

SUBSIDIARY LEGISLATION 419.06**NOTIFICATION PROCEDURE REGULATIONS**

21st November, 2003;
1st May, 2004

LEGAL NOTICE 373 of 2003, as amended by Legal Notice 313 of 2007.

1. The title of these regulations is the Notification Procedure Regulations. Citation.

2. For the purposes of these regulations all the definitions of the Act shall apply, and in addition: Interpretation.

"competent authority" means any public authority or agency which prescribe any:

- (a) technical regulations; and, or
- (b) rules on information services:

Provided that the Authority may identify those local or regional councils which have to notify technical regulations and, when this is the case, the Authority shall submit a list of these local or regional councils to the European Commission;

"draft standard" means a document containing the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the national standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny;

"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, and, in any case, prior to the submission of the text for signature by the Minister into whose portfolio the competent authority drawing up the text falls;

"European standardization body" is a body referred to in Schedule I;

"national standardization body" is a body referred to in Schedule II;

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

"product" means any industrially manufactured product and any agricultural product, including fish products;

"rule on services" means a requirement of general nature relating

to the taking-up and pursuit of service activities within the meaning of the definition of "service" in this regulation, 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;

"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:

- (a) "at a distance" means that the service is provided without the parties being simultaneously present;
- (b) "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;
- (c) "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 Schedule III;

"standard" means a technical specification approved by a recognized standardization body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

- (a) international standards: that is, a standard adopted by an international standardization organization and made available to the public;
- (b) European standard: a standard adopted by a European standardization body and made available to the public;
- (c) national standard: a standard adopted by a national standardization body and made available to the public;

"standards programme", a work programme of a recognized standardization body listing the subjects on which standardization work is being carried out;

"technical regulation" means technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in regulation 10, 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.

De facto technical regulations include:

- (a) laws, regulations or administrative provisions of a Member State 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;
- (b) voluntary agreements to which a public authority is a contract 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;
- (c) 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 specification or other requirements or rules on services linked to national social security systems are not included;

"technical specification", a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the products as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;

"technical specification" shall also cover production methods and processes used in respect of agricultural products as referred to Article 38(1) to the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65165/EEC as well as production methods and processes relating to other products, where these have an effect on their characteristics.

3. (1) These regulations shall not apply to those measures which Malta shall consider necessary under the Treaty for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products. Applicability.

(2) These regulations shall not apply to:

- (a) radio broadcasting;
- (b) television broadcasting services covered by point (a) of Article 1 of Directive 89/522/ECC.

(3) These regulations shall 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) These regulations shall also 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.

(5) With the exception of regulation 8(3), 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.

(6) For the purposes of subregulation (5):

- (a) 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 provision is to regulate such services in an explicit and targeted manner;
- (b) 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.

Notification point.

4. 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.

Information to be given.

5. (1) The Commission and the standardization bodies referred to in Schedules I and II shall be informed of the new subjects for which the national bodies referred to in Schedule II have decided, by including them in their standards programme, to prepare or amend a standard, unless it is an identical or equivalent transposition of an international or European standard.

(2) The information referred to in subregulation (1) shall indicate, in particular, whether the standard concerned:

- (a) will transpose an international standard without being the equivalent,
- (b) will be a new national standard, or
- (c) will amend a national standard.

(3) Upon request of the Commission, the Authority shall communicate to it all or part of the standards programmes.

(4) The Authority shall also make this information available to the Member States in a form which allows the different programmes to be assessed and compared.

Draft standards.

6. (1) The Authority shall send to the standardization bodies referred to in Schedules I and II and the Commission all draft standards on request.

(2) They shall also be kept informed by the body concerned of the action taken on any comments they have made relating to drafts.

Duties of the Authority.

7. (1) The Authority shall take all the necessary steps to ensure that it:

- (a) communicates information in accordance with regulations 5 and 6;

- (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 standardization in their work programme being discussed at European level in accordance with the rules laid down by the European standardization bodies and undertake no action which may prejudice a decision in this regard.

(2) In particular, any act of recognition, approval or use by reference to a national standard adopted in breach of subregulation (1) and regulations 5 and 6, is prohibited.

8. (1) During the preparation of a European standard or after its approval, the Authority shall not take any action which could prejudice the harmonization 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.

European standards.

(2) For the purposes of this regulation, the term "preparation of a European standard" shall refer to the request by the Commission to the European standards institution to draw up a European standard within a given time limit.

9. Regulation 8 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.

Exception.

10. (1) The Authority shall communicate all requests of the kind referred to in regulation 9 to the Commission as draft technical regulations and shall state the grounds for their enactment.

Communication of requirements.

(2) The provisions of regulation 11(6) shall apply to the communication referred to in the subregulation (1).

11. (1) The competent authority shall communicate to the Authority any draft technical regulation forthwith and 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.

Further communications.

(2) The provisions of subregulation (1) shall not apply where the draft technical regulation merely transposes the full text of an international or European standard, in which case, information regarding the relevant standard shall suffice.

(3) 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 regulations.

(4) The competent authority shall communicate the draft again under the foregoing provisions of this regulation, if they make changes to the draft 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.

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

(6) The Authority shall be bound to communicate forthwith to the Commission the information received by the competent authority under the foregoing provisions of this regulation and, in any case, not later than the first working day following that of the reception of the information as aforesaid.

(7) Without prejudice and subject to subregulation (6), the Authority shall regulate its own procedure on dealing with the information received by the competent authorities.

(8) Such procedure shall be published and communicated to all the competent authorities.

Responsible
person.

12. (1) For the purposes of regulation 11, each competent authority shall appoint a person, who shall be responsible for all the communication which would have to be made between the competent authority and the Authority pursuant to these regulations.

(2) Such person shall also be responsible for all the correspondence between the Authority and the competent authority:

Provided that for the purposes of this regulation, "correspondence" shall strictly refer to all the correspondence, electronic or otherwise, arising out of the obligations under these regulations.

Comments.

13. (1) Following communication to the Commission of a draft technical regulation under the provisions of regulation 11, the Authority shall receive comments which would have been made by the Commission or the Member States, should this be the case.

(2) The Authority shall forward such comments to the competent authority responsible for the draft technical regulation and such competent authority shall take such comments into

account as far as possible in the subsequent preparation of the technical regulations.

(3) The competent authority shall communicate the definitive text of a technical regulation to the Authority without delay.

(4) The Authority shall be bound to communicate forthwith to the Commission the definitive text of a technical regulation received and the provisions of regulation 11(3) shall apply *mutatis mutandis* to such communication.

(5) All the information supplied under this regulation and regulation 11 shall not be confidential except at the express request of the notifying competent authority. Any such request shall be supported by reasons.

(6) In such cases, if necessary precautions are taken, the Authority may seek expert advice from persons in the physical or legal sectors.

(7) When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Community act, the competent authority may make a communication to the Authority in terms of regulation 11(6) under that other Community act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.

(8) Such communication shall be made to the Authority and the Authority shall forward such communication to the Commission.

(9) The provisions of regulation 11(6) shall apply *mutatis mutandis* to the communication mentioned in subregulation (8).

14. (1) The competent authority shall postpone the publication of the draft technical regulation by three months from the date of receipt by the Commission of the Communication referred to in regulation 11(6).

Publication shall be postponed.

(2) Such period shall be reckoned to start running from the day following the day on which the Commission receives from the Authority the communication in terms of regulation 11(6).

(3) The competent authority shall postpone:

- (a) for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of the explanation of the *de facto* technical regulations in regulation 2;
- (b) without prejudice to subregulations (7), (8) and (9), for six months the adoption of any other draft technical regulation (except for draft rules on services),

to be reckoned from the date of receipt by the Commission of the communication referred to in regulation 11(6) if the Commission or another Member State delivers a detailed opinion within three months of such date of receipt of communication by the Commission, to the effect that the measures envisaged may create obstacles to the free movement of goods within the internal market;

- (c) without prejudice to subregulations (8) and (9), for

four months the adoption of any draft rule on services, from the date of receipt by the Commission of the communication referred to regulation 11(6) if the Commission or another Member State delivers a detailed opinion, within three months of such communication, 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 internal market.

(4) With regard to draft rules on services, detailed opinions from the Commission or Member State shall not affect any cultural policy measures, in particular in the audiovisual sphere, which might be adopted in accordance with Community law, taking account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.

(5) The competent authority concerned shall communicate to the Authority the action it proposes to take on such detailed opinions.

(6) With respect to rules on services, however, the competent authority concerned shall communicate to the Authority, where appropriate, the reasons why the detailed opinions cannot be taken into account.

(7) The provisions of regulation 11(6) shall apply to the communications listed in subregulations (4) and (5).

(8) With the exclusion of draft rules relating to services, the competent authority shall postpone the publication of a draft technical regulation for twelve months from the date of receipt by the Commission of the communication referred to in regulation 11(6), if within three months of the receipt by the Commission of the communication by the Authority in terms of regulation 11(6), the Commission announced its intention of proposing or adopting a directive, regulation or decision on the matter in accordance with Article 189 of the Treaty.

(9) The competent authority shall postpone the publication of a draft technical regulation for twelve months from the date of receipt by the Commission of the communication referred to in regulation 11(6), if, within the three months following that date, the Commission announces its findings that the draft technical regulation concerns a matter which is covered by proposal for a directive, regulation or decision presented to the Council in accordance with Article 189 of the Treaty.

(10) If the Council adopts a common position during the standstill period referred to in subregulations (8) and (9), the period shall, subject to subregulation (11), be extended to eighteen months.

(11) The obligations referred to in subregulations (7), (8) and (9) shall lapse:

- (a) when the Authority is informed by the Commission that the latter no longer intends to propose or adopt a binding Community act;

- (b) when the Authority is informed by the Commission of the withdrawal of its draft or proposal;
- (c) when the Commission or the Council has adopted a binding Community act.

(12) The provisions of this regulation shall not apply in cases where:

- (a) 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 Member State 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;
- (b) 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, the competent authority is obliged to enact and implement rules on financial services immediately.

(13) In the communication mentioned in regulation 11(1), the competent authority shall give reasons for the urgency of the measures taken, which reasons shall be communicated to the Commission under the provisions of regulation 11(6).

(14) The Commission shall give its views on the communication as soon as possible and it shall be incumbent on the Authority to forward this communication as soon as it is received by it.

15. (1) Regulations 11 and 14 shall not apply to those laws, regulations and administrative provisions which:

Non-applicability
of certain
regulations.

- (a) comply with binding Community acts which result in the adoption of technical specifications or rules on services;
- (b) fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Community;
- (c) make use of safeguard clauses provided for in binding Community acts;
- (d) apply Article 8(1) of Directive 92/59/EEC;
- (e) restrict themselves to implementing a judgment of the Court of Justice of the European Communities;
- (f) restrict themselves to amending a technical regulation within the meaning of the definition of "technical regulations" listed in regulation 2, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services to the free movement of services or the freedom of establishment of services operators.

(2) Regulation 14 shall not apply to laws, regulations and administrative provisions prohibiting manufacture insofar as they do not impede the free movement of products.

(3) Regulation 14(7), (8) and (9) shall not apply to voluntary agreements in terms of within the meaning of the explanation of the second indent of the *de facto* technical regulations in regulation 2.

(4) Regulation 14 shall not apply to the technical specifications or other requirements or the rules on services within the meaning of the explanation of the second indent of the *de facto* technical regulations in regulation 2.

Technical
regulation.

16. (1) When a competent authority publishes a technical regulation, it shall contain a reference to Directive 98/34 accompanied by such reference on the occasion of its official publication.

(2) The Authority shall prescribe the methods of making such reference.

Action to be taken
by the Minister.

17. The Minister 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 Standards

ETSI

European Telecommunication Standards Institute

SCHEDULE II

National Standardization Bodies

*Substituted by:
L.N. 313 of 2007*

1. BELGIUM

IBN/BIN

Institu belge de normalization

Belgisch Instituut voor Normalisatie

CEB/BEC

Comité électrotechnique belge

Belgisch Elektrotechnisch Comité

2. BULGARIA

БИС

Български институт за стандартизация

3. CZECH REPUBLIC

CSNI

Ceský 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

EAOT

Ελληνικός Οργανισμός Τυποποίησης

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 Ireland

ETCI

Electrotechnical Council of Ireland

11. ITALY

UNI*

Ente nazionale italiano di unificazione

CEI

Comitato elettrotecnico italiano

* UNI and CEI, in cooperation with the Istituto superiore delle Poste e telecomunicazioni and the Ministero dell'Industria, have allocated the work within ETSI to CONCIT, Comitato nazionale di coordinamento per le tecnologie dell'informazione.

12. CYPRUS

ΟΠΠ

Κυπριακός Οργανισμός Προώθησης Ποιότητας (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

L-Awtorità ta' Malta dwar l-Istandards (Malta Standards Authority)

18. NETHERLANDS

NNI

Nederlands Normalisatie-instituut

NEC

Nederlands Electrotechnisch Comité

19. AUSTRIA

ON

Österreichisches Normungsinstitut

OVE

Österreichischer Verband für Elektrotechnik

20. POLAND

PKN

Polski Komitet Normalizacyjny

21. PORTUGAL

IPQ

Instituto Português da Qualidade

22. ROMANIA

ASRO

Asociatia de Standardizare din România

23. SLOVENIA

SIST

Slovenski inštitut za standardizacijo

24. SLOVAKIA

SÚTN

Slovenský ústav technickej normalizácie

25. FINLAND

SFS

Suomen Standardisoimisliitto SFS ry

Finlands Stanadrdiseringsförbund SFS rf

THK/TFC

Tlehallintokeskus

Teleförvaltningscentralen

SESKO

Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ry

Finlands Elektrotekniska Standardiseringsförening SESKO rf

26. SWEDEN

SIS

Stanardiseringen i Sverige

SEK

Svenska elektriska kommissionen

ITS

Informationstekniska standardiseringen

27. UNITED KINGDOM

BSI

British Standards Institution

BEC

British Electrotechnical Committee

SCHEDULE III

Indicative list of services not covered by regulation 2 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"

i. 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 accessing and/or ensuring correct payment is made.

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

iii. 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 regulation 3(4):

- i. Investment services;
- ii. Insurance and reinsurance operations;
- iii. Banking services;
- iv. Operations relating to pension funds;
- v. Services relating to dealings in futures or options.
Such services include in particular:
 - i. investment services referred to in the Schedule to Directive 93/22/EEC services of collective investment undertakings;
 - ii. services covered by the activities subject to mutual recognition referred to in the Schedule to Directive 89/646/EEC;
 - iii. operations covered by the insurance and reinsurance activities referred to in:
 - (a) regulation 1 of Directive 73/329/EEC,
 - (b) the Schedule to Directive 79/267/EEC,
 - (c) Directive 64/225/EEC
 - (d) Directives 92/49/EEC and 92/96/EEC