

9 th of June 2011, given comments by EC

MK comments on 10th of October 2011

(Official Gazette of the Republic of Macedonia No. 107/2007 from 7th of September 2007) Pursuant to Article 32 paragraph 1 of the Law on Safety of Products (“Official Gazette” No.33/06, 63/07, 24/2011 and 51/2011), the Government of the Republic of Macedonia at its meeting held on _____ adopted the following

**Decree on Amendment of the Decree
on the procedure on notification to the European Commission on adoption of
technical standards and regulations,**

I. GENERAL PROVISIONS

Article 1

This Decree regulates the procedure on notifying the European Commission on adoption of technical standards, technical specification, technical regulations and of rules on information society services.

Article 2

Certain terms used in this decree shall have the following meaning:

1. “product” is any industrially manufactured product
2. „service,, is any information society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services; This service will not apply to radio broadcasting service and television broadcasting services.

For the purpose of this definition:

-at a distance, means that the services is provided without the parties being simultaneously present,

-,by electronic means, means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,

-,at the individual request of a recipient of services, means that the service is provided through the transmission of data on individual request.

An indicative list of services not covered by this definition is set out in Annex

3. „rule on services,, requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of services, in particular provisions concerning the service providers, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in it. This definition shall not apply to rules relating to legislation in the field of financial services, telecommunications services and for other markets or bodies carrying out clearing or settlement functions for those markets.

For the purpose of this definition:

-a rule shall be considered to be specifically aimed at Information Society system where, having regard to its statement of reasons and its operative part,

the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,

A rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner.

4. “technical specification” is specification contained in a document which determines the required characteristics of a product, such as the quality level, performances, safety or dimensions, including the requirements applied for the product in terms of the name under which the product is being sold, the terminology, symbols, testing and the methods of testing, packing, marking or labelling and the procedures for conformity assessment, as well as production methods and processes relating to other products, where these have an effect on their characteristics

5. “other requirements” are requirements which are different from the technical specifications, and are imposed for a product in order to protect, in particular, consumers or the environment, and which have impact on its life cycle once it is released in sales, such as conditions for use, recycling, for re-use or for disposal, when those conditions have significant impact on the composition and nature of the product or on its advertising;

6. “standard” is a technical specification approved by a recognized standardization body for re-use or for permanent use, according to which the harmonization is not compulsory and which is one of the following:

– international standard is a standard adopted by an international standardization organization and is available for the public,

– European standard is a standard adopted by a European standardization body and is available for the public,

– national standard is a standard adopted by a national standardization body and is available for the public,

7. “programme for standards” is a working programme of a recognized standardization body listing the subjects of standardization work is being carried out;

8. “draft-standard” is a document containing the text of the technical specification referring to given subject, which is on review for adoption in accordance with the national procedure for standards, as well as a document in the same form as after the preparation work and upon its release in circulation to get public opinion or critics.

9. “European standardization body” is a standardization body stated in Annex 1;

10. “national standardization body” is a standardization body stated in Annex 2;

11. “technical regulation” are technical specifications and other requirements or rules on services, including the relevant administrative provisions, whose observance is obligatory de jure or de facto, in case of marketing, provision of a service, establishment of a service operator or use in any member state of the European Union (hereinafter: member state) or in the largest part of it, as well as laws, secondary regulations or administrative regulations of the member states, except those stated in Article 16 of this Decree, prohibiting production, import, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider

De facto technical regulations include:

– laws, secondary regulations or administrative provision of a member state referring either to the technical specifications or to other requirements or to rules on services, or to professional codes or to codes in practice, which refer to the technical specifications or to other requirements or to rules on services, compliance with which

confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,

– voluntary agreements, where the government authorities are one of the agreement parties, providing, for common interest, for compliance with the technical specifications or of other requirements, excluding the specifications for tenders or public procurements.

– technical specifications or other requirements or rules on services which are connected with fiscal or financial measures having influence on consumption of the products or services, encouraging the harmonization with these technical specifications, or other requirements or rules of services; technical specifications or other requirements or rules of services connected with the national social security system are excluded.

12. “draft technical regulation” is wording of the technical specification or other requirement or of a rule of services, including the administrative provisions, formulated in order to be adopted or to be passed as a technical regulation, while the wording is in preparation phase in which it is still possible to make significant amendments and supplements.

Annexes.1 and 2 of paragraph 1 items 7 and 8 of this article are integral part of this decree.

II. PROCEDURE ON NOTIFICATION TO THE EUROPEAN COMMISSION ON ADOPTION OF TECHNICAL STANDARDS AND REGULATIONS

1. Notification adoption of technical standards and regulations

Article 3

The Government authorities preparing technical regulations are obliged to notify the European Commission for those regulations through the contact point-Ministry of Economy.

The notification of paragraph 1 of this article should contain, in particular:

1. data on the Government authority having passed the technical regulation,
2. data on the person appointed to contact the Ministry of Economy,
3. legal basis for preparation of the technical regulation,
4. data on the products and rule of services included by the technical regulation which is in the process of preparation,
5. aims and reasons for preparation of the technical regulation,
6. data on the international regulations or documents the technical regulations are based on or which are applied for the same products and
7. reasons for each discordance with the international regulations or documents.

Notification of paragraph 2 of this article should be submitted by the Government authorities to the Ministry of Economy in written form along with the technical regulation they prepare.

Notification of paragraph 2 of this article shall not be confidential, except if it is explicitly required by the competent Government authority for which it gives explanation in accordance with the regulations on classified information.

Article 4

The Ministry of Economy is obliged to decide on the need of sending the received notification to the European Commission. When making decision the Ministry of Economy shall adhere to the procedure determined by the provisions of this decree and the assessment and explanation of the competent authority regarding this issue.

The Ministry of Economy is obliged to send the positively assessed notification immediately to the European Commission through Technical Regulation Information System.

The Ministry of Economy is also obliged to inform the competent Government authority on the notification performed under paragraph 2 of this article.

Article 5

The provisions of Article 3 of this decree shall not be applied if the draft technical regulation is subject to transposition of entire wording of an international or European standard.

In the case of paragraph 1 of this article it shall be sufficient to have information indicating the relevant standard.

Article 6

Along with the notification of Article 3 of this decree, where appropriate, and if not already sent along with that notification, the Government authorities shall simultaneously submit the wordings of the basic laws or of the secondary regulations the technical regulations refer to mainly and directly, if it is necessary to have consultation for those wordings in order to assess the consequences from the draft technical regulation.

Article 7

The Government authorities shall once again submit the draft technical regulation to the European Commission in accordance with the procedure determined in Article 3 of this decree, if there are significant amendments made to the draft resulting in particular amendment of its contents, if the term originally set for its conduct is shortened, if additional specifications or requirements are added or if the draft is made to be more restrictive.

Article 8

If the draft technical regulations in particular includes limit of advertising or use of certain chemical compound, of the preparation or of the product based on protection of the health of people or of the consumers or the environment, the competent Government authority shall submit to the European Commission a review or references for all relevant data known in connection with the compound, along with the preparation or with the product, as well as for the replacements available, when that information is accessible.

Apart from the information of paragraph 1 of this article, the competent Government authority shall also submit to the European Commission an explanation for the forecasted effects from the draft technical regulation on the health of the people and for the protection of the consumers and environment, along with analysis of the risk that is considered to be appropriate in accordance with the regulations and general principles for risk assessment regarding the existing and new chemical compounds.

Article 9

If the European Commission and the member states submit comments regarding the draft technical regulation, the competent Government authority is obliged to take

those remarks into consideration if they are acceptable in the further preparation of the technical regulation.

The competent Government authority is obliged to submit to the European Commission the final wording of the technical regulation through the contact point – the Ministry of Economy, immediately.

Article 10

When the draft technical regulation is subject to notification to the European Commission in the preparation phase based on another act of the European Union, then the competent Government authority may submit a notification in terms of Article 3 of this decree pursuant to that act, provided that it obligatory states that the notification also means notification for the aims of the Directive 98/34/EC and 98/48/EC.

Article 11

The Government authorities are obliged to postpone the adoption of the draft technical regulation for three months as from the date of receipt of the notification stated in Article 3 of this decree by the European Commission.

Article 12

If the European Commission or any member state submits, in the period of three months from the receipt of the notification stated in Article 3 of this decree by the European Commission, detailed opinion indicating that the provided measure may cause obstacles in the free movement of products within the internal market or in the rules of services, the free movement of services or the freedom of establishment of service operator and not the fiscal or financial aspects of the measure, the competent

Government authority is obliged to postpone:

- adoption of the draft technical regulation for four months in form of voluntary agreement in terms of Article 2 paragraph 1 item 11 line 2 of this decree;
- adoption of any other draft technical regulation for six months, without prejudice to Article 13 of this decree.

In the case of paragraph 1 of this article, the competent Government authority is obliged to submit to the European Commission report on the activities proposed to be undertaken by it based on the received detailed opinion through the contact point – the Ministry of Economy.

Article 13

The Government authorities are obliged to postpone the adoption of the technical regulation for 12 months from the date of receipt of the notification stated in Article 3 of this decree by the European Commission, if in the period of three months from that date, the European Commission announces:

- its intentions to propose or adopt a directive, regulation or decision in the same area in accordance with the Treaty on the Functioning of the European Union, or
- its statements that the draft technical regulation refers to matters included in the draft directive, regulative or decision submitted to the Council of the European Union in accordance with the Treaty on the of Functioning of the European Union.

If the Council of the European Union reaches common opinion during the stand-by period of paragraph 1 of this article, that period shall be extended for 18 months and it shall be subject to the provisions of Article 14 of this decree.

Article 14

The obligations stated in Article 13 of this decree shall cease when:

- the European Commission notifies the Republic of Macedonia that it does not have intention any more to propose or adopt a binding act of the European Union of Article 13 paragraph 1 line 1 of this decree;
- the European Commission notifies the Republic of Macedonia on withdrawal of its draft or proposal,
- the European Commission or the Council of the European Union adopts a binding act of the European Union.

Article 15

The provisions of Articles 11, 12 and 13 of this decree shall not be applied in case when due to urgent reasons caused by serious and unpredictable circumstances connected with protection of health of the people or of the public safety, protection of animals and plants and for rules on services, also for public policy, notably the protection of minors, the competent Government authority is obliged to prepare technical regulations in a very short period in order to adopt and apply immediately, without possibility for any consultations or

- For urgent reasons, occasioned by serious and circumstances relating to the protection of security and the integrity of the financial system, notably thr protection of depositors, investors and insured persons, the competent Government authority is obliged to enact and implement rules or financial services immediately.

The competent Government authority shall explain the urgency of the undertaken measures of paragraph 1 and 2 of this article in the notification stated in Article 3 of this decree.

Article 16

The provisions of Articles 3 to 15 of this decree shall not be applied on laws, secondary regulations or administrative regulations or on voluntary agreements by means of which the Government authorities:

- accord with the binding acts of the European Union, resulting in adoption of technical specifications or rules of services,
- fulfil the obligations arising from the international agreements, resulting in adoption of common technical specifications or rules in services in the European Union,
- use the protection clauses provided in the binding acts of the European Union,

– implement Article 6 and 12 of the Directive 2001/95/ EC,– limit themselves to conducting a verdict reached by the Court of Justice of the European Union,

– limit themselves to amending and supplementing certain technical regulation in terms of Article 2 paragraph 1 item 11 of this decree, in accordance with the requirement of the European Commission, due to removal of certain obstacle in the trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators .

The provisions of Articles 11 to 15 of this decree shall not be applied on laws, secondary regulations or administrative regulations by means of which the Government authorities prohibit production, if they do not hinder the free movement of products thereby.

The provisions of Articles 13 and 14 of this decree shall not be applied on voluntary agreements stated in Article 2 paragraph 1 item 11 line 2 of this decree.

The provisions of Articles 11 to 15 of this decree shall not be applied on technical specifications or on other requirements or the rules of services stated in Article 2 paragraph 1 item 11 line 3 of this decree.

Article 17

The technical regulations having passed the procedure for notification set by the provisions of this decree must be followed by explanation explaining that the technical regulation had been passed in accordance with the Directive 98/34/EC and 98/48/EC and it is published attached to the technical regulation in the “Official Journal of the Republic of Macedonia”.

Article 18

Provisions of Articles 3 to 17 of this decree shall apply for notification to the European Commission for adoption of technical regulations and of rules on information society services.

2. Notification for adoption of technical specifications and standards

Article 19

The European Commission and the standardization bodies stated in Annexes 1 and 2 of this decree (hereinafter: standardization bodies), shall be notified by the Standardization Institute on the new subjects included in its standardization programme, referring to preparation or amendment to a national standard, unless identical or equivalent transposition of some international or European standard is carried out thereby.

Notification of paragraph 1 of this article should in particular indicate whether that standard:

– transposes an international standard without being equivalent,

– shall be a new national standards, or

– shall amend a national standard.

Article 20

At request of the European Commission and the standardization bodies, the Standardization Institute is obliged to send all the draft standards to them, as well as to inform them on the undertaken activities based on their remarks regarding the draft standards.

Article 21

At request of the standardization bodies stated in Annex 2 of this decree, the Standardization Institute is obliged to enable their passive or active inclusion by sending monitoring people in realization of its activities planned by the programme for standards.

Article 22

The Standardization Institute is obliged to enable discussion for its subjects of standardization determined in the programme for standards on European level in accordance with the rules set by the European standardization bodies.

Article 23

The Standardization Institute is obliged to conduct the preparation and adoption of Macedonian standards in accordance with the procedure for notification set in Article 19 of this decree.

Article 24

During preparation of the European standards or upon its approval by the European standardization bodies, the Standardization Institute is obliged not to undertake any activities by which it could disrupt the process of harmonization with that European standard, and especially in that area not to prepare and adopt a new or amended Macedonian standard which is completely in discordance with the existing European standard..

As an exception from paragraph 1 of this article, at request of the competent Government authorities in case of specific products, the Standardization Institute may prepare technical specifications or standards for the purpose of passing technical regulations for those specific products.

The European Commission shall be notified for the technical regulations of paragraph 2 of this article in accordance with the procedure set in Articles 3 to 17 of this decree.

Article 25

Provisions of Articles 19 to 24 of this decree shall also be applied for notification to the European Commission for adoption of technical specifications.

III. TRANSITIONAL AND CLOSING PROVISIONS

Article 26

The provisions of this decree shall be applied as from the date on which the Republic of Macedonia will join the European Union, except for the products for which there is appropriate protocol concluded for conformity assessment setting free movement of products between the Republic of Macedonia and the European Union, as from the date of enforcement of that protocol, and the provisions regulated in article 25 of this degree referring to application of Standardization Institute in CEN/CENELEC

Article 27

This decree shall come into effect on the eighth day following the date of its publication in the “Official Journal of the Republic of Macedonia”.

No. _____

Skopje, _____2007

**PRIME MINISTER
OF THE REPUBLIC OF MACEDONIA**

Nikola Gruevski, MA, sgd.

Annex

1

EUROPEAN STANDARDIZATION BODIES

1. CEN

European Committee for Standardisation

2. Cenelec

European Committee for Electrotechnical Standardisation

3. ETSI

European Telecommunications Standards Institute

Annex 2

NATIONAL STANDARDIZATION BODIES

1. BELGIUM

IBN/BIN

Institut belge de normalisation

Belgisch Instituut voor Normalisatie

CEB/BEC

Comité électrotechnique belge

Belgisch Elektrotechnisch Comité

2. BULGARIA

БИС

Български институт за стандартизация

3. CZECH REPUBLIC

ČSNÍ

Český normalizační institut

4. DENMARK

DS

Dansk Standard

NTA

Telestyrelsen, National Telecom Agency

5. GERMANY

DIN
Deutsches Institut für Normung e.V.

DKE
Deutsche Elektrotechnische Kommission im DIN und VDE

6. ESTONIA

EVS
Eesti Standardikeskus Sideamet

7. GREECE

ELOT
Hellenic Organization for Standardization

8. SPAIN

AENOR
Asociación Española de Normalización y Certificación

9. FRANCE

AFNOR
Association française de normalization

UTE
Union technique de l'électricité - Bureau de normalisation auprès de l'AFNOR

10. IRELAND

NSAI
National Standards Authority of Ireland

ETCI
Electrotechnical Council of Ireland

11. ITALY

UNI
Ente nazionale italiano di unificazione

CEI
Comitato elettrotecnico italiano

12. CYPRUS

KOIII
The Cyprus Organisation for Quality Promotion

13. LATVIA

LVS
Latvijas Standarts

14. LITHUANIA

LST
Lietuvos standartizacijos departamentas

15. LUXEMBOURG

ITM
Inspection du travail et des mines

SEE
Service de l'énergie de l'État

16. HUNGARY

MSZT
Magyar Szabványügyi Testület

17. MALTA

MSA
Malta Standards Authority

18. NETHERLANDS

NNI
Nederlands Normalisatie Instituut

NEC

Nederlands Elektrotechnisch Comité

19. AUSTRIA

ÖN
Österreichisches Normungsinstitut

ÖVE
Österreichischer Verband für Elektrotechnik

20. POLAND

PKN
Polski Komitet Normalizacyjny

21. PORTUGAL

IPQ
Instituto Português da Qualidade

22. ROMANIA

ASRO
Asociatia de Standardizare din Romania

23. SLOVENIA

SIST
Slovenski inštitut za standardizacijo

24. SLOVAKIA

SŮTN
Slovenský ústav technickej normalizácie

25. FINLAND

SFS
Suomen Standardisoimisliitto SFS ry
Finlands Standardiseringsförbund SFS rf

THK/TFC
Telehallintokeskus
Teleförvaltningscentralen

SESKO
Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry

26. SWEDEN

SIS

Standardiserings i Sverige

SEK

Svenska elektriska kommissionen

ITS

Informationstekniska standardiseringen

27. UNITED KINGDOM

BSI

British Standards Institution

BEC

British Electrotechnical Committee