

Law No.: 4703

Publication Date in the Official Gazette: 11 July 2001

Number of the Official Gazette: 24459

Entry into Force: 11 January 2002

THE LAW ON THE PREPARATION AND IMPLEMENTATION OF TECHNICAL LEGISLATION ON PRODUCTS

PART ONE

Objective, Scope and Definitions

Objective

Article 1- The objective of this Law is to lay down the principles and the procedures for the placing on the market of the products, conformity assessment, market surveillance and inspection and the notifications relating to these arrangements.

Scope

Article 2- This Law covers; the conditions of placing on the market of the products; the obligations of the producers and the distributors; conformity assessment bodies; notified bodies; market surveillance and inspection; prohibition of the placing on the market of the products, withdrawal and destruction of the marketed products and the notifications relating to these arrangements.

Definitions

Article 3- For the purposes of this Law;

- a) **Undersecretariat** shall mean the Undersecretariat for Foreign Trade,
- b) **Commission** shall mean the Commission of the European Union,
- c) **product** shall mean any product, which is intended for being placed on the market,
- d) **last product** shall mean the product, which was last put into market, among those products subject to the same certificate stating the conformity with the relevant technical regulation,
- e) **safe product** shall mean any product which, under normal conditions of use, does not present any risk or presents only risks considered as acceptable and brings a high level of protection with respect to the essential requirements,
- f) **essential requirements** shall mean the minimum safety conditions which the product shall present regarding the level of protection for the health of persons, safety of persons and their properties, life and health of animals and plants, environment and the consumer,
- g) **producer** shall mean any real or legal person who manufactures, reconditions the product or presents himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark; when the manufacturer is established abroad, the authorised representative and/or the importer; and also other real or legal persons in the supply chain, in so far as their activities may affect the safety properties of a product placed on the market,
- h) **distributor** shall mean any real or legal person in the supply chain whose activity does not affect the safety properties of a product,
- i) **standard** shall mean any voluntary document which is accepted by consensus and ratified by an authorised body; aims to provide an optimum order under the existing conditions; lays down, for common and repeated use, the characteristics, processing and production methods of a product, as well as one or more of the related terminology, symbols, packaging, marking, labelling and conformity assessment procedures aspects,
- j) **technical regulation** shall mean any mandatory document which lays down the characteristics or processing and production methods of a product, including the administrative provisions, as well as one or more of the related terminology, symbols, packaging, marking, labelling and the conformity assessment procedures aspects,

- k) **placing on the market** shall mean the action of making a product available on the market, for payment or free of charge, with a view to supply or use,
- l) **Public authority** shall mean any public body which is legally authorized for preparing and implementing the legislation relating to the products, and for implementing the provisions of this Law for the products under its responsibility,
- m) **conformity assessment** shall mean any procedure concerning the testing, inspection and/or certification of a product's conformity with the relevant technical regulation,
- n) **conformity assessment body** shall mean any private or public body which carry out the conformity assessment procedures by testing, inspecting and/or certifying a product according to the relevant technical regulation,
- o) **notified body** shall mean any public or private conformity assessment body which is designated by the related Public authority from among the testing, inspection and/or certification bodies, in accordance with the principles laid down in this Law and the relevant technical regulation, to carry out conformity assessment procedures laid down in one or more technical regulations,
- p) **conformity mark** shall mean the mark which indicates that the product is in conformity with the requirements in the relevant technical regulation and the product has been subject to all the required conformity assessment procedures,
- r) **module** shall mean each of the ways that describes the conformity assessment procedures to be followed, in relation to the hazards involved in the product, according to the relevant legislation,
- s) **market surveillance and inspection** shall mean the action which is carried out by the public authorities in order to check or have it checked whether the product is in conformity with the relevant technical regulation and with the requirements related to safety at the stage of placing on the market or distribution of the product concerned or when it is on market,
- t) **code of good practice** shall mean any specific practical principles related to the health and safety in the framework of the existing technological level and scientific criteria in the sector concerned.

PART TWO

Technical regulations relating to the products, Obligations of the producers and distributors relating to the placing the products on the market

Technical regulations relating to the products

Article 4- Technical regulations on the products shall be prepared by the public authorities.

Obligations of the producers and distributors relating to the placing the products on the market

Article 5- The new products to be placed on the market shall be in conformity with the relevant technical regulations. This provision shall also apply to used products which are planned to be placed on the market after being subject to a change and to old and used products which are imported from the countries except the member states of European Union.

The Council of Ministers has the authority to arrange or to set a limit and to provide exception to the provisions laid down in the first paragraph.

Producers shall place only safe products on the market. Products in compliance with the relevant technical regulations, are assumed as safe. In the absence of a relevant technical regulation, safety of a product shall be assessed in accordance with the national or international standards and in the absence of these, with the codes of good practice in the sector concerned or with the state of science and technology or with the safety which consumers may reasonably expect.

The producer shall not be held responsible, if he proves that he did not place the unsafe product on the market or the unsafety of the product results from the compliance with the technical regulation.

For a product to be accepted as safe, it shall ensure a high level of protection in respect of the essential requirements, taking into account the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance; the effects it will have on other products, where its use with other products is foreseen; the instructions concerning its placing on the market, labelling, use and disposal and other information provided by the producer, the categories of consumers at risk using the product.

The possibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not, unless stated in the relevant technical regulation, constitute grounds for considering a product to be unsafe.

Producers shall take appropriate measures in order to provide consumers with the necessary information regarding the risks in the product that can not be perceived without adequate warning throughout the normal or reasonably foreseeable period of its use; to mark the product in such a way that its characteristics can be identified; if necessary, to sample test of marketed products, to investigate complaints and to keep distributors informed of the results of such monitoring, including withdrawal from the market and disposal of the products in question to avoid these risks.

Producers shall keep all the documents required in the relevant technical regulations, for the period stated in the technical regulation, and if no period is mentioned in the technical regulation, for the period determined by the public authority from the date the last product has been manufactured or imported and to submit, if demanded, these documents to the Public authorities.

Distributors, within the limits of the information they have, shall not supply products which they know as unsafe. Within the limits of their respective activities, they shall inform the related people about products' risks and the measures necessary to avoid these risks. When it is impossible to determine the producer, the distributor who does not inform the Public authority of the identity of the producer and/or of the person from whom he supplied the product shall be assumed as the producer.

Distortion or imitation and misusing of the conformity certificate and/or mark are prohibited.

PART THREE

Provisions relating to the conformity assessment bodies and notified bodies; Activities, branches and agents of the notified bodies, and the obligations of the conformity assessment bodies and the notified bodies

Provisions relating to the conformity assessment bodies

Article 6- The minimum requirements relating to the technical competence of the conformity assessment bodies shall be laid down in the relevant technical regulations and/or in the regulations relating to the principles and procedures of the implementation of this Law.

Conformity assessment bodies shall be liable for their activities within the context of a technical regulation to the public authority which implements that technical regulation.

Provisions relating to the notified bodies

Article 7- Within the framework of the related technical regulations and/or this Law and the regulations relating to the principles and procedures of the implementation of this Law, the Public authorities shall designate any number, they consider necessary, of testing, inspection and/or certification bodies established in Turkey to carry out the conformity assessment procedures, laid down in one or more technical regulations.

The name and address of the designated testing, inspection and/or certification body and the modules through which and the products for which it will carry out the conformity assessment shall be notified to the Commission. This body shall gain the status of notified body following the publication of these information together with the identification number given by the Commission in the Official Gazette.

Activities, branches and agents of the notified bodies

Article 8- The certificates to be issued as a result of the activities of the notified bodies' branches or agents established in Turkey and/or abroad shall be granted by the notified bodies.

The notified bodies may subcontract with the other bodies to carry out a part of their activities for which they have been designated, on behalf of themselves. The subcontracting notified body remains in all cases responsible for all the activities covered by the notification and the certificates to be given as a result of the activities of the subcontractor shall be granted by the notified body.

Obligations of the conformity assessment bodies and the notified bodies

Article 9- The conformity assessment bodies and the notified bodies shall carry out their conformity assessment services in compliance with the requirements of the relevant technical regulations and/or this Law and the regulations relating to the principles and procedures of the implementation of this Law in an independent and impartial manner.

When it is found that conformity assessment bodies and the notified bodies no longer comply with the requirements of the relevant technical regulation and/or this Law and the regulations relating to the principles and procedures of the implementation of this Law or that it no longer performs its obligations, public authority shall temporarily cease that body's activities in the context of the related technical regulation.

In case that the concerned body fails to meet the requirements or perform the obligations within the period stated in the technical regulation, and, if not stated, within the period determined by the public authority, the public authority shall cease that conformity assessment body's activities and shall withdraw the status of that notified body, in the context of the related technical regulation.

The public authority shall publish the decisions of suspension and withdrawal of the status of the notified body in the Official Gazette and notify the Commission.

The conformity assessment bodies and the notified bodies shall keep any information, records and documents concerning their activities for the period stated in the technical regulation, and if no period is mentioned in the technical regulation, for the period determined by the public authority and to submit, if demanded, these documents to the public authorities. The conformity assessment bodies and the notified bodies whose activities have been suspended by the public authorities or whose activities have come to an end by their own consent, shall deliver any information, records and documents concerning the conformity assessment activities realized within the period of their activity to the public authority to be transferred to other conformity assessment bodies or notified bodies operating in the same field. However, the responsibility of the conformity assessment bodies and the notified bodies for the information, records and documents mentioned, continues for the period stated in the technical regulation, and if no period is mentioned in the technical regulation, for the period determined by the public authority.

PART FOUR

Market surveillance and inspection, Prohibition of the placing on the market of the product, Withdrawal and destruction of the product placed on the market

Market surveillance and inspection

Article 10- Market surveillance and inspection shall be carried out in accordance with the procedures and principles laid down in the relevant technical regulations and/or this Law and the regulations relating to the implementation of this Law. The required administrative arrangements shall be determined by the Public authorities.

For the market surveillance and inspection, the public authorities, may use, when deemed necessary, the facilities of the testing, inspection and/or certification bodies, which have not been involved in the conformity assessment procedures of the product subject to market surveillance and inspection. The final decision, however, belongs to the public authorities. In case that the facilities of the testing, inspection and/or certification bodies are used and the product is found not to be safe, the producer shall pay the costs of testing and inspection.

Names of the public authorities responsible for market surveillance and inspection shall be notified to the Commission through the Undersecretariat.

Prohibition of the placing on the market of products, withdrawal and destruction of the product placed on the market

Article 11- In case that there are definite indications that a product is unsafe, even if its conformity with the relevant technical regulation has been certified, the public authority shall temporarily prohibit the placing on the market of the product concerned, during the period required for necessary checks.

If the product concerned is found to be unsafe after the control, the public authority shall take the measures below, on condition that the expenses be covered by the producer:

- a) prohibition of the placing on the market of the product,
- b) withdrawal of the marketed products,
- c) whole or partial disposal of the products in case where it is impossible to render them safe,
- d) announcement of the necessary information relating to the measures laid down in the paragraphs (a), (b) and (c) to the persons at risk by publishing this information in two daily newspapers and two television channels having nationwide distribution and reach.

If the persons at risk can be informed by local televisions and newspapers, this announcement shall be done by means of these local organisations. In case where the persons at risk can be identified individually, the announcement shall be done by means of informing these persons directly.

Measures taken by the Public authorities within the scope of this Article shall be notified to the Commission, where necessary.

PART SIX Miscellaneous Provisions

Penalty provisions

Article 12- For the purpose of this Law;

- a) for the producers who act contrary to the first paragraph of the Article 5, 2 billion Turkish Liras,
- b) for the producers who act contrary to the third paragraph of the Article 5, 10 billion Turkish Liras,
- c) for the producers who act contrary to the seventh paragraph of the Article 5, 2 billion Turkish Liras,
- d) for the producers who act contrary to the eighth paragraph of the Article 5, 2 billion Turkish Liras,
- e) for the suppliers who act contrary to the ninth paragraph of the Article 5, 1 billion Turkish Liras,
- f) for the producers who act contrary to the tenth paragraph of the Article 5, 5 billion Turkish Liras,
- g) for the conformity assessment bodies and notified bodies which act contrary to the first paragraph of the Article 9, 25 billion Turkish Liras,
- h) for the conformity assessment bodies and notified bodies which act contrary to the fifth paragraph of the Article 10, 5 billion Turkish Liras

shall be applied as penalty.

In case that the act is repeated in the same year, the penalty shall be doubled for each infringement.

The Council of Ministers has the authority to increase the penalties foreseen in this Law by 100% or decrease by 50%, on the basis of the amount of the penalties calculated in respect of the Additional Article 2 of the Turkish Law on Penalties.

The penalties laid down in this Law shall apply only where no penalties are foreseen for the same act in other Laws.

Authorization and prescription for penalty

Article 13- The penalties imposed in this Law shall be applied by the Public authorities and shall be paid to tax offices within thirty days from the date of notification. Objections against these penalties can be brought before the relevant administrative court within thirty days from the date of notification. Objections, however, do not suspend the collection of the penalties.

The penalties applied under this Law are collected in accordance with the provisions of the "Law Regarding the Procedures of Collecting the Public Receivables" No. 6183.

The prescription period for the penalties laid down in this Law is five years from the date that the violation took place, and it is one year from the date that the Public authorities were informed of the violation. In case that a procedure is initiated with a view to control and inspect the activities of the producers, the suppliers, the conformity assessment bodies or the notified bodies, the prescription period shall expire.

Regulations

Article 14- For the purpose of this Law;

- a) The principles and the procedures concerning the notifications to the Commission, European Union Member States and other bodies of the European Union shall be laid down in the regulations to be prepared by the Undersecretariat by taking into account the opinions of the Public authorities.
- b) The principles and the procedures regarding market surveillance and inspection, conformity assessment bodies and notified bodies and other issues shall be laid down in the regulations to be issued by the Council of Ministers.

Article 15- Article 19 of the "Law Relating to The Consumer Protection" No. 4077 is hereby amended as follows:

"Inspection of the Services

Article 19- Services supplied to the consumer shall not cause any damage to the safety of human life and properties, as well as the environment, and shall be in compliance with the relevant legislation or standard, and in the absence of these, with the technical specifications laid down. The Ministry is responsible for carrying or having carried the inspections according to these principles."

Entry into Force

Article 16 – This Law shall be put into force after six months from the date of publication.

Implementation

Article 17 – This Law shall be enforced by the Council of Ministers.