



European Commission

Enterprise and Industry Directorate General

Information Procedure in the Field of Technical Regulations -Directive 98/34/EC-

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Today's Presentation

1. Directive 98/34/EC and the Internal Market
2. Objectives of Directive 98/34/EC
3. Legal basis of the application of the procedure between the EC and Turkey
4. Scope of Directive 98/34/EC
5. Moment of notification and relevant documents
6. Notification Process / Reactions / Simplified procedure
7. Request for urgency
8. Exceptions / Links with other notification procedures
9. Lack of notification - relevant ECJ cases
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11. Coordination of the procedure in Turkey
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What is Directive 98/34/EC?

A system of notification
of technical regulations
in draft form
applying standstill periods
during which the Commission
and all Member States
can react in a specific form.

Objectives of Directive 98/34/EC

- Transparency

- All participants in the notification process are informed

- Prevention

- Avoiding barriers to trade before they appear

- Subsidiarity

- Detecting those cases where community intervention appears most appropriate

Optimal functioning of the Internal Market

Better Regulation - Greater competitiveness for enterprises

Application to Turkey

1. Decision 1/95 of the EC-Turkey Association Council on implementing the final phase of the Customs Union (Art. 8)
2. **Decision 2/97 of the EC-Turkey Association Council: list of Community instruments relating to the removal of technical barriers to trade** (Annex II, chapter XIX, no. 1)
3. Decision 2/99 of the EC-Turkey Association Council: list of committees (extended to 98/34 Committee)

Principle of Free Movement of Goods

- “Quantitative restrictions on imports and **all measures having equivalent effect shall be prohibited**” (Art. 28 EC Treaty = Art. 5 Decision 1/95 EC-Turkey Association Council)
- **Justification** of obstacles only on **grounds of overriding public interest** (see Art. 7 Decision 1/95 EC-Turkey Association Council: public morality, policy, security; health/life of humans, animals or plants; national treasures; industrial/commercial property)
- Interpretation in conformity with case-law of the European Court of Justice
- Principle of **mutual recognition** of products legally manufactured or marketed in another Member State or in Turkey

Example of Mutual Recognition Clause

Commission's interpretative communication on the practical application of mutual recognition

published in OJEU 265/02 of 4.11.2003



Model clauses

Short version:

"This [law/regulation/decreed] does not apply to products lawfully manufactured or marketed in another Member State of the European Community [or in Turkey] and to products lawfully manufactured in another State party to the European Economic Area Agreement, unless the competent authorities can demonstrate in each specific case, on the basis of all the relevant scientific elements available to them and in accordance with Article 30 of the EC Treaty, that there are overriding grounds in the general public interest for not allowing such products in their current form and that less restrictive measures cannot be used."

Scope of Application of Directive 98/34/EC (1)

- The Directive applies to all industrial and agricultural products
- Directive 98/48/EC extended the notification procedure to Information Society Services (not applicable to Turkey)

Scope of Application of Directive 98/34/EC (2)

- Factors triggering a notification:

a) must contain technical regulations

b) must fall outside the “harmonised” area

c) measures must be imputable to the state

Scope of Application of Directive 98/34/EC (3)

Technical regulations:

Technical specifications

- levels of quality, performance, safety
- dimensions
- terminology, symbols, labelling
- testing, testing methods
- conformity assessment procedures

Other requirements

- affecting the life cycle after placing on the market
- such as conditions of use, recycling, reuse or disposal

Laws, regulations or administrative provisions prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service

Rules on services

The Lindberg Case of the ECJ Case C-267/03

- National provisions which entail a prohibition on the organization of a service using certain products, if that prohibition:
 - Leaves no room for any use which can reasonably be expected of the product or
 - May significantly influence the composition or nature of the product or its marketing
- Redefining a service connected with the design of a product if that rule adds new or additional specifications.

Information Society Services (1)

Rules on services

Requirements of a general nature relating to

- the taking up
and
- pursuit of services activities

Information Society Services (2)

Information Society Services

- At a distance
- By electronic means
- At the individual request of a recipient of services

Exceptions:

- Article 10
- Telecommunications services
- Financial services
- Regulated markets

“De jure” and “de facto” compulsory

Art 1(11) Directive 98/34/EC

- **Compulsory « de jure »**

technical regulation contained in a mandatory legal act (law, decree, etc.)

- **Compulsory « de facto »**

not imposed by a formally binding act of the public authority, but State encourages the observance of technical specifications (similar effect on trade)

De facto technical regulations (1)

For example:



Voluntary agreements



Fiscal or financial measures
affecting the consumption of
products or services



Reference to technical reg. in
third documents +
presumption of conformity

De facto technical regulations (2)



fiscal and financial measures

- ‘soft’ policy instrument to influence behaviour of businesses and consumers (e.g. ecotaxes on certain packaging, financial incentives for purchase of certain environmentally friendly equipment, tax reduction for ‘clean cars’, etc.)
- no standstill period
- fiscal/financial measure itself not subject to scrutiny, but related technical regulations and possible barriers to trade
- not covered: State Aids (Articles 87-89 EC Treaty) and measures linked to social security systems

Moment of Notification

When to notify a text:

- when a text is still at a draft stage
- when substantial amendments can still be made
- in any case before its adoption

Documents to be submitted

Documents to be submitted for notification:

- notification message (message 001)
- text of the notified draft
- basic texts (if useful also texts referred to in the notified draft)
- any other useful texts (impact studies, scientific data, etc.)

NB: For restrictions on chemicals, article 8(1) requires submission of risk analysis

Notification Process (1)

Member State, Turkey notifies

Commission opens 3 month standstill period

Comments

MS, Turkey +
Com.

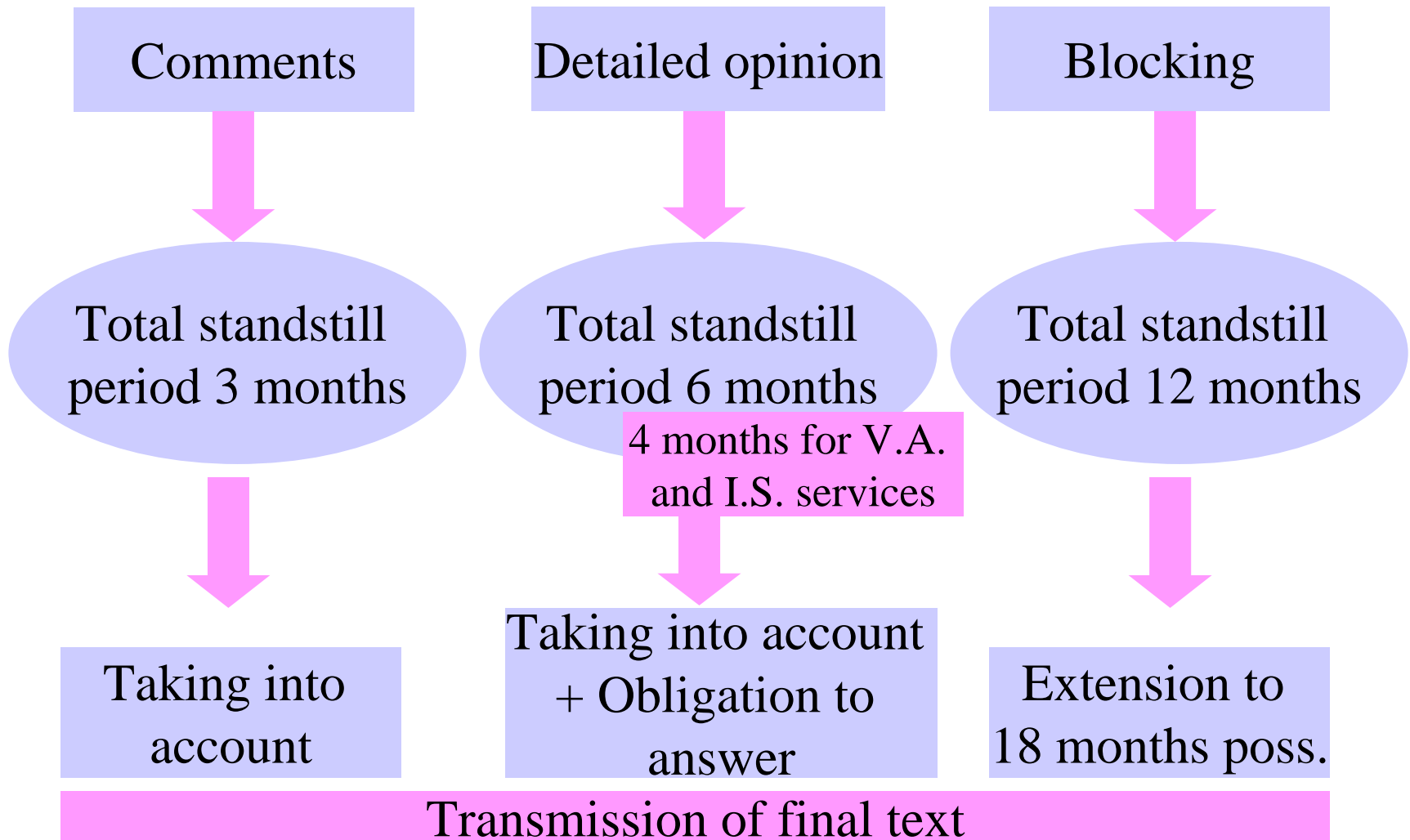
Detailed opinion

MS + Com.

Blocking

only Com.

Notification Process (2)



Simplified Procedure

Standstill period:
max. 3 months

only 'comments' can
be made

they should be taken
into account

Transmission of final text

Need for a New Notification

Amendments necessitating re-notification:

- significantly altering its scope
- shortening the timetable for implementation
- adding specifications or requirements
- making specifications or requirements more restrictive

(no new notification required when amendments take account of a detailed opinion or comments)

Request for Urgency (1)

Article 9.7

The original 3 months standstill period does not apply if a Member State invokes serious and unforeseeable circumstances relating to:

- protection of public health or safety, protection of animals and plants
- for rules on services, also to public policy, notably the protection of minors

Request for Urgency (2)

| | Requests | Accepted | Refused | Closed |
|------|----------|----------|---------|---|
| 2005 | 30 | 12 | 7 | 4 closed und 7 under special procedure (avian flu) |
| 2006 | 19 | 4 | 15 | 0 |
| 2007 | 6 | 1 | 2 | 1 |

Exceptions

- Main exceptions to notification (Art.10):
 - complying with binding Community (EC) acts;
 - fulfilment of obligations under an international agreement;
 - implementation of an ECJ judgment;
 - amendment of a technical regulation in accordance with a Commission request;
 - making use of safeguard clauses; and
 - technical specifications linked to national social security systems.

« One Stop Shop »

General Notification Procedure

Specific Notification Procedure

Directive 98/34/EC



- Directive 2000/13/EC: labelling of foodstuffs
- Regulations (EC) 852-854/ 2004: hygiene of foodstuffs
- Regulation (EEC) 315/93 : contaminants in food
- Art. 33 Euratom Treaty
- Directive 1999/5/EC: R&TTE
- Directive 94/62/EC: packaging and packaging waste

Member State : clear indication of the specific Community act in notification message (item 7)

Commission : comprehensive examination of the draft according to general and specific procedures

Absence of Notification (1)

Cases on procedure:

- CIA Security (C-194/94)

- Inapplicability of non-notified technical regulations

- Unilever (C-443/98)

- Inapplicability of texts for which standstill period has not been respected

Absence of Notification (2)

Cases on the Directive's scope of application

- Unilever (C-443/98) and Canal Satélite Digital (C-390/99)
 - Narrow interpretation of « harmonised » area
- Lemmens (C-226/97)
 - Rules falling under criminal law need to be notified if they contain technical regulations

Results of the Procedure (1)

| | Total | Detailed opinions | Comments |
|----------------------------|-------|---------------------|-----------------------|
| 2005 | 739 | 77 (COM) 45 (MS) | 263 (COM) 227 (MS) |
| 2006 | 668 | 60 (COM) 52 (MS) | 154 (COM) 172 (MS) |
| 2007 (until 22/05/2007) | 279 | 9 (COM) 4 (MS) | 15 (COM) 25 (MS) |

Results of the Procedure (2)

Some statistics for 2006 :

- 668 notifications made by Member States
- 36 notifications made by EFTA
- 19 notifications made by Turkey

Main sectors:

- Foodstuffs, Agricultural products (112)
- Building and construction (105)
- Mechanics (89), Telecommunications (88)

| | | |
|-------------------|----------|---------|
| Detailed opinions | 60 (COM) | 52 (MS) |
|-------------------|----------|---------|

| | | |
|----------|-----------|----------|
| Comments | 183 (COM) | 207 (MS) |
|----------|-----------|----------|

Turkey's Notifications

| Year | Total | Comments received by TR | Comments issued by TR |
|----------------------------|--------------|------------------------------------|----------------------------------|
| 2004 | 3 | 3 EC | 0 |
| 2005 | 0 | 0 | 0 |
| 2006 | 19 | 15 EC | 0 |
| 2007 (until 22/05/2007) | 0 | 0 | 0 |



Useful links and contacts

Commission Internet site:

<http://ec.europa.eu/enterprise/tris>

Commission email:

Dir83-189-central@ec.europa.eu



The TBT Notification Procedure

1. Objectives of the TBT Procedure
2. Scope of Application
3. Procedure: three cases
4. Links with the 98/34 Procedure
5. Statistics
6. Internet Site

Objectives of the TBT Procedure

- **Transparency**
 - To inform WTO Members
- **Dialogue**
 - To avoid obstacles to trade
- **Harmonization**
 - To encourage compliance with international standards



Scope of Application

- Technical regulations
- Conformity assessment procedures

Conditions for the notification:

- Absence of relevant international standards /guides or non conformity with such standards/ guides
- Significant effect on trade



Procedure

- Community texts
- Member States' texts
 - Member States directly notify to the WTO
 - The Commission, on behalf of the European Communities, answers 3rd country comments
- Third country texts

Commission prepares comments on 3rd country notifications; input from Member States and enterprises

Links with Directive 98/34/EC

Point 16 of notification message 001

- Member States should indicate whether the notified draft will be notified under the TBT Agreement
- In case of a negative answer, Member States should give the reasons for not notifying:
 - The draft is neither a technical regulation nor a conformity assessment procedure as defined in annex 1 of the TBT Agreement
 - The draft is in accordance with an international standard or guide
 - The draft does not have a significant impact on trade

Statistics

| | Total | Third Countries | European Communities | Turkey | Reactions of EC to 3 rd country notifications |
|----------------------|-------|-----------------|----------------------|--------|--|
| 2005 | 770 | 576 | 22 | 0 | 61 |
| 2006 | 874 | 754 | 41 | 0 | 53 |
| 2007 (22/05/2007) | 356 | 304 | 15 | 0 | 35 |



Useful links and contacts

Commission Internet site:

<http://ec.europa.eu/enterprise/tbt/>

Commission e-mail:

ec-tbt@ec.europa.eu

WTO Internet site:

www.wto.org