

**DRAFT****LAW OF UKRAINE****„On development and application of 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*, the granting of the right to use conformity marks for all *products, processes and services*, whether of domestic or foreign origin, to economic operators, bodies of executive power, and public organisations and also the supervision of the implementation of this Law.

**CHAPTER I. GENERAL PROVISIONS****Article 1. Definitions of Terms Used in the Law**

In this Law, the following terms shall have the following meanings:

**Accreditation** – a procedure in the course of which an accreditation body conducts documentary certification of the competence of a legal entity or a *conformity assessment body* to carry out specific activities (testing, calibration, certification, inspection);

**Safe product (process)** – a *product* and *process* that does not have a harmful effect, directly or indirectly, on human, plant and animal health and life, as well as the environment and natural resources, provided that this *product* or *process* is used according to its intended use and is *placed in circulation* in compliance with the requirements of this Law;

**Placement in circulation** – the first transfer from the final stage of production or import stage to the utilization stage, of a *product* either for the use of third parties or for own use, or the use of a *process* or *system* by a specific person for the first time, or provision of a *service* to a specific person for the first time.

**Testing** – determination of one or more characteristics of a given *product, process, system* or *service*;

**Producer** – the *person* that manufactured or processed a *product*, or the *person* that placed, or had another place, on the *product* its trade name or name identifying it as the *producer*, or the *person* that designed a *process* or transferred rights to use a *process*.

**International and regional standardisation organisations** – international and regional organisations responsible for development of *international and regional standards* and *conformity assessment procedures*, of which Ukraine is or may become a member.

**International agreement** – any international agreement, 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*.

**Declaration of conformity** – the document issued by the *first party* following *attestation*;

**Product declaration** – the listing of mandatory information by the *producer* or *supplier* on the packing or label for identifying the *product, product type*, its *supplier*, main characteristics and other mandatory information required by a *technical regulation*.

**Mark of conformity with state system of certification** – mark designating compliance of *products, systems processes*, and *services* with requirements of *standards*.

**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.

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

**International and regional standards** – standards established by international or regional standardisation organisations.

**Minimum requirements for product quality** – prescribed product characteristics, specified in terms of organoleptic, chemical, biological and/or physical characteristics of a product, which must be met by the product in order for it to be deemed acceptable for use (consumption) during the expected life of the product. Minimum requirements for product quality that are prescribed in a technical regulation shall be subject to mandatory fulfilment.

**National conformity mark** – a mark, with which the producer marks a product, according to the provisions of this Law, to indicate compliance of the product with relevant technical regulations.

**National standards** – standards that are developed and adopted by the national standardization body in accordance with this law and which are available for a wide range of users.

**Normative document** – a document, which may be a standard, code of practice or technical specification, that provides rules, guidelines or characteristics for activities or their results.

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

**Standardisation body** – a body that deals with standardisation, recognized at the national, regional or international level, with the key functions of development, approval or adoption of standards;

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

**Organizations** – consumers and subjects of economic activity and their associations, ecological and similar associations, and non-governmental entities;

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

**First party** – producer, supplier, or official representative thereof;

**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;

**Service** – the result of an economic activity that does not result in a product, but can be bought and sold in a commercial transaction.

**Supplier** – producer, provider of services, importer, representative of a foreign enterprise in the consignment sale of products, or person, which placed in circulation a product, process, system or service, or made possible the utilization of a product, process, system or service.

**Rule of good practice** – a document recommending practices or procedures for designing, manufacturing, installing, maintaining and deploying equipment, structures or products. A rule of good practice may be a standard, part of a standard or a separate document.

**Designation** – governmental authorization of a conformity assessment body to perform specified conformity assessment activities.

**Product** – a physical good resulting from a process that is intended for placement in circulation;

**Conformity assessment procedure** – any 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* and, when the mark of conformity with *national standards* has been applied to a *product*, for compliance with such standard;

**Certificate of conformity** – the document issued by a *third party* following *attestation*;

**Certification** – *attestation* by a *third party* related to *products, processes, systems* and *personnel*;

**Conformity assessment system** – rules, procedures and management for carrying out *conformity assessment*;

**Environmental management system** – part of an *organisation's* management system, including organisational structure, planning activities, responsibilities, practices, procedures, processes and resources, used to develop and implement its environmental policy

**Quality management system** – an aggregate of bodies and objects of management, interacting with the help of material and technical and informational means while managing *product quality*;

**Standard** – a document developed on the basis of consensus and approved by the relevant state body that provides, for common and repeated use, rules, guidelines or characteristics for an activity or its results, including *products*, related *processes* or *services*, with which compliance is not mandatory. A *standard* may include or deal exclusively with symbols, packaging, marking or labelling requirements as they apply to a *product* or *process* or with terminology requirements as applied to an activity, *product*, *process* or *service*.

**Standardisation** – activities related to determining provisions for general and repeated use, in respect of existing or potential problems or tasks, with the aim of achieving an optimal degree of order in a certain sphere, which results in improvement in the suitability of *products, processes* and *services* to their intended use, removal of trade barriers, and promotion of scientific and technical cooperation;

**Legal regulation in the technical sphere** – activity that includes prescribing mandatory *product* characteristics, related *processes* and *systems*, requirements for *services*, personnel and bodies, as well as verifying compliance with such, by means of *conformity assessment* and/or *market supervision*.

**Technical regulation** – legal act approved by a body of executive power, 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.

**Technical specification** – a document or part of a document which defines technical criteria to be fulfilled by a *product*, *process* or *service*.

**Third party** – *conformity assessment body* independent from the *first party* and consumer or user of the *product*, *process*, or *service*, as well as *systems* and *personnel*;

**Quality** – The degree to which a set of inherent characteristics of a *product*, *process* or *service* fulfils the needs or expectations of those consuming or using such *product*, *process* or *service*.

## **Article 2. Sphere of Application of the Law**

This law regulates relations arising among producers, suppliers, organisations, conformity assessment bodies and corresponding state bodies in standardisation, legal regulation in the technical spheres, and conformity assessment.

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 nuclear materials, pharmaceutical products, standards of medical service, 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 by the customs authorities due to violation of relevant legislation of Ukraine, 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 exclusive (one-off) *products*, as well as *products* imported individually for personal needs, unless specified otherwise by other legislation of Ukraine.

## **Article 3. 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.

## **Article 4. Objects of Standardisation, Legal Regulation in the Technical Sphere and Conformity Assessment**

Objects of *standardisation* and *legal regulation in the technical sphere* are *products*, *processes*, *systems*, *services*, *personnel* and *bodies*; in particular, materials, component parts, and equipment, as well as terminology, symbols, packaging, marking or labelling requirements.

Objects subject to *conformity assessment* are objects subject to *standardisation* and to *legal regulation in the technical sphere*, and management systems including *quality management systems* and *environment management systems*.

## **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:

*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 in good standing of the *relevant international or regional organisations*, or with which a *relevant international agreement* 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 item 1 of paragraph 1 of this Article exist but are not used as the basis for a *standard, technical regulation or conformity assessment procedure*, a written explanation identifying why such *international or regional standards* are ineffective or inappropriate shall be promptly provided upon the request of a party with which a *relevant international agreement* is in force.

*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 clear, precise and uniform in structure.

Comments received on draft *national standards* and other *standards, technical regulations, and conformity assessment procedures* from any interested party, whether domestic or foreign, shall be given equal consideration by the relevant technical committee, expert working group or other body developing the *standard, technical regulation or conformity assessment procedure*.

Comments on draft *national standards* and other *standards, technical regulations and conformity assessment procedures* received through foreign standardising bodies or *relevant international and regional organisations* that have accepted the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the World Trade Organisation Agreement on Technical Barriers to Trade shall, if so requested, be replied to as promptly as possible. When applicable, the reply shall include an explanation why a deviation from a relevant *international or regional standard* is necessary.

#### **Article 6. Language of Documents**

*National standards, technical regulations, and conformity assessment procedures* shall be composed in the Ukrainian language and, if needed, in one of the languages of the *relevant international and regional organisations*, all of which shall be maintained in electronic form in those formats. The form of *certificates of conformity* shall be composed in the Ukrainian language and at least one of the official languages of the *relevant international and regional organisations*.

#### **Article 7. Confidentiality of Information**

All information that is defined as confidential by the owner of such information that is provided in the course of any procedure administered pursuant to the provisions of this Law on a confidential basis shall be 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 legislation of Ukraine.

## **CHAPTER II. STANDARDISATION**

#### **Article 8. Goals and State Policy in the Sphere of Standardisation**

The goal of *standardization* in Ukraine is to promote the rational use of all kinds of national resources, ensure 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*.

State policy for *standardization* is based on the following principles:

Ensuring participation of all interested parties in development of *standards* and free choice regarding whether or not to use *standards*;

Openness and transparency of the procedures for development and adoption of *standards*;

Accessibility of *standards* and information to users;

Conformity of *standards* to legislation;

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 Annex 3 of the World Trade Organisation Agreement on Technical Barriers to Trade;

Introduction of 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 *standardization* rules and procedures;

Participation in the work of the *relevant international and regional organisations* with the aim of promotion of Ukraine's interests.

## **Article 9. Authority of the Central Body of Executive Power for Standardisation Issues**

The central body of executive power for *standardisation* issues 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 *standardisation* body - represent Ukraine in *relevant international and regional organizations*.

The key functions of the central body of executive power for *standardisation* issues are as follows:

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 Annex 3 of the World Trade Organisation Agreement on Technical Barriers to Trade;

Participate in development of legislative acts regarding *standardisation*;

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

Establish rules for development, adoption, revision, and abolishment of *national standards*, assigning identifying codes, classifications according to types and other criteria, their encoding and registration;

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

Abolish and adopt *national standards* ;

Ensure that all *national standards* comply with this Law;

Undertake measures for harmonization of *national standards* with relevant *international and regional standards*;

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*;

Take measures to fulfil membership commitments of *relevant international and regional organizations*;

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 the central body of executive power for *standardisation* issues 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;

Provide information services for *standardisation* and inform the public, relevant state bodies, and other interested parties of the work of the central body of executive power for *standardisation*; and

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

The central body of executive power for *standardisation* issues may have other functions and authorities according to laws of Ukraine.

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

#### **Article 10. Standardisation Council**

The Standardisation Council is a collective consultative and advisory body at the central body of executive power for *standardisation* issues and consists of representatives of executive power bodies, producers, suppliers and consumers. The Council consists of 15 members in relation to the degree of interest in results of standardisation.

The Standardisation Council's statutes and the procedure of identifying its members shall be approved by the Cabinet of Ministers of Ukraine.

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

A key function of the Standardisation Council is study, analysis and elaboration of propositions regarding improvement of activity for *standardisation* with respect to:

Optimization of the structure of technical committees for *standardisation* and determining their scope of work;

Prioritization of directions (areas) of harmonization of *national standards* with *international or regional standards*;

Formation of the *standardisation* work programme.

The Standardisation Council shall recommend to the central body of executive power for standardisation issues priorities for development and review of *national standards*.

The Council has the right to:

obtain from bodies of executive power and organisations 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.

#### **Article 11. Technical Committees for Standardization**

The central body of executive power for *standardization* issues establishes technical committees that shall be entrusted with the functions of development, consent and approval, review, amendment, and proposing abolishment of *national standards*, as well as review, comment and consent (recommend adoption or rejection) of draft *international and regional standards*.

Technical committees for *standardization* shall be from the ranks of relevant experts and formed on the principle of representation of all interested parties, including representatives of state bodies, *producers, suppliers*, consumers, scientific and engineering fellowships (unions), as well as eminent scientists and professionals.

Membership in the technical committees for *standardization* is on a voluntary basis.

Organisational support to technical committees shall be provided by their Secretariats.

Provisions on technical committees are adopted by the central body of executive power for *standardization* issues.

Technical committees may not receive any type of profit from their activities.

#### **Article 12. Other Bodies and Organisations that Deal with Standardisation**

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 regional organizations*, wherein they are members or with which they cooperate on the basis of the statutes of those organizations or relevant agreements, as well as delegate these authorities to organisations.

Central bodies of executive power and organisations shall inform the central body for executive power for *standardisation* issues on their activities in *standardisation* in their fields with the aim to ensure fulfilment of the requirements of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the World Trade Organisation Agreement on Technical Barriers to Trade.

The central body of executive power for defence—taking into account peculiarities of the field of defence—establishes the procedure of *standard* application to secure needs of defence of Ukraine in compliance with the functions entrusted to it.

The bodies referred to in paragraphs 1, 2 and 3 of this Article shall, in particular, observe relevant requirements of Article 5 and 8 of this Law.



### **Article 13. Normative Documents on Standardisation and Application of Standards**

Depending on the level of the body that adopts or approves *normative documents* on *standardisation*, they are subdivided into:

Nationally applicable *national standards*, *rules of good practice* and classifiers that are adopted or approved, as well as catalogues and registers that are issued, by the central body of executive power for *standardisation* issues, ;

*Standards*, *technical specifications* and *rules of good practice* adopted or approved by other bodies and *organisations* that deal with *standardisation* as well as catalogues issued by the latter.

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

The implementation of *standards* is voluntary except for cases when application of *standards* is required by *technical regulations*.

*Standards* 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.

### **Article 14. Proposals for Conducting Standardisation Works**

Interested parties shall submit proposals for conducting *standardisation* works to the central body of executive power for *standardisation* issues.

Proposals shall be considered by a relevant technical committee. When deciding on a proposal, the relevant technical committee for *national standards* shall take into consideration the priorities for *standardisation*, the existence or impending adoption of relevant *international and regional standards* as well as country specific knowledge and information, such as the geographic and climatic characteristics of the State, and the state of economic development.

The central body of executive power for *standardisation* issues shall inform the submitting party about the findings of the technical committee for the *national standard* with respect to the validity of the proposal no later than 60 calendar days of the date of receipt of the proposal.

The central body of executive power for *standardisation* shall establish the criteria, format and other procedures to be used when considering whether to accept or reject proposals.

### **Article 15. Preparation of the Work Programme for Standardisation**

The central body of executive power for *standardisation* issues shall prepare a *standardisation* work programme on the basis of accepted proposals from interested parties, which shall include activities for developing, reviewing, and amending *national standards*.

The *standardisation* work programme shall serve to coordinate the development of *national standards* for various activities and harmonization of *national standards* with *international and regional standards*.

The central body of executive power for *standardisation* issues shall make every effort to avoid duplication of, or overlap with, the work of *international or regional standardisation organisations*.

The *standardisation* work programme shall, for each *standard*, indicate the classification relevant to the subject matter according to a scheme of the *international and regional standardisation organisations*, the stage attained in the *standard's* development, and the references of any *international standards* taken as a basis.

The central body of executive power for *standardisation* issues shall, at least once every six months, publish the *standardisation* work programme containing its name and address, as well as titles of specific draft *standards* under development or review. A notice on the publication of the *standardisation* work programme

shall be published in an official monthly publication of the central body of executive power for *standardisation* issues.

At the time of the publication of the *standardisation* work programme, a notification of the existence thereof to the *relevant international and regional organisations* using the required reporting format and language of such organisations.

#### **Article 16. Development and Notification of Draft Standards, Solicitation for Comments, and Incorporation of Comments in the Final Draft Standard**

*National standards* are developed by technical committees for *standardization* and in the case of their absence, by *organisations* that have relevant scientific and technical experience in this sphere.

When the first draft of the *national standard* is available, the central body of executive power for *standardisation* issues shall publish in its official publication, as well as in mass media:

The identifying code and title of the draft *national standard*;

The degree of deviation of the draft *national standard* from relevant *international and regional standards*;

The address and period for submitting comments by all interested parties;

Information on the manner in which the draft can be obtained.

The comment period for drafts of a *national standard* may not be less than 60 days from the date of publication of the information specified in paragraph 1 of this Article except when urgent problems of national security, health, safety or the environment arise or threaten to arise and a *national standard* is needed to prepare or complete a relevant *technical regulation*.

Following the expiration of the comment period, the developer of the *national standard* shall consider the comments in accordance with the provisions of paragraphs 6 and 7 of Article 6 of this Law and reach a conclusion concerning the incorporation of comments in the final draft of a *national standard*.

#### **Article 17. Adoption of National Standards**

*International and regional standards* may be adopted as *national standards* by the central body of executive power in the sphere of *standardization* issues.

When the final draft of the *national standard* is approved, the central body of executive power for *standardisation* issues makes a decision on its adoption.

When adopting a *national standard*, the central body of executive power for *standardisation* issues shall determine the date when the *national 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, shall be published the following month in an official publication of the central body of executive power for *standardisation* issues.

#### **Article 18. Review, Amendment, and Abolishment of National Standards**

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 15 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 existing national standards 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.

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 17 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*.

### **Article 19. Property Right to National Standards**

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* developed by organisations belongs to the *persons* at whose expense they are developed, or to whom it is transferred according to the procedure established by legislation.

A standard may be developed for products and processes that are objects of standardization and are also objects of intellectual or industrial property if, according to established procedure, the developer of such *standard* obtained permission from the owner of the property rights of such products and processes.

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

In the case of a *person* reproducing or disseminating a *standard* or *rules of practice* without the permission of the owner or his authorized *person*, the body or organisation that developed the standard shall not 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.

The holder of the property right is entitled to reimbursement of losses caused to him by unauthorized dissemination of the *standard*, *rules of practice*, classifiers and catalogues according to the law.

### **Article 20. Publication and Dissemination of Standards**

*National standards*, *rules of practice*, classifiers and catalogues are published and disseminated by the central body of executive power for *standardisation* issues.

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.

#### **Article 21. Financing of Standardisation Works**

*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 programmes and projects;
- funds of subjects of economic activity;
- bank credits;
- other funds envisaged by legislation.

The expenses of subjects of economic activity related to the development of *standards* are included in the expenses on scientific and technical supply of their business activity.

Expenses on *standards* works of the budget-financed institutions and organisations 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 regulation of technical matters in certain spheres of activity in accordance with legislation.

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

#### **Article 22. Use of Funds Received from Sales of Standards**

Funds received from sales of *national standards*, as well as *international and regional standards*, shall be allocated exclusively for fulfilment of *standardization* works and development of the necessary scientific and technical base.

### **CHAPTER III. LEGAL REGULATION IN THE TECHNICAL SPHERE**

#### **Article 23. Goals and State Policy for Development and Application of Technical Regulations**

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.

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

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*.

*Technical regulations* shall not be more trade-restrictive than necessary to meet the goals specified in paragraph 1 of this Article;

*Technical regulations* shall not be maintained (kept) if the circumstances or objectives giving rise to their adoption no longer exist or if changed circumstances or objectives can be addressed in a less trade-restrictive manner;

Identical requirements shall be imposed for *products* of domestic and foreign origin when applying *technical regulations*;

The *technical regulations* of Ukraine's trading partners shall be accepted as equivalent to those of Ukraine even if such regulations differ, when it is determined that such regulations adequately fulfil the goals of Ukraine's *technical regulations*.

#### **Article 24. Authority of the Cabinet of Ministers of Ukraine**

The Cabinet of Ministers of Ukraine shall:

Assign to central bodies of executive power the functions of *legal regulation in the technical sphere* in their defined spheres of activities, including development of *technical regulations* (hereinafter: *relevant central bodies of executive power*) ;

Adopt *technical regulations*;

Approve mutual recognition agreements regarding equivalence of foreign and domestic *technical regulations*.

#### **Article 25. 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*;

Prepare a programme for development of *technical regulations*;

Ensure the review of *technical regulations* if the circumstances or objectives giving rise to their adoption no longer exist or if changed circumstances or objectives can be addressed in a less trade-restrictive manner;

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

#### **Article 26. Technical Regulations Council**

The Technical Regulations Council is a collective consultative and advisory body at the Cabinet of Ministers of Ukraine.

The Technical Regulations 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, producers, suppliers and consumers, proportional to the goals of legal regulation in the technical sphere.

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

The statutes of the Technical Regulations Council are approved by the Cabinet of Ministers of Ukraine.

The key functions of the Technical Regulations Council are:

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

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 *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*.

The Technical Regulations Council has the right to:

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

, involve specialists of executive power bodies, scientific and research institutions and *organizations* in the work of the Technical Regulations Council as experts according to the established procedure.

The Technical Regulations Council shall meet at least once every six months or more frequently as required.

The central body of executive power for legal regulation in the technical sphere issues shall act as the secretariat for the Technical Regulations Council.

#### **Article 27. Authority of other State Bodies in Legal Regulation in the Sphere of Technical Regulation**

Central bodies of executive power designated by the Cabinet of Ministers of Ukraine in accordance item 1 paragraph 1 Article 25 of this Law have the right to:

Establish working groups of experts for developing *technical regulations* (hereinafter: *working groups*);

Participate in the work of *working groups* developing and/or reviewing *technical regulations*.

#### **Article 28. Working Groups for Developing Technical Regulations**

*Relevant central bodies of executive power*; shall establish expert working groups from representatives of central body of executive power for coordination of legal regulation in the technical sphere, existing technical committees, other interested central bodies of executive power, *organisations*, which shall be entrusted with the functions of development of final drafts, consent and approval, amendment, and proposing abolishment of *technical regulations*.

All persons expressing an interest in participating in the work of the *working groups* shall be invited to be members of the expert working group.

Participation of the experts in the activities of the *working groups* shall be on a voluntary basis without any form of compensation.

The *relevant central body of executive power* shall appoint one of its officials or one official from its subordinate organisations to act as Secretary for each *working group*.

#### **Article 29. Preparation of a Work Programme for Technical Regulations**

Interested parties (hereinafter: *submitting parties*) shall submit proposals for development, amendment or abolishment of *technical regulations* to the central body of executive power for legal regulation issues in the technical sphere.

The central body of executive power for legal regulation in the technical sphere issues shall establish the criteria, format and procedures to be used when considering whether to accept or reject proposals. Proposals that do not fulfil the criteria and format shall be returned to the *submitting party*.

The central body of executive power for legal regulation in the technical sphere issues shall review, in accordance with established procedure, all proposals for development, amendment or abolishment of a *technical regulation* that fulfil the criteria and required format for their acceptance.

The central body of executive power for of legal regulation issues in the technical sphere shall inform the *submitting party* no later than 60 days of the date of receipt of the proposal about the decision of whether or not the proposal was accepted.

All accepted proposals and the list of *technical regulations* that must be reviewed in accordance with Article 35 of this Law shall be consolidated into a draft work programme for development of technical regulations. The draft work programme shall be reviewed and evaluated by the Technical Regulations Council. The review and evaluation shall include prioritisation of the accepted proposals for each *relevant central body of executive power*.

When the draft work programme is approved by the Technical Regulations Council, the programme for development of technical regulations shall be adopted by the central body of executive power for legal regulation of the technical sphere issues.

The work programme for development of technical regulations adopted by the central body of executive power legal regulation of the technical sphere shall be published in its official publication and in other media not later 30 days of adoption to enable interested parties to participate in preparing *technical regulations*.

### **Article 30. 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 existence 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 existence 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* for a *product*, *process* or *service*;

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

Minimum quality requirements for products placed in circulation

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

The contents of the *declaration of conformity* of the *product* or *process* with the requirements of a *technical regulation* if such content differs from that specified in Article 46 of this Law.

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 legal regulation in technical sphere 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 31. 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. When applicable, the notification procedures prescribed in Article 60 of this Law shall also be implemented.

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 23 of this Law and when necessary, submit comments on the draft indicating the non-compliant portions of the draft.

Following the expiration of the period for submitting comments on the draft *technical regulation*, the *working group* shall consider the comments in accordance with the provisions of paragraphs 6 and 7 of Article 5 of this Law and reach a conclusion concerning the incorporation of comments in the final draft *technical regulation*.

### **Article 32. Approval and Adoption 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 Ukraine for a decision regarding adoption or rejection of the technical regulation.

In case of major disagreements between central bodies of executive power concerning draft technical regulations, drafts of technical regulations shall be submitted to the Technical Regulations Council for consideration. Based on the results of the consideration, the Cabinet of Ministers of Ukraine shall make a decision regarding adoption or rejection of the final draft technical regulation.

### **Article 33. Procedures upon Adoption of a Technical Regulation**

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

The date of implementation of *technical regulations* 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 34 of this Law.

### **Article 34. Urgent Need for a Technical Regulation**

Should urgent reasons of national security, 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 a final 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.



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*, the central body of executive power for coordination of legal regulation in the technical sphere shall obtain approval from the Technical Regulations Council to immediately begin development of the *emergency technical regulation*. Relevant central body of executive power which developed the urgent technical regulation according to the established procedure shall provide it to Cabinet of Ministers for its adoption.

The *emergency technical regulation* adopted by the Cabinet of Ministers shall be immediately implemented and published promptly in the Official Gazette.

If the adopted *emergency technical regulation* is expected to significantly affect the trade of other countries, the *emergency technical regulation* shall be subject to the provisions of Article 58 of this Law.

Comments on an adopted *emergency technical regulation* received in writing from countries with which a *relevant international agreement* 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 according to the provisions of Article 35 of this Law.

If the relevant *working group* concludes that an *emergency technical regulation* continues to be needed, any comments 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 as a *technical regulation*, and published and notified according to the provisions of paragraphs 3 and 4 of this Article.

### **Article 35. Review of Adopted Technical Regulations**

The review of a *technical regulation* shall be carried out by a relevant *working group* prior to the expiration of a [five-year period] from the date of its publication in the Official Gazette. The *relevant central body of executive power* shall publish in its official publication, [in the official publication of the central body of executive power for *standardisation*] 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 and 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 29 of this Law.

In case the Technical Regulations 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 30, 31 and 32 of this Law, and upon completion of the final draft technical regulation, the procedures referred to in Article 33 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.

### **Article 36. Procedure for Making a Decision Regarding the Equivalence of Foreign and Ukrainian Technical Regulations**

The equivalence of the *technical regulations* of Ukraine and states and other subjects of international law that are participants of *relevant international agreements* 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 based on legislated use of relevant *international and regional standards*; analysis objectives of the foreign and domestic *technical regulation*; 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 proposal and the justification of the *working group* by the Technical Regulations Council. The decision of the Technical Regulations Council shall be basis for adoption for decision by the Cabinet of Ministers.

Upon acceptance by the *working group* of equivalence of a foreign *technical regulation* to a Ukrainian *technical regulation*, the recommendation shall be forwarded to the Cabinet of Ministers of Ukraine for adoption. The decision shall be published promptly in the Official Gazette and be recorded in the registry of *technical regulations*.

### **Article 37. Financing Works Associated with Development of Technical Regulations**

Works associated with the development of technical regulations shall be financed by the customer of these works.

The sources of financing are:

- Funds of the State Budget of Ukraine;
- Funds allocated for the implementation of the programmes and projects;
- Funds of subjects of economic activity;
- Bank loans;
- Other funds envisioned by legislation.

The costs incurred to subjects of economic activity related to the development of technical regulations are attributed to the costs allocated for scientific and technical support of their activities.

Expenses on works associated with the development of technical regulations of the budget-financed institutions and organisations are reimbursed through the funds allocated for their maintenance.

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

## CHAPTER IV. CONFORMITY ASSESSMENT

### **Article 38. Goal and State Policy for of Conformity Assessment**

Goal of conformity assessment is to ensure that established requirements for products, process, system, person or body are satisfied.

State policy for *conformity assessment* is based on the following principles:

*Impartiality, transparency and accessibility of conformity assessment* procedures and complete information on them for all interested parties;

*Conformity assessment* shall not be more strict than is necessary to give adequate confidence that *products, processes and services* conform with the applicable *technical regulations* or *standards*, taking into account of the risks non-conformity would create;

Taking into account international practice for development and application of *conformity assessment procedures*;

Identical requirements and *conformity assessment procedures* shall apply for *products* of domestic and foreign origin;

Accessibility of *Conformity assessment procedures* for *producers* of *products* originating in the territories of countries with which a *relevant international agreement* is in force and under conditions no less favourable than those accorded to *producers* of like *products* of Ukrainian origin or those originating in any other country;

Conformity assessment procedures may be developed as parts of standards or parts of technical regulations or as national standards or technical regulations themselves.

*Conformity assessment procedures* shall be performed according to the requirements and in the manner specified in the relevant *national standard* or *technical regulation*.

### **Article 39. Authority of the Cabinet of Ministers of Ukraine in the area of conformity assessment**

The Cabinet of Ministers of Ukraine shall:

Establish the design for (description of) the *national conformity mark*;

Approve mutual recognition agreements regarding recognition of foreign conformity marks and *certificates of conformity* for *products, processes and services*, and membership of Ukraine in relevant certification systems.

Approve the order of performing the conformity assessment procedures of designated bodies for assessing conformity of products, processes and services with the requirements of technical regulations.

### **Article 40. Authority of the Central Body of Executive Power for Conformity Assessment Issues**

The central body of executive power for conformity assessment issues shall:

Ensure implementation of state policy for *conformity assessment*;

*Designate conformity assessment bodies* to conduct works on assessment of the *conformity* with the requirements of *technical regulations* upon to the proposals of *relevant central bodies of executive power*;

Organize supervision of the activity of *designated conformity assessment bodies*; and

Develop and propose, in accordance with current legislation of Ukraine, agreements with foreign countries and regional and international institutions and bodies regarding the mutual recognition of

conformity marks and *certificates of conformity* for compliance with *technical regulations* for *products, processes* and *services*.

#### **Article 41. Conformity Assessment for Technical Regulations**

The assessment of conformity with *technical regulations* shall be performed by *designated conformity assessment bodies*.

*Relevant central bodies of executive power* shall recommend for *designation* only *conformity assessment bodies* which are residents of Ukraine and are capable of performing at the required level of competence and meet the following criteria:

Have no commercial or other interest in the products, processes or services being assessed. The designated body, its manager or personnel, authorized to perform conformity assessment shall not be identified as developer, producer, supplier, installer or user of relevant product, process, service or as authorized representative of one of the mentioned above persons;

Availability of qualified personnel and means required for performing conformity assessment procedures and of access to equipment required for carrying out testing;

Availability of guarantees related to the independence of personnel performing conformity assessment procedures;

Independence of payment to personnel carrying out conformity assessment procedures from number and results of performed conformity assessment procedures;

The central bodies of executive power which recommend *conformity assessment bodies* for *designation* shall if possible take into account the availability of accreditation by the national accreditation body.

Central bodies of executive power which recommend the *designation* of *conformity assessment bodies* shall be responsible for activities of the *designated* bodies and shall in a timely manner recommend to the central body of executive power for conformity assessment issues the withdrawal of *designation* if it is established that the *designated conformity assessment body* does not meet the established criteria or does not perform its duties in accordance with this Law.

The information concerning *designation* or withdrawal of *designation* of *conformity assessment bodies* shall be published in an official publication of the central body of executive power for conformity assessment issues.

#### **Article 42. Obligations of Designated Conformity Assessment Bodies**

Conformity assessment bodies shall apply only those conformity assessment procedures for which they are designated.

Conformity assessment bodies shall have in place a contract for liability insurance if such liability is envisaged by the legislation of Ukraine.

The personnel of conformity assessment bodies shall observe the principle of professional secrecy except as provided for in the legislation of Ukraine.

The designated conformity assessment bodies shall report on a regular basis about its activities to the central body of executive power which recommended its designation and also to the central body of executive power for conformity assessment issues

The designated conformity assessment body shall ensure:

equal access to producers whether domestic or foreign to conformity assessment procedures, in particular the possibility to perform conformity assessment at the site of facilities and to receive the national conformity mark;

that the standard processing period of each conformity assessment procedure is published or that the anticipated processing period is communicated to the applicant upon request;

Prompt examination of the application of interested party, as well as completeness of the documentation and informing the applicant in a precise and complete manner of all deficiencies;

The results of the *conformity assessment* are transmitted as soon as possible in a precise and complete manner to the *applicant* so that corrective action may be taken if necessary;

Upon the request of the applicant, the conformity assessment body proceeds as far as practicable with conformity assessment, even when the application has deficiencies, or is informed of the stage of the procedure, with any delay being explained;

Information requirements associated with *conformity assessment procedures* are limited to what is necessary to assess *conformity* and determine fees;

The confidentiality of information about *products*, arising from or supplied in connection with *conformity assessment procedures*, whether from a domestic or foreign *producer* or *supplier*, shall be respected in a manner that legitimate commercial interests are protected;

any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of like products for domestic or foreign producers (suppliers), taking into account communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body

The location of facilities used in conformity assessment procedures and the selection of samples shall not cause unnecessary inconvenience to applicants or their agents.

If specifications of a *product* are changed subsequent to the determination of its *conformity* to the applicable *technical regulations*, the *conformity assessment procedure* for the modified *product*, *process* or *service* shall be limited to what is necessary to determine whether adequate confidence exists that the product still meets the *technical regulations* of concerned.

*Conformity assessment bodies* shall have in place the procedures of reviewing claims related to performance of conformity assessment procedures considering provisions of Article 44 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 established procedure to the state registry of *certificates of conformity*.

### **Article 43. Costs of Conformity Assessment**

The costs of assessment of *conformity* shall be borne by the applicant requesting the *conformity assessment procedure*.

Fees for *conformity assessment procedures* performed by *designated conformity assessment bodies* shall be determined by the rules of determining the costs of conformity assessment work established by the Cabinet of Ministers of Ukraine.

Fees for assessment of conformity for compliance with *voluntary standards* shall be established on contractual basis.

### **Article 44. 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 on mutual recognition of the results of conformity assessment of which Ukraine is a party.

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 and regional 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 45. 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.

If one party disagrees with the decision of the commission for appeals of a conformity assessment body, the decision may be appealed with the commission for appeals of the central body of executive power for conformity assessment issues.

Any expenses incurred in resolution of the appeal shall be borne by the applicant. In the event that a second *conformity assessment* yields results different from that of the original *conformity assessment*, any fees paid by the applicant to the original *conformity assessment body* shall be promptly refunded to the applicant.

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.

#### **Article 46. Declaration of Conformity and Certificate of Conformity**

The producer of a product shall issue 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 name and address of the *producer* of the *product*;

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;

The statement that the declaration is issued under the sole responsibility of the *producer*;

Name, address and identification number, 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* referred to in item 7 of paragraph 2 of this Article, 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 issue a form for the *declaration of conformity*.

#### **Article 47. Use of Conformity Marks**

The Cabinet of Ministers shall designate a design for (description of) and approve rules for application of the *national conformity mark* to be used to indicate compliance with relevant *technical regulations*.

The *national conformity mark* shall be applied to all *products placed in circulation* that are subject to and comply with a relevant *technical regulation*.

If the *conformity* of a *product* subject to *technical regulations* is assessed by an designated *conformity assessment body*, the *relevant conformity mark* shall be supplemented with the identification number of this body.

The central body of executive power for *standardisation* may introduce a *standards conformity sign*, which may be applied to *products* meeting the requirements of a *national standard*. The description and the rules of application of the *standards conformity sign* are established by the central body of executive power for *standardisation* issues.

Conformity marks and the *standards conformity sign* may be applied to *product* declarations and packaging and used in promotional material for *processes* or *services* that comply with relevant *technical regulations* or *national standards*.

*Products, processes and services* that do not comply with *technical regulations* or *national standards*, and *products, processes and services* not eligible for application of the *national conformity mark* or the *standards conformity sign*, including marking of *product declarations*, packaging and promotional material, shall not be marked with signs or other markings including statements or other markings that imply compliance with *technical regulations* or *national standards* that are similar to the prescribed *national conformity mark* or to the *standards conformity sign* to a degree that could cause confusion.

Application of 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. Conformity Assessment of products, processes and services, which are not object to technical regulations

#### **Article 48. Conformity Assessment of products, processes and services, which are not object to technical regulations**

The Conformity Assessment of products, processes and services, which are not object to technical regulations, is performed on a voluntary basis.

The Conformity Assessment of products, processes and services, which are not object to technical regulations is conducted by the accredited according to the legislation conformity assessment bodies;

The Conformity Assessment of products, processes and services, which are not object to technical regulations, may be performed by conformity assessment bodies designated in accordance with the requirements of Article 41 of this law.

The rules of conformity assessment procedure of products, processes and services, which are not object to technical regulations, shall be established by the conformity assessment body.

While performing conformity assessment procedures for of products, processes and services, which are not object to technical regulations the relevant conformity assessment bodies shall observe the provisions of Articles 41 and 42 of this Law with the exception of obligations related to reporting to the relevant bodies of executive powers.

#### **Article 49. Article 49. Financing of activity in the area of conformity assessment to the requirements of technical regulations**

The activity in the area of conformity assessment to the requirements of technical regulations shall be financed at the expense of:

- Funds received by the designated conformity assessment bodies from applicants as a payment for the performed works associated with conformity assessment;
- funds of the State budget of Ukraine;
- other funds envisaged by the law.

The budget funds in conformity assessment area shall be allocated to finance:

- Scientific and research works;
- Participation in work of international (regional) organization.

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

## **CHAPTER V. OBLIGATIONS OF PRODUCERS AND SUPPLIERS OF OBJECTS SUBJECT TO TECHNICAL REGULATIONS**

### **Article 50. Obligations of Producers and Suppliers**

*Producers or suppliers* shall offer and deliver only those *services* or employ those *processes* or *place in circulation* those *products*, whether of foreign or domestic origin, that is safe for life and health of human, animal, plant, ensure protection of national security, environment and natural resources and prevent deceptive practices.

Before *placing in circulation* a *objects subject to technical regulations*, *producers* shall ensure fulfilment of the requirements of the relevant *technical regulations*.

The *placing in circulation* of *objects subject to technical regulations* is accompanied by a declaration of the compliance or/and certificate of compliance, as well as marking by the national sign of compliance in accordance with the requirements established by relevant *technical regulations*.



The *producer*, or his authorised representative in Ukraine, shall:

Apply the *national conformity mark* on *products* subject to *technical regulations* that are *placed in circulation*;

Provide consumers of a *product* with relevant information to enable them to assess the risks inherent in a *product* when such risks are not immediately obvious without adequate warnings, and to take precautions against those risks;

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 chief market inspectors

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 chief market inspectors, 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*;

withdraw 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.

## CHAPTER VI. MARKET SUPERVISION

### Article 51. Goal of Market Supervision

The goal of market supervision is to ensure that placed in market products, processes and services fulfil requirements of technical regulations and minimum quality requirements without discrimination on the basis of the origin and also to protect the subjects of entrepreneurial activities from deceptive practices.

Market supervision is implemented only by the bodies of state power

### Article 52. Authority of the Cabinet of Ministers for market supervision

Cabinet of Ministers shall:

Assign authorities for *market supervision* to central bodies of executive power

approves procedures for market supervision of the objects subject to technical regulations

assign central body of the executive powers responsible for coordination the activity of the market supervision bodies and approves the procedures for coordination such activity

### **Article 53. Authorities Market Supervision Body**

To implement its activities the market supervision body shall have sufficient resources, authorities, technical competence and qualified personnel. Activities of the market supervision body shall be independent, non-discriminatory, based on the principal of proportionality

With the aim to ensure effective market supervision officials of the market supervision body shall have the right to :

- regular and unhindered access to trading and industrial facilities and storages;
- regular and unhindered access to working places and other facilities, where they put products into operation;
- carry out unexpected random inspections;
- take samples of products and arrange for their expertise and testing;
- require subjects of entrepreneurial activity to provide all necessary information regarding the products placed in circulation;
- inspect production facilities to determine the reasons of incompliance of products, placed in the market, with minimum requirements for product quality and requirements of technical regulations;
- require a producer or a supplier to withdraw from circulation the products that fail to comply with minimum requirements for product quality and requirements of technical regulations;
- file a claim with a court in case a producer or a supplier refuses to withdraw from circulation the products that fail to comply with technical regulations;
- pursuant to current legislation take administrative actions against producers and suppliers, which placed into circulation the products that fail to comply with minimum requirements for product quality and requirements of technical regulations.

The market supervision body shall allow to present at trade fairs, exhibitions and shows the products that fail to comply with the requirements of technical regulations only under condition if the latter have clear marks prohibiting their sale or putting into operation prior to ensuring compliance with the requirements of technical regulations and taking necessary actions during the show for ensuring safety for human, animal, plant life and health, protection of the environment and natural resources.

The market supervision body shall arrange for inspections according to the plans for conducting inspections that shall be elaborated pursuant to the rules and procedures for carrying out market supervision, approved by the Cabinet of Ministers of Ukraine, and upon a justified request from the central bodies of executive power, subjects of entrepreneurial activities and consumers with regard to incompliance of products, placed into circulation, to minimum requirements for product quality and requirements of technical regulations.

Other authorities of the market supervision body and its officials shall be prescribed by the Cabinet of Ministers of Ukraine.

### **Article 54. Authorities of the Customs Bodies**

The customs authorities shall not permit entry to the customs territory of Ukraine of *products* subject to *technical regulations* if the product:

Displays characteristics which give rise to a significant concern as to the existence of a serious risk to health and/or safety; or

Is not accompanied by documents or does not bear a conformity mark in accordance with applicable requirements in a relevant *technical regulation*.

The customs authorities shall provide, for any *product* denied entry to Ukraine, the relevant market supervision authorities with the trade name, *producer* and/or *supplier*, and other critical information identifying such products.

#### **Article 55. Financing of the Market Supervision**

Activity of the Body for Market Supervision is financed at the expense of funds of the State budget of Ukraine;

The budget funds shall be allocated to finance:

Scientific and research works;

Participation in work of international (regional) organization;

Labor payment of the officials of Bodies for Market Supervision

Activity related with the fulfillment the obligations of the officials of Bodies for Market Supervision

### **CHAPTER VII. PROVIDING INFORMATION ON TECHNICAL REGULATIONS, STANDARDS AND CONFORMITY ASSESSMENT PROCEDURES**

#### **Article 56. Authority of the Cabinet of Ministers**

The Cabinet of Ministers of Ukraine shall:

establish an enquiry and notifications centre for standards, technical regulations, and conformity assessment procedures (hereafter Enquiry and Notifications Centre).

#### **Article 57. Main Functions Enquiry and Notifications Centre**

The *enquiry and notifications centre* shall have the following functions:

Responding to or coordinating the response to enquiries from domestic and foreign interested parties regarding *national standards, technical regulations, and conformity assessment procedures*;

Receiving and disseminating to relevant central bodies of executive power and subjects of entrepreneurial activity notifications prepared by other countries regarding their standards, *technical regulations* and *conformity assessment procedures* ;

preparation and forwarding comments on notifications prepared by other countries regarding their standards, *technical regulations* and *conformity assessment procedures*.

Providing information on the membership and participation of Ukraine in the *international and regional standardization organisations* and *conformity* assessment systems, as well as in bilateral and multilateral agreements governing the development and application of *standards, technical regulations* and *conformity assessment procedures*;

Providing the location of notices published pursuant to this Law or information as to where such information can be obtained;

Providing the location of the *enquiry and notifications centre* ,if it is decided to establish several such centres

Other services requested by users.

Enquiry and Notification Centre at the request of foreign party shall provide translation of the documents to the official language of the international organizations, the in case of voluminous documents, summaries of such documents.

Any fees charged for copies of documents and translation to the official language of the documents requested by interested parties shall be the same for domestic and international parties, except for the real cost of delivery of such documents.

#### **Article 58. Obligations of the central bodies of executive power**

Central bodies of executive power bodies which develop *standards, technical regulations, and conformity assessment procedures* shall promptly provide copies of such documents within five working days of completion of draft *standards, technical regulations and conformity assessment procedures* to the *enquiry and notifications centre*.

#### **Article 59. Obligations on Providing Notifications**

When an adopted *emergency technical regulation* and/or *emergency conformity assessment procedure* or draft *technical regulation* and/or *conformity assessment procedure* is expected to have a significant effect on 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*.

The notification for a draft *technical regulation* and/or *conformity assessment procedure* shall be submitted in the format and with the information required by the agreement or organisation no less than [60/] calendar days before 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 *enquiry and notifications centre* after their publication in the Official Gazette according to the format and with the information required under the *relevant international agreement* or by the *relevant international and regional organisations*.

Upon request of any interested party within the territory of a member of a *relevant international or regional organisation* of which Ukraine is a member or any interested party from a country with which a *relevant international agreement* is in force, the *enquiry and notifications centre* or responsible State body shall promptly provide, or arrange to provide, a copy of the relevant draft or adopted document.

When required by *relevant international agreements* in force, if a bilateral or multilateral agreement on issues related to *standards, technical regulations or conformity assessment procedures* may have a significant effect on the foreign trade of countries not included in the agreement, a notification of ratification of such agreement, including identification of the products to be covered by the agreement and a brief description of the agreement, shall be sent by the *enquiry and notifications centre* to [parties/countries] with which the *relevant international agreement* is in force.

#### **Article 60. Financing of the activity of the Enquiry and Notification Centre**

The activity of the Enquiry and Notifications Centre shall be financed at the expense of funds of the State budget of Ukraine and Funds received from users;

The budget funds shall be allocated to finance:

Scientific and research works;

Providing notifications to the international and regional organizations.

Functioning of the Enquiry and Notifications Centre

Funds received from users of the Enquiry and Notifications Centre shall be allocated exclusively for development of its scientific and technical base..

## **CHAPTER VIII. INTERNATIONAL COOPERATION**

### **Article 61. International Cooperation**

The central body of executive power for *standardisation* shall according to the Law represent the interests of Ukraine in the international and regional standardization organisations, take actions for compliance of the legislation of Ukraine for standardization with norms and principles of WTO, cooperate with relevant bodies of other countries, decide to accede to international and regional standardization systems, sign agreements on cooperation and conducting works in the sphere of standardization.

The central body of executive power for legal regulation of the technical sphere shall according to the Law cooperate in this sphere with relevant bodies of other countries and pursuant Cabinet of Ministers instruction sign cooperation agreements in the legal regulation of technical sphere.

The central body of executive power for conformity assessment shall according to the Law represent the interests of Ukraine in international organizations on *conformity* assessment, cooperate in this sphere with relevant bodies of other countries, make decisions on the accession to international and regional *certification* systems, and negotiate agreements on mutual recognition of the results of *conformity* assessment works.

### **Article 62. International Agreements**

The provisions of this Law shall not apply if the matter is otherwise regulated by an international agreement ratified by Ukraine.

## **CHAPTER IX. FINAL PROVISIONS**

This Law becomes effective from the day of its publication, except for Articles 53 i 54 of this Law, which shall be effective from the January 1, 2007.

The Laws of Ukraine № 2408-III of May 17, 2001 „On Standardization” and № 2406-III of May 17, 2001 „On Conformity Assessment” shall be null and void.

The Cabinet of Ministers of Ukraine shall:

Within five years upon this Law coming into effect provide for revision of current national standards and replacing the latter with voluntary national standards or revoking those that are no longer valid;

Within three years upon this Law coming into effect provide for elaboration, adoption and application of technical regulations according to the provisions of this Law.

Until current national standards are revised and technical regulations are adopted pursuant to items four and five of paragraph three of the Final Provisions of this Law, current national standards and conformity assessment procedures shall be applied according to the requirements of the Decree of the Cabinet of Ministers of Ukraine N 46-93 of May 10, 1993 „On Standardization and Certification”.

After the time-period, specified in items four and five of paragraph three of the Final Provisions of this Law, the Decree of the Cabinet of Ministers of Ukraine N 46-93 of May 10, 1993 „On Standardization and Certification” shall become null and void.