

LAW of UKRAINE

No.2406-III

May 17, 2001

On Conformity Assessment

This law sets up legal and organizational framework of conformity assessment of products, quality systems, quality management systems, environment management systems, personnel to the requirements, and is aimed at ensuring a uniform technical policy in the sphere of conformity assessment.

Chapter 1. General provisions

Article 1. Principal terms and their definitions

In this law terms are used in the following meaning:

Product – any good, process or service that has been manufactured, supplied or provided for the public needs;

Producer – a legal entity or a physical person – subject of entrepreneurial activity - responsible for design, manufacturing, packaging and marking of the product notwithstanding whether these operations are performed by this person or on his behalf;

Quality system – an aggregate of interconnected and interacting elements of the organizational structure, established mechanisms of responsibility, authorities and procedures of the organization, as well as processes and resources securing general management of quality and its conformity to established requirements;

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

Environment management system – an aggregate of the organizational structure, activity and relevant resources and methods of development, implementation, analysis and actualization of the environmental policy;

Supplier – a legal entity or a physical person – a subject of entrepreneurial activity, who places the product on the market or participates in this;

Conformity assessment – activity, the result of which is assurance that products, quality systems, quality management systems, environment management systems, personnel meet the requirements established by legislation;

Declaring of conformity – a procedure, through which a producer or a person authorized by him (hereinafter – producer) under his responsibility states in written that the product meets the requirements established by legislation;

Certification – a procedure, through which a body recognized according to the established procedure states in written the conformity of products, quality systems, quality management systems, environment management systems, personnel to the requirements established by legislation;

Testing laboratory – a laboratory that carries out technical operations lying in identification of one or more characteristics of a given product in compliance with the established procedure;

Certificate of conformity – a document, confirming that products, quality systems, quality management systems, environment management systems, personnel meet requirements to the specific standard or other legislative document, established by legislation;

Declaration of conformity – a written statement of a producer, wherein there is a guarantee of conformity of the product to the requirements established by legislation;

Certification auditor – a person that has a relevant qualification, theoretical and practical training, necessary for performing of one or more types of certification works, certified according to the established procedure, and included in a special register;

Technical regulation on conformity assessment – a legislative act, adopted by the Cabinet of Ministers of Ukraine, which contains a list of types of products liable to mandatory conformity assessment, requirements for the safety of life and health of a person, animals, plants, as well as property and environment protection, procedures for conformity assessment to these requirements, rules of marking and placing the products on the market;

Certificate of conformity recognition – a document that certifies the recognition of foreign documents on conformity assessment of products to the requirements, established by Ukrainian legislation;

Placing the product on the market – manufacturing or importing the product into the customs territory of Ukraine with its following direct or indirect sale within the Ukrainian territory;

Legally regulated sphere – a sphere, wherein the placing of the product on the market is regulated by legislation;

Legally unregulated sphere – a sphere, wherein the placing of the product on the market is not regulated by legislation.

Article 2. The scope of this Law

This law regulates relations, arising in the process of conformity assessment of products, quality systems, quality management systems, environment management systems, personnel to the requirements established by Ukrainian legislation and is extended to producers and suppliers of products notwithstanding the forms of ownership and types of activity, to certification bodies, testing laboratories, as well as to corresponding state authorities.

Article 3. Legislation of Ukraine in the sphere of conformity assessment

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

Article 4. Objects of conformity assessment

According to this law the objects of conformity assessment are products, quality systems, quality management systems, environment management systems, personnel.

Article 5. Main principles of the state policy in the sphere of conformity assessment

State policy in the sphere of conformity assessment is based on the following principles:

coordination of activity of bodies of executive power in the sphere of conformity assessment, delineation of their spheres of authority and elimination of the doubling of functions;

impartiality, transparency and accessibility of the procedures of conformity assessment;

application of the procedures for conformity assessment, taking into account international practice depending on potential risk;

ensuring identical procedures for conformity assessment for the products of domestic and foreign origin;

harmonization of national legislative acts on conformity assessment with international and European ones;

encouragement of the development of conformity assessment in the legally unregulated sphere;

observance of the confidentiality of information, obtained during the conformity assessment works;

provision of complete and comprehensive information on conformity assessment issues to all interested parties.

Article 6. Authority of bodies of executive power in the sphere of conformity assessment

The Cabinet of Ministers of Ukraine in the sphere of conformity assessment shall:

ensure implementation of the state policy in the sphere of conformity assessment;

determine central bodies of executive power for technical regulations in the relevant spheres;

determine central bodies of executive power entrusted with development of technical regulations;

approve of technical regulations on conformity assessment;

conclude international agreements in the sphere of conformity assessment, accession of Ukraine to international (regional) certification systems.

The specially authorized central body of executive power in the sphere of conformity assessment shall:

participate in formation of the state policy in the sphere of conformity assessment;

carry out the uniform state technical policy in the sphere of conformity assessment;

develop propositions on conclusion of international agreements in the sphere of conformity assessment, accession of Ukraine to international (regional) certification systems, make decisions on the procedure of recognition of the results of certification works, carried out by the certification bodies of other countries;

coordinate activity of central bodies of executive power in the relevant spheres of activity on conformity assessment in the legally regulated sphere;

organize development of draft legislative acts that set up general requirements and rules of procedure for conformity assessment in legally regulated sphere;

provide methodological assistance to the central bodies of executive power during the development of draft laws, other legislative acts on conformity assessment, including technical regulations;

coordinate technical regulations on conformity assessment, developed by the bodies of executive power, and submitted for approval to the Cabinet of Ministers;

keep the state register of authorized certification bodies and set up a procedure for the provision of information on the issued certificates of conformity and certificates of conformity recognition;

organize training and certification of certification auditors;

keep the national archive of legislative acts on conformity assessment issues;

provide information on conformity assessment issues.

Central bodies of executive power, entrusted with the functions of technical regulation in the relevant spheres of activity shall:

develop propositions for approval of certification bodies to conduct conformity assessment activities in the legally regulated sphere;

participate in development of draft technical regulations and other legislative acts on conformity assessment in this sphere;

organize training and improvement of skills of conformity assessment personnel.

Central body of executive power for economic issues shall:

authorize certification bodies (authorized certification bodies) to conduct works on conformity assessment in the legally regulated sphere with the agreement of a specially authorized central body of executive power in the sphere of conformity assessment and with central bodies of executive power entrusted with the functions of technical regulation in the relevant spheres of activity;

organize supervision of the activity of authorized certification bodies.

Article 7. Conformity assessment

Conformity assessment procedure in the legally regulated sphere is mandatory for a producer, supplier or an authorized certification body.

Conformity assessment in the legally unregulated sphere is carried out on the voluntary basis.

The conformity of products to the established requirements is evidenced by the declaration of conformity or the certificate of conformity.

Article 8. National conformity sign

The national conformity sign – is a sign that certifies conformity of designated products to the requirements of conformity assessment regulations applied to these products.

Description and the rules of application of the national conformity sign shall be determined by the Cabinet of Ministers of Ukraine.

The producer shall place the national conformity sign in the legally regulated sphere on the products, whose conformity is certified by the declaration. In case conformity is assessed by the authorized certification body, the national certification sign shall be supplemented with the identification number of this body.

Chapter II. Conformity assessment in the legally regulated sphere

Article 9. Conformity assessment in the legally regulated sphere

The conformity assessment procedure in the legally regulated sphere for certain types of products, which can present risk for the life and health of people, animals, plants as well as for property and environment, is introduced by the technical regulations on conformity assessment.

Simultaneously with the adoption of technical regulations on conformity assessment, the specially authorized body of executive power in the sphere of conformity assessment shall officially publish the list of the national standards, voluntary application of which can be evidence of product conformity to the essential requirements of technical regulations. Producer or supplier also has the right to assure conformity of the product to the essential requirements of technical regulations by ways other than conformity to standards, permitted by these regulations.

Article 10. Declaring of conformity in the legally regulated sphere

Producer shall ensure conformity assessment and draw up the declaration of conformity if it is envisioned by the technical regulation on conformity assessment for the particular product. If the producer is not resident of Ukraine, he is obliged to appoint according to the established procedure an authorized person – a resident of Ukraine - to carry out conformity assessment.

The form, contents and the period of keeping of the declaration of conformity are established by the technical regulation on conformity assessment.

The producer shall adduce to the state monitoring bodies in the sphere of conformity assessment the declaration of conformity and documentation that confirms the declared conformity within the established period of storage.

Article 11. Certification in the legally regulated sphere

Certification in the legally regulated sphere is carried out in accordance with the requirements of technical regulations on conformity assessment.

Based on the results of the certification works and in case of positive decision of an authorized certification body, the certificate of conformity shall be issued to the applicant, the template of which is approved by the specially authorized central body in the sphere of conformity assessment.

Article 12. Authorized certification bodies that carry out activity in the legally regulated sphere

Conformity assessment is carried out by accredited certification bodies of any form of ownership according to the procedure, established by legislation, which have been approved to carry out activities in the legally regulated sphere.

Authorized certification bodies can only be residents of Ukraine.

Authorized certification bodies keep registers of the issued certificates of conformity, certificates of conformity recognition and submit according to the established procedure information on them to the state register of certificates of conformity and certificates of conformity recognition.

Approved certification bodies are entitled to make agreements, with the approval of the specially authorized central body of executive power in the sphere of conformity assessment on mutual recognition of results of works on conformity assessment with authorized bodies of other countries.

Requirements for authorized certification bodies and procedure of their authorization are established by the Cabinet of Ministers.

Article 13. Obligations of producers and suppliers of products subject to conformity assessment in the legally regulated sphere

The producer is obliged to:

contribute to performing of all procedures of conformity assessment, established for a specific type of product;

place the national conformity sign on products in the legally regulated sphere;

cover damages, suffered by consumers of a product in case of detection of non-conformity of the product to the requirements, indicated in the declaration of conformity and/or the certificate of conformity or the certificate of conformity recognition.

The supplier is obliged to:

sell products only if a copy of the certificate of conformity and/or copy of the declaration of conformity or copy of the certificate of conformity recognition - established by legislation - is available;

suspend selling of a product if it does not meet the requirements of legislative documents indicated in the declaration of conformity or in the certificate of conformity or the certificate of conformity recognition.

Article 14. State monitoring over conformity assessment in the legally regulated sphere

State monitoring of the compliance with conformity assessment requirements in the legally regulated sphere is carried out according to the procedure established by legislation.

Article 15. Appeal on the decisions of authorized bodies

A person, who applied for conformity assessment, can appeal on actions and decisions of an authorized certification body by means of submitting an appeal to the corresponding commission for appeals, or in compliance with the court procedure.

Appeals are considered by commissions for appeals that are established within authorized certification bodies.

The typical provision of commissions for appeals, and the procedure of consideration of appeals is approved by the specially authorized central body of executive power in the sphere of conformity assessment.

In case of disagreement of one of the parties with the decision of a commission for appeals, further consideration of appeal is carried out by the specially authorized central body of executive power in the sphere of conformity assessment.

Chapter III. Conformity assessment in the legally unregulated sphere

Article 16. Declaring of conformity in the legally unregulated sphere

The producer can complete the declaration of conformity on his own initiative or on the basis of agreement with the consumer. In this case he is liable for putting unreliable information in the declaration according to laws of Ukraine.

Article 17. Certification in the legally unregulated sphere

Certification in the legally unregulated sphere is carried out on the voluntary basis, and according to the procedure stipulated by the agreement between the applicant (producer, supplier) and the certification body. The conformity of products, quality systems, quality management systems, environment management systems, personnel to any declared requirements shall be confirmed in this case.

Certification body sets up rules for certification, determines participants of certification works.

Certification on the voluntary basis can also be carried out by certification bodies, authorized for conducting works in the legally regulated sphere.

Chapter IV. Financing of works on conformity assessment

Article 18. Financing of works on conformity assessment in the legally regulated sphere

Activities of conformity assessment bodies in the legally regulated sphere shall be financed at the account of:

funds, obtained by authorized certification bodies from applicants as fees for works on conformity assessment;

funds of the state budget of Ukraine;

other funds envisaged by legislation.

The following is financed through allocated budget funds:

activities of the state executive bodies, entrusted with the functions of technical regulation according to legislation;

state monitoring over compliance with requirements;

scientific research;

development of draft technical regulations, international and national normative documents, which establish relevant rules and requirements;

participation in the international (regional) organizations activities.

Central bodies of executive power, entrusted by legislation with technical regulation in particular spheres of activity, are principal customers of conformity assessment works, financed through the state budget of Ukraine.

Article 19. Fees for conformity assessment works

The amount of fees for conformity assessment works in the legally regulated sphere is determined in accordance with the rules of calculation of costs for these works, established by the Cabinet of Ministers.

The amount of fees for conformity assessment works in the legally unregulated sphere is determined on the contractual basis.

Chapter V. Liability for violation of legislative requirements in the sphere of conformity assessment

Article 20. Liability for violation of legislation in the sphere of conformity assessment

Persons guilty of violation of legislation in the sphere of conformity assessment shall be held liable according to laws of Ukraine.

Chapter VI. International cooperation

Article 21. Participation of Ukraine in international cooperation in the sphere of conformity assessment

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

Article 22. International agreements

If the international agreements of Ukraine, ratified by the parliament of Ukraine, contain other provisions than those contained in this law, the provisions of the international agreements are applied.

Chapter VII. Final provisions

1. This law becomes effective from the day of its publication.
2. Conformity assessment of a product in accordance with the requirements of the Decree of the Cabinet of Ministers of Ukraine No.46-93 dd. May 10, 1999 “On Standardization and Certification” (in its certification part) is valid until a relevant technical regulation on conformity assessment is introduced.
3. The Cabinet of Ministers of Ukraine within a six-month period after the publication of this law shall:

submit to the Verkhovna Rada proposals on bringing legislative acts in line with this Law;

ensure bringing its normative and legislative acts, and those of ministries and other central bodies of executive power in line with the norms of this Law;

elaborate and approve of normative and legislative acts, envisaged by this Law.

4. Certificates of conformity and certificates of conformity recognition issued according to the established procedure within the state system of certification of products and services before this Law enters into force remain valid before their term of validity expires.

5. Article 5 of the Law of Ukraine “On Taxation of Enterprise Profit” (Vidomosti Verkhovnoyi Rady Ukrainy, 1995, N 4, art. 28; 1998, N 10, art. 35; 1999, N 39, art. 357, N 48, art. 418; 2000, N 32, art. 254, N 39, art. 333, N 45, art. 375) shall be supplemented with subclause 5.2.15 of the following contents:

“5.2.15. Amounts of costs, incurred by conformity assessment of products, quality systems, quality management systems, environment management systems, personnel to established requirements according to the Law of Ukraine “On Conformity Assessment”.

President of Ukraine

L. KUCHMA

Kyiv