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REGULATION RELATING TO THE MARKET SURVEILLANCE AND INSPECTION OF THE PRODUCTS

PART ONE

Objective, Scope, Legal Basis and Definitions

Objective

Article 1- The objective of this Regulation is to lay down the principles and the procedures for the surveillance and inspection of the conformity of a product 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; measures to be taken after surveillance and inspection; establishment of a Board which will co-ordinate Public Authorities and take advisory decisions and tasks of the Board.

Scope

Article 2- This Regulation contains; the provisions relating to the preparation of the technical regulations; the principles concerning the conformity of the products with technical regulations and product safety; the obligations of the producers and the distributors at the stage of placing the product on the market; the principles and the procedures for market surveillance and inspection; the tasks and the obligations of the public authorities; the measures to be taken within the framework of the market surveillance and inspection; the establishment of the Co-ordinating Board on Market Surveillance and Inspection; the tasks and working principles and procedures of the Board.

Legal Basis

Article 3- This Regulation has been prepared relying on the Article 14 of the “Law Relating to the Preparation and Implementation of the Technical Legislation on the Products” no. 4703.

Definitions

Article 4- For the purpose of this Regulation;

- a) **Undersecretariat** shall mean the Undersecretariat for Foreign Trade,
- b) **Commission** shall mean the Commission of the European Union,
- c) **General Directorate** shall mean the General Directorate of Standardisation for Foreign Trade,
- d) **product** shall mean any product, which is intended for being placed on the market,

- e) **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 legislation,
- 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) **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,
- h) **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,
- i) **distributor** shall mean any real or legal person in the supply chain whose activity does not affect the safety properties of a product,
- j) **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,
- k) **harmonised European standard** shall mean any standard which is adopted by a European Standardisation Body upon a remit from the Commission and whose name is published in the Official Journal of the European Communities,
- l) **harmonised national standard** shall mean any national standard which adopts the harmonised European standard and which is approved and published as a Turkish Standard by the Turkish Standards Institution,
- m) **technical specification** shall mean the specification contained in a document and which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures and which may also cover the production methods and processes where these have an effect on the product's characteristics,
- n) **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,

- o) **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,
- p) **Public Authority** shall mean any public body which is legally authorised for preparing and implementing the legislation relating to the products, and for implementing the provisions of the Law no. 4703 and this Regulation for the products under its responsibility,
- r) **conformity assessment** shall mean any procedure concerning the testing, inspection and/or certification of a product's conformity with the relevant requirements in the relevant technical regulation,
- s) **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,
- t) **notified body** shall mean any public or private 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 the Law no. 4703, Regulation Relating to the Conformity Assessment Bodies and Notified Bodies and the relevant technical regulation, to carry out conformity assessment procedures laid down in one or several technical regulations,
- u) **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,
- v) **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,
- y) **the Board** shall mean the Co-ordinating Board on Market Surveillance and Inspection.

PART TWO

Provisions relating to the preparation of the technical regulations

Provisions relating to the preparation of the technical regulations

Article 5- Technical regulations on the products shall be prepared by the Public Authorities.

Preparation, modification and revision of the relevant harmonised national standards referred to in the technical regulations shall be carried out by Turkish Standards Institution on its own account or due to the request of the Public Authorities.

The references and the names of the harmonised European standards and harmonised national standards referred to in the technical regulations and their amendments shall be published in the Official Journal by the Public Authorities, including the technical regulation these standards relate to.

PART THREE

Provisions relating to the conformity of the products with the technical regulations, Provisions relating to the product safety, Obligations of the producers and distributors

Provisions relating to the conformity of the products with the technical regulations and the obligations of the producers

Article 6- 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 the European Union.

Products which are in conformity with the harmonised national standard or standards referred to in a technical regulation shall be assumed to be in conformity with the essential requirements applicable to these products and laid down in the technical regulation concerned.

Where no harmonised European standard and harmonised national standard exist, products which are in conformity with the international standards, national standards or other documents referred to in the technical regulations providing a presumption of conformity with the essential requirements within the context of the principles and procedures laid down in the technical regulation shall be presumed to be in conformity with the technical regulation. Public Authority shall publish the references and the names of these documents in the Official Journal, if stated in the relevant technical regulation.

Where a Public Authority considers that the documents mentioned in the paragraphs 2 and 3 of this Article do not entirely meet the essential requirements referred to in the technical regulation, it shall immediately inform the Commission through the Undersecretariat.

In cases where a product is subject to multiple technical regulations requiring the affixing of the same conformity mark, the said mark indicates the conformity of the product with the provisions of all the relevant technical regulations and the product has been subjected to all the relevant conformity assessment procedures laid down in the technical regulations.

The marks which are given as a result of the conformity assessment procedures not referred to in the technical regulations and/or indicating the conformity to the national or international standards might be affixed on products or on the package by an appropriate form. These marks shall not, however, mean the conformity with the technical regulation, deceive third parties as to the meaning and form of the conformity mark and reduce the legibility of the conformity mark.

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

Provisions relating to the product safety and obligations of the producers and the distributors

Article 7- The products to be placed on the market must be safe. This provision shall not apply to the products supplied as antiques, provided that the producer and the distributor clearly informs the person to whom he supplies the product.

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 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 having regard to national standards approved as Turkish Standards by Turkish Standards Institution and giving effect to a European standard, or where they exist, to Community technical specifications or in the absence of these to other national standards approved as Turkish Standards by Turkish Standards Institution or to the codes of good practice in respect of health and safety in the sector concerned or to state of science and technology and to the safety which consumers may reasonably expect.

Conformity of a product with the provisions mentioned in paragraph 4 of this Article shall not bar the public authorities from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or its destruction where there is evidence that, despite such conformity, the product is not safe.

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.

Producers, concerning their activity fields, 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, within the period stated in the technical regulation, if no period is mentioned in the technical regulation within 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 or of the person from whom he supplied the product shall be assumed as the producer.

PART FOUR

The principles and the procedures for market surveillance and inspection

General provisions

Article 8- Market surveillance and inspection contains any 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; to ensure the recovery of the unsafety of the product and if necessary carry out penalties concerning these actions.

The products mentioned below are not considered as being placed on the market:

- a) without prejudice to the provisions in a technical regulation concerning the exportation of a product, products produced with a view to exporting it to the countries except the member states of the European Union,
- b) products to be displayed at fairs and exhibitions, in case that a visible sign clearly indicates that the product may not be placed on the market until it has been made to comply with the relevant technical regulation and the requirements related to safety,
- c) products transferred from a producer in abroad to his authorised representative or to the importer in Turkey for the conformity assessment procedures,
- d) without prejudice to the provisions in a technical regulation, products transferred from another producer or when the producer in question is in abroad products imported by the producer for further measures such as assembling, packaging, processing or labelling,

- e) products not yet released by the customs authorities for free circulation and products has been placed in free zones.

In case that the products mentioned above are intended to be placed on the market, the provisions of this Regulation shall be applied to these products.

Market surveillance and inspection shall be carried out in accordance with the procedures and principles laid down in the relevant technical regulations and/or the Law no. 4703 and the regulations relating to the implementation of this Law. The required administrative arrangements shall be determined by the Public authorities.

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

The tasks and the obligations of the Public Authorities

Article 9- In order to check whether the products are in conformity with the technical regulations and the requirements of safety, the Public Authorities shall;

- a) regularly visit commercial and storage premises,
- b) regularly inspect, if necessary, work places and other premises where products are put into service,
- c) organise random and spot checks in the places and premises mentioned in the paragraphs (a) and (b),

The Public Authority shall require the documents below from the producer during market surveillance and inspection;

- a) relating to the products which are covered by technical regulations, the documents and/or information indicating that the product is produced according to the requirements laid down in the technical regulation,
- b) relating to the products which are not covered by technical regulations, the documents and/or information indicating that the product is safe according to the requirement or requirements, which are applied by the producer, among those laid down in the paragraph 4 of Article 7.

The Public Authority, where necessary, shall take samples of a product or a product line and subject them to examination and testing according to the technical regulation and requirements of safety.

The Public Authority shall check whether the marks indicating conformity with the technical regulation have been affixed and used properly and whether the rules laid down in the paragraph 6 of Article 6 regarding the marks which are given as a result of conformity assessment procedures not referred to in the technical regulations and/or indicating conformity to national or international standards have been met and take appropriate measures.

In cases where a product is subject to multiple technical regulations and these technical regulations are under the responsibility of different Public Authorities, market surveillance and inspection activities shall be carried out in co-ordination by the relevant Public Authorities in order to ensure that the checks on the conformity of the products with all relevant technical regulations are carried out simultaneously.

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 were not 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 expenditures of testing and inspection. For the expenses applied, the provisions of the “Law Regarding the Procedures of Collecting the Public Receivables” No. 6183 shall be applied.

The impropriety to the relevant current legislation concerning a product which has come out from an inspection carried out by public authorities for other purposes, the information obtained by analysing the factors that caused an accident, complaints from consumers, users, rival producers, distributors, conformity assessment bodies and notified bodies, other public institutions and non-governmental organisations about a product not in conformity with the technical regulation or requirements relating to safety and information obtained within this context can also be taken into consideration for market surveillance purposes.

PART FIVE

Temporarily prohibition of placing on the market of products

Article 10- In case that there are precise and consistent 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 and inform the producer immediately of the decision.

In order to prevent the probable risks which the product might present, the producer, within the context of the provisions laid down in the paragraph 7 of Article 7, shall inform the distributors of the measure and provide the groups under risk with the necessary information regarding the risks in the product.

The Public Authority shall begin the inspection at the latest 24 hours after the precise and consistent indication has been determined.

The producer, upon request from the Public Authority and in addition to the information and documents stated in the paragraph 2 of Article 9, shall provide the information and documents below to the Public Authority.

- a) if the producer has applied to a conformity assessment body or a notified body since it is stated in a technical regulation, the copies of the documents the

manufacturer has submitted to the notified body or conformity assessment body in question;

- b) the addresses of the places of manufacture and storage;
- c) a detailed description of manufacture and design;
- d) other information and documents demanded by the Public Authority.

The period for temporarily prohibition shall not be more than 3 days unless it requires more time for carrying out tests for technical reasons.

If the product concerned is found unsafe after the control, the Public Authority shall take the measures laid down in Article 11.

PART SIX

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

Article 11- In case that a product is found unsafe after the market surveillance and inspection, even if its conformity with the relevant technical regulation has been certified, the Public Authority shall take the measures given below, on condition that the expenses shall be covered by the producer:

- a) prohibition of the placing on the market of the product,
- b) withdrawal of the products placed on the market,
- c) if it is possible, warning the producer to recover the unsafety of a product within the period stated in the technical regulation, if no period is stated in the technical regulation within the period determined by the public authority,
- d) whole or partial disposal of the product in case it is impossible to recover the unsafety or the unsafety is not recovered by the producer.

The Public Authority, where appropriate, shall inform the producer, distributor and where necessary any other person with regard to co-operation in action taken avoid risks from a product of any decision on the measures laid down in the paragraphs (a), (b) and (d) and the reasons on which they are based in order to encourage them to contribute to the implementation of such measures.

The Public Authority, whenever feasible, shall give an opportunity to the producers, distributors and any other person with regard to co-operation in action taken avoid risks from a product to submit their views on the measures to be taken in the context of this Article unless the matter is urgent.

The Public Authority shall ensure the announcement of the measures mentioned in the paragraphs (a), (b) and (d) in two newspapers and two television

channels having the highest circulation throughout the country, on condition that the expenses shall be covered by the producer.

If the persons at risk can be informed by the local televisions and newspapers, this announcement shall be done by means of these local organisations. In case that the number of persons at risk is limited, the announcement shall be done by means of informing these persons directly.

For the expenses stated at this article, the provisions of the “Law Regarding the Procedures of Collecting the Public Receivables” No. 6183 shall be applied.

PART SEVEN

Co-ordinating Board on Market Surveillance and Inspection

Establishment of the Board

Article 12- The Board consists of the permanent representatives of the Public Authorities with the presidency of the Director General of the General Directorate of Standardisation for Foreign Trade or Deputy Director General who has been charged by the Director General.

The chairman of the Board, due to the agenda of the meetings, may invite the representatives of the conformity assessment bodies and notified bodies, the representatives of the private sector and other relevant experts to the meetings of the Board for inquiry.

The secretariat services of the Board shall be carried out by the General Directorate.

The tasks of the Board

Article 13- The tasks of the Board are,

- a) to ensure co-ordination among the Public Authorities concerning market surveillance and inspection in order to get the effective functioning of the market surveillance and inspection activities,
- b) to suggest solutions for the removal of the problems which the Public Authorities face during the market surveillance and inspection,
- c) to monitor the preparation and implementation of the technical legislation on products by the Public Authorities,
- d) where necessary, to take advisory decisions relating to the market surveillance and inspection.

Working principles and procedures of the Board

Article 14- The Board shall meet three times a year. The chairman of the Board, where necessary, may call for a meeting in extraordinary cases.

The members of the Board shall inform the General Directorate of the topics which they request to be handled in the meetings of the Board at least 20 days before each meeting with the summary of the information about the topics concerned to make them included into the agenda and make other members to be informed.

The General Directorate shall inform the members of the Board of the agenda and summary information relating to the topics included in the agenda at least 5 days before each meeting.

If the chairman considers it appropriate, the topics not included in the agenda may be discussed during the meetings of the Board.

The Board shall take advisory decisions mentioned in the paragraph 1 (d) of Article 13 by absolute majority. In cases where the absolute majority has not been obtained, the decisions shall be taken in the next meeting and the members shall be informed of the situation. The absolute majority shall not be required in the next meeting. The decisions shall be taken by the large majority of the participants. In case of deadlock of votes, the vote of the chairman will determine the decision. The participants which are not the members of the Board have no right to vote.

Annual report

Article 15- The Public Authorities shall prepare annual reports including results of their activities within the framework of the market surveillance and inspection. The Public Authorities shall notify these annual reports to the General Directorate which carries out the secretariat services of the Board until the end of the second month of the following year at the latest.

PART EIGHT Miscellaneous Provisions

The Principles relating to the notification

Article 16- The procedures and principles for the notification of the measures taken by the Public Authorities within the context of market surveillance and inspection activities to the Commission, European Union and other bodies of the European Union shall be laid down in the regulation to be prepared by the Undersecretariat by taking into account the opinions of the Public Authorities.

Provisions relating to importation

Article 17- The surveillance and inspection of a product with the relevant technical regulation and with the requirements related to safety at the stage of importation shall be carried out according to the principles and procedures laid down in the Law no. 4703, this Regulation and the Decree on the Regime of Technical Regulations and Standardisation For Foreign Trade and its supplementary legislation.

Confidentiality of the information

Article 18- The information obtained during market surveillance and inspection must be confidential unless the health and safety of the groups at risk is subject to serious and immediate danger.

Translation of the documents

Article 19- The Public Authority may require the Turkish translation of the documents mentioned in the paragraph 2 of Article 9 and paragraph 4 of Article 10

from the producer if these documents were prepared in foreign language. The translated documents shall be submitted to the Public Authorities within the period determined by these authorities.

Penalty provisions

Article 20- For the actions contrary to the provisions of this Regulation, the penalties laid down in the Law no. 4703 shall be applied.

Temporary Provision- Within the framework of the customs union between Turkey and the European Union, if a product coming from the European Union, which is under the scope of the legislation of which Turkey has not harmonised yet, is found not to be safe, though certified according to the relevant Community legislation, the provisions laid down in Article 10 of the Association Council Decision between Turkey and the European Community numbered 1/95 shall be applied for the restriction and prohibition of the product from placing on the market by the Public Authority or its withdrawal.

Entry into force

Article 21- This Regulation shall enter into force from 11 January 2002.

Implementation

Article 22- This Regulation shall be enforced by the Council of Ministers.