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## REGULATION ON THE EXCHANGE OF INFORMATION ON TECHNICAL LEGISLATION ON GOODS AND STANDARDS BETWEEN TURKEY AND THE EUROPEAN UNION

#### PART ONE

### Aim, Scope, Legal Base, Definitions

#### Aim

**Article 1-** The aim of this Regulation is to provide information exchange between Turkey and the European Union on technical legislation and standards.

#### Scope

**Article 2-** This Regulation covers the principles and the procedures for the notification of the technical legislation and standards to the European Union and for the transmission of the notifications received from the European Union to the public authorities.

## Legal basis

**Article 3-** This Regulation is based on Article 14 of the Law on the Preparation and Implementation of Technical Legislation on Products dated 11.07.2001 and numbered 4703.

#### Definitions

Article 4- For the purpose of this Regulation;

- a) Undersecretariat shall mean the Prime Ministry Undersecretariat for Foreign Trade,
- b) Member States shall mean the European Union Member States,
- c) Commission shall mean the Commission of the European Union,
- d) **Public Authority** shall mean any public body which is legally authorized for preparing and implementing the legislation relating to the products, and/or any Public Body which will implement the provisions of this regulation within the context of its responsibilities,
- e) **Product** shall mean all the products which are planned to be placed on the market,
- f) 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. When the agricultural and medicinal products are concerned, these production methods and processes are not required to have an effect on the product's characteristics in order to be considered a technical specification; but for other products, these should have an effect on the product's characteristics in order to be considered a technical specification,
- g) **Requirements which affect the life of a product after it has been placed on the market** shall mean the requirements imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;
- h) 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,
- i) **International standard** shall mean a standard adopted by an international standardisation organisation and made available to the public,

- j) **European standard** shall mean a standard adopted by a European standardisation body and made available to the public,
- k) **National standard** shall mean a standard adopted by a national standardisation body and made available to the public;
- l) **Standards programme** shall mean a work programme of a national standardisation body listing the subjects on which standardisation work is being carried out;
- m) European standardisation bodies shall mean the bodies referred to in Annex I;
- n) National standardisation bodes shall mean the bodies referred to in Annex II;
- o) TSE shall mean the Turkish Standards Institute,
- p) **Technical regulation** shall mean any mandatory document, which lays down one or more from among the technical specifications of a product, including the administrative provisions.

#### PART TWO

# Technical Legislation Subject to Notification, Principles and Procedures of Notification, Standstill Period for Notification, Evaluation of the Comments about the Notification, Publication of the Notified Technical Legislation, Notifications Received from the Commission

## Technical legislation subject to notification

**Article 5-** Public authorities shall notify the following legislation, in their draft form, to the Commission through the Undersecretariat if these are prepared for the marketing or use of a product in Turkey or in a definitive part thereof:

- a) Technical regulations,
- b) Legislation laying down the requirements which affect the life of a product after it has been placed on the market,
- c) Legislation prohibiting the manufacture importation, marketing or use of a product,
- d) Voluntary agreements to which a public authority is a contracting party and which provide, in the public interest, for compliance with technical specifications or other requirements or excluding public procurement tender specifications,
- e) Legislation which are linked to fiscal or financial measures affecting the consumption of products by encouraging compliance with technical specifications or the requirements other than those linked to national social security systems, which affect the life of a product after it has been placed on the market,
- f) laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to professional codes or codes of practice which in turn refer to technical specifications or other requirements, and compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions.

# Technical Legislation which do not require notification

Article 6-The technical legislation mentioned in Article 5, shall not be subject to notification if they are prepared in order to:

- a) Provide harmonization with the EU legislation,
- b) Use the safeguard clauses provided in the EU legislation,
- c) Prevent, restrict or impose specific conditions on the the placing on the market or use of a product, by reason of a serious risk, due to the Regulation Relating to the Market Surveillance and

Inspection of Products, which was approved on 13.11.2001 and published in the Official Gazette of 17.1.2002 No: 24643.

- d) Make the requested amendment in a legislation in accordance with a Commission request, and with a view to removing an obstacle to trade ,
- e) protect persons, in particular workers, when products are used, provided that such measures do not affect the products

## Principles and Procedures of Notification

Article 7- Notification mentioned in Article 5 shall consist of:

- a) Draft technical legislation concerned; in case that it merely transposes the full text of an international or European standard, only the information regarding the relevant standard,
- b) A statement of the grounds which make the preparation of such a technical regulation necessary, where these have not already been made clear in the draft,
- c) The text of the national legislation principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft, unless it has already been sent with a prior communication,
- d) Where appropriate, the information and documents required by the Commission.

The new text of the draft shall also be communicated as soon as possible to the Commission through the Undersecretariat where the changes made to the draft technical legislation have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

Where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, public authorities shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and acceptable substitutes, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment. Where the notification is about an existing substance, it shall be accompanied by an analysis of the risk carried out as appropriate in accordance with the related legislation. In case of a new substance, analysis of the risk shall be carried out as referred to in the related Articles of the Regulation on Dangerous *Chemicals* published in the Official Gazette dated 11 July 1993 and numbered 21634.

Information notified to the Commission referred to in this Article and the Article 8 shall not be kept secret unless the notifying Public authority so demands. In such a case, the Public Authority shall communicate the Undersecretariat the demand and its grounds together with the notification.

In case that a draft technical legislation, which is in the scope of this Regulation, is also required to be notified to the Commission under another legislation, notification in the context of this Regulation can be made together with the notification foreseen in the latter. In this case, it is formally indicated within the notification that the communication also meets the notification requirement of this Regulation, and the Undersecretariat shall be informed accordingly.

#### **Standstill Period for Notification**

**Article 8-** Public authorities shall postpone the submission of the notified technical legislation for publication, and the approval of them when the voluntary agreements mentioned in Article 5(d) are concerned, for three months from the date of receipt by the Commission of the communication, in order to give an opportunity to the Commission and Member States to evaluate the concerned draft. However this three-month standstill shall not apply in those cases where, for urgent reasons, occasioned by serious and unforeseeable circumstances, relating to the protection of public and animal health, the preservation of plants or safety, public authorities are obliged to prepare technical legislation in a very short space of time in order to enact and introduce them immediately without any consultations being possible. In this case, the notification to be made by the public authorities shall also include the reasons which warrant the urgency of the measures taken in addition to the subjects laid down in the first paragraph of Article 7.

Three month standstill period stated in the first paragraph of this Article shall not apply to the drafts of the technical legislation given in the point (e) of Article 5 and to the drafts of the technical legislation prohibiting manufacture insofar as they do not impede the free movement of products.

Where the Commission requires the three month standstill period, stated in the first paragraph of this Article, to be extended to six months, this shall be communicated to the public authorities by the Undersecretariat.

## Evaluation of the Comments about the Notification

**Article 9-** Comments received from the Commission and the Member States on the notified drafts shall be communicated to the public authorities by the Undersecretariat. Public authorities shall take such comments into account as far as possible in the subsequent preparation of the draft. The final version of the draft shall be communicated as soon as possible to the Commission through the Undersecretariat.

#### Publication of the Notified Technical Legislation

**Article 10-** While Public authorities publish a technical legislation, which is subject to notification due to this Regulation, there shall be a reference to this Regulation in the concerned legislation and, in the text of the agreement when the voluntary agreements mentioned in Article 5(d) are concerned. Concerned reference shall indicate that the notification required by this Regulation was performed.

## Notifications Received from the Commission

**Article 11–** Notifications concerning the draft technical legislation of the Member States to be sent from the Commission to Turkey within the context of the rules<sup>1</sup> mentioned in Article 16, shall be communicated to the relevant Public authorities by the Undersecretariat. Public authorities shall submit their possible comments on the draft concerned to the Commission through the Undersecretariat, within a period of time determined by the Undersecretariat.

Comments of the Public authorities on the draft technical legislation, which is communicated by the Commission and which is within the scope of the point (e) of Article 5 may concern only the provisions which may hinder trade, and not the fiscal and the financial aspects of the draft.

Public authorities may seek expert advice from physical or legal persons in the private sector during the preparation of comments about the notifications of the member States, which were received from the Commission through the Undersecretariat. But in case that the notifying Member State requires the information within the notification to be kept secret; the Public authorities shall take all necessary precautions while seeking expert advice from physical or legal persons in the private sector.

## PART THREE Notification of Standards

#### Information exchange concerning the standards programme

**Article 12-** TSE shall inform the Commission and the standardisation bodies referred to in Annexes I and II of the new subjects for which it has decided, by including them in its standards programme, to prepare a new standard or amend or revise the existing standard. This provision shall not be applied to the harmonization activities of an identical or equivalent transposition of an international or European standard.

The information referred to in paragraph 1 shall indicate, in particular, whether the standard concerned will transpose an international standard without being the equivalent; will be a new national standard, or will amend a national standard.

Upon the Commission's request, TSE shall communicate the Commission all or part of the standards programme.

TSE shall grant the bodies referred to in Annex II the right to be involved passively as an observer or actively in its planned activities,

<sup>&</sup>lt;sup>1</sup> Meaning the Directive 98/34/EC and the related adoptation rules of the Association Council Decision No. 2/97.

TSE shall not object to a subject for standardisation in its work programme being discussed at European level in accordance with the rules laid down by the European standardisation bodies and shall undertake no action which may prejudice a decision in this regard.

#### **Notification of Standards**

Article 13- TSE shall, upon request, shall send all draft standards to the standardisation bodies referred to in Annexes I and II, and the Commission. In case that the standardisation bodies referred to in Annexes I and II, and/or the Commission makes comments about the concerned standards, TSE shall keep the bodies concerned and the Commission of the action taken on any comments they have made relating to drafts.

TSE shall publish the draft standards in such a way that comments may also be obtained from parties established in Member States.

#### **Standardization Activities**

**Article 14-** TSE, during the preparation of a European standard or after its approval, shall not take any action which could prejudice the harmonisation intended and shall not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard. This provision shall not apply to the work of TSE undertaken at the request of the public authorities to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products. However, the draft of this technical regulation shall be communicated by the public authority to the Commission through the Undersecretariat in accordance with Articles 5 and 7 of this Regulation.

TSE may not recognize, approve or use a standard, by making a reference to it, which was adopted in breach of Articles 12 and 13 of this Regulation.

## PART FOUR Miscellaneous Provisions

#### **Preparation of the Notifications**

**Article 15-** All draft texts, information and documents, which will be sent to the Undersecretariat by the public authorities in accordance with the notification procedure under this Regulation, shall be prepared in Turkish and English.

# **Related EU Legislation**

Article 16- This Regulation is prepared taking into consideration of the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, which repealed and consolidated Council Directive 83/189/EEC of 23 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations and its amendments; and of the adaptation instructions about Directive 83/189/EEC, except the one leaving the Articles on standards out of the scope of harmonization, given in Part XIX of the Annex II of the EC-Turkey Association Council Decision No. 2/97.

#### Authorization

Article 17- The Undersecretariat is authorized to issue Communiqués, lay down the principles and the procedures concerning the preparation and transmission of the notifications and comments, to issue necessary instructions, to make the necessary changes and take the necessary measures in each stage of notifications laid down in this Regulation.

#### Enforcement

Article 18- This Regulation shall be enforced one month after its publication.

#### Implementation

Article 16- This Regulation shall be enforced by the Minister whom the Undersecretariat for Foreign Trade is connected with.

# ANNEX: 1 EUROPEAN STANDARDISATION BODIES:

CEN European Committee for Standardisation

Cenelec European Committee for Electrotechnical Standardisation

ETSI

European Telecommunications Standards Institute

## ANNEX: 2 NATIONAL STANDARDISATION BODIES

1. BELGIUM IBN/BIN Institut belge de normalisation Belgisch Instituut voor Normalisatie CEB/BEC-Comité électrotechnique belge Belgisch Electrotechnisch Comité

2. DENMARK DS Dansk Standard NTA Telestyrelsen, National Telecom Agency

3. GERMANY DIN Deutsches Institut für Normung e.V. DKE Deutsche Electrotechnische Kommission im DIN und VDE

4. GREECEΕΛΟΤΕλληνιχός Οργανισμός Τυποποίησης

5. SPAIN AENOR Asociación Espanola de Normalización y Certificación

6. FRENCH
AFNOR
Association française de normalisation
UTE
Union technique de l'électricité-Bureau de normalisation auprés de l'AFNOR

7. IRELAND NSAI National Standards Authority of Ireland ETCI Electrotechnical Council of Ireland

ITALY
 UNI (1)
 Ente nazionale italiano di unificazione

CEI (1)

Comitato elettrotecnico italiano (1) İtalyan Ulusal Standardizasyon Kuruluşları UNI ve CEI, telekomünikasyon konusundaki çalışmalarını İtalya'daki CONCIT Enstitüsüne devretmiştir.

9. LUXEMBOURG ITM Inspection du travail et des mines SEE-Service de l'énergie de l'État

10. NETHERLANDS NNI Nederlands Normalisatie Instituut NEC Nederlands Electrotechnisch Comité 11. AUSTRIA ON Österreichisches Normungsinstitut ÖVE Österreichischer Verband für Elektrotechnik

12. PORTUGAL IPQ Instituto Português da Qualidade

13. UNITED KINGDOM BSI British Standards Institution BEC British Electrotechnical Committee

14. FINLAND SFS Suomen Standardisoimisliitto SFS ry Finlands Standardiseringförbund SFS rf THK/TFC Telehallintokeskus Teleförvaltningscentralen SESKO Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry Finlands Elektrotekniska Standardiseringförening SESKO rf

15. SWEDEN SIS Standardiseringen i Sverige SEK Svenska elektriska kommissionen ITS Informationstekniska standardiseringen