LAW of UKRAINE

No. 2408-III

On Standardization

This Law sets up legal and organizational framework for standardization in Ukraine and is intended to ensure the uniform technical policy in this sphere.

Chapter 1. General provisions

Article 1. Main terms and their definitions

In this law terms are used in the following meaning:

standardization – activity that consists in setting up provisions for general and multiple application with regard to existing or possible tasks with the purpose of reaching an optimal level of order in a certain sphere, which results in an increase of the conformity rate of products, processes and services to their functional destination, removal of trade barriers, and promotion of scientific and technical cooperation;

international standardization – standardization, carried out at the international level participation in which is open for relevant bodies of all the countries;

regional standardization – standardization, conducted at a corresponding regional level, and participation in which is open for relevant bodies of the countries of a certain geographical or economic area;

national standardization – standardization, which is conducted at the level of one country;

 $standardization\ body$ – a body that deals with standardization, recognized at the national, regional or international level, with the key functions of development, approval or adoption of standards;

normative document – a document that sets up rules, general principles or characteristics of various types of activity or their results. This term incorporates such notions as "standard", "code of practice", and "technical specifications";

consensus – general agreement characterized by the absence of serious objections on significant issues with most of the interested parties, and is reached in the result of the procedure that takes into consideration opinions of all parties, and reaching understanding on disputable issues;

standard – a document that sets up rules for general and multiple application, general principles or characteristics related to an activity or its results with the purpose of reaching an optimal level of order in a certain sphere, and developed on the basis of consensus according to the established order;

international and regional standards – standards, established by an international and regional standardization body respectively;

national standards – state standards of Ukraine, established by the central body of the executive power in the sphere of standardization and are accessible to a wide range of users;

code of practice (collection of the rules) – a document that contains practical rules or procedures of design, manufacturing, mounting, technical maintenance, use of the equipment, constructions or products. The code of practice may be a standard, a part of a standard or a separate document;

technical specifications – a document that sets up technical requirements the products, processes and services must conform to. Technical specifications may be a standard, a part of a standard or a separate document;

technical regulation – a normative and legal act, adopted by a state body that sets up technical requirements to products, processes or services directly or through references to standards, or reproduces their contents.

Article 2. The scope of the Law

This Law regulates relations, connected with standardization activity and application of its results, and extends to economic operators notwithstanding the type of ownership and activity types, bodies of executive power as well as public organizations.

This law does not apply to nuclear materials, pharmaceutical products, standards of medical service, accounting, education and other social standards, whose scope is regulated by other laws.

Article 3. Legislation of Ukraine in the field of standardization

Legislation of Ukraine in the field of standardization consists of this law and other normative and legislative acts that regulate relationships in this sphere.

Article 4. Objects of standardization

Objects of standardization are products, processes and services (hereinafter – products), in particular materials, component parts, equipment, systems, their compatibility, rules, procedures, functions, methods or activities.

Article 5. Goal and basic principles of the state policy in the field of standardization

The goal of standardization in Ukraine is to ensure safety for the health and life of persons, animals, plants, as well as property and environment protection, to create conditions for rational use of all kinds of national resources as well as for conformity of objects of standardization to their intended use, to eliminate technical barriers to trade.

The state policy in the field of standardization is based on the following principles:

- ensuring participation of physical persons and legal entities in development of standards and free choice of standard types while producing or supplying products unless otherwise stipulated by legislation;

- openness and transparency of the procedures for development and adoption of standards with consideration of interests of all interested parties, increase of competitiveness of home products;
- accessibility of relevant standards and information to users;
- conformity of standards to legislation;
- adaptation to modern achievements of science and technology taking into account the state of the national economy;
- priority of direct introduction in Ukraine of international and regional standards;
- compliance with international and European standardization rules and procedures;
- participation in international (regional) standardization.

Chapter 2. Organization of standardization

Article 6. Subjects of standardization

Subjects of standardization are:

central body of executive power in the field of standardization;

Standardization Council;

technical committees for standardization.

other bodies that deal with standardization.

Article 7. Central body of executive power in the field of standardization

The central body of executive power in the sphere of standardization shall organize, coordinate and carry out activities in development, approval, adoption, revision, amendment and dissemination of national standards according to the scope of this law, and – as the national standardization body - represent Ukraine in international and regional standardization organizations.

The key functions of the central body of executive power in the field of standardization are as follows:

ensuring implementation of the state policy in the field of standardization;

undertaking measures for harmonization of the developed national standards with relevant international (regional) ones;

participation in development and approval of technical regulations and other legislative standardization acts:

setting up rules for development, approval, adoption, revision, amendment and withdrawal of the national standards, their designation, classification according to the types and other criteria, their encoding and registration;

taking measures to perform liabilities, stipulated by membership in international (regional) standardization organizations;

cooperation with relevant bodies of other countries in the field of standardization;

elaboration of the work program on standardization, coordination of its implementation;

making decisions on the establishment and termination of activities of technical committees for standardization, determining their authorities and the procedure of establishment;

creation and upholding of the national archive of normative documents and the national information center of the International information network ISONET WTO;

providing information services in the field of standardization.

The central body of executive power in the field of standardization can have other functions and authorities according to laws of Ukraine.

The central body of executive power in the field of standardization shall submit proposals to the Cabinet of Ministers of Ukraine on delegating authorities related to organization of development, approval, adoption, revision and amending of the national standards in the field of construction and construction materials to another body of executive power in this field of activity.

Article 8. Standardization Council

Standardization Council (hereinafter – the Council) is a collective consultative and advisory body at the Cabinet of Ministers of Ukraine.

The Council's members and the Council's Provisions are approved by the Cabinet of Ministers of Ukraine.

The principal objective of the Council's activities is to develop an interaction between manufacturers, consumers of products and state authorities, coordination of interests in the field of standardization, promotion of standardization development.

The Council is formed on the parity basis from the representatives of executive power bodies, the central body of executive power in the field of standardization, economy subjects, the National Academy of Sciences of Ukraine, branch-wise academies of sciences and corresponding public organizations. Council's activities are based on the principles of transparency and publicity.

The key functions of the Council are study, analysis and elaboration of propositions regarding improvement of activity in the field of standardization with respect to:

setting up of technical committees for standardization and determining their scope of work;

adoption of an international, regional or other standard as a national standard;

expertise of the draft technical regulations and other normative documents in the field of technical regulation;

standardization work programs.

The Council has the right to:

obtain from bodies of executive power information and materials on the issues within its scope of work;

if necessary involve specialists of executive power bodies, scientific and research institutions and organizations in the work of the Council according to the established procedure;

submit proposals to corresponding executive power bodies and local governments on the issues being in its competence.

Article 9. Technical committees for standardization

The central body of executive power in the field of standardization establishes technical committees that shall be entrusted with the functions of development, consideration and agreement of international (regional) and national standards.

Technical committees for standardization are formed on the principle of representation of all interested parties. Authorized representatives of government agencies, local governments, entrepreneurs and their associations, scientific and engineer fellowships (unions), consumer associations and other public organizations, eminent scientists and professionals can participate in the activities of the technical committees for standardization on the voluntary basis.

Organizational supply of technical committees' activities is conducted by their secretariats.

Provisions on technical committees are adopted by the central body of executive power in the field of standardization.

Technical committees may have generating profit from their activities as their goal.

Article 10. Other bodies that deal with standardization

Central bodies of executive power, the Supreme Council of the Autonomous Republic of Crimea, the Council of Ministers of the Autonomous Republic of Crimea, local bodies of executive power and local governments, entrepreneurs and their associations, and corresponding public organizations have the right to organize and conduct standardization activities in the fields within their scope and within authorities, established by law and with regard to their business and professional interests, including:

development, approval, adoption, revision, change of standards of a relevant level, and suspension of their validity, setting up rules for development, designation and application of those standards;

submission to the central body of executive power in the field of standardization of proposals regarding the setting up of technical committees for standardization and development of national standards or adoption of international (regional) or their own standards as national ones;

representation of Ukraine in corresponding international and regional specialized organizations for standardization, meeting obligations, imposed by the membership in those organizations;

setting up and upholding information archives of legislative acts and normative documents for their activities and information exchange;

publication and dissemination of their own standards, documents of specialized international, regional organizations for standardization, wherein they are members, or with which they cooperate on the basis of the statutes of those organizations or relevant agreements, and delegation of these authorities to other legal entities;

keeping the central body of executive power in the field of standardization informed on their activities in standardization.

Any interested persons can deal with standardization, consider drafts of national standards being developed and submit to the developer relevant proposals and comments on them.

The Ministry of Defense of Ukraine – taking into account peculiarities of the field of defense – establishes the procedure of standard application to secure needs of defense of Ukraine in compliance with the functions entrusted to it.

Chapter 3. Standards and their application

Article 11. Development, adoption, examination, amendment, and revision of standards

Depending on the level of the body that adopts or approves the standards, standards are subdivided into:

national standards, codes of practice and classifiers, adopted or approved by the central body of executive power in the field of standardization, catalogues and registers of general use all over the country issued by it;

standards, codes of practice and technical specifications adopted or approved by other bodies that deal with standardization.

Standards shall meet the market needs, encourage the development of free trade, increase of competitiveness of home products, and shall be stated in such a way that it would be impossible to apply them to mislead consumers about a product, covered by the standard, or for giving preference to the producer of a product or a product on the basis of the place of its manufacturing.

Object of standardization can be an object of intellectual or industrial property, if the developer of a standard according to established procedure obtained permission from the owner of the rights on this object.

Annually the central body of executive power in the field of standardization elaborates the work program (hereafter-program) for standardization activities. The program is formed taking into account state priorities, proposals of the technical committees for standardization and other subjects of standardization, involved in elaboration. The program contains a list of national standards that have been accepted for development. The program shall be published at least once per six months in the official edition of the central body of executive power in the field of standardization, and placed in information networks.

National standards are developed by technical committees for standardization and in the case of their absence – by other bodies of standardization that have relevant scientific and technical potential.

The rules and the procedure of development, approval, adoption, revision, amendment and termination of national standards validity, which are set up by the central body of executive power in the field of standardization, have to provide:

criteria of consideration or rejection of proposals concerning development of national standards;

criteria of determination of developers of national standards;

procedure for determination of priorities concerning application of international (regional) standards;

procedure for appeals;

procedure for informing interested parties on the works in the field of national standardization. The term of consideration of a draft national standard and submission of comments cannot be less than 60 days from its publication date;

familiarization of all interested parties with draft national standards;

While approving or adoption of a national standard the central body of executive power in the field of standardization determines the date, when the standard enters into effect taking into consideration the time for preparatory measures with respect to its introduction.

The list of national standards, approved and adopted within a month, is published next month in the official edition of the central body of executive power in the field of standardization.

International (regional) standards become effective as national ones provided they have been adopted by the central body of executive power in the field of standardization.

Adoption of an international (regional) standard is publication of the national standard, based on a corresponding international (regional) standard, or confirmation that the international (regional) standard has the same status that has the national standard, specifying any deviation from the international (regional) standard.

Examination of the existing national standards for conformity to legislation, state interests, consumer needs, level of science and technology development, requirements of international (regional) standards is carried out by corresponding technical committees and other standardization subjects in compliance with this Law. Standards for products are examined at least once per five years. Corresponding technical committees or other standardization subjects submit proposals on revision,

amendment or repeal of standards to the central body of executive power in the field of standardization by the results of examination.

Revision, in the result of which a new national standard is developed, or amendments made to the existing standard, is carried out in compliance to the procedure established for standard development.

Termination of a national standard is conducted by the central body of executive power in the field of standardization in case the product regulated by the given standard is phased out, and in case of development, approval or adoption of another standard instead of the existing one on request of a corresponding technical standardization committee or other subject of standardization in compliance with this Law.

Information on changes, text of changes to national standards is published in the official edition of the central body of executive power in the field of standardization not later than 90 days before they enter into effect.

Article 12. Procedure of standards application

Standards are applied on voluntary basis, unless otherwise stipulated by legislation.

Standards are applied either directly or through references to them in other documents.

Application of standards or their certain provisions can become mandatory:

for all entrepreneurs, if this is stipulated in technical regulations or other normative and legislative acts;

for parties under agreement (contract) on the design, manufacturing or supply of a product, if standards are referred to in this agreement (contract);

for a producer or supplier of a product if he filled in the declaration of conformity of product to certain standards or used designation of those standards in product's marking;

for a producer or supplier of product if his product has been certified with regard to the requirements of those standards.

International (regional) standards and standards of other countries, if their provisions do not contradict to legislation, can be applied in Ukraine according to the established procedure through references to them in national standards and other standards.

Standards that have been applied during the manufacturing of a product shall be kept for 10 years after the manufacturing of the last item of the product.

Article 13. Application of standards in technical regulations and other normative and legislative acts

Technical regulations and other normative and legislative acts set up mandatory requirements for:

protection of life, health or property of a person;

protection of animals and plants;

environment protection;

safety of products, processes or services;

preventing deception regarding the intended use and safety of products;

elimination of a threat to the national security.

In the case of reference to standards in technical regulations or normative and legislative acts it is pointed out whether the compliance with certain standards is the only or just one of the ways of meeting the requirements of these documents. Manufacturer or supplier has to prove that products, manufactured without application of standards, meet the requirements of certain technical regulations or other normative and legislative acts.

In case of arising of objective obstacles to application of mandatory requirements of the national standards, manufacturer or supplier shall notify about it the central body of executive power in the field of standardization. At the same time manufacturer can address the central body of executive power in the field of standardization with proposals related to repeal, extraordinary revision and making corresponding changes to this standard, or with a substantiated petition on issuing the permit to temporary production with deviation from the specified mandatory requirements. The central body of executive power in the field of standardization studies the foundation of manufacturer's petition, conducts corresponding expertise if necessary, and once there are sufficient grounds, and when agreed upon with the central body of executive power that conducts control over observation of corresponding requirements of the national standard, may issue such a permit, and introduce limits to the term of validity of the permit.

In case of manufacturing the products for export and if the agreement (contract) contains other requirements than those, set up in the technical regulations or other normative and legislative acts of Ukraine, it is permitted to apply the requirements of the agreement (contract), if they do not contradict to legislation in the part that regulates the process of production, storage and transportation within the territory of Ukraine.

State monitoring over the compliance with the requirements of technical regulations or other normative and legislative acts of Ukraine is conducted in accordance with legislation.

Persons guilty of violation of legislation in the field of standardization are held liable in accordance with Ukrainian legislation.

Article 14. Mark of conformity to national standards

The central body of executive power in the field of standardization has the right to introduce a mark of conformity of products to national standards.

The national mark of conformity of products to national standards is a mark that certifies conformity of the marked products to all standard requirements, extending to the given product.

The description and the rules of application of the national mark of conformity of products to national standards are established by the central body of executive power in the field of standardization.

Conformity of product to national standards can be voluntarily assured according to the procedure, established by the central body of executive power in the field of standardization.

Chapter 4. Provision of information, and the property right to standards, codes of practice and technical specifications

Article 15. Property right, publication and dissemination of standards

The property right to national standards, codes of practice, classifiers and catalogues belongs to the State. The central body of executive power in the field of standardization practices owner's right to these documents on behalf of the State.

The property right to other standards, developed by other subjects of standardization belongs to subjects at whose expense they are developed, or to whom it is transferred according to the procedure established by legislation.

National standards, codes of practice, classifiers and catalogues are published, republished and disseminated by the central body of executive power in the field of standardization.

Publication and dissemination of documents of international (regional) standardization organizations, wherein Ukraine is a member, is conducted by the central body of executive power in the field of standardization and other standardization subjects on the grounds of statutes of these organizations.

Full or partial reproduction, copying and distribution as official editions of any standards, codes of practice, technical specifications or their parts is forbidden without the permission from their owner or his authorized person, except for cases stipulated by the Law.

In case of reproduction or dissemination of a standard, code of practice, technical specifications without the permission of the owner or his authorized person, the standardization subject shall be held responsible for discrepancy between the text of the disseminated document and its official text, or consequences caused by application of the disseminated document.

Subject of standardization is entitled to reimbursement of losses, caused to him by unauthorized dissemination of the standard, the code of practice, technical specifications according to the law.

The procedure for publication and dissemination of technical regulations is established by law.

Article 16. Provision of information services

Provision of information services is conducted through the publication of official texts of standards, information and reference publications as well as dissemination via information networks either on one's own initiative or on request.

The central body of executive power in the field of standardization provides information to domestic as well as foreign users through the main information archive of normative documents and the National information center of the International information network ISONET WTO.

To provide information to users the central body of executive power in the field of standardization forms the catalogue of normative documents in the field of standardization on the national level and sets up rules for its creation and upholding.

Standardization subject, responsible for the development and adoption of standards that are likely to create technical barriers to trade, provides relevant information to the central body of executive power in the field of standardization, which transfers this information to users through the information network ISONET WTO within the terms, established by the "Code of Good Practice".

Chapter 5. International cooperation

Article 17. International cooperation in the field of standardization

The central body of executive power in the field of standardization according to the legislation represents interests of Ukraine in the international standardization bodies, takes measures for the adaptation of the Ukrainian legislation on standardization with the legislation of European Union, cooperates in this sphere with relevant bodies of other countries, makes decisions on the accession of Ukraine to the international (regional) standardization systems, concludes agreements on cooperation and performing of works in the sphere of standardization.

If an international agreement of Ukraine, consent to obligation of which is given by the Verkhovna Rada, contains other provisions than those contained in this law, the provisions of an international agreement are applied.

Chapter 6. Financing of the standards works

Article 18. Source of financing

Standards works are financed by customers of these works.

The sources of financing are:

funds of the State budget of Ukraine;

funds, allocated for implementation of programs and projects;

funds of subjects of economic activity; bank credits;

other funds, envisaged by legislation.

The expenses of enterprises related to the development of standards are included into the expenses on scientific and technical supply of their business activity.

Expenses on standards works of the budget-financed institutions and organizations are reimbursed through the funds, allocated for their maintenance.

The customers of standards works, financed through the state budget, are the central bodies of executive power, responsible for technical regulation in certain spheres of activity in accordance with legislation.

Orders of standardization works at the expense of the State budget of Ukraine, including the state defense order are conducted without any trades (tenders).

Article 19. Use of funds, received from sales of standards

Funds received from sales of national, regional and international standards are allocated exclusively for fulfillment of standardization works and development of scientific and technical base.

Chapter 7. Final provisions

This law becomes effective on the day of its publication.

2. The Cabinet of Ministers shall be liable to do the following within a year after this Law enters into force:

submit to the Verkhovna Rada of Ukraine draft laws on bringing the laws of Ukraine into line with this Law;

adopt normative and legislative acts, arising of this Law;

ensure bringing of its normative and regulatory acts, as well as those of ministries and other central bodies of executive power into line with the norms hereof;

determine the procedure and terms of validity of branch-wise standards or other normative documents of the former USSR regarded as such standards.

- 3. State and other standards remain valid before they are terminated, or corresponding standards are adopted in compliance with requirements of this Law.
- 4. Requirements of state and other standards, mandatory for implementation remain valid before corresponding technical regulations and other normative and legislative acts regulating these issues are adopted.
- 5. Before legislation is brought into line with this Law, legislative and other normative and legislative acts shall be applied to the extent that does not contradict to this Law.

President of Ukraine

L. KUCHMA

Kyiv May 17, 2001 N 2408-III