

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 in the area of standardization, technical regulation and conformity assessment.

General Provisions

Definitions of Terms Used in the Law

Specified requirements — requirements, prescribed in the technical regulations, standards, codes of the good practice and technical specifications;

Equivalency— sufficiency of different conformity assessment results to provide the same level of assurance 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 provisional suspension from designation.

Organizations – enterprises, establishments, organizations, state power bodies or other establishments, their departments or associations with the status of legal entity or without, public or private, or other forms of ownership, which operate independently, have statute and own management structure;

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

Attestation – issuance of a document (certificate of conformity or declaration of conformity) based on a decision following relevant (necessary) conformity assessment procedure used, directly or indirectly, to determine that prescribed requirements in relevant technical regulations or standards are fulfilled. Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

Process – a procedure or method, including a production method;

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 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.

Sphere of Application of the Law

This law regulates relations, connected with activity in the sphere of standardization, technical regulation, including conformity assessment, application of its results and applies to subjects of business activity notwithstanding the forms of ownership and types of activity, state bodies and relevant public organizations.

The requirements of this Law shall not apply for procedural issues concerning development, adoption, review, amendment and cancelling technical regulations, which are approved by the law.

This law shall not apply to sanitary measures developed and applied specifically to protect human health from food-borne health hazards, to phytosanitary measures developed and applied to protect plant health and life from hazardous organisms, and to veterinary-sanitary measures developed and applied to protect animal and human

health and life from animal diseases, as well as to conduct with nuclear materials, pharmaceutical products, standards of medical service, construction norms, accounting, education and other social standards, whose scope is regulated by other legislation of Ukraine.

The provisions of this Law and regulations adopted for the enforcement of this Law shall not apply to products confiscated due to violation of administrative legislation of Ukraine and are placed in the disposal of by the customs authorities, amateur home-built products, used and repaired products transferred (traded) outside business activities, products modified by consumers after purchase, works of art, products of handicrafts, applied arts and the artistic trades and unique memorials of cultural heritage, as well as products imported individually for personal needs, unless specified otherwise by other legislation of Ukraine.

Legislation of Ukraine for Standardisation, Legal Regulation in the Technical Sphere and Conformity Assessment

Legislation of Ukraine for standardisation, legal regulation in the technical sphere, and conformity assessment consists of this law and sub-legal acts issued pursuant to this law that regulate relationships in this sphere.

Objects of Standardisation and Legal Regulation in the Technical Sphere

Objects of standardisation are products, processes and services, in particular, materials, component parts, equipment, systems, their compatibility, rules, procedures, functions, methods or activity, personnel and bodies, as well as terminology, symbols, packaging, marking or labelling requirements.

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:

International and regional standards, if they exist or if their completion is imminent, except where they would be ineffective or inappropriate due to, an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems or country specific characteristics, conditions and institutions;

Standards, technical regulations and conformity assessment procedures, or the relevant parts of them, from countries that are members of the relevant international or regional organisations, or with which a relevant international agreement Ukraine is in force, or with which a mutual recognition agreement regarding development and application of standards, technical regulations and conformity assessment procedures is in force;

Scientific achievements, knowledge and practice.

If relevant international or regional standards referred to in paragraph two of this Article are not used as the basis for a standard, technical regulation or conformity assessment procedure, a written explanation shall be provided upon the request of an interested party.

Standards, technical regulations and conformity assessment procedures shall, when possible, take into account the special development, financial and trade needs of developing country members of the World Trade Organisation.

Standards and technical regulations shall be elaborated based on product requirements in terms of performance rather than design or descriptive characteristics and shall be cl

Interested parties shall submit proposals for conduc

The central body of executive power for standardisation issues shall coordinate the examination of existing national standards for compliance with legislation, producer and consumer needs, scientific and technological development, state interests and international and regional standards. Examination of existing national standards shall be conducted by corresponding technical committees or by organisations with relevant scientific and technical experience. National standards for products shall be examined at least once per five years.

In accordance with the provisions of Article 8 of this Law, interested parties may submit proposals for the review, amendment or abolishment of a national standard.

The relevant technical committee shall evaluate proposals regarding amendment of national standards in force and if approved, such proposals are submitted to the central body of executive power for standardisation issues with the aim of entering the latter in the work programme.

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.

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consists of 17 members. Not less than half of the Council

The work programme for development of technical regulations adopted by the central body of executive

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 emergency technical regulation shall be taken into account without discrimination and the emergency technical regulation revised as necessary. The revised emergency technical regulation shall be adopted and published according to the provisions of paragraphs 3 and 4 of this Article.

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.

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 submitted to the central body of executive power for legal regulation in the technical sphere issues for such assessment by any interested party, whether domestic or foreign. The proposal shall include a copy of the foreign technical regulation translated into Ukrainian, identification of the relevant Ukrainian technical regulation and sufficient information to demonstrate equivalence of the technical regulations.

Evaluation of the equivalence of a foreign technical regulation with a relevant Ukrainian technical regulation shall be performed by the working group established by the central body of executive power for legal regulation in the technical sphere issues based on mandatory analysis of relevant international and regional standards; analysis objectives of the foreign and domestic technical regulations; and the level of protection afforded by the technical regulations. Equivalence shall not be denied solely because the means for meeting the objectives and the means of ensuring the required level of protection differ.

If the working group concludes that the foreign technical regulation is not equivalent to the relevant Ukrainian technical regulation, justification for the decision shall be prepared and the central body of executive power for legal regulation in the technical sphere issues shall forward such justification to the interested party that submitted the proposal for equivalence. The interested party may appeal the decision by requesting evaluation of the

that the standard processing period of each conformity assessment proc

The typical provision of commissions for appeals, and the procedure of consideration and resolution of appeals shall be established and approved by the central body of executive power for for conformity assessment issues.

Declaration of Conformity and Certificate of Conformity

The producer of a product shall compile a declaration of conformity for all products subject to technical regulations that are placed in circulation, unless otherwise stipulated in technical regulations.

Unless otherwise stated in a relevant technical regulation, the declaration of conformity shall include at least the following information:

The identification of the product (name, type or model number, and any relevant supplementary information such as lot, batch or serial number, sources and numbers of items);

All relevant requirements of the technical regulation(s) that a product complies with, including reference to national standards when relevant;

Supplementary information such as grade or category of the product if applicable according to the technical regulation;

Date of issue of the declaration, name and title of the signatory and signature of the producer or his designated representative;

Name, address and identification number in register of designated bodies, if any, of the conformity assessment bodies that conducted conformity assessment procedures; and

A contact name and address where the technical documentation attesting to conformity is held.

The producer must possess certificates of conformity issued by the conformity assessment bodies according to the law, when so required by the relevant technical regulation, to validate the declaration of conformity.

The central body of executive power for conformity assessment issues shall establish a form for the declaration of conformity.

The declaration of conformity issued in accordance with the requirements of technical regulations shall be

Withdraw from circulation products that do not comply with relevant technical regulations;

Maintain declaration and/or certificates of conformity and other technical documentation proving conformity with relevant technical regulations for the expected life of products placed in circulation and provide such information upon request to market supervision bodies.

Cover damages suffered by consumers of a product in cases where lack of conformity of the product to the requirements indicated in the declaration of conformity and/or the certificate of conformity is demonstrated.

When the producer is not resident in Ukraine, and there is no authorised representative of the producer in Ukraine, the supplier of a product placed in circulation is obliged to:

Provide market supervision bodies, with necessary information regarding the product, including a copy of the declaration of conformity and, when required by the relevant technical regulation, the certificate of conformity and/or other technical documentation verifying conformity of the product with relevant technical regulations;

Stop or suspend selling of the product if it is shown that the product fails to comply with relevant technical regulations or the provisions of this Law.

Goal of Market Supervision

The goal of market supervision is to control that placed in market products, processes and services fulfil

the relevant expert working group is scheduled to finalise a draft technical regulation or conformity assessment procedure.

Adopted emergency technical regulations and/or emergency conformity assessment procedures shall be notified promptly through the Centre after their publication in the Official Gazette of Ukrai(h)4.4(j(d)-fyo(e)2.1d)4.4(rai

Objects of standardisation are products, processes and services, in particular, materials, component parts, equipment, systems, their compatibility, rules, procedures, functions, methods or activity, personnel and bodies, as well as terminology, symbols, packaging, marking or labelling requirements.

c) in Article 5:

paragraph one shall read:

“The goal of standardization in Ukraine is to ensure the rational use of all kinds of national resources, conformity of objects of standardization to their intended use, inform consumers about the quality of products, processes and services, and support development of, and promote, internationally competitive production and trade in products and services”.

add paragraph two with item ten that shall read:

“Adoption and implementation by standardising bodies in the territory of Ukraine of the Code of Good Practice for the Preparation, Adoption and Application of Standards in accordance with the World Trade Organisation Agreement on Technical Barriers to Trade”, which is the Annex to the Marrakech Agreement on Establishing of the World Trade Organization 1994;

d) Item 3 of Article 6 shall read

“Standardization and Technical Regulation Council”;

e) in Article 7:

in paragraph two item 2 shall read:

“Ensure implementation of state policy for standardisation, including taking reasonable measures to ensure that other state and non-governmental standardizing bodies within Ukraine, as well as regional standardizing bodies established within the territory of Ukraine and of which a relevant state body is a member, accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in accordance with the World Trade Organisation Agreement on Technical Barriers to Trade”, which is the Annex to the Marrakech Agreement on Establishing of the World Trade Organization 1994;

Delete items 8 and 10

Add new items that shall read:

“Ensure adaptation of standards, conformity assessment procedures and certification procedures and practices according to modern achievements of science and technology;

Prescribe the procedure for establishing technical committees, establish technical committees, determine their authorities and tasks, and terminate their activities;

Ensure that all national standards comply with this Law;

Establish a symbol or symbols (marks) to be used to indicate conformity of products with national standards (hereinafter: standards conformity sign);

Participate in development of technical regulations and contribute to preparation of a work programme for technical regulations;

Participate in the preparation of international and regional standards by relevant international and regional organisations due to the adoption or elaboration of national standards and in the preparation of recommendations for conformity assessment procedures, ensuring that the interests of Ukraine are taken into account;

Cooperate and consult with relevant bodies of other countries for standardisation, and, when necessary, make an objective effort to resolve any disputes or complaints that arise;

Prepare a standardisation work programme and at least semi-annually, update and publish the above programme;

Maintain a register of standards and standardisation-related documents;

Organises creating and maintaining the national inventory of normative documents and the national information centre of the international information network ISONET;

Organises dissemination and sale of official publications of national standards, rules of good practice, and classifiers and other printed material related to adopted national standards as well as documents of the international and regional standardisation organisations of which it is a member or collaborates with on the basis of the statutes of, and/or applicable agreements with, the above organisations and also delegates this authority to other organisations;

Promote and help develop interaction between producers, suppliers, consumers of products, processes and services, and relevant state bodies in the sphere of standardisation.”

f) Article 8 shall be removed;

g) add Article 9 with the paragraph 6 that shall read:

“Membership in the technical committees for standardization is voluntary”.

h) Article 10 and 11 shall read:

“Article 10. Other subjects that deal with standardization

Central bodies of executive power and organizations have the right to organize and conduct standardisation activities with regard to their authorities and business and professional interests, including:

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;

Setting up and maintaining an inventory of legislative acts and normative documents for their activities and informational exchange;

Publish, and disseminate of their own standards, documents of the specialised relevant international and

Publication and dissemination of documents of the relevant international and regional organizations of which Ukraine is a member is conducted by the central body of executive power for standardisation and organisations involved in standardisation on the grounds of their statutes.

To provide information to interested parties, the central body of executive power for standardisation shall function as the national information centre of the international information network for standards (ISONET) and maintain a catalogue of national standards.

Bodies and organisations that develop and adopt standards that are likely to create barriers to foreign trade shall provide copies of draft and adopted standards to the central body of executive power for standardisation, which has the right to disseminate this information to interested parties through the national information centre of ISONET.

Information services shall be provided by means of publication of official texts of standards, information and reference publications as well as their dissemination via information networks either upon one's own discretion or on request.

k) in the Law language "central body of executive power in the sphere of standardization" shall be replaced by language "central body of executive power for standardization issues" respectively.

3) In the Law of Ukraine „On Conformity Assessment” (Vidomost of Verkhovna Rada of Ukraine 2001 p., N 32, p. 169; 2005, N 2, p 33)

a) in Article 1:

item 8 and 15 shall read:

”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”;

e) in the Law language “authorized certification body”, “specially authorized central body of executive power in the sphere of conformity assessment”, “technical regulation on conformity assessment” shall be replaced 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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