

LAW OF UKRAINE

„On standards, technical regulations and conformity assessment procedures

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

General Provisions

Definitions of Terms Used in the Law

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

Equivalency— sufficiency of different conformity assessment results to provide the same level of assurance of conformity with regard to the same specified requirements;

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

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

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

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

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

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

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

Attestation – issuance of a document (certificate of conformity or declaration of conformity) based on a decision following relevant (necessary) conformity assessment 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.

Designation – providing to a conformity assessment body to perform specified conformity assessment activities.

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, legality of application of the National mark of conformity, completeness and reliability of product information;

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

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

Sphere of Application of the Law

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

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

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

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

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

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

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

Objects of Standardisation and Legal Regulation in the Technical Sphere

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

General Principles of Development of Standards, Technical Regulations and Conformity Assessment Procedures

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

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

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

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

Scientific achievements, knowledge and practice.

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

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

Standards and technical regulations shall be elaborated based on product requirements in terms of performance rather than design or descriptive characteristics and shall be 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 according of the WTO Agreement on Technical Barriers to Trade, Annex to Marrakech Agreement on establishing of the World Trade Organisation 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.

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.

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 the Law.

development and application of standards

Proposals for Conducting Standardisation Works

Interested parties shall submit proposals for conducting standardisation works to the central body of executive power for standardisation issues. Format and terms of submitting proposals are established by 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. Priority for application shall be given to the existing international standard.

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.

Standard is regarded as being developed upon taking the decision on its development till the date of its adoption by the central body of executive power for standardisation issues.

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

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.

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, protection of health, safety of environment arise or threaten to arise and a national standard is needed to develop a relevant technical regulation.

Comments of all interested national or foreign parties on drafts of national standards shall be considered by the relevant technical committee or other body, which develops the standard.

Following the expiration of the comment period, the developer of the national standard shall consider the comments and take them into consideration in the final draft of a national standard or reject them.

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.

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

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

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

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

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

Technical Regulations

Goals and State Policy in the legal regulation of technical sphere

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

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

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

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

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

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;

Requirements established by technical regulations shall be imposed on goods of domestic and foreign origin irrespective of their origin;

The technical regulations of Ukraine's trading partners shall be accepted according to the legislation 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.

Authority of the Cabinet of Ministers of Ukraine

The Cabinet of Ministers of Ukraine shall:

Coordinate and lead central bodies of executive power assigned with 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 unless the technical regulations are introduced by the Law;

Conclude Ukraine's mutual recognition agreements regarding results of conformity assessment and equivalence of foreign and domestic technical regulations;

Perform other duties in this sphere assigned by the Law.

Authority of the Central Body of Executive Power for Legal Regulation in the Technical Sphere Issues

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

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

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

Prepare a programme for development of technical regulations;

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

Standardization and Technical Regulation Council

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

The Council is formed from representatives of the Cabinet of Ministers of Ukraine, relevant central bodies of executive power, the central body of executive power for legal regulation in technical sphere, the central body of executive power on standardisation issues, subjects of economic activity, producers and consumers. The Council

consists of 17 members. Not less than half of the Council shall be formed of representatives subjects of economic activity, consumers and scientific establishments' organizations.

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

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

The key functions of the Council are:

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

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

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

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

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

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

The Council has the right to:

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

when necessary involve specialists of executive power bodies, scientific and research institutions and organizations in the activities of the Council as experts according to legislation.

The 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 Council.

Authority of other State Bodies in Legal Regulation of the Technical Sphere

Central bodies of executive power assigned with the duty to develop technical regulations in accordance item 2 of paragraph 1 of Article 14 of this Law shall:

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

Assign representatives for participation in activities of the working groups developing or reviewing technical regulations.

Working Groups for Developing Technical Regulations

Central bodies of executive power assigned with the duty to develop technical regulations shall establish expert working groups from representatives of central body of executive power for legal regulation in the technical sphere issues, existing technical committees, other authorised central bodies of executive power and organisations, which shall be entrusted with the functions of development, consent and approval of final drafts, amendment, and proposing abolishment of technical regulations.

If interested persons (or their authorized representatives) submitted their proposals regarding standardization activities to the central body of executive power on standardization issues and those proposals received positive conclusion of the central body of executive power on standardization issues, the mentioned above interested persons shall be involved in activities of the relevant working group for developing technical regulations.

All persons expressing an interest in participating in activities of the working groups shall be involved as experts upon their consent.

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.

Preparation of a Work Programme for Technical Regulations

Interested parties shall submit proposals for development, amendment or abolishment of technical regulations to the central body of executive power for legal regulation in the technical sphere issues. The proposal submission form shall be established by the central body of executive power for legal regulation in the technical sphere issues. Proposals which are inconsistent with the form shall be returned to the submitting party without consideration.

The central body of executive power for legal regulation in the technical sphere issues shall establish the procedure of proposal consideration and criteria used to make a decision whether to accept or reject proposals.

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 legal regulation in the technical sphere issues 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 24 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 Council. The review and evaluation shall include prioritisation of the accepted proposals for each relevant central body of executive power.

The central body of executive power for legal regulation in the technical sphere issues shall approve the draft work programme for development of technical regulations considering the Council's proposals.

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

Preparation of a Draft Technical Regulation

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

Draft technical regulations, as a rule, shall contain:

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

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

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

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

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

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

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

Notifying Draft Technical Regulations, Soliciting Comments, and Incorporating Comments in the Final Regulation

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

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

Adoption and Rejection of Technical Regulations

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

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

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

Publication of the Technical Regulation

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

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

Urgent Need for a Technical Regulation

Should urgent reasons of national security, health, human life and health safety or environmental and natural resource protection require immediate development and/or adoption of a technical regulation, the relevant central body of executive power shall develop draft of the technical regulation (hereinafter: emergency technical

regulation), which shall be reviewed for compliance with the provisions of this Law by the central body of executive power for legal regulation in the technical sphere issues.

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

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

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

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

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

If the relevant working group concludes that an emergency technical regulation continues to be needed or any comments are available received from interested parties, whether domestic or foreign, on the adopted emergency technical regulation shall be taken into account without discrimination and the emergency technical regulation revised as necessary. The revised emergency technical regulation shall be adopted and published according to the provisions of paragraphs 3 and 4 of this Article.

Review of Adopted Technical Regulations

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

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

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

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

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

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

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

Procedure for Making a Decision Regarding the Equivalence of Foreign and Ukrainian Technical Regulations

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

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

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

proposal and the justification of the experts of Council. While adopting the relevant decision the Cabinet of Ministers of Ukraine shall consider proposals of the Council.

Upon acceptance by the working group of equivalence of a foreign technical regulation to a Ukrainian technical regulation, central body of executive power for legal regulation in the technical sphere issues shall submit proposals to the Cabinet of Ministers of Ukraine for adoption. The decision, adopted by the Cabinet of Ministers shall be published promptly in the Official Gazette and be recorded in the registry of technical regulations, maintained by the central body of executive power for legal regulation in the technical sphere issues.

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 budget 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.

Conformity Assessment procedures for requirements of technical regulations

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 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.

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 by the law.

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;

equitable level 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 concern.

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

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

Acceptance of Conformity Assessment Conducted Outside the Country

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

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

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

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

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

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

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

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 submission 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 conformity assessment issues.

Declaration of Conformity and Certificate of Conformity

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

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

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

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

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

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

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

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

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

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

The declaration of conformity issued in accordance with the requirements of technical regulations shall be subject to registration with the central body of executive power for legal regulation in the technical sphere issues within 3 day period. To register the declaration of conformity an applicant shall submit the declaration of conformity issued in accordance with the requirements of technical regulations to the central body of executive power for legal regulation in the technical sphere issues.

The procedure of maintaining the register of declarations of conformity as well as the procedure of providing information regarding registered declarations shall be established by the central body of executive power for conformity assessment issues.

National Conformity Mark

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 National conformity mark shall be supplemented with the identification number of this body.

National conformity mark may be applied to product labelling and packaging and used in promotional material for processes or services that comply with relevant technical regulations.

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

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

Obligations of Producers and Suppliers of products Objects to Technical Regulations and Control of Compliance with the Requirement of Technical Regulations

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 objects to technical regulations, producers shall ensure fulfilment of the requirements of the relevant technical regulations.

The placing in circulation of objects to technical regulations is accompanied by a declaration of the compliance or/and certificate of compliance, as well as marking by the national conformity mark 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 object 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 market supervision bodies.

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

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

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

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

Goal of Market Supervision

The goal of market supervision is to control that placed in market products, processes and services fulfil requirements of technical regulations in order to protect health of human, plant and animal, protect the environment and natural resources, ensure national security, as well as prevent deceptive practices and also to protect the subjects of entrepreneurial activities from deceptive practices.

Market supervision shall be implemented only by the bodies of executive power in accordance with the law.

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

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

Providing Information on technical regulations, standards and conformity assessment procedures

The Procedure of Establishing Enquiry and Notifications Centre

The Cabinet of Ministers of Ukraine shall establish an enquiry and notifications centre for standards, technical regulations, and conformity assessment procedures (hereafter Centre).

Main Functions of Centre

The 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;

Providing notifications concerning drafts or adopted technical regulations, national standards and conformity assessment procedures;

Briefing relevant central bodies of executive power and domestic producers and entrepreneurs on standards, technical regulations and conformity assessment procedures of the other countries;

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.

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 parities, except for the real cost of delivery of such documents.

Authorities of the central bodies of executive power on providing notifications

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

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 form 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 Centre after their publication in the Official Gazette of Ukraine 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 Centre or responsible State body shall promptly provide, or arrange to provide, a copy of the relevant draft or adopted document.

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 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 Centre to such countries.

Financing of the activity of the Enquiry and Notification Centre

The activity of the 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 Centre

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

Chapter vii. Final Provisions

1. The Law shall become effective from the date of its publication.

2. The Law shall introduce amendments to the following legal acts of Ukraine:

1) Article 15 of the Commercial Code of Ukraine (Vedomosti of Verkhovna Rada of Ukraine, 2003, # 18-22, p. 144) shall read:

Article 15. Technical Regulation in the sphere of commercial activity.

1. In the sphere of commercial activity the following shall be applied:

technical regulations;

standards;

code of practice;

classifiers;

technical specifications.

2. Application of standards or their provisions shall be mandatory for:

subjects of commercial activity, if the technical regulations refer to the standards;

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

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

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

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

a) in Article 1:

item 9 shall read:

“Standard – a document developed on the basis of consensus and approved by the 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.”

Item 14 shall be removed.

b) Article 4 shall read:

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

c) in Article 5:

paragraph one shall read:

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

add paragraph two with item ten that shall read:

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

d) Item 3 of Article 6 shall read

“Standardization and Technical Regulation Council”;

e) in Article 7:

in paragraph two item 2 shall read:

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

Delete items 8 and 10

Add new items that shall read:

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

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

Ensure that all national standards comply with this Law;

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

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

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

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

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

Maintain a register of standards and standardisation-related documents;

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

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

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

f) Article 8 shall be removed;

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

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

h) Article 10 and 11 shall read:

“Article 10. Other subjects that deal with standardization

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

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

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

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

Publish, and disseminate of their own standards, documents of the specialised relevant international and 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 accordance with the World Trade Organisation Agreement on Technical Barriers to Trade which is the Annex to the Marrakech Agreement on Establishing of the World Trade Organization 1994.

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

“Article 11. 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.

Order of development, review, amendment, adoption and publication of standards shall be determined in the Law of Ukraine “On standards, technical regulations and conformity assessment procedures”.

i) Delete Articles 12 and 13;

j) Chapter IV shall read:

Chapter IV. Providing of information, and the property right to standards, codes of practice and technical specifications

Article 15. 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, technical specifications and codes of good practice, adopted or approved by other bodies or organisations, which conduct standardization works, belongs to the organizations at whose expense they are established, 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 owner of the object 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 16. 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.

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

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

a) in Article 1:

item 8 and 15 shall read:

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

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

Add new items that shall read:

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

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

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

Designation – provision the rights to perform specified conformity assessment activities to requirements of the technical regulations by the body established or empowered the Cabinet of Ministers of Ukraine to a conformity assessment body.

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”.

b) in Article 5:

add Article with item 10 that shall read:

“development and application of conformity assessment procedures in a way adequate to ensure that the products, processes and services conform with the applicable technical regulations or standards, taking into account of the risks non-conformity would create”;

c) in Article 6:

add paragraph one with item 7 that shall read:

“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”.

add paragraph two with items 13 and 14 that shall read:

“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”;

Paragraph three shall be removed.

d) articles 7, 8, 10, 12, 15 shall be removed.

e) in the Law language “authorized certification body”, “specially authorized central body of executive power in the sphere of conformity assessment”, “technical regulation on conformity assessment” shall be replaced by language “designated conformity assessment bodies”, “central body of executive power for conformity assessment issues”, “technical regulation” respectively.

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

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

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

President of Ukraine

V. Jushchenko

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