

DRAFT**LAW OF UKRAINE****„On development and application of standards, technical regulations and conformity assessment procedures**

This Law establishes the legal and organisational framework for development and application of *national standards, technical regulations, and conformity assessment procedures*, the granting of the right to use conformity marks for all *products, processes and services*, whether of domestic or foreign origin, to economic operators, bodies of executive power, and public organisations and also the supervision of the implementation of this Law.

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

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

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

Safe product (process)

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

Inspection (control) –

Conformity assessment procedure – any procedure used, directly or indirectly, to determine that prescribed requirements in relevant *technical regulations* or *standards* are fulfilled. *Conformity assessment procedures* include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, *accreditation* and approval as well as their combinations.

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

Risk – the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified time period.

Market supervision – the ongoing monitoring of *products placed in circulation* for compliance with relevant *technical regulations* and, when the mark of conformity with *national standards* has been applied to a *product*, for compliance with such standard;

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

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

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

Article 2. Sphere of Application of the Law

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

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

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

Accessibility of *standards* and information to users;

Conformity of *standards* to legislation;

Adoption and implementation by standardising bodies in the territory of Ukraine of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the World Trade

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*

Article 13. Normative Documents on Standardisation and Application of Standards

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

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

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

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

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

Standards shall be stated in such a way that it would be impossible to apply them to mislead consumers about a *product* covered by the standard or for giving preference to the *producer* of a *product* or a *product* on the basis of the place of its manufacturing.

Article 14. Proposals for Conducting Standardisation Works

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

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

The central body of executive power for *standardisation* issues shall inform the submitting party about the

The relevant technical committee shall evaluate proposals regarding amendment of existing national

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

Article 21. Financing of Standardisation Works

Standards works are financed by customers of these works.

The sources of financing are:

- funds of the State budget of Ukraine;
- funds allocated for implementation of programmes and projects;
- funds of subjects of economic activity;
- bank credits;
- other funds envisaged by legislation.

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

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

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

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

Article 22. Use of Funds Received from Sales of Standards

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

CHAPTER III. LEGAL REGULATION IN THE TECHNICAL SPHERE

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

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

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

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

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

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

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

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

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

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

All *emergency technical regulations* shall be reviewed by a relevant *working group* within six months of adoption to determine the continuing need for the *emergency technical regulation*. If the *technical regulation* adopted for urgent reasons is no longer needed, it shall be abolished according to the provisions of Article 35 of this Law.

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

Article 35. Review of Adopted Technical Regulations

CHAPTER IV. CONFORMITY ASSESSMENT

Article 38. Goal and State Policy for of Conformity Assessment

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

conformity marks and

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 commesTc.36(i)8.6(a)-5ltd i0 Tw[(sup)i0ssre320 Twhs57asresined; 9.7884

Ukraine, according to international agreements on mutual recognition of the results of conformity assessment of which Ukraine is a party.

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

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

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

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

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

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

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

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

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

The activity in the area of conformity assessment to the requirements of technical regulations shall be

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

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

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

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

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

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

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

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

withdraw or suspend selling of the *product* if it is shown that the *product*

Article 53. Authorities Market Supervision Body

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

Article 55. Financing of the Market Supervision

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

The budget funds shall be allocated to finance:

Scientific and research works;

Participation in work of international (regional) organization:

Labor payment of the officials of Bodies for Market Supervision

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

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

Article 56. Authority of the Cabinet of Ministers

The Cabinet of Ministers of Ukraine shall:

establish and maintain a system of technical regulations, standards and conformity assessment procedures in accordance with the provisions of the Law of Ukraine "On Technical Regulations";

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

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

Article 58.

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

CHAPTER VIII. INTERNATIONAL COOPERATION

Article 61. International Cooperation

The central body of executive power for *standardisation*