

LAW OF UKRAINE

„On standards, technical regulations and conformity assessment procedures

This Law establishes the legal and organisational framework for development and application of national standards, technical regulations, and conformity assessment procedures, as well as principles of state policy

of conformity with regard to the same specified requirements;

Comments — remarks and proposals to the drafts of standards, technical regulations and conformity assessment procedures;

Inspection (control) – examination of a product design, product, process or installation and determination of its compliance to prescribed requirements;

International agreements of Ukraine – any international agreement of Ukraine, including bilateral and multilateral mutual recognition agreements, of which Ukraine is a participant, regarding development and application of standards, technical regulations and conformity assessment procedures.

Conformity assessment body – a body that performs conformity assessment services;

Designating authority – body established within government or empowered by government to designate conformity assessment bodies, provisionally suspend or withdraw their designation or remove their

Risk – the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified time period.

Market supervision – the ongoing monitoring of products placed in circulation for compliance with relevant technical regulations, legality of application of the National mark of conformity, completeness and reliability of product information;

Legal regulation in the technical sphere – legal regulation of the relations in the sphere that includes prescribing, application and fulfilment of prescribed requirements to products and related processes, systems services, personnel and bodies, as well as verifying compliance with such, by means of conformity assessment and/or market supervision.

Technical regulation – law of Ukraine or normative-legal act approved by Cabinet of Ministers of Ukraine, which lays down product characteristics or their related processes and production methods, as well as

**Article 5.** General Principles of Development of Standards, Technical Regulations and Conformity Assessment Procedures

Standards, technical regulations and conformity assessment procedures shall not be developed, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

National standards, technical regulations and conformity assessment procedures shall be developed on the basis of:

protected as a commercial secret and the persons to which such information was disclosed shall not, without the express consent of the person providing the confidential information, release such information except as required by the Law.

## **CHAPTER II.**



If during the review process or in the process of evaluating proposals, a technical committee approves abolishment of a national standard, the central body of executive power for standardisation issues makes a decision regarding abolishment.

If a decision to abolish a national standard is adopted, a notice of such shall be published in an official publication of the central body of executive power for standardisation.

Amendments to national standards shall be subject to the provisions of Article 10 of this Law. Upon approval of the final draft of the amended national standard by the relevant technical committee, the central body of executive power for standardisation issues shall adopt and promptly publish the amendments or, when appropriate, the amended national standard.

### **CHAPTER III.**

### **TECHNICAL REGULATIONS**

**Article 13.** Goals and State Policy in the legal regulation of technical sphere

The goal of development and application of technical regulations is to protect human, animal and plant health and life, the environment and natural resources, national security, and prevent deceptive practices.

The compliance of products, processes and services placed in circulation in Ukraine with technical regulations is mandatory.

Requirements imposed by technical regulations shall reflect the risk to consumers or the environment or natural resources that non-compliance of products, processes and/or services will create. In assessing the risk, relevant elements of consideration are, inter alia, available scientific and technical information, related processing technology or intended end-uses of products, processes and services.

State policy for development and application of technical regulations is based on the following principles:

Technical regulations shall not be more trade-restrictive than necessary to meet the goals specified in part one of this Article;

**Article 15.** Authority of the Central Body of Executive Power for Legal Regulation in the Technical Sphere Issues

The central body of executive power for legal regulation in the technical sphere issues:

Ensure implementation of the state policy in legal regulation in technical sphere:

Coordinate development of technical regulations and activity of bodies which implement market supervision of objects subject to technical regulations;

Prepare a programme for development of technical regulations;

Organise development of rules of procedures for market supervision of objects subject to technical regulations by relevant central bodies of executive power;

**Article 16.** Standardization and Technical Regulation Council

The Standardization and Technical Regulation Council (hereinafter: Council) is a collective consultative and advisory body at the Cabinet of Ministers of Ukraine.

The Council is formed from representatives of the Cabinet of Ministers of Ukraine, relevant central bodies of executive power, the central body of executive power for legal regulation in technical sphere, the central body of executive power on standardisation issues, subjects of economic activity, producers and consumers. The Council consists of 17 members. Not less than half of the Council shall be formed of representatives of subjects of economic activity, consumers and scientific establishments' organizations.

The Council's activities are based on the principles of transparency and openness.

The statute of the Council is approved by the Cabinet of Ministers of Ukraine.

The key functions of the Council are:

Reviewing and evaluating the draft programme for development of technical regulations and providing relevant recommendations (regarding the programme);

Study, analysis and elaboration of proposals regarding improvement of activity in the sphere of standardisation

Review and recommend resolution of disputable issues associated with draft technical regulations and their compliance with the goals of legal regulation in the technical sphere.

Reviewing, accepting or rejecting proposals for development of technical regulations;

Identifying priority areas of development of standards and technical regulations on the basis of social, economic, and consumer needs;

Advising the Cabinet of Ministers of Ukraine on whether or not to adopt a proposed technical regulation.

**Article 17.** Authority of other State Bodies in Legal Regulation of the Technical Sphere

Central bodies of executive power assigned with the duty to develop technical regulations in accordance item



other mass media not later 30 days of adoption to enable interested parties to participate in preparing technical regulations.

**Article 20.** Preparation of a Draft Technical Regulation

The relevant central body of executive power, in cooperation with the central body of executive power for standardisation issues, shall provide the working group with information on the validity of appropriate national standards or other standards in the field to be regulated by the technical regulation, or the impending adoption of such, including the time frame for the adoption of such national or other standards, as well as information on the validity of appropriate international or regional standards and, when the latter do not exist, relevant standards and technical regulations of other countries.

Draft technical regulations, as a rule, shall contain:

Technical requirements (including safety requirements) for a product, process or service to comply with the scientific and technical level achieved at the moment of development;

Conformity assessment procedures that may or must be used for verification of compliance of products with the technical requirements;

Requirement for the packaging, contents of the product declaration, specifications and, if necessary, critical information for consumers (instructions, operating manuals) that must accompany a product or process when placed in circulation;

If the draft technical regulation envisages the possibility to declare conformity, the draft shall include the conformity declaring procedure, form and contents as well as retention period for declarations of conformity.

The list of national standards, which, in case of voluntary application, are proof of the conformity of a product with the requirements of technical regulations shall be formed by the central body of executive power for standardisation issues upon request of the relevant central bodies of executive power and if they are not available, upon request of these bodies, shall organise the development of such standards. The list of national standards which, in case of voluntary application, are proof of conformity of a product with the requirements of technical regulations shall be published in an official publication of the central body of executive power for standardization issues. .

In the case of reference to national standards in technical regulations, it shall be stated whether compliance with such standards shall be the only way or one of the ways of meeting the requirements of the technical regulation.

Requirements for conformity assessment shall reflect the level of risk presented by the product or process to which the technical regulation applies.

**Article 21.** Notifying Draft Technical Regulations, Soliciting Comments, and Incorporating Comments in the Final Regulation

When a draft technical regulation is completed, the relevant central body of executive power shall publish in its official publication and in mass media a notice of availability of the draft for review and comment by any interested party. The notice shall include the title and abstract of the draft technical regulation, the address and period for submitting comments, as well as information on the manner in which the draft can be obtained. The notifications shall be provided according to the procedure prescribed in Article 40 of this Law.

During the comment period for a draft technical regulation, the central body of executive power for legal regulation in the technical sphere issues shall review the draft for compliance with Articles 5 and 13 of this

**Article 22.** Adoption and Rejection of Technical Regulations

Upon completion of the final draft of a technical regulation, the working group shall submit the final draft of the technical regulation to the relevant central body of executive power, which shall circulate the final draft for approval by all interested central bodies of executive power.

The central body of executive power for legal regulation in the technical sphere shall provide the reviewed final draft technical regulation to the Cabinet of Ministers of.

In case of major disagreements between central bodies of executive power concerning draft technical regulations which are drafts normative-legal acts to be adopted by the Cabinet of Ministers of Ukraine, draft technical regulations shall be submitted to the Cabinet of Ministers of Ukraine for consideration. The Cabinet of Ministers of Ukraine shall make a decision regarding adoption or rejection of the final draft technical regulations taking into account the Council's proposal.

**Article 23.** Publication of the Technical Regulation

Technical regulation adopted by the Cabinet of Ministers shall be published promptly in the Official Gazette.

The date of entering into force of technical regulation shall be no less than six months from the date of publication in the Official Gazette in order to allow market participants to adjust to the new technical regulation, except in the case of urgent circumstances referred to in Article 24 of this Law.

**Article 24.** Urgent Need for a Technical Regulation

Should urgent reasons of national security, health, human life and health safety or environmental and natural resource protection require immediate development and/or adoption of a technical regulation, the relevant central body of executive power shall develop draft of the technical regulation (hereinafter: emergency technical regulation), which shall be reviewed for compliance with the provisions of this Law by the central body of executive power for legal regulation in the technical sphere issues.

In the event that the central body of executive power for legal regulation in technical sphere issues determines there is an urgent need for development of the technical regulation, it shall prepare the relevant justification considering proposals of the Council and immediately provide the draft emergency technical regulation to the Cabinet of Ministers.

The emergency technical regulation adopted by the Cabinet of Ministers shall be published promptly in the Official Gazette of Ukraine and come into force from the date of its publication.

Information regarding draft emergency technical regulation shall be provided in accordance with the Article 39 of this Law.

Comments on an adopted emergency technical regulation received in writing from countries with which a relevant international agreement of Ukraine is in force shall be discussed with the relevant country upon request. The comments and results of the discussion taken into account, and when necessary, the emergency technical regulation shall be accordingly revised.

All emergency technical regulations shall be reviewed by a relevant working group within six months of adoption to determine the continuing need for the emergency technical regulation. If the technical regulation adopted for urgent reasons is no longer needed, it shall be abolished by the Cabinet of Ministers of Ukraine.

If the relevant working group concludes that an emergency technical regulation continues to be needed or any comments are available received from interested parties, whether domestic or foreign, on the adopted

**Article 25.** Review of Adopted Technical Regulations

The review of a technical regulation shall be carried out by a relevant working group during five-year period from the date of its publication in the “Official Gazette of Ukraine”. The relevant central body of executive power shall publish in its official publication and, if necessary, other media, its views on the need to amend, modify or abolish the given technical regulation along with a solicitation for comments on its views, and the address and period for submitting comments to the relevant central body of executive power. The period for submitting comments shall not be less than 60 days.

Following the expiration of the period referred to in paragraph 1 of this Article, the working group shall consider the comments and reach a conclusion concerning the need to amend, modify or abolish the technical regulation.

Interested bodies, organisations and persons may submit proposals for the review of a technical regulation to the central body of executive power for legal regulation in the technical sphere issues, which shall process them according to the provisions of Article 19 of this Law.

In case the Council decides that amending or modifying of a technical regulation is necessary, the relevant central body of executive power shall form or convene, as necessary, an working group.

Amendments or modifications to the technical regulation shall be elaborated and established as prescribed by Articles 20, 21 and 22 of this Law. Upon adoption of the final draft technical regulation, the procedures referred to in Article 23 of this Law shall be undertaken.

Those technical regulations that have been reviewed but not amended, modified or abolished shall be identified in the registry by a mark that will be determined by the central body of executive power for legal regulation in the technical sphere issues.

Technical regulations not reviewed within five-years from the date of publication in the Official Gazette shall be deemed to be abolished starting from the date of expiration of five-year period.

**Article 26.** Procedure for Making a Decision Regarding the Equivalence of Foreign and Ukrainian Technical Regulations

The equivalence of the technical regulations of Ukraine and other states shall be assessed upon a proposal

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regulations, maintained by the central body of executive power for legal regulation in the technical sphere issues.

body of executive power for conformity assessment issues

Conformity assessment bodies shall have in place the procedures of reviewing claims related to performance of conformity assessment procedures considering provisions of Article 31 of this Law. The procedures of claim review shall envisage the taking of corrective measures/approval of corrective measures, if it is proven that the claim is justified.

Conformity assessment bodies that perform conformity assessment procedures shall maintain the registry of issued certificates of conformity and provide a copy of issued certificates according to the procedure to the state registry of certificates of conformity established by the central body of executive power for conformity assessment issues.

**Article 30.** Acceptance of Conformity Assessment Conducted Outside the Country

Results of conformity assessment procedures, (including certificates of conformity and other documents regarding results of testing of products) conducted outside of Ukraine, shall be accepted and recognized in Ukraine, according to international agreements of Ukraine on mutual recognition of the results of conformity assessment. The results of conformity assessment (certificates of conformity, conformity marks, reports on product testing) shall be recognized based on agreements on mutual recognition of results of conformity assessment concluded by Ukrainian and foreign designated bodies for conformity assessment issues.

When signing international agreements on mutual recognition of results of conformity assessment it is necessary to insure/verify:

Adequacy and technical competence of the relevant conformity assessment bodies of the party to the agreement;

Ensuring by the conformity assessment body of the party to the agreement long-term reliability of their assessment results;

Observance by the conformity assessment bodies of the party to the agreement of guidelines and recommendations of international standardisation organisation.

Recognition of the results of conformity assessment may be limited to acceptance of results of conformity assessment of certain conformity assessment bodies of the party to the agreement.

The conformity assessment results may be recognized without concluding relevant international agreements on mutual recognition when Ukraine and the party which requests recognition are members of international or regional conformity assessment organisations. The recognition of conformity assessment results shall be performed in accordance with procedures established by these international or regional organisations.

**Article 31.** Complaints Regarding Conformity Assessment Procedures

A person, who applied for conformity assessment, may appeal the actions and decisions of a conformity assessment body by means of submitting an appeal to the commission for appeals established within conformity assessment bodies or to the appeals commission of the relevant central body of executive power or in compliance with the court procedure.



Application of National conformity marks to product, processes or services that are subject to technical regulations when conformity marks are not specified in relevant technical regulations shall not be permitted.

**CHAPTER V. OBLIGATIONS OF PRODUCERS AND SUPPLIERS OF PRODUCTS OBJECTS TO TECHNICAL REGULATIONS AND CONTROL OF COMPLIANCE WITH THE REQUIREMENT OF TECHNICAL REGULATIONS**



**Article 36.** The Procedure of Market Supervision and Authorities of Bodies of Executive Power in the Sphere of Market Supervision.

The law establishes the procedure of conducting market supervision, rights, obligations, authorities and responsibility of state officials, measures to be taken according to results of supervision.

**CHAPTER VI. PROVIDING INFORMATION ON TECHNICAL REGULATIONS, STANDARDS**

the foreign trade of countries with which a relevant international agreement is in force or when required by a relevant international agreement or the terms of membership of the relevant international and regional organisations of which Ukraine is a member, a notification regarding the abovementioned drafts shall be sent to interested parties according to the procedures stipulated by the relevant international agreements and/or relevant international and regional organisations.

parties of agreement (contract) concerning development, production or supply of products, if the agreement (contract) refers to the standards;

producer or supplier of products if the producer or supplier compiled declaration of conformity attesting to conformity of products with the certain standards or used standard sign in product marking.

3. If the products are produced for export and the agreement (contract) defines other requirements than those established by the technical regulations, application of the agreement (contract) provisions shall be allowed unless these provisions contradict the legislation of Ukraine regarding requirements to products manufacturing, storing and transportation at the territory of Ukraine.

2) In the Law of Ukraine „On Standardization” (Vidomosti of Verkhovna Rada of Ukraine, 2001, N 31, p. 145)

a) in Article 1:  
item 9 shall read:

“Standard – a document developed on the basis of consensus and approved by the rele TD.011.6(mt)83s-9.6(t)8.3(p rodv-567(ri7.1(od-567(res,)-5.7(tfr sco-567(rmmon)-5.7(tan-567(rd-567(rrelpea-567(rt7.1(o)-111(od-567(r)5.6(a)-11uOb-5.9(ej7.9( e-.3(r)-5.9(t)723(s) )-5.9(n)6.79 stand)-5.59()5.4(i)-4.3(idis)-5.9(ti)nii.pnuct s,proi.ssn urvcae werrials ob-4.3(o)di, b,harjst-5.9(eg-4.3(o)5(78r-5.76ogj-ay-9.268(,2)11.4)5.7(r)7(2)5.5)5.6(1)5.6(ow-9778gh)14aicto pPr.ce -5.6(f)7.2(o)-5.3( r)h.n,oAd-5.64od5.4(p)-5.7( )8.74 i2.48o n1721 nd 12.48oo8.2(.c-5.7( a-5.7( )8.74 : uOrganisoA-9778g re entooTchns Brie564(lt-3.4.d to )5.6(pT-6.18lt-3.4.d)564(l)-5.52ae”564(l),5.6(ow-9778gh)14aicto



Development, approval, adoption, review, and revision of standards of a relevant level, and suspension of their validity, setting up rules for development, assigning identifying codes and application of those standards;

Representation of Ukraine in specialised international and regional organizations for standardisation, meeting obligations prescribed by regulations of these organizations;

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The property right to national standards, rules of practice, classifiers and catalogues belongs to the State. The central body of executive power for standardisation issues practices owner's right to these documents on behalf of the State.

The property right to standards, technical specifications and codes of good practice, adopted or approved by

”Attestation – issuance of a document (certificate of conformity or declaration of conformity) based on a decision following relevant (necessary) conformity assessment procedures that proved compliance with prescribed requirements”;

“Technical regulation – law of Ukraine or legal act approved by Cabinet of Ministers of Ukraine, which lays down product characteristics or their related processes and production methods, as well as requirements for services, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process, or production method”.

Add new items that shall read:

“Conformity assessment body – a body that performs conformity assessment services;

Designating authority – body, established or empowered by the Cabinet of Ministers of Ukraine to designate conformity assessment bodies, suspend or withdraw their designation or remove their suspension from designation.

Conformity assessment – establishing proof, by conducting testing, inspection and certification, that prescribed requirements relating to a product, process, system, person or body are fulfilled.

Designation – provision the rights to perform specified conformity assessment activities to requirements of the technical regulations by the body established or

by language “designated conformity assessment bodies”, “central body of executive power for conformity assessment issues”, “technical regulation” respectively.

3. The Cabinet of Ministers of Ukraine shall within the month period:

bring its normative-legal acts in compliance with this Law;

ensure bringing by the Ministers and other central bodies of executive power their normative-legal acts in compliance with this Law;

President of Ukraine

V. Jushchenko

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