

LAW OF UKRAINE

On Standards, Technical Regulations and Conformity Assessment Procedures

(Vidomosti Verkhovnoi Rady (VVR), 2006, N 12, p. 101)

The present Law defines legal and organisational foundations for development and application of the national standards, technical regulations and conformity assessment procedures, as well as the fundamental principles of the state policy in the sphere of standardisation, technical regulations and conformity assessment.

Section I

GENERAL PROVISIONS

Article 1. Terms and definitions

In the present Law, the terms below shall have the following meanings:

specified requirements – requirements set in technical regulations, standards, codes of generally accepted practices and technical terms;

equivalence – sufficiency of various results of conformity assessment to ensure one and the same level of attestation of conformity in respect to one and the same set of requirements;

comments – remarks and proposals to draft standards, technical regulations and conformity assessment procedures;

control – examination of project documentation for products, processes of it manufacturing and assembly, and determining of the degree of its conformity with the specified requirements;

international agreements of Ukraine – any international agreements of Ukraine, including bilateral and multilateral ones, about mutual recognition, development and application of standards, technical regulations and conformity assessment procedures, that Ukraine is a party to;

conformity assessment authority – an authority providing conformity assessment services;

appointing authority - a body designated or authorised by the Cabinet of Ministers of Ukraine to appoint conformity assessment authorities, temporarily suspend their appointment or cancel the temporary suspension of their appointment;

organisations - enterprises, institutions, organisations, bodies of power or other institutions and sub-units or associations thereof, possessing the status of a legal

entity or without the same; public organisations, private businesses or enterprises based upon a different form of ownership, or institutions and organisations performing their independent functions, have documents on establishment (Charter) and their management structure;

conformity assessment – proving that the specified requirements to products, processes, systems, person or body have been met by way of testing, control or certification;

conformity attestation – issuance of a document (declaration of conformity or a certificate of conformity) on the basis of the decision taken after the corresponding (necessary) conformity assessment procedures have proven that the specified requirements have been met;

service – result of economic activities that do not create goods but that are sold and bought in the course of trading transactions;

conformity assessment procedure – any procedure that is directly or indirectly applied to determining whether requirements set in the respective technical regulations or standards have been met. Conformity assessment procedures include procedures for sampling, testing, control, assessment, examination, registration, accreditation and approval, as well as their combinations;

appointment – granting by the body designated or authorised by the Cabinet of Ministers of Ukraine to the conformity assessment authority of the right to perform certain activities for assessment of conformity with the requirements set in the technical regulations;

risk – probability of emergence and possible consequences of negative effects over a certain period of time;

market supervision – permanent oversight of conformity of the products launched into circulation with the technical regulations, legitimacy of application of the National Conformity Mark, fullness and accuracy of information about such products;

technical administration – legal regulation of relations in the sphere of definition, application of, and compliance with the mandatory requirements to products and related processes, systems and services, personnel and authorities, as well as verification of their observance by way of conformity assessment and/or market surveillance;

technical regulations – a Law of Ukraine or a regulatory act, passed by the Cabinet of Ministers of Ukraine, that define characteristics of a product or related manufacturing processes or methods, as well as requirements to services, including respective provisions, compliance with which is mandatory. They can also contain requirements to terminology, records, packaging, marking or labelling that are applied to certain products, processes or manufacturing methods.

Article 2. The Scope of Application of the Law

The present Law shall regulate relations connected with the activities in the sphere of standardisation, technical administration, including conformity assessment, with application of its results, and shall extend over objects of economic activities, regardless of their forms of ownership and types of operation, over bodies of the state power, as well as over the respective public organisations.

Requirements of the present Law shall not extend over procedural matters concerning development, approval, revision, amending and cancellation of technical regulations to be approved by law.

The effect of the present Law shall not extend over sanitary measures developed and applied for protection of human beings from risks connected with food products; phytosanitary measures developed and applied to protect plants from harmful organisms; veterinary and sanitary measures developed and applied to protect life and health of human beings and animals from animal diseases; and also over managements of nuclear materials, medicines, construction norms, standards of medical services, accounting reporting, education and other social standards that are regulated by the Ukrainian legislation.

Provisions of the present Law shall not be applied to goods confiscated in connection with administrative offence and being held by customs authorities; non-professional artisan products; used and repaired products transferred outside the boundaries of economic activities; goods altered by consumers after their purchase; objects of arts and unique items of folk crafts imported and used for personal needs, unless otherwise stipulated by law.

Article 3. Ukrainian Legislation in the Sphere of Standardisation, Technical Administration and Conformity Assessment

The Ukrainian legislation in the sphere of standardisation and technical administration, including conformity assessment, shall consist of the present Law and other regulatory acts regulating relations in that sphere.

Article 4. Objects of Standardisation and Technical Administration

Objects of standardisation and/or technical administration shall include products, processes and services, specifically, materials, components, equipment, systems, their compatibility, rules, procedures, functions, methods or activities, personnel and bodies, as well as requirements to terminology, designation, pre-packing, packaging, marking, labelling, quality control and environment management systems.

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

The national standards, technical regulations and conformity assessment procedures shall be developed in such a manner as not to create, or cause creation of, unnecessary obstacles for trade.

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

international and regional standards, if those have been adopted or are at the final stage of their development, with the exception of instances when those are inefficient or inadequate with regard to the insufficient level of protection or the basic climatic or geographical conditions, technological problems or specific features of the state, conditions and substantial technical issues;

standards, technical regulations and conformity assessment procedures, or respective parts thereof of the states that are parties to the corresponding international or regional organisations that Ukraine concluded respective international agreements with (agreements on mutual recognition, development or application of standards, technical regulations and conformity assessment procedures);

scientific attainments, knowledge and practice.

In the event when the international standards, defined in part two of the present Article, are not taken as the basis for standards, technical regulations or conformity assessment procedures, written explanations shall be provided by request of the interested party.

Standards, technical regulations and conformity assessment procedures must, if possible, take into consideration the specific requirements of development and financial and trading requirements of the developing countries – members of the WTO.

Standards and technical regulations must be accurate, clear and structurally unified, and the requirements, if possible, must be related to characteristics of the products, and not requirements to its construction or description.

Comments concerning draft national standards, technical regulations and conformity assessment procedures by all interested national or foreign parties shall be reviewed by a respective technical committee for standardisation, a working group or another body that develops a standard, technical regulations or a conformity assessment procedure.

Replies to comments regarding draft national standards, standards of bodies of executive power, technical regulations and conformity assessment procedures, obtained from foreign, international or regional standardisation authorities that abide by the Code of Good Practice on development, approval and application of standards, in compliance with the WTO Agreement on Technical Barriers to Trade (981_008), which is an Annex to the 1994 Marrakech Agreement on Establishing the World Trade Organisation (995_342), shall be provided within shortest time limits possible, but not later than the adoption date. If possible, replies must contain explanations concerning the necessity of deviation from the international or regional standard.

Article 6. Language of Documents

National standards, technical regulations and conformity assessment procedures shall be prepared in the Ukrainian language, and, in case of necessity, in the languages of the respective international or regional organisations. The formats for the conformity certificates and declarations of compliance shall be prepared in the Ukrainian language and in at least one of the official languages of the respective international or regional conformity assessment organisations that Ukraine is a member of.

Article 7. Confidentiality of Information

All information that is confidential or that was provided under the provisions of the present Law on the confidential basis shall be provided by the rules applied to commercial secrets. The respective authorities shall not disclose that information

without prior consent of the persons or bodies that provided it, unless otherwise stipulated by applicable law.

Section II

STANDARDS DEVELOPMENT AND ADOPTION PROCEDURES

Article 8. Proposals for Standardisation Work

Interested parties shall provide their proposals concerning standardisation work to the central body of the state executive power in charge of standardisation. The form and time limits for provision of the proposals shall be established by that central body of the state executive power in charge of standardisation.

Proposals concerning development of the national standard shall be considered by the respective technical committee with account to priorities in standardisation. Taking the decision concerning the proposal on development of the national standard, the respective technical committee must take into account the effective international or regional standards or those that are at the final stage of its development, as well as the specific features of the country, corresponding information, geographical and climatic characteristics of the country and the level of its economic development. In doing so, preferences in application must be given to the currently effective international standard.

The central body of the state executive power shall notify the party that submitted the proposals about the decision taken by the technical committee within 60 days upon the day when the proposals were received.

A standard shall be regarded as being at the development stage beginning on the day when the decision about its development has been passed to the date when it has been approved by the central body of the state executive power in charge of standardisation.

The central body of the state executive power in charge of standardisation shall establish the criteria, form and other procedures for consideration of the proposal concerning development of the national standards.

Article 9. Preparation of Standardisation Work Programme

Proceeding from proposals by interested parties, the central body of the state executive power in charge of standardisation shall prepare a standardisation work programme, which shall include work for development, revision and amendment of the standards.

The standardisation work programme shall be prepared for coordination of development of the national standards for various kinds of activities and harmonization of the national standards with the corresponding international and regional standards.

The central body of the state executive power in charge of standardisation must take measures to prevent publication of efforts by the respective international or regional organisations.

The standardisation work programme must contain classification for each standard in accordance with the methodology of the respective international or regional organisations, the stage achieved in development of the standard, and references to the international standards taken as the basis.

The central body of the state executive power in charge of standardisation must at least one time every six months publish its standardisation work programme, indicating its designation and address, as well as names of the specific draft standards that are being developed or reviewed. Notifications about publication of standardisation work shall be published in the official publication of the central body of the state executive power in charge of standardisation.

After publication of the standardisation work programme, the central body of the state executive power in charge of standardisation shall notify the respective international or regional organisations about the fact, using those organisations' reporting formats.

Article 10. Development and Notifications about Draft Standards, Requests for Comments and Inclusion of Comments into the Final Draft Standard

The national standards shall be prepared by technical committees for standardisation (technical committees), and in case of their absence – by organisations that have the corresponding research and development experience in that sphere.

After preparation of the first draft of a national standard, the central body of the state executive power in charge of standardisation shall publish that draft in its official publication and in mass media. The advertisement shall specify:

designation and name of the national standard;

degree of deviation of the national standard from the corresponding international standards;

address and time limits for comments by all interested parties;

information about ways of obtaining of the standard.

Comments to draft national standards shall be provided for 60 days upon the day of publication of the information, specified in part two of this Article, with the exception of urgent matters of defence, health protection, environmental safety and preparation of the national standard for development of the corresponding technical regulations.

Comments by all interested national or foreign parties concerning draft national standards shall be considered by the respective technical committee for standardisation, or by another body that develops that standard.

Upon expiry of the term for provision of comments to the draft national standards, the developing agency shall consider the comments received and take those into account in the final draft of the national standard, or decline those in a substantiated manner.

Article 11. Adoption of the National Standards

International and regional standards shall be adopted as the national standards by the central body of the state executive power in charge of standardisation.

In the event of approval of the final draft of the national standard, the central body of the state executive power in charge of standardisation shall pass the decision about its adoption.

The central body of the state executive power in charge of standardisation shall determine the term for enactment of the national standard, with regard to the period of preparatory measures.

The list of national standards, approved and adopted over one month, shall be published the following month in the official publication of the central body of the state executive power in the sphere of standardisation.

Article 12. Revision, Amendment and Cancellation of National Standards

The central body of the state executive power in charge of standardisation shall coordinate activities for review of the national standards for compliance with the legislation, meeting of the requirements by producers and consumers, correspondence to level of science and engineering, and to the requirements of international and regional standards. Revision of the national standards is to be carried out by technical committees or organisations with the corresponding research and development experience. National standards for products shall be reviewed not less than one time every five years.

Following the procedures, stipulated by Article 8 of the present Law, the interested parties shall provide their proposals for revision, amendment or cancellation of national standards.

The corresponding technical committee shall consider proposals concerning modifications in the effective national standards and, in the event of their approval, shall submit those to the central body of the state executive power in charge of standardisation for decision on their inclusion in the standardisation work programme.

In case the technical committee approves proposals concerning cancellation of the national standards, the central body of the state executive power in charge of standardisation shall take its decision on that matter.

In case the central body of the state executive power in charge of standardisation takes the decision to cancel a national standard, notification about the fact shall be published in its official publication.

Modifications in the national standards shall be made in accordance with the procedures stipulated by Article 10 of the present Law. Upon approval of the modified national standard by the respective technical committee, the central body of the state executive power in charge of standardisation shall adopt and publish the modified national standard.

Section III

Technical Regulations

Article 13. Goal and State Policy in the Sphere of Technical Administration

The goal of development and application of technical regulations is to protect life and health of human beings, animals, plants; to ensure national security, protection of environment and the natural resources; prevention of abusive practices.

Compliance of products, processes and services, being introduced in Ukraine, with the technical regulations shall be mandatory.

Requirements set by the technical regulations must reflect risks concerning consumers, the natural environment and natural resources that may be posed by non-conformity of products, processes and services. In order to evaluate risks, the available scientific and engineering information related to processing technologies and final use of products, processes or services, must be reviewed.

The state policy in the sphere of development and application of technical regulations shall be based on the following principles:

technical regulations may not restrict trade more than may be necessary to reach the goal specified in part one of the present Article;

technical regulations must be changed or cancelled if circumstances or purposes that caused their adoption no longer exist, or if the changed circumstances or purposes make it possible to apply measures that produce a lesser restrictive effect on trade;

requirements set by technical regulations shall be applicable to domestic and foreign products, regardless of their origin;

technical regulations of Ukraine's trading partners, in accordance with the procedures stipulated by law, shall be recognised as the equivalent technical regulations of Ukraine, even in case those are different, provided those regulations comply with the goal of the technical regulations of Ukraine.

Article 14. Powers of the Cabinet of Ministers of Ukraine in the Sphere of Technical Administration

The Cabinet of Ministers of Ukraine shall:

coordinate and direct the central bodies of the state executive power assigned to perform technical administration functions in the defined spheres of activities, including development of technical regulations (hereinafter referred to as the «respective central bodies of the state executive power»);

approve technical regulations, in case those have not been approved by a law;

conclude international agreements of Ukraine concerning mutual recognition of conformity assessment results and equivalence of foreign and national technical regulations;

execute other powers in that sphere, as stipulated by law.

Article 15. Competences of the Central Body of Executive Power on Matters of Technical Administration

The central body of the state executive power on matters of technical administration shall:

ensure implementation of the state policy in the sphere of technical administration;

coordinate development of technical regulations and activities by bodies exercising supervision over objects of technical regulations on the market;

prepare technical regulations development programme;

organise preparation of rules and procedures for market supervision over objects of technical regulations with participation of other respective central bodies of the state executive power.

Article 16. Council for Standardisation and Technical Administration

The Council for Standardisation and Technical Administration (hereinafter referred to as «the Council») shall be a collective advisory body under the Cabinet of Ministers of Ukraine.

The Council shall consist of representative of the Cabinet of Ministers of Ukraine, respective central bodies of the state executive power, in part, the central body of the state executive power on matters of technical administration, the central body of the state executive power in charge of standardisation, as well as economic subjects, producers and consumers. The Council composition shall include 17 members. At least one half of the Council for Standardisation must be composed of representatives of associations of economic entities, consumers' associations, as well as representatives of scientific institutions.

Activities by the Council shall be based on the principles of openness and transparency.

Provisions on the Council shall be approved by the Cabinet of Ministers of Ukraine.

The main functions of the Council for technical administration shall be the following:

consideration and analysis of draft technical regulations development programme and preparation of corresponding proposals;

examination, analysis of, and preparation of proposals concerning improvement of activities in the sphere of standardisation;

consideration of disputable issues concerning drafts of technical regulations and their correspondence to the main goal of technical administration;

revision, approval or declining of proposals concerning development of technical regulations;

setting of priorities in development of standards and technical regulations on the basis of social and economic needs, and consumers' needs;

providing of recommendations to the Cabinet of Ministers of Ukraine concerning adoption or declining of draft technical regulations.

The Council shall have the right to:

obtain information and materials on matters within its competence from bodies of the state executive power;

in case of necessity and following the procedures, stipulated by law, engage specialists from bodies of the state executive power and experts from scientific and research institutions for work at the Council.

The Council shall hold its meeting as may be necessary, but not less than one time every six months.

The central body of the state executive power on matters of technical administration shall perform the functions of the Council Secretariat.

Article 17. Powers of the Central Bodies of the State Executive Power in the Sphere of Technical Administration

The central bodies of the state executive power whose competences under the law include organisation of development of technical regulations, following the procedures specified in paragraph two in Article 14 of the present Law, shall:

establish expert working groups (hereinafter referred to as «the working groups») for development of technical regulations;

appoint their representatives for participation in activities of the working groups for development or revision of the technical regulations.

Article 18. Working Groups for Development of Technical Regulations

The central bodies of the state executive power whose competences under the law include organisation of development of technical regulations shall establish working groups from representatives of technical committees, the central body of the state executive power for matters of technical administration, other authorised central bodies of the state executive power and organisations in charge of function of development, coordination and approval of the final draft of technical regulations, and making of modifications and proposals concerning their cancellation.

Interested parties (or their authorised representatives) that submitted to the central body of the state executive power in charge of standardisation their proposals on standardisation activities, and whose proposals were approved by the central body of the state executive power on matters of technical administration, on the basis of a written request, shall be engaged in activities of a corresponding working group for development of technical regulations, on the mandatory basis.

Persons who expressed their willingness to be engaged in activities of a working group shall be invited to work as experts upon their consent.

The respective central body of the state executive power shall appoint a secretary of the working group, out of its officers or employees of its subordinate organisations.

Article 19. Preparation of the Technical Regulations Development Work Programme

The interested parties shall provide their proposals concerning development, modification or cancellation of technical regulations to the central body of the state executive power for matters of technical administration. The format for submitting of proposals shall be determined by the central body of the state executive power for matters of technical administration. Proposals that do not comply with that format shall be returned to the applicant without consideration.

The central body of the state executive power for matters of technical administration shall establish the procedures for consideration of the proposals and the criteria that are used for decision about their approval or declining.

The central body of the state executive power for matters of technical administration, following the established procedures, shall consider all proposals that meet the specified criteria and forms.

Not later than in 60 days upon receipt of the proposals, the central body of the state executive power for matters of technical administration shall notify the applicants about acceptance or declining of their proposals.

All accepted proposals and the list of technical regulations that are considered in accordance with Article 24 of the present Law shall be added to the draft technical regulations development work programme. The draft of the working programme shall be considered and analysed by the Council. In the course of consideration and analysis of proposals, priorities for each respective body of the state executive power shall be defined.

The central body of the state executive power for matters of technical administration shall approve the draft technical regulations development work programme with account to proposals by the Council.

The approved work programme for development of technical regulations shall be published not later than in 30 days upon its approval in the official publication of the central body of the state executive power on matters of technical administration and in other mass media in order to ensure participation of all interested parties in development of the technical regulations.

Article 20. Preparation of Draft Technical Regulations

The respective central body of the state executive power, jointly with the central body of the state executive power in charge of standardisation, shall provide the working group with information about validity of the respective national or other standards in the sector that is regulated by the technical regulations in question, or their expected approval, including the time period for adoption of the national or other standards, as well as information about validity of the corresponding international or regional standards, and in their absence – the corresponding standards and technical regulations of other states.

As a rule, draft technical regulations shall contain:

technical requirements, including those related to safety, to products, processes or services, that meet the scientific and engineering level attained as of the moment of development;

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

requirements to packaging, contents of the product marking, specifications, and in case of necessity – important information for consumers (descriptions, manuals) that accompanies the product or process being launched.

In case when the draft technical regulations envisage possibilities for declaration of conformity, that draft must contain the procedures for declaration of conformity, the format, content and expiry date of the declaration of conformity.

The list of national standards that in case of voluntary application are the proof of conformity of the products to the requirements of technical regulations shall be formed by the central body of the state executive power in charge of standardisation upon request of the respective central bodies of the state executive power, and in the absence of those standards, development of the respective standards shall be done upon request of those bodies. The list of national standards that in case of voluntary application are the proof of conformity of the products to the requirements of technical regulations shall be published in the official publication of the central body of the state executive power in charge of standardisation.

In case of reference to the national standards, the technical regulations shall specify whether conformity with certain standards is the only method, or one of the methods to meet the requirements of the technical regulations.

Requirements to conformity assessments shall reflect the level of risks created by the product or the process that the technical regulations are applied to.

Article 21. Notification about the Draft Technical Regulations, Requests for Comments and Adding Comments to the Final Draft of the Technical Regulations

Upon completion of development of draft technical regulations, the respective central body of the state executive power shall publish in its official publication or in mass media a notification about the draft being open for consideration and for comments by any interested party. The notification shall contain the designation of the draft, address and terms for comments, and information about ways to obtain the draft. Notifications shall be provided in accordance with the procedures stipulated by Article 39 of the present Law.

Over the period for providing of comments to the draft technical regulations, the central body of the state executive power for matters of technical administration shall review the draft for compliance with Articles 5 and 13 of the present Law and, in case of necessity, provide comments to the draft, with indication of any parts that are in contradiction to the present Law.

Upon expiry of the term for providing of the comments to the draft technical regulations, the working group shall review the comments, provide responses to those in accordance with the provisions in parts six and seven in Article 5 of the present Law and shall reach agreement on incorporation of comments in the final draft of the technical regulations.

Article 22. Acceptance or Declining of Technical Regulations

Upon completion of final drafting of the technical regulations, the working group shall submit the draft to the respective central body of the state executive power, which shall coordinate it with all interested central bodies of the state executive power.

The central body of the state executive power for matters of technical administration shall submit the agreed draft technical regulations to the Cabinet of Ministers of Ukraine.

In presence of substantial differences between the central bodies of the state executive power concerning the draft technical regulations, which is a draft legal regulation act, adoption of which is within the competence of the Cabinet of Ministers of Ukraine, it shall be submitted for consideration by the Cabinet of Ministers of Ukraine, that will take a decision on acceptance or declining of the draft technical regulations, with account to proposals by the Council.

Article 23. Publication of Technical Regulations

Technical regulations adopted by the Cabinet of Ministers of Ukraine shall be published in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin.

The technical regulations shall become effective no earlier than in 6 months upon its publication in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin, in order to grant market agents to prepare for fulfilment of requirements of the new technical regulations, with the exception of urgent circumstances specified in Article 24 of the present Law.

Article 24. Urgent Necessity for Adoption of Technical Regulations

In the event when circumstances in the sphere of defence, public health protection, national security and safety of life and health of people, protection of the natural environment and natural resources require immediate development and/or adoption of technical regulations, the respective central body of the state executive power shall develop a draft of the technical regulations (hereinafter referred to as «the urgent technical regulations»), which shall be considered by the central body of the state executive power for matters of technical administration for consistency with the stipulations of the present Law.

If the central body of the state executive power for matters of technical administration establishes the necessity for urgent development of a technical regulation, with due account to proposals by the Council, it shall prepare the corresponding conclusions and shall urgently submit the draft urgent technical regulations to the Cabinet of Ministers of Ukraine.

The urgent technical regulations, approved by the Cabinet of Ministers of Ukraine, shall be published in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin, and shall become effective beginning on the day of its publication.

Information about the draft urgent technical regulations shall be made available for distribution in accordance with Article 39 of the present Law.

Written comments concerning the adopted urgent technical requirements, received from countries that Ukraine concluded corresponding international agreements, shall be discussed with representatives of the corresponding country upon its request. Comments expressed as a result of the discussion shall be taken into consideration, and, in case of necessity, the urgent technical regulations shall be reviewed.

All urgent technical regulations shall be reviewed by the respective working group for six months upon their adoption, in order to determine the necessity for their prolongation or cancellation. In case the need in the urgent technical regulation has disappeared, it shall be cancelled by the Cabinet of Ministers of Ukraine.

In the event when the respective working group has concluded that there exists a need in further effect of the technical regulation, or in presence of any comments received by any national or foreign party in relation to the urgent technical regulation, that technical regulation may be reviewed with account to the said comments. The reviewed urgent technical regulation shall be approved and published in accordance with parts three and four of this Article.

Article 25. Revision of the Adopted Technical Regulations

The approved technical regulations shall be reviewed by the working group for the five-year period since their publication in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin. The respective central body of the state executive power shall publish in its official publication, and if necessary, also in other mass media, proposals for modifications in, or cancellation of the technical regulations, along with a request for comments, address and time limits for submitting comments to the central body of the state executive power. The time period for comments may not exceed 60 days.

Upon expiry of the time period specified in part one of the present Article, the working group shall review comments and draw conclusions regarding the need for modification or cancellation of the technical regulations.

Interested bodies, organisations and persons may submit their proposals concerning revision of the technical regulations to the central body of the state executive power for matters of technical administration, which shall consider those in compliance with Article 19 of the present Law.

In case the Council passes the decision on the necessity to make modifications in the technical regulations, the respective central body of the state executive power shall establish a working group or convene its session.

Modifications in the technical regulations shall be developed and approved in accordance with Articles 20, 21 and 22 of the present Law. Upon approval of the final draft of the technical regulations, measures envisaged in Article 23 of the present Law shall be applied.

Technical regulations that were reviewed but underwent no changes, or were not cancelled, shall be marked in the register with a special mark, specified by the central body of the state executive power for matters of technical administration.

Technical regulations that have not been reviewed for five years since the day of their publication in the official publication of the central body of the state executive power on matters of technical administration shall be regarded as cancelled beginning on the day when the five-year term of their validity has expired.

Article 26. Procedures for Making Decisions on Equivalence of Foreign and Ukrainian Technical Regulations

Equivalence of technical regulations of Ukraine and other countries shall be assessed on the basis of proposals submitted by an interested party to the central body of the state executive power for matters of technical administration. The proposals must contain a copy of the foreign technical regulation, translated into the Ukrainian language, designation of the corresponding Ukrainian technical regulation, and sufficient information as proof of equivalence of the technical regulations.

Assessment of equivalence between foreign technical regulations and the corresponding Ukrainian technical regulations shall be carried out by a working group, established by the central body of the state executive power for matters of technical administration, on the basis of mandatory assessment of the relevant international and national standards, analysis of purposes of the foreign and the Ukrainian technical regulations, as well as the level of protection established by the technical regulations. Equivalence shall not be challenged on the sole reason of ways of reaching the purposes and methods of ensuring protection being different.

In case the working group decides that the foreign technical regulation is not equivalent to the Ukrainian technical regulation, the respective conclusion shall be prepared, which the central body of the state executive power for matters of technical administration shall then address to the interested party that put forward the proposal about equivalence assessment. The interested party may dispute the conclusion and demand assessment of the proposals and the conclusion by the Council experts. In making its respective decision, the Cabinet of Ministers of Ukraine shall take proposals by the Council into consideration.

After the working group has established the equivalence between the foreign technical regulation and the Ukrainian technical regulation, the central body of the state executive power for matters of technical administration shall submit the corresponding proposals to the Cabinet of Ministers of Ukraine for decision making. The decision made by the Cabinet of Ministers of Ukraine shall be published in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin and entered into the register of technical regulations, maintaining of which shall be organised by the central body of the state executive power for matters of technical administration.

Article 27. Financing of Technical Regulations Development Work

Any work for development of technical regulations shall be financed by its sponsors.

The sources of financing may be as follows:

funds of the State Budget of Ukraine;

funds allocated for fulfilment of budget programmes and projects;

funds of economic entities;

bank loans;

other funds envisaged by law.

Costs incurred by economic entities in connection with development of technical regulations shall be accounted for as expenditures on research-and-development support of their economic activities.

Costs for development of technical regulations by budget-financed institutions and organisations shall be covered from funds allocated for their maintenance.

Central bodies of the state executive power in charge of matters of technical administration in their specific spheres of activities shall be Customers of works for development of technical regulations for funds of the State Budget of Ukraine.

Section IV

PROCEDURES FOR ASSESSMENT OF CONFORMITY WITH THE REQUIREMENTS OF TECHNICAL REGULATIONS

Article 28. Assessment of Conformity with the Requirements of Technical Regulations

Assessment of conformity with the requirements of technical regulations shall be carried out by the designated conformity assessment authorities.

The respective central bodies of the state executive power must only suggest appointment of the conformity assessment authorities that are residents of Ukraine and are able to confirm their level of competence, as well as meet the following criteria:

absence of commercial or any other interests regarding products, process or services that they assess. The designated authority, its manager and staff who are authorised to carry out conformity assessments may not be identified as developers, producers, supplier, assembler or user of the respective products, processes or services or an authorised representative of any of those entities/persons;

availability of qualified personnel and means necessary for performance of conformity assessment procedures, and possibilities to gain access to equipment that may be necessary to conduct tests;

availability of guarantees concerning independence of personnel conducting conformity assessment procedures;

payment of salaries of personnel conducting conformity assessment procedures that is independent from the number and results of the conformity assessment procedures conducted.

The central bodies of the state executive power that provide proposals concerning appointment of conformity assessment procedures must take into account the availability of accreditation by the national accreditation authority.

The central bodies of the state executive power that provide proposals concerning appointment of conformity assessment authorities must withdraw their proposals in a timely manner if it has been detected that the appointed conformity assessment authority does not meet the specified criteria or does not fulfil its obligations under the present Law.

Information about appointment or cancellation of the decision on appointment of the conformity assessment authority shall be published in the official publication of the central body of the state executive power on matters of conformity assessment.

Article 29. Responsibilities of the Appointed Conformity Assessment Authorities

The conformity assessment authorities shall only perform procedures, for performance of which they have been authorised.

Personnel of conformity assessment authorities shall be obligated to preserve commercial secrets, unless otherwise stipulated by applicable law.

The appointed conformity assessment authority shall regularly report on its activities to the central body of the state executive power that put forward the proposal on its appointment, as well as the central body of the state executive power for matters of conformity assessment.

The appointed conformity assessment authority shall ensure:

equal access for producers, including those from foreign countries, to the conformity assessment procedures, specifically, a possibility to carry out conformity assessment at production sites and obtaining of the National Conformity Mark;

publication or communicating to of any interested party, upon its request, of information about the standard or expected period for completion of each conformity assessment procedure;

timely consideration of requests by interested parties, including examination of documentation for fullness, and providing exhaustive and accessible information about all drawbacks detected to the applicant;

urgent communication of the conformity assessment results to applicants to enable them to take corrective measures, if necessary;

conducting, upon an applicant's request (even if the application has drawbacks), of conformity assessment procedures, to the extent that doing so is possible, and notifying the applicant about the implementation stage of the conformity assessment procedures, with explanation of any delays;

minimisation of requirements to the information needed for conformity assessment;

setting the size of payments for conformity assessment procedures;

observing confidentiality of information about the products generated by manufacturers (suppliers), to include those from foreign countries, to ensure conformity assessment procedures being carried out for the purposes of protection of legitimate commercial interests;

equal size of any fees levied for procedures of conformity assessment of similar products, for domestic and foreign producers (suppliers) with account to transportation, communication and other costs caused by the different location of the applicant's production site and that of the conformity assessment authority;

placement of objects that are used in the conformity assessment procedures, and carrying out of sampling procedures so as not to create unnecessary inconvenience for applicants or their representatives.

In case modifications are made in products after the conformity attestation was completed, the conformity assessment procedures in relation to those modified products must only be limited to the measure that are necessary to gain sufficient confidence that the said products still meet the specified technical regulations.

The conformity assessment authorities must define the procedures for consideration of claims that are related to conducting of conformity assessment procedures, with account to provisions of Article 31 of the present Law. Procedures for consideration of claims must envisage approval of corrective measures that are applicable in case it has been proven that the claim is grounded.

The conformity assessment authorities maintain a register of the conformity certificates issued and provide a copy of the certificate in accordance with the procedures, approved by the central body of the state executive power for matters of conformity assessment, to the state register of conformity certificates.

Article 30. Recognition of Results of Conformity Assessments Conducted Outside Ukraine

Results of conformity assessments (conformity certificates, marks of conformity, product testing protocols, etc.), that were conducted outside Ukraine, shall be recognised on the basis of international agreements of Ukraine about mutual recognition (acceptance) of results of conformity assessment procedures, concluded between the Ukrainian and foreign conformity assessment authorities.

In the course of conclusion of international agreements about mutual recognition of results of conformity assessment procedures, it is necessary to verify:

adequacy of technical qualifications of conformity assessment authorities of the party that the agreement is being made with;

ensuring of long-term reliability of results of conformity assessment procedures by the party that the agreement is being made with;

observance of instructions and recommendations of international standardisation authorities by the conformity assessment authorities of the party that the agreement is being made with.

Recognition of results of conformity assessment can be limited to acceptance of results of conformity assessment by the conformity assessment authorities of the party that the agreement is being made with.

Results of conformity assessment may be recognised without conclusion of the corresponding international agreements of Ukraine in the event when Ukraine and the country that claims recognition of results of the corresponding work are both members of international or regional conformity assessment organisations.

Results of conformity assessment shall be determined in accordance with the procedures established by those international and regional organisations.

Article 31. Disputing of Conformity Assessment Procedures

Any person that is a customer for conformity assessment procedures may dispute actions and decisions by a conformity assessment authority by filing an objection to the appeals commission established under conformity assessment authorities, or following judicial procedures.

In case any of the parties concerned disagrees with the decision taken by the appeals commission under the conformity assessment authority, it can be disputed at the appeals commission under the central body of the state executive power on matters of conformity assessment.

Expenditures for filing of the objection shall be covered by the claimant. In case the second conformity assessment differs from the previous one, all costs incurred by the claimant shall be compensated by the conformity assessment authority that arrived at incorrect results of conformity assessment.

The standard provisions on appeals commission and the procedures for consideration of complaints by them shall be approved by the central body of the state executive power for matters of conformity assessment.

Article 32. Declaration of Conformity and Certificate of Compliance

Producers shall prepare declarations of conformity of all of its products launched into circulation, which are objects of technical regulations, unless otherwise specified by the technical regulations.

Unless otherwise specified in the technical regulations, declaration of conformity must contain the following information:

designation of the product (name, type or number of the model, any other additional information, for example, batch number or serial number, designations of component parts);

requirements of technical regulations that the products meets, including references to the respective National standards;

additional information (sort or category of products) in accordance with the technical regulations;

date of preparation of the declaration, name, address, status and signature of the producer or its authorised representative;

name, address and identification code in the register of appointed authorities under the conformity assessment authority that carried out the conformity assessment procedure;

title and address where documentation on conformity certification is stored.

Producers shall be obligated to obtain a conformity certificate at the conformity assessment authority in accordance with the requirements of law, if that procedure is envisaged for the applicable technical regulations, in order to confirm compliance.

The format of the declaration of compliance shall be determined by the central body of the state executive power for matters of conformity assessment.

Declarations of compliance, made in accordance with the requirements specified in the technical regulations, shall be subject to registration by the central body of the state executive power in the sphere of technical administration within a time period not to exceed three days. In order to secure registration of its declaration of compliance, a claimant shall submit its declaration of compliance, prepared in accordance with the requirements set in the technical regulations, to the central body of the state executive power in the sphere of technical administration.

The procedures for maintaining of the register of declarations of compliance, as well as the procedures for providing of information about the registered declarations shall be determined by the central body of the state executive power in the sphere of conformity certification.

Article 33. The National Conformity Mark

The Cabinet of Ministers of Ukraine shall approve the specimen (description) and the rules for application of the National Conformity Mark, which is used for certification of conformity with the technical regulations.

The National Conformity Mark, specified in the technical regulations, shall be applied to all products that are the object of, and meet the requirements of those technical regulations.

In case of conformity assessment of products that are an object of technical regulations, the appointed conformity assessment authority shall attach the identification code of that authority to the National Conformity Mark.

The National Conformity Mark shall be affixed to the packaging or label of products and to promotional materials for processes or services that meet the requirements of technical regulations.

Marks or other signs similar to the approved National Conformity Mark, or any other signs, shall not be affixed to products, processes or services that do not meet the technical regulations, or to products, processes or services that do not qualify for application of the National Conformity Mark or marks of compliance with standards, and signs or marks similar to the approved National Conformity Mark shall not be affixed to promotional and packaging materials.

Application of the National Conformity Mark to products, processes or services that are objects of technical administration, if doing so is not specified in technical regulations, shall be prohibited.

Section V

OBLIGATIONS OF PRODUCERS AND SUPPLIERS OF PRODUCTS THAT ARE OBJECTS OF TECHNICAL REGULATIONS, AND CONTROL OVER COMPLIANCE WITH THE REQUIREMENTS OF TECHNICAL REGULATIONS

Article 34. Obligations of Producers and Suppliers

Producers and suppliers must only offer or provide services, or use processes or launch products of domestic or foreign origin that are safe for life and health of

human beings, for animals and plants, that ensure national security, protection of the natural environment and natural resources, and prevent unfair competition.

Producers and suppliers must ensure compliance with all requirements stipulated by the respective technical regulations before launching of objects of technical regulations.

Launching of objects of technical regulations shall be accompanied by declaration of conformity and/or certificate of compliance, as well as by marking of the products by the National Conformity Mark, in case doing so is envisaged by the respective technical regulations.

Producers or their authorised representatives in Ukraine are to:

provide consumers with the information relevant for assessment of risks connected with their products, if those risks are not obvious without warnings, and take measures to prevent such risks;

withdraw products from circulation, in case they do not meet the requirements of the respective technical regulations;

keep declarations on compliance and/or conformity certificates, as well as other documents attesting to conformity with technical regulations, for the duration of the envisaged period of use of the products launched in circulation, and make that information available upon request of market surveillance authorities;

compensate damages inflicted to consumers of products, processes and services in case when their non-conformity with the requirements of technical regulations, specified in their declaration of compliance and/or certificate of conformity has been proven.

In case the producer is not a resident of Ukraine, and an authorised representative of that producer in Ukraine is non available, the supplier of the product launched shall be obligated:

provide market surveillance bodies, upon their request, with the necessary information about the products, in part, a copy of the of compliance and, if doing so is envisaged by the technical regulations requirements, of the certificate of conformity and/or technical documentation concerning conformity attestation technical regulations;

discontinue or suspend sales of the products if it has been proven that the products do not conform with the technical regulations or provisions of the present Law.

Article 35. Purpose of Market Surveillance

The purpose of market surveillance is to exercise control over conformity of products, processes and services, launched into circulation, with the requirements of technical regulations in relation to safety of life and health of human beings, animals and plants, protection of the environment and natural resources, prevention of unfair practices, as well as assisting subjects of entrepreneurial activities through ensuring of fair competition.

Market surveillance shall be exercised by bodies of the state executive power in accordance with the law.

Article 36. Procedures for Exercising of Market Surveillance and Powers of Bodies of the State Executive Power in the Sphere of Market Surveillance

Procedures for exercising of market surveillance, and rights, powers and responsibilities of officials engaged in it, and the procedures for taking measures by the surveillance results, shall be defined by law.

Section VI

PROVIDING OF INFORMATION ON TECHNICAL REGULATIONS, STANDARDS AND CONFORMITY ASSESSMENT PROCEDURES

Article 37. Establishment of the Centre for Processing of Enquiries and Providing of Notifications

The Centre for Processing of Enquiries and Providing of Notifications on standards, technical regulations and conformity assessment procedures (hereinafter referred to as «the Centre») shall be established by the Cabinet of Ministers of Ukraine.

Article 38. Principal Functions of the Centre

The Centre shall perform the following principal functions:

providing, or organisation of providing of responses to enquiries on part of the domestic and foreign interested parties concerning the national standards, technical regulations and conformity assessment procedures;

providing of information about draft or approved technical regulations, national standards, conformity assessment procedures;

informing of the respective central bodies of the state executive power, national producers and entrepreneurs about technical regulations, standards and conformity assessment procedures in foreign countries;

preparation of, and commenting on notifications, prepared by foreign countries on their standards, technical regulations and conformity assessment procedures;

providing of information about participation and membership of Ukraine in international or regional organisations for standardisation, conformity assessment systems, and also on conclusion of bilateral or multilateral agreements that regulate development and application of standards, technical regulations and conformity assessment procedures;

providing of information concerning place of publication of notifications or places where that information can be obtained;

providing of information on location of enquiry processing centres and providing of notifications, in case a decision is made on establishment of more than one centre;

other information services provided on users' requests.

Upon request of a foreign party, the Centre must provide documents translated into a language used in international organisations, and in case the volume of those documents is large – a description of those documents.

Payment for copying of the documents and their translation into a language used in international organisations, which are provided upon request of interested parties, shall be equal for both the national and foreign parties, with the exception of actual costs of delivery of those documents.

Article 39. Competences of the Central Bodies of the State Executive Power on Providing of Notifications

The central bodies of the state executive power that develop standards, technical regulations and conformity assessment procedures must provide the Centre with copies of such documents within five working days upon completion of work on draft standards, technical regulations and conformity assessment procedures.

In case it is envisaged that the approved urgent technical regulation and/or conformity assessment procedure, or draft technical regulations and/or conformity assessment procedures significantly affect trade with countries that Ukraine has an international agreement with, or if there exist commitments that arise from Ukraine's membership in an international or regional organisation, notifications about the said drafts shall be addressed to the interested parties in accordance with the procedures envisaged in the respective international agreement of Ukraine or the international or regional organisation.

Notifications about draft technical regulations and/or conformity assessment procedures, specified in part one of the present Article, shall be provided in the formats and volumes specified in the rules of the agreement or procedures of the respective international or regional organisations, not later than in 60 calendar days before the working group has completed development of the draft technical regulations or the conformity assessment procedures.

Information about the adopted urgent technical regulations and/or conformity assessment procedures shall be made known by the Centre after their publication in the *Ofitsiyny Visnyk Ukrainy* (Official Bulletin of Ukraine) information bulletin, in accordance with the procedures specified in the respective international agreement of Ukraine or at the international or regional organisation.

Upon request of an interested entity within the boundaries of a country that is a member of the corresponding international or regional organisation that Ukraine is a party to, parties to the respective international agreement, the Centre or another competent state authority must ensure that the said entity is provided with a copy of the respective draft or the approved document.

In the event when bilateral or multilateral agreements on standards, technical regulations and conformity assessment procedures significantly affect trade by countries that are not parties to those agreements, the Centre shall send those state a notification about such agreements, along with designation of the products and description of the agreement.

Article 40. Financing of Activities by the Centre

Activities by the Centre shall be financed at the expense of the State Budget of Ukraine and funds collected from users of its services.

The allocated budget funds shall be used for financing of:

research and development work;

notifications to international and regional organisations;

maintenance and operation of the Centre.

Funds collected from users of the Centre shall be used solely for development of its research and engineering capacity.

Section VII

FINAL PROVISIONS

1. The present Law shall become valid beginning on the day of its publication.
2. The following legislative acts of Ukraine are to be modified as specified below:
 - 1) Article 15 of the Economic Code of Ukraine (436-15) (Bulletin of the Verkhovna Rada of Ukraine, 2003, NN 18-22, p. 144) shall be set forth in the following version:
«Article 15. Technical Administration in the Sphere of Economic Management
 1. The following shall be used in the sphere of economic management:
technical regulations;
standards;
codes of accepted practices;
classifiers;
technical requirements.
 2. Application of standards or separate provisions thereof shall be mandatory for :
subjects of economic activities, if technical regulations contain references to the standards;

participants of an agreement (contract) for development, manufacturing or supply of products, if those contain references to certain standards;

manufacturers or suppliers of products, if those have submitted a declaration of compliance of their products to certain standards or used symbols of those standards in their labelling.
 3. In the event when products are manufactured to be exported, if an agreement (contract) specifies requirements that are different from those contained in the technical regulations, it shall be permissible to apply provisions of the agreement (contract), provided those do not contradict the Ukrainian legislation pertaining to requirements of product manufacturing, storage and transportation on the territory of Ukraine»;
 - 2) in the Law of Ukraine «On Standardisation» (2408-14) (Bulletin of the Verkhovna Rada of Ukraine, 2001, N 31, p. 145):
 - a) in Article 1:
paragraph nine is to be set forth in the following version:

«a standard is document developed on the basis of a consensus and approved by a competent authority that establishes generally applicable and multiple-use rules, instructions or characteristics that are related to activities or their results, including products, processes or services, compliance with which is not mandatory. A standard may contain requirements to terminology, signs, packaging, markings or labelling that are applicable to certain products, processes or services»;

paragraph fourteen is to be removed;

b) Article 4 is to be set forth in the following version:

«Article 4. Objects of Standardisation

Objects of standardisation shall include products, processes and services, in part, materials, component parts, equipment, systems, their compatibility, rules, procedures, functions, methods or activities, personnel and authorities, and well as requirements to terminology, signs, pre-packaging, packaging, marking, labelling»;

c) in Article 5:

part one is to be set forth in the following version:

«The goal of standardisation in Ukraine is to ensure rational utilisation of the natural resources, conformity of objects of standardisation with their intended use, informing consumers about the quality of products, processes and services, support of development and international competitive properties of products and trade in goods and services»;

part two is to be appended with paragraph ten, with the following content:

«approval and application on the territory of Ukraine of the Code of Good Practice on development, approval and application of standards, in compliance with the WTO Agreement on Technical Barriers to Trade (981_008), which is an Annex to the 1994 Marrakech Agreement on Establishing the World Trade Organisation (995_342)»;

d) paragraph three in Article 6 is to be set forth in the following version:

«Council for standardisation and technical administration»;

e) in Article 7:

in part two:

paragraph two is to be set forth in the following version:

«shall ensure implementation of the state policy in the sphere of standardisation, specifically, take substantiated measures for adoption and application by standardisation authorities on the territory of Ukraine, as well as by the regional standardisation authorities established on the territory of Ukraine that they are members of, of the Code of Good Practice on development, approval and application of standards, in compliance with the WTO Agreement on Technical Barriers to Trade (981_008), which is an Annex to the 1994 Marrakech Agreement on Establishing the World Trade Organisation (995_342)»;

paragraphs eight and ten are to be removed;

shall be appended by paragraphs of the following content:

«shall ensure adaptation of standards, conformity assessment procedures, certification procedures and practices in accordance with the modern achievements in science and engineering»;

shall establish procedures and take decisions on establishing and termination of technical committees for standardisation, define their competences and the procedures for establishment;

shall ensure compliance of the national standards with the present Law;

shall approve symbols and marks that attest to the conformity of products to the national standards (hereinafter referred to as «the standard conformity mark»);

shall participate in development of technical regulations and preparation of technical regulations development programme;

shall participate in preparation of international and regional standards that are developed by the respective international and regional organisations, and in preparation of recommendations for conformity assessment procedures, ensuring that interests of Ukraine are taken into consideration;

shall cooperate and conduct consultations with the respective bodies in the sphere of standardisation in foreign countries, and, in case of necessity, shall take measures aimed at resolution of any arising disputes or complaints;

shall formulate standardisation development programmes and, at least on time every six months, publish the updated programme;

shall maintain a register of standards and documents on standardisation;

shall organise creation and operation of the national fund of regulatory documents and the National Information Centre within the ISONET international information network;

shall organise distribution of official publications of the national standards, generally accepted practices and classifiers, and other printed matter related to the approved national standards, standards and documents of the corresponding and regional standardisation organisations that it is a member of, or with which it cooperates in accordance of provisions of those organisations or the respective agreements, and shall also delegate those competences to other organisations;

support and facilitate cooperation between producers, suppliers, consumers of products, processes and services, and the respective state authorities in the sphere of standardisation»;

f) Article 8 is to be removed;

g) Article 9 is to be appended with part six, of the following content:

«Membership in technical committees for standardisation shall be voluntary»;

h) Articles 10 and 11 are to be set forth in the following version:

«Article 10. Other Subjects Engaged in Standardisation

The central bodies of the state executive power and organisations shall have the right to organise and perform standardisation works, in the corresponding spheres of activities and within their competences, with account to their economic and professional interests, specifically:

to develop, approve, adopt, review and modify standards of the respective level and suspend their effect; determine rules for their development, designation and application;

to represent Ukraine in the respective specialised international and regional organisations for standardisation, and to fulfil obligations envisaged by provisions on those organisations;

to create and maintain registers of regulatory documents to ensure their activities and information exchange;

to publish and distribute their standards, documents by the respective specialised international and regional organisations for standardisation that they are members of, or with which they cooperate on the basis of provisions on those organisations or corresponding agreements, and also to delegate those competences to other organisations.

The central bodies of the state executive power and organisations must inform the central body of the state executive power in charge of standardisation about standardisation works in their directions, for the purpose of fulfilment of the Code of Good Practice on development, approval and application of standards, in compliance with the WTO Agreement on Technical Barriers to Trade (981_008), which is an Annex to the 1994 Marrakech Agreement on Establishing the World Trade Organisation (995_342).

Ministry of Defence of Ukraine, in consideration of specific properties of that sphere, shall determine the procedures for application of standards to meet the needs of defence of Ukraine in line with the functions that it is in charge of.

Article 11. Regulatory Documents on Standardisation and Application of Standards

Depending on the level of the body that accepts or approves regulatory documents on standardisation, those shall be divided into:

National standards, rules of generally accepted practices and classifiers, accepted or approved by the central body of the state executive power in charge of standardisation, as well as catalogues and registers of the national-wide applicability, issued by it;

standards, technical requirements and generally accepted rules, adopted or approved by other bodies and organisations in charge of standardisation matters, as well as catalogues, issued by them.

Standards shall be applied directly, or by way of reference to them in other documents.

Standards shall be applied on the voluntary basis, except in cases when application of those standards is required by technical regulations.

Standards must be formulated in such a manner so as to preclude their possible use for the purpose of deliberate misinformation of consumers of products that the standard concerns, or to give preferences to certain manufacturers of products, or to certain products depending on its place of origin.

The procedures for development, revision, modification, approval and publication of standards shall be specified by the Law of Ukraine «On standards, technical regulations and conformity assessment procedures»;

- i) Articles 12 and 13 are to be removed;
- j) Section IV is to be set forth in the following version:

«Section IV INFORMATION SUPPORT AND THE RIGHT OF OWNERSHIP FOR STANDARDS, CODES OF ACCEPTED PRACTICES AND TECHNICAL REQUIREMENTS

Article 15. Right of Ownership to Standards

The right of ownership to the National standards, rules of generally accepted practices, classifiers and catalogues shall belong to the state. The ownership rights to those documents on behalf of the state shall be exercised by the central body of the state executive power in charge of standardisation.

The right of ownership to standards, technical requirements and codes of generally accepted practices, approved or adopted by other authorities and organisations engaged in standardisation, shall belong to organisations and institutions at whose expense those were created or to which it was transferred in accordance with the procedures, stipulated by law.

A standard may be developed for a product and a process that are objects of standardisation and, simultaneously, objects of intellectual or industrial property, in case the developer of the standard received permissions from the holder of the rights to the products or processes, in accordance with the procedures, stipulated by law.

Except in cases, envisaged in the present Law, it shall be prohibited to reproduce, replicate and distribute as official publications, either in full or partially, any standards, codes of accepted practices, classifiers or parts thereof, without prior consent of their owners or persons, duly authorised by them, except in cases envisaged by the present Law.

In the event of replication or distribution of a standard or a rule of accepted practices without prior consent of their owners or persons, duly authorised by them, the authority or organisation that adopted the standard shall not be responsible for any inconsistencies between the text of the distributed document and its official text, or for any consequences that may be caused by application of the distributed document.

The owner of an object of ownership shall be entitled to compensation of damages inflicted to it by illegitimate distribution of standards, rules of accepted practices, classifiers or catalogues, in accordance with the law.

Article 16. Publication and Distribution of Standards

National standards, rules of accepted practices, classifiers and catalogues shall be published and distributed by the central body of the state executive power in charge of standardisation.

Publication and distribution of documents by the respective international and regional organisations that Ukraine is a member of, shall be carried out by the central body of the state executive power in charge of standardisation, other bodies and organisations in charge of standardisation, in accordance with their provisions.

In order to provide information to the interested parties, the central body of the state executive power in charge of standardisation shall function as the National information centre within the ISONET international information network, and shall maintain a catalogue of the national standards.

Authorities and organisations that develop and adopt standards that may create obstacles for trade shall provide copies of draft and adopted standards to the central body of the state executive power in charge of standardisation, which shall make that information available for the interested parties via the National information centre within the ISONET international information network.

Information services shall be provided through publication of the official texts of standards, information and reference bulletins, as well as their distribution by information networks by way of initiative or upon request»;

k) throughout the text of the Law, the words «central body of the state executive power in the sphere of standardisation» in all grammatical cases are to be replaced, respectively, by the words «central body of the state executive power in charge of standardisation» in the corresponding grammatical case;

3) in the Law of Ukraine «On Confirmation of Compliance» (2406-14) (Bulletin of the Verkhovna Rada of Ukraine, 2001, N 32, p. 169; 2005, N 2, p. 33):

a) in Article 1:

paragraphs eight and fifteen are to be set forth in the following version:

«conformity attestation – issuance of a document (declaration on conformity or a certificate of compliance) on the basis of the decision taken after completion of the respective (necessary) conformity assessment procedures that proved fulfilment of the requirements set»;

«technical regulation – a law of Ukraine or a regulatory act, approved by the Cabinet of Ministers of Ukraine, which defines characteristics of a product or related manufacturing processes or methods, as well as the requirements to services, including the respective mandatory provisions. It can also contain requirements to terminology, symbols, packaging, marking or labelling that are applied to certain products, process or manufacturing methods»;

shall be appended by paragraphs with the following content:

«conformity assessment authority – an authority providing conformity assessment services;

an appointing authority – a body designated or authorised by the Cabinet of Ministers of Ukraine to appoint conformity assessment authorities, to suspend or cancel their appointment, or cancel suspension of their appointment;

conformity assessment - proving that the specified requirements to products, processes, systems, person or body have been met by way of testing, control or certification;;

appointment – granting by the body designated or authorised by the Cabinet of Ministers of Ukraine to the conformity assessment authority of the right to perform certain activities for assessment of conformity with the requirements set in the technical regulations;

conformity assessment procedure – any procedure that is directly or indirectly applied to determining whether requirements set in the respective technical regulations or standards have been met. Conformity assessment procedures include procedures for sampling, testing, control, assessment,

examination, registration, accreditation and approval, as well as their combinations»;

b) Article 5 is to be appended by paragraph ten, with the following contents:

«development or application of the conformity assessment procedures in a manner sufficient to ensure compliance of products, processes and services to the technical regulations or standards, with regard to risks in the event of non-compliance»;

c) in Article 6:

part one is to be appended by paragraph seven of the following contents:

«shall approve the procedures to carry out appointment of conformity assessment authorities, which verify compliance of products, processes and services with the requirements of technical regulations»;

part two shall be appended by paragraphs thirteen and fourteen, of the following contents:

«shall appoint the conformity assessment authorities upon proposals by the respective central bodies of the state executive power;

shall organise supervision over conformity assessment activities by the appointed conformity assessment authorities»;

part four is to be removed;

d) Articles 7, 8, 10, 12, 15 are to be removed;

e) throughout the text of the Law, the words «authorised certification body», «specially authorised central body of the state executive power in the sphere of confirmation of compliance», «technical regulations for confirmation of compliance» in all grammatical cases and numbers shall be replaced, respectively, by words «the appointed conformity assessment authority», «central body of the state executive power for matters of conformity assessment», «technical regulations» in the corresponding grammatical case and number.

3. Within one-month term, the Cabinet of Ministers of Ukraine shall:

bring its regulatory acts into consistency with the present Law;

ensure bringing of regulatory acts of Ministries and other central bodies of the state executive power into consistency with the present Law.

President of Ukraine V.YUSHCHENKO

City of Kyiv, December 1, 2005, N 3164-IV