Law of Ukraine

On Conformity Assessment

No.6013

August 4, 2000

This law sets up legal, organizational and economic framework for correspondence of conformity assessment of products to the requirements, established in Ukraine, 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 or physical person, responsible for design, manufacturing, packaging and marking of the product before placing it on the market under his name or on behalf of his name, notwithstanding whether these operations are performed by this person or on behalf of his name:

Supplier - a legal or 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 the product meets the established requirements;

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

Certification – a procedure, through which an independent body states in written the conformity of the product to the established requirements;

Certification body – a body that carries out certification. Certification body has a right to carry out testing or inspection or to control this activity, if it is carried out by other bodies on its commission;

Testing laboratory – a laboratory that carries out testing;

Certificate of conformity – a document, issued in accordance with the established rules, which confirms that a properly identified product meets the established requirements;

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

National mark of conformity – a mark, protected in accordance with legislation, which certifies the conformity of the product, marked herewith, to all requirements of technical regulations on conformity assessment, which apply to this product;

Technical regulation on conformity assessment – a legislative act, adopted by the Cabinet of Ministers, which contains a description of types of products liable to mandatory conformity assessment, essential requirements for the safety of life, health of a person and domestic animals, of property and environment, procedures for conformity assessment to these requirements, rules of marking and placing the products on the market as well as may contain requirements for terminology, packaging, marking and labelling;

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

Placing the product on the market – the first offer of the product for payment or free of charge, with the purpose of distribution and (or) use on the market of Ukraine, notwithstanding whether this product is new or completely reconditioned;

Legally regulated sphere – a sphere, wherein the placing of the product on the market is regulated by laws or other legislative acts;

Legally unregulated sphere – a sphere, wherein the placing of the product on the market is not regulated by laws or other legislative acts.

Article 2. The scope of this Law

This law regulates relations, connected with conformity assessment, and applies to producers, suppliers notwithstanding the type of their ownership and activity, to certification bodies and testing laboratories as well as to the bodies of executive power.

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 regulations that do not contradict this law.

Article 4. Objects of conformity assessment

According to this law the objects of conformity assessment are products (according to the definition provided in article 1), systems of quality, systems of management and 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 for conformity assessment;

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

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

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

encouragement of the development of conformity assessment in 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 specially authorized central body of executive power in the sphere of conformity assessment:

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

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

develops propositions for international and interstate agreements in the sphere of conformity assessment, accession of Ukraine to the international (regional) certification systems, makes decisions on the procedure for recognition of the results of certification works, carried out by the certification bodies of other countries (international systems);

coordinates activity of central bodies of executive power in the sphere of mandatory conformity assessment;

organizes the development of regulations that set up general requirements and rules of procedure for conformity assessment in legally regulated sphere and publishes official information about them;

provides methodological assistance to the bodies of executive power during the development of draft laws, drafts of other legislative acts and draft technical regulations on mandatory conformity assessment;

approves technical regulations on conformity assessment, developed by the bodies of executive power, and submits them for adoption to the Cabinet of Ministers;

keeps the state register of approved certification bodies and sets up a procedure for the provision of information on the issued certificates of conformity and certificates of conformity recognition;

organizes training and attestation of certification auditors;

keeps the archive of regulations and other legislative acts on conformity assessment issues;

provides information on conformity assessment issues.

Bodies of executive power in the relevant spheres of technical regulation:

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

organize the development of laws, regulations and technical regulations on mandatory conformity assessment;

organize training and improvement of skills of conformity assessment personnel.

The specially authorized central body of executive power in the sphere of economy:

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

organizes supervision of the activity of approved certification bodies.

Article 7. Conformity assessment

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

Conformity assessment in legally unregulated sphere is carried out by a producer, supplier or a certification body on the voluntary basis.

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

Chapter II. Conformity assessment in legally regulated sphere

Article 8. Conformity assessment in legally regulated sphere

Conformity assessment in legally regulated sphere (hereafter "mandatory conformity assessment") for certain types of products, which can present risk for the life, health of a

person and domestic animals as well as for property and environment, is introduced by the technical regulations on conformity assessment, which are adopted by the Cabinet of Ministers of Ukraine with the parallel determination of the bodies of executive power responsible for the development of these technical regulations.

Procedures for conformity assessment are laid down in the technical regulations on conformity assessment. Technical regulations must take into account the specificity of conformity assessment of products for manufacturing purposes, the specifics of entrepreneurial activity as well as the relevant European practice.

Simultaneously with the adoption of technical regulations on conformity assessment, the specially authorized body of executive power in the sphere of conformity assessment, determined according to article 6 of this law, officially publishes the list of standards of Ukraine, voluntary application of which can be evidence of product conformity to the essential requirements of technical regulations. Producer or supplier also has a 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 9. Declaring of conformity in legally regulated sphere

Before placing the product on the market, the producer is obliged to carry out conformity assessment and to fill in the declaration of conformity if it is envisioned by the technical regulation on conformity assessment. If the producer is not resident of Ukraine, he is obliged to appoint according to the established procedure a person – resident of Ukraine, who has a right to operate on his behalf as an authorized person. This is done for the purpose of the declaring of conformity and/or keeping of documentation on conformity assessment.

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

On the request of the state monitoring bodies in the sphere of conformity assessment the producer within the established period must adduce to them the declaration of conformity and documentation that confirms the declared conformity.

The producer is obliged to mark the products, whose conformity he has declared, with the National mark of conformity. If an approved certification body participated in the procedures for conformity assessment, the National mark of conformity must contain the identification number of this body.

The form, size and rules of application of the National mark of conformity are established by the separate technical regulation.

Article 10. Certification in legally regulated sphere

Certification in 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 approved certification body, the certificate of conformity of the established form is issued.

The producer is obliged to mark the certified products with the National mark of conformity, containing the identification number of an approved certification body.

Article 11. Approved certification bodies that carry out activity in legally regulated sphere

Conformity assessment is carried out by accredited certification bodies of any type of organization, which have been approved to carry out activities in legally regulated sphere.

Only certification bodies - residents of Ukraine - can be approved.

Approved certification bodies keep registers of certificates of conformity, certificates of conformity recognition and submit information on them to the state register of certificates of conformity and certificates of conformity recognition.

Approved certification bodies have a right to make agreements, with the approval of the specially authorized central body of executive power in the sphere of conformity assessment, determined according to article 6 of this law, on mutual recognition of results of works on conformity assessment with approved bodies of other countries.

Requirements for approved certification bodies and procedure of their approval are established by the Cabinet of Ministers.

Article 12. Obligations of producers and suppliers

The producer of a product, liable to mandatory conformity assessment, is obliged:

to carry out all procedures of conformity assessment, established for a specific type of product;

to cover damages, suffered by the consumers of a product, in case of the detection of nonconformity of the product to the requirements, pointed up in the declaration of conformity and/or certificate of conformity or certificate of conformity recognition.

The supplier is obliged:

to sell products only if a copy of certificate of conformity and/or copy of declaration of conformity or copy of the certificate of conformity recognition is available;

suspend or stop selling of a product if it does not meet the requirements, pointed up in the declaration of conformity or in certificate of conformity or certificate of conformity recognition.

Article 13. State monitoring in the sphere of obligatory conformity assessment

State monitoring of the compliance with requirements in the sphere of mandatory conformity assessment is carried out in the manner, prescribed by legislation.

Article 14. Appeal on the decisions of approved bodies

A person, who applied for conformity assessment, can appeal on actions and decisions of an approved certification body in case of denial to grant a certificate of conformity or certificate of conformity recognition, in case of suspension or invalidation of a certificate.

Appeals are reviewed by commissions for appeals that are established within approved certification bodies. Complaints are considered exclusively by employees of an approved certification body, who did not take part in making an appealed decision.

In the absence of agreement of one of the parties with the decision of a commission for appeals within an approved certification body, further consideration of appeal is carried out by a commission for appeals that is established under the specially authorized central body of executive power in the sphere of conformity assessment, determined according to article 6 of this law.

Decisions of the commission for appeals under the specially authorized central body of executive power in the sphere of conformity assessment, determined according to article 6 of this law, can be appealed in arbitration court.

Chapter III. Conformity assessment in legally unregulated sphere

Article 15. Goal of conformity assessment in legally unregulated sphere

Conformity assessment in legally unregulated sphere is carried out with the goal to increase competitiveness of the products and to assist consumers in the choice of a proper product.

Article 16. Declaring of conformity in 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 according to article 21 of this law.

Article 17. Certification in legally unregulated sphere

Certification in legally unregulated sphere is carried out on the voluntary basis. The conformity of a product to any requirements is assured on the basis of agreement between the applicant (producer, supplier) and the certification body.

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

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

Certification on the voluntary basis does not exempt the producer (supplier) from carrying out the procedures for mandatory conformity assessment, if a product is liable to this.

Chapter IV. Financing of works on conformity assessment

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

The sources of financing of conformity assessment, including participation of Ukraine in international cooperation, are the following:

funds, obtained by an approved certification body from the applicant through the fees for works on mandatory conformity assessment;

funds of the state budget of Ukraine;

other funds that are not prohibited by the legislation.

The following is financed through allocated budget funds: activities of the state bodies, responsible for technical regulation according to the legislation, state monitoring of compliance with requirements, scientific research, development of draft laws, legislative and normative documents of Ukraine, international and national normative documents, which establish relevant rules and requirements, participation in the international (regional) organizations activities as well as relevant scientific and methodological and coordination work.

Central bodies of executive power, which are responsible for technical regulation in particular spheres of activity, are principal recipients of the funds, provided through the state budget of Ukraine.

Article 19. Fees for conformity assessment works

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

Expenses incurred by the conformity assessment works are included into gross expenses of a producer or supplier.

Chapter V. Liability for violation of the provisions of this law

Article 20. Liability of approved certification bodies and testing laboratories

Approved certification bodies are liable for violation of the requirements of technical regulations on conformity assessment, for groundless or unauthorized issuance of the certificate of conformity as well as for violation of the rules of certification.

Testing laboratories are liable for falsity of testing results.

Certification bodies and testing laboratories are liable in the established manner for damages incurred as a result of the above-mentioned violations.

Article 21. Liability of producer and supplier

Producer is liable according to the legislation for including false information into the declaration of conformity.

Supplier is liable according to the legislation for the sale of a product without the documentary assurance of its conformity.

Producer and supplier are liable according to the legislation for damage caused to the life, health of a person, property and environment.

Chapter VI. International cooperation

Article 22. 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, determined in accordance with article 6 of this law, in the manner, prescribed by the legislation, can 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 23. 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

This law becomes effective from the day of its publication.

Conformity assessment of a product in accordance with the requirements of the Decree of the Cabinet of Ministers of Ukraine of May 10, 1999 No.46-93 "On Standartization and Certification" (in its certification part) is valid until a relevant technical regulation on conformity assessment is introduced.

The Cabinet of Ministers of Ukraine shall within a six month period after the publication of this law:

determine the bodies of executive power responsible for the development of technical regulations for certain types of products that can present risk for the life, health of a person and domestic animals as well as for property and environment; adopt a resolution on introduction in Ukraine of the schemes of conformity assessment, harmonized with Decision of Council of European Union 93/465/EEC.

bring its legislative acts into correspondence with this law, develop and submit according to the established procedure relevant propositions on amendments and additions to the legislation of Ukraine. Certificates of conformity and certificates of conformity recognition, issued according to the established procedure in the state system for certification of products and services before the adoption of this law, remain valid until the date of their expiry.

Until the bringing of the laws and other legislative acts into correspondence with this law, the laws and other legislative acts are valid in the part, which does not contradict this law.