L.N. 65 of 2001

MALTA STANDARDS AUTHORITY ACT, 2000 (ACT NO. XIX OF 2000)

Procedure for the Provision of Information in the field of Technical Standards and Regulations and of Rules of Information Society Services Regulations, 2001

IN exercise of the powers conferred by article 21(f) of the Malta Standards Authority Act, 2000, hereinafter referred to as "the Act", the Minister for Economic Services, after consultation with the Malta Standards Authority, has made the following regulations:-

Citation and commencement.

1.1. The title of these regulations is the Procedure for the Provision of Information in the field of Technical Standards and Regulations and of Rules of Information Society Services Regulations, 2001.

1.2. These regulations shall become operative on 1st April, 2001, which date shall be notified by the Malta Standards Authority in the Gazette.

1.2.1. Provided that requirements to send draft standards, technical regulations and rules on Information Society Services to the Commission and other Member States, shall come into force on such date as the Minister responsible for industry, after consultation with the Malta Standards Authority, shall prescribe.

Scope.

2.1. These regulations lay down a procedure for the provision of information in the field of technical standards and regulations and of rules of Information Society services, implementing European Community Directive 98/34/EC[1] as amended by Directive 98/48/EC[2].

Definitions.

3.1. In these regulations:

3.1.1. All the definitions of the Act shall apply, and in addition:

3.1.2. "the Directive" means European Community Directive 98/34/EC[1] as amended by Directive 98/48/EC[2] laying down a procedure for the provision of information in the field of technical standards and regulations and of rules of Information Society services;

---

[1] OJ No. L204, 21-07-98, P.37
[2] OJ No. L217, 05-08-98, P.18

3.1.3. "competent authority" means any public authority, including a local council, or agency which prescribe any:

(a) technical regulations; and/or

(b) rules on Information Services;

3.1.4. "service" means 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;

For the purposes of this definition:

♦ "at a distance" means that the service 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.

3.1.4.1. An indicative list of services not covered by this definition is set out in Schedule III to these regulations.

3.1.4.2. This Directive shall not apply to:

♦ radio broadcasting services,

♦ television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC[3];

3.1.5. "other requirements" means a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as

[3] OJ No. L298, 17-10-1989, P.23. Directive as last amended by Directive 97/36/EC (OJ No. L202, 30-07-1997, P. 1)

conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

3.1.6. "rule on services" means a requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of paragraph 3.1.3, in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

3.1.6.1. These regulations do not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC[4].

3.1.6.2. These regulations shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Schedule IV to these regulations.

3.1.6.3. With the exception of paragraph 6.1.5, these regulations shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

3.1.6.4. For the purposes of this definition:

- a rule shall be considered to be specifically aimed at Information Society services 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;

3.1.7. "technical regulation" means technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory,

[4]OJ No. L 192, 24-07-1990, P.1. Directive as amended by Directive 97/51/EC (OJ L No. L295, 29-10-1997, P.23)

de jure or *de facto*, in the case of marketing, provision of a service, establishment of a service operator or use in Malta, as well as local laws, regulations or administrative provisions, except those provided for in Article 10 of the Directive, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider;

3.1.7.1. *De facto* technical regulations include:

- local laws, regulations or administrative provisions which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to 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 to which a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications,

- technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included;

3.1.8. "draft technical regulation" means the text of a technical specification or other requirement or of a rule on services, including administrative provisions, formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made;

3.1.9. "OJ" means *The Official Journal of the European Communities;*

3.1.10. "Community" means the European Community.

4.1. For the purposes of these regulations, the Malta Standards Authority is hereby being designated as Malta's "Notification Point" for technical standards, regulations and for rules on Information Society Services.

Notification Procedure for draft standards.

5.1. The Authority shall send all draft standards, on request by the Commission and the standardisation bodies referred to in Schedules I and II to these regulations, and it shall keep them informed of the action taken by the Authority on any comments they have made relating to drafts.

5.2. The Authority shall take all necessary steps to ensure that it:

(a) communicates information in accordance with article 16 (e) of the Act,

(b) publishes the draft standards in such a way that comments may also be obtained from parties established in other Member States,

(c) grants the other bodies referred to in Schedule II the right to be involved passively or actively (by sending an observer) in the planned activities,

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

5.2.1. In particular, any act of recognition, approval or use by reference to a national standard adopted in breach of article 16(e) of the Act and paragraphs 5.1 and 5.2 of these regulations, is prohibited.

5.3. During the preparation of a European standard referred to in the first indent of Article 6(3) of the Directive, or after its approval, the Authority shall not take any action which could prejudice the harmonisation intended and, in particular, that it does not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard.

5.3.1. Paragraph 5.3 of these regulations shall not apply to the work of the Authority undertaken at the request of the competent authority to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products.

5.3.2. The Authority shall communicate all requests of the kind referred to in sub-paragraph 5.3.1 to the Commission as draft technical regulations, in accordance with paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations, and shall state the grounds for their enactment.

Notification Procedure for draft technical regulation.

6.1. The competent authority shall immediately communicate to the Authority any draft technical regulation; it shall also let the Authority have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

6.1.1. Where appropriate, and unless it has already been sent with a prior communication, the competent authority shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

6.1.2. The competent authority shall communicate the draft again under the above conditions if changes to the draft are made that 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.

6.1.3. 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, the competent authority 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 available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation

[5]Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ No. L 84, 05-04-1993, P. 1).

[6]Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ No. L 196, 16-08-1967, P. 1). Directive, as amended by Directive 92/32/EEC, (OJ No. L 154, 05-06-1992, P. 1).

(EEC) No 793/93[5] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC[6], in the case of a new substance.

6.1.4. With respect to the technical specifications or other requirements or rules on services referred to in the third indent item 3.1.7.1, the comments or detailed opinions of the Authority may concern only aspects which may hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators and not the fiscal or financial aspects of the measure.

6.1.5. After taking comments into account as far as possible in the subsequent preparation of the technical regulation, the competent authority shall communicate the definitive text of a technical regulation to the Authority without delay.

6.1.6. Information supplied under paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations shall not be confidential except at the express request of the notifying competent authority. Any such request shall be supported by reasons.

6.2. The competent authorities shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Authority of the communication referred to in paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations.

6.3. Competent authorities shall postpone:

- for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of the second indent of item 3.1.7.1 of these regulations,

- for six months the adoption of any other draft technical regulation (except for draft rules on services), from the date of receipt by the Authority of the communication referred to in paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations if the Authority delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the international market;

- for four months the adoption of any draft rule on services, from the date of receipt by the Authority of the communication referred to in paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations if the Authority delivers a detailed

opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of services or to the freedom of establishment of service operators within the international market.

6.3.1. The competent authority concerned shall report to the Authority on the action it proposes to take on such detailed opinions. The Authority shall comment on this reaction.

6.3.2. With respect to rules on services, the competent authority concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.

6.4. Paragraph 6.3 and subsequent sub-paragraphs 6.3.1 and 6.3.2 of these regulations shall not apply in cases where:

- for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants and, for rules on services, also for public policy, notably the protection of minors, a competent authority is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible or

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

6.4.1. In the communication referred to in paragraph 6.1 and subsequent sub-paragraphs 6.1.1 to 6.1.6 of these regulations, the competent authority shall give reasons for the urgency of the measures taken. The Authority shall give its views on the communication as soon as possible.

6.5. The Minister responsible for industry shall take all appropriate action possible in cases where improper use is made of the procedures contemplated in any part of these regulations.

SCHEDULE I

EUROPEAN STANDARDIZATION BODIES

CEN
European Committee for Standardization

Cenelec
European Committee for Electrotechnical Standardization

ETSI
European Telecommunications Standards Institute

SCHEDULE II

NATIONAL STANDARDIZATION BODIES

1. BELGIUM
IBN/BIN
Institut belge de normalisation - Belgisch Instituut voor Normalisatie

CEB/BEC
Comité électrotechnique belge - Belgisch Elektrotechnisch Comité

2. DENMARK
DS
Dansk Standard

NTA
Telestyrelsen, National Telecom Agency

3. GERMANY
DIN
Deutsches Institut für Normung e.V.

DKE
Deutsche Elektrotechnische Kommission im DIN und VDE

4. GREECE
ΕΛΟΤ
Ελληνιχος Οργανισμος Τνποποιησης

5. SPAIN
AENOR
Asociación Española de Normalización y Certificación

6. FRANCE
AFNOR
Association française de normalisation

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

7. IRELAND
NSAI
National Standards Authority of Ireland

ETCI
Electrotechnical Council of Ireland

8. ITALY
UNI[7]
Ente nazionale italiano di unificazione

CEI[8]
Comitato elettrotecnico italiano

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 Elektrotechnisch 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 Standardiseringsförbund SFS rf

---

[7]UNI and CEI, in cooperation with the Istituto Superiore delle Poste e Telecommunicazioni and the Ministero dell'Industria, have allocated the work within ETSI to CONCIT, Comitato nazionale di coordinamento per le tecnologie dell'informazione.
[8]Idem 4.

THK/TFC
Telehallintokeskus
Teleförvaltningscentralen

SESKO
Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry
Finlands Elektrotekniska Standardiseringsförening SESKO rf

15. SWEDEN
SIS
Standardiseringen i Sverige

SEK
Svenska elektriska kommissionen

ITS
Informationstekniska standardiseringen

SCHEDULE III

Indicative list of services not covered by paragraph 3.1.4 of these regulations:

1. Services not provided "at a distance"

Services provided in the physical presence of the provider and the recipient, even if they involve the use of electronic devices:

(a) medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present;

(b) consultation of an electronic catalogue in a shop with the customer on site;

(c) plane ticket reservation at a travel agency in the physical presence of the customer by means of a network of computers;

(d) electronic games made available in a video-arcade where the customer is physically present.

2. Services not provided "by electronic means"

– Services having material content even though provided via electronic devices:

(a) automatic cash or ticket dispensing machines (banknotes, rail tickets);

(b) access to road networks, car parks, etc., charging for use, even if there are electronic devices at the entrance/exit controlling access and/or ensuring correct payment is made.

– Off-line services: distribution of CD-roms or software on diskettes.

– Services which are not provided via electronic processing/inventory systems:

(a) voice telephony services;

(b) telefax/telex services;

(c) services provided *via* voice telephony or fax;

(d) telephone/telefax consultation of a doctor;

(e) telephone/telefax consultation of a lawyer;

(f) telephone/telefax direct marketing.

3. Services not supplied "at the individual request of a recipient of services"

Services provided by transmitting data without individual demand for simultaneous reception by an unlimited number of individual receivers (point to multipoint transmission):

(a) television broadcasting services (including near-video on-demand services), covered by point (a) of Article 1 of Directive 89/552/EEC;

(b) radio broadcasting services;

(c) (televised) teletext.

SCHEDULE IV

Indicative list of the financial services covered by paragraph 3.1.6 of these regulations:

- Investment services
- Insurance and reinsurance operations
- Banking services
- Operations relating to pension funds
- Services relating to dealings in futures or options

Such services include in particular:

(a) investment services referred to in the Schedule to Directive 93/22/EEC[9]; services of collective investment undertakings,

(b) services covered by the activities subject to mutual recognition referred to in the Schedule to Directive 89/646/EEC[10],

(c) operations covered by the insurance and reinsurance activities referred to in:

- Article 1 of Directive 73/239/EEC[11],
- the Schedule to Directive 79/267/EEC[12],
- Directive 64/225/EEC[13],
- Directives 92/49/EEC[14] and 92/96/EEC[15].

---

[9]OJ No. L141, 11-06-1993, P. 27.
[10]OJ No. L386, 30-12-1989, P. 1. Directive as amended by Directive 92/30/EEC (OJ No. L110, 28-04-1992, P. 52).
[11]OJ No. L228, 16-08-1973, P. 3. Directive as last amended by Directive 92/49/EEC (OJ No. L228, 11-08-1992, P.1).
[12]OJ No. L63, 13-03-1979, P. 1. Directive as last amended by Directive 90/619/EEC (OJ No.L330, 29-11-1990, P. 50).
[13]OJ No. 56, 04-04-1964, P. 878/64. Directive as amended by the 1973 Act of Accession.
[14]OJ No. L228, 11-08-1992, P. 1.
[15]OJ No. L 360, 09-12-1992, P. 1.