee comprised of the scientists and experts from relevant field.

Committee of paragraph 2 of this Article shall be appointed by the Minister responsible for pronouncing technical regulation.

In addition to technical regulation of paragraph 1 of this Article, a list of technical specifications shall be issued and method and state of affairs of making available technical specifications to the public, shall be prescribed.

Article 6

Technical regulations shall specify the products for which, prior to placing them on the market or putting them into service, the supplier is required to:

1. ensure implementation of the procedures for assessment of conformity with the prescribed technical requirements;
2. issue or provide a declaration of certificate of conformity;
3. produce and keep technical documentation within the prescribed form and scope, and keep this documentation within the prescribed manner and time limits;
4. implement prescribed marks of conformity.

Prescribed conformity assessment procedures may be specified directly, in technical regulation, or indirectly, in technical specification or standard adopted by Macedonian Standardization Institute.

Products which are assessed as non-conforming to prescribed technical requirements, and products which in accordance of law or other regulation are exempted from marking with mark of conformity, shall not be marked with any mark of conformity or other mark, whose similarity with the prescribed mark of conformity would be such that they could mislead the consumers or create confusion on the market.

Article 7

In dependance of the degree of complexity of the product and estimated risk related to its use, implementation of one or several following procedures for conformity assessment of product, may be specified by a technical regulation:

1. The manufacturer's conformity assessment of the product;
2. Conformity assessment of the product performed by a conformity assessment body, either on a sample or on a statistically selected sample taken from the production process;
3. The manufacturer's management of the production process quality system, or
4. Evaluation of adequacy and supervision of the manufacturer's production process quality system, carried out by a conformity assessment body.

Article 8

In technical regulation shall be laid down the requirements to be fulfilled by conformity assessment body, especially concerned to:

- professionally trained staff, space and technical equipment;
- independence and impartiality in relation to the legal or natural persons directly or indirectly connected with the product under conformity assessment;
- business confidentiality;
- liability insurance for the work done, except in the case where liability is insured on a statutory basis by the State;

- other conditions ensuring appropriate implementation of prescribed procedure.

Article 9

The legal or natural person wishing to obtain status of conformity assessment body, shall assign to the Ministry responsible for issuing technical regulation, request for assessment of the conditions prescribed in the technical regulation in accordance of Article 8 of this Act.

If it is assessed that the conditions for obtaining status of conformity assessment body, prescribed in technical requirement, are fulfilled, Minister responsible for issuing technical regulation, in accordance with prior provided agreement of the Minister of Economy and obtained opinion of the Macedonian Accreditation Institute, shall authorise, by decision, the legal or natural person to perform conformity assessments.

Macedonian Accreditation Institute is responsible, during evaluation of the opinion of paragraph 2 in this Article to respect the statements of technical regulation and the relevant accreditation criteria.

The decision of paragraph 2 of this Article shall be published in "Official Journal of the Republic of Macedonia".

The decision of paragraph 2 of this Article, shall be time limited.

Article 10

The legal or natural person designated as conformity assessment body shall permanently meet and maintain the requirements prescribed by technical regulation and relevant accreditation criteria defined by Macedonian Accreditation Institute.

Should relevant inspection body find that the body of paragraph 1 of this Article fail to meet particular requirement prescribed by technical regulation, the inspection body shall propose to the Minister responsible for issuing technical requirement to announce decision for withdrawing decision of paragraph of Article 9 of this Act.

Article 11

Assessment of conformity shall be performed by inspection or other state body, if it is defined in the technical regulation.

Inspection or other state body of paragraph 1 of this Article when performing tasks of conformity assessments, has status of conformity assessment body.

Article 12

Conformity assessment body shall issue certificates of conformity on the basis of customer's request.

When conformity assessment body assess that for a particular product can not be issued conformity certificate, a decision for refusing request shall be issued.

There is appeal to the Minister responsible for Issuing technical regulation against decision of paragraph 2 of this Article.

Article 13

Responsible Ministry shall make evidence and publish list of conformity assessment bodies, types legible certificates and certification marks.

The amount and the method of payment expenses for issuing certificate of conformity, the issues concerning the maintenance of certification mark, as well as the other mutual relations between the conformity assessment body and the customer, shall be settled by a contract.

Conformity assessment bodies shall conclude a contract with every legal or natural person wishing to obtain a certificate of conformity.

Article 14

In the Republic of Macedonia are legible certificates and certification marks of foreign origin only if they are issued in compliance with ratified international

treaties and agreements by the Republic of Macedonia.

Minister responsible for issuing technical regulation, may recognize the legibility of certificates or certification marks of foreign origin, if those certificates confirm the conformity with the requirements comprised in technical regulations in force, and if the competence of the bodies involved in the conformity assessment is designated according relevant procedure and they are in conformity with the requirements prescribed for those bodies in the issued technical regulation.

The relevant Ministry shall make evidence and publish the lists of the conformity assessment bodies and types legible certificates and certification marks of foreign origin in the Official Journal of the Republic of Macedonia.

V. SURVEILLANCE

Article 15

Surveillance of the implementation of the provisions of this Act, underlaw documents issued on its basis, and technical regulations, shall be caried out by ministries responsible for issuing technical regulations, by relevant inspection bodies.

In addition to the authorities and measures based on particular regulations concerning their work, competent inspectors, shall hereby authorized to:

1. merform supervision of the certificates of conformity issued, as well as the technical documentation, which on the inspector's request, the supplier is obliged to provied on evidence ad use;
2. make the appropriate checks and tests of conformity of products with the regulations, also after these have been placed on the market or put into service;
3. take samples of products and have them checked for conformity;

Alternative for the paragraphs 2 and 3 of Article 2:

If during inspection procedure is concluded that cheks are nedded to be performed,

the inspector may take samples of the products because of checking their conformity with regulations.

Article 16

When inspector, during inspection procedure, confirm that the provisions of this Act or technical regulation issued on its basis are harmed, shall issue decision of:

a) instruct:

1. withdrawal of certificates of conformity for non-conforming products;
2. elimination of nonconformances found;
3. marking of products with the prescribed marks, or removal of illicit marks;
4. withdrawal of non-conforming products, if it is essential for the protection of health and safety of people, environment and nature;
5. cessation of use of non-conforming products, and take additional measures to ensure observance of the prohibition;
6. cessation of use of non-conforming products, and take additional measures to ensure observance of the prohibition.

b) ban:

1. placing on the market, or restrict circulation of non-conforming products and take additional measures to ensure observance of the prohibition;
2. putting into service, or restrict use of non-conforming products and take additional measures to ensure observance of the prohibition;
3. for the time necessary to make various checks and tests, temporarily ban any supply, offer to supply or exhibition of products, as soon as there is ground to suspect that the products are not conforming to the regulations.

Appeals against decisions in paragraph 1 of this Article, shall not withhold their execution.

Article 17

During inspection procedure, the inspector may take declarations from responsible person in the legal or natural person, from witnesses, may take samples for making checks and tests in connection with undertakings referred to Article 16 of this Act.

When performing analyses of taken samples may be used services by authorised institutions.

When results of analyses yield non-conformity of products with requirements of particular certificates and certification marks, costs of analyses shall be borne by the legal or individual body on which the supervision is performed.

Article 18

The Government of Republic of Macedonia, on proposal of the minister responsible for issuing technical regulation, may restrict circulation or instruct elimination of separate products from domestic market, for the purpose of protecting domestic products and elimination of separate disturbances of the relations on the market.

For the undertakings of paragraph 1 of this Article, Government of the Republic of Macedonia shall inform other countries and relevant international organizations.

Penal Provisions

Article 19

A fine of 50 000 to 150 000 denars shall be imposed on a legal person which:

1. placed on the market or put into service products non-conforming with prescribed technical requirements (Article 1 paragraph 2);
2. placed on the market or put into service products whose conformity is not assessed with technical requirements according prescribed procedure (article 1 paragraph 2);

3. placed on the market or put into service products which are not marked on a proper way (article 1 paragraph 2);
4. placed on the market or put into service products which are not folowed by documents determined in technical regulation (article 1 paragraph 2);
5. marked the products with marks of conformity or other marks whose similarity to the marks of conformity could create aconfusion on the market or could mislead the consumers (article 6 paragraph 3);

Exept the fine of paragraph 1 of this Article, safety measure of forbidding performing activities of one to three years should be anounced.

A fine of 15 000 to 45 000 denars shall be imposed on a responsible person in legal person for the activities of paragraph 1 of this Article.

Exept fine of paragraph 2 of this Article, safety measure of forbidding activities of one to three years shell be imposed.

TRANSITIONAL AND FINAL PROVISIONS

Article 20

Regulations which are determing technical requirements of products, procedures for assessment of their conformity with technical regulations, marking of products as well as required documentation folowing the products, which are adopted or implementing on the basis of the Act on Standardization ("Official Journal of the Republic of Macedonia" 23/95) or on the basis of other Laws, shall apply untillissuing regulations on the basis of this Act.

Article 21

On the efective date of this Act, shall cease to apply provisions of the ("Official Journal of the Republic of Macedonia" 23/95) concerning technical requirements

of products, procedures of assessment their conformity with technical requirements, marking of products and needed documentation following the products.

Article 22

This Act shall enter into force on the fifteenth day after its publication in the Official Gazette of the Republic of Macedonia.