

ADDITIONAL QUESTIONS FOR TURKEY

GENERAL PRINCIPLES

Free Movement of Goods in the Non-Harmonised Area

How does Turkey intend to ensure the free circulation of products with *all* Member States?

Turkey is in a Customs Union with the EC, the application of which has been extended to the ten new members by a Decree dated 2 October 2004. Subsequently, products circulate freely with all EU members. Indeed, latest foreign trade figures confirm that Turkey has trade relations with all EU members within the framework of the Turkey-EC Customs Union.

Furthermore, according to Article 11 of the Decree on Technical Regulations and Standardization for Foreign Trade issued by the Council of Ministers and published in the Official Gazette on 13 October 2005, the importation of the products covered by the Customs Union cannot be restricted or impeded provided that these products are lawfully produced and/or put into free circulation in member countries of the EU in conformity with the relevant harmonised EU legislation and/or individual country legislation.

HORIZONTAL MEASURES

Standardisation

The Commission, in its Communication of 18 October 2004 has underlined the role of European standardisation in the framework of European policies and legislation and has formulated recommendations with a view to the improvement of the European system. The Council, in its Resolution on standardisation of 1999 and its recent Conclusions from 21 December 2004, has confirmed the co-responsibility of the European Union and the Member States for the viability of the European standardisation system, including in particular its efficiency, effectiveness, financial viability and the inclusion of all stakeholders.

Questions:

1) Given the wide impact of standardisation on society and economy in Europe, will you provide an outline of your government's policies and measures undertaken/envisaged to ensure a stable and sustainable legal, political and financial framework by which your national standards body (or bodies) can contribute to the European standardisation system and process?

TSE, as the national standards body, already takes part in the European standards development system as an affiliate member. In this context experts of TSE are regularly participating and contributing in working groups of European Standardization Organizations (CEN/CENELEC).

2) Given that the acceptability and relevance of standards depends on the involvement of all interested parties in the standardisation process, will you describe your government's policy and measures (including human and financial resources made available p.a.) to ensure the inclusion of all stakeholders in the standardisation process (in particular those representing SMEs, consumers, workers, environmental aspects, authorities)?

All stakeholders are included in the standardization process. Additionally, in December 2004, TSE has established 117 mirror committees in order to give the opportunity to the all stakeholder groups like SME's, companies, associations, universities, chambers of commerce, Ministries, etc. to take part in the national, regional and international standards development process.

3) Will you describe policies implemented in your country to support the access to European standards issued by CEN, CENELEC and ETSI (e.g. transposition of standards, publication of hits of harmonised standards).

TSE, as the national standards body, undertakes the duty of adopting European Standards as Turkish standards and currently more than 88 % of the European standards were published as Turkish standards.

PROCEDURAL MEASURES

Directive 98/34 Notification procedures

Why the number of notifications currently received by the European Commission is so small?

Turkey has needed certain supportive activities, such as training of the public authorities on the principles of the non-harmonised area, raising awareness about the notification responsibilities, establishing a stable network within the competent public authorities as well as between these bodies and the central unit.

Turkey has begun to receive the positive results of these supportive activities quite recently. In this manner, the efforts towards better implementation are accelerating, which also include plans for introducing certain means to direct all draft technical legislation to the Central Unit before its publication process.

On the other hand, certain “corrective actions” are on the agenda of Turkey, such as:

- Introducing a screening process of the existing national technical regulations (NTRs),
- Preparing a list of NTRs published from 2002 (the date of Turkey’s inclusion in the system) until today, which require revision and in this respect, providing relevant measures to be taken.

NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION

Safety of toys :

- Is market surveillance in place in this sector?

The first phase of the market surveillance has focused on whether the products are affixed CE marking. Accordingly, 68 types of toys with no CE marking were detected in 2006. The analysis of these products are going on within the context of the provisions of "Regulation on Toys" and "Law No: 4703" and the implementation regulations of the mentioned law.

Manufacturers/importers have voluntarily accepted to recall their products and to put these products on market after the conformity is provided.

As the second phase of market surveillance, the warnings and signs, which should be on the labels of the toys for the children under 36 months, will be evaluated. Additionally, the complaints in this regard are also taken into consideration.

The procedures of CE marking and other necessary information for manufacturers/importers are given in the “Frequently Asked Questions” section of the MoH web site.

“Consumer’s Guide” including the recommendations concerning toys, accident risks of toys and

other necessary information for consumers is available via the MoH web site.

The inspectors in İstanbul, Ankara, İzmir, Urfa and Adana provinces, in which the customs entrance is intense, are trained on market surveillance. It is planned to train the inspectors in the provinces of Interior Anatolian region in the first quarter of 2006. Other trainings will continue on a regional base.

Textiles:

- Concerning the labelling requirements, is size, care and/or origin labelling mandatory in Turkey? If yes, we need more details on the legislation and on what grounds such labelling is stipulated mandatorily.

As of 1 January 2002, mandatory enforcement of Turkish Standards numbered “TS 10059 EN 23758 - Textiles – Care labelling code using symbols” and “TS 1418 Labelling of Textile Products – Fibre Composition” which fall under the scope of Regulation Textile Names were repealed in accordance with the Communiqué published in the Official Gazette No. 24621, dated 25.12.2001. In this regard, care labelling of textile products is voluntary.

The mandatory enforcement of 12 Turkish Standards (TS 260, TS 262, TS 263, TS 265, TS 606, TS 2792, TS 7777, TS 11846, TS 12829, TS 12848, TS 2793, TS 13043), which fall under the scope of two Regulations corresponding 96/73/EC and 73/44/EC, will be repealed in the short term.

Concerning the origin labelling; pursuant to Article 12 of the “Law on Consumer Protection” (Law No. 4077) and Article 5 of the “Regulation on Labels and Price Lists”, it is mandatory to use a phrase indicating “the name of the country” in which the product was produced or the phrases “import”, “imported product” or “foreign” for the labels of imported products. In the event that such a phrase is not present on the label or phrases like “domestic”, “domestic goods”, “Made in Turkey” shall indicate that the goods were produced domestically.

- Concerning US x EU fibre names, which system of naming fibres Turkey uses now?

Turkey uses EU system of fibre names.

Council Directive 76/768/EEC on cosmetic products compared to Law and regulation on Cosmetics

Animal Testing

Commission services acknowledge that it is foreseen in article 7 of the Regulation that particulars related with the animal testing shall be drawn up in a communiqué to be published by the Ministry.

When this communiqué will be available?

Commission services would like to underline that article 12 (h) of the Regulation will then have to be adapted accordingly.

The Communiqué about the animal testing will be available following the completion of the transposition of the Directives 67/548 EEC, 99/45 EC, 91/155 EEC, 93/67 EEC by the MoEF,

Regulation of Ingredients

Commission services would like to know why the Turkish authorities mention in article 9 of the Regulation that *“annexes of this Regulation shall be updated in light of scientific and technological developments”*? Do the Turkish authorities intend to have their own scientific committee?

In article 7c of the Regulation the mention *“other than those”* is missing. The article should read as follow *“c) coloring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing coloring agents intended solely to color hair”*. [underlined added]

There is no scientific committee under Turkish cosmetic legislation for the time being and there is no intention to have one. Regarding the remark on Article 9 specified by the European Commission, it should be mentioned that the Turkish text is in conformity with the related provision of the original EU legislation.

On the other hand, differences between the original Directive and the English version of the corresponding Turkish legislation stem from translation errors.

Labelling

In article 10(a) of the Regulation it is mention that *“[...] the country of origin of imported products shall be specified”*. What do Turkish authorities mean by the word ‘imported’: from third countries than EU or from third countries than Turkey? According to EU Directive, this mention may be required only when the product is from a third country than EU.

In article 10(g) of the Regulation It is mentioned that *“[...] the list shall be preceded by the word ‘ingredients’ or its equivalent in meaning in Turkish or in any other language”*.

However article 6.1(g) of the Regulation mentioned that that the list shall be preceded by the word ‘ingredients’ and no other possibilities are foreseen by the Directive. Therefore the options proposed by the Turkish regulations are not possible.

Turkey is not able to receive information on notifications made in the EU at this moment. Under these circumstances, in order to establish a database for an effective and functioning market surveillance system, Turkey needs as much information as possible.

There is no contradiction between European Commission’s position and Turkey. By this approach Turkey aims at making it easier for operators by giving the possibility to use either ‘ingredients’ or equivalent words both in Turkish and/or in a languages of the Member States.

Notification

Articles 3 of the Law and 14 of the Regulation provide the notification obligation.

However, Commission services would like to draw the attention of Turkish authorities to article 7a.4 of the Cosmetics Directive: *“the manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market”*.

Therefore the notification should occur in Turkey when the product is manufactured in Turkey or when it is marketed for the 1st time in EU on the Turkish market.

However, articles 3 of the Law and 14 of the Regulation seem to ask for notification of any product which is marketed in the Turkish market (even if it was already marketed in one of the EU Member State).

In articles 14 and 15 of the Regulation a reference is made to Annexes IX and X. Those annexes have not been communicated to the Commission.

Turkey needs to establish a recording mechanism in order to operate an effective market surveillance system. For this reason, the notification requirement is stressed by the legislation.

Characteristics of cosmetic products

Articles 4d of the Law and 6 of the Regulation provide that the product should not cause damage to health. One part of the correspondent article 2 of the Cosmetics Directive is missing “under normal and reasonable foreseeable conditions” [underlined added]

Differences between the original Directive and the English version of the corresponding Turkish legislation stem from translation errors. In fact, the matter specified by the European Commission is in conformity with the original EU legislation.

Market Surveillance

The functioning of the Cosmetics Directive relies on market surveillance. How many inspectorates will be in charge of this surveillance? Are they going to deal with other sectors than cosmetic? Which ones?

Market surveillance system is carried out by the MoH and Local Health Authorities affiliated with the Ministry in cooperation.

Beside the cosmetics sector, they perform market surveillance on medical products for human use, detergents, medical devices, drug precursors, and toys.

GMP

In the Regulation, there is a reference to GMP guidelines. Would it be possible to have this text? As no Good Manufacturing Practices were adopted at EU level, as foreseen in the Cosmetics Directive in article 7a.1 (c) of the Cosmetics Directive, they can be laid down at National level. However, Commission services would like to inform Turkish authorities that a mandate has been sent to the CEN (Centre Européen de Normalisation) in order to take over the ISO standard on GMP in cosmetic sector which is currently in the process of being adopted.

Turkey adopted the GMP Guideline at the National level and it is in force. This document is available only in Turkish.

For texts of Annexes IX and X and for the GMP guidelines (in Turkish), please see Annex V.

Cableway installations

Directive 2000/9/EC relating to cableway installations designed to carry persons

For each of the following points, please describe the current status and the foreseen evolution with a precise timetable if possible.

▪ **Cableway installations and manufacturers**

- ✓ **How many and what type of installations among those covered by Directive 2000/9/EC does Turkey have? Please describe.**

The cableway installations used for tourist purposes and in ski centres as well as the projects for construction of new cableway installations in Turkey are listed below:

a) Cableway Installations, already in operation:

Bursa (Uludağ), Istanbul (Maçka, Piére Lotie Taksim: Funicular system), Çankırı (Ilgaz), Izmir (Balçova), Antalya (Tahtalı), Gümüşhane (Süleymaniye), Kayseri (Erciyes), Erzurum (Palandöken), Kars (Sarıkamış), Antalya (Saklıkent), Isparta (Davraz), Samsun (Baruthane), Bitlis (Center), Bingöl (Yolçatı), Bayburt (Kapdağ), Bolu (Kartalkaya)

b) Cableway installations, construction projects:

Aksaray (Ihlara), Adıyaman (Nemrut), Ordu (Boztepe), Eskişehir, Trabzon (Maçka), Yozgat (Karaburun-Akdağ), Ankara (Keçiören), Tunceli (Ovacık), Bolu (Gerede), İzmir (Bozdağ), Rize (Ayder), Erzincan (Ergan), Antalya (Akseki), Antalya (Kemer), Antalya (Saklıkent), Denizli (Tavas- Buzdağı), Bitlis (Tatvan), Artvin (Sacinka), İçel (Anamur), Sivas (Yıldızeli), Adana (Bozantı), Ordu (Çambaşı), Giresun (Kumkent), Van (Gevaş).

- ✓ **Does Turkey have (or plans to have) manufacturers of cableway installations and/or their components?**

According to the available data, there is no cableway installation or safety component manufacturer in Turkey. An inventory survey will be carried out to determine the manufacturers.

▪ **Harmonisation of law relating to cableway installations including technical regulations**

- ✓ **Turkey has transposed Directive 2000/9/EC into Turkish legislation:**

- Date of Official Gazette 19.01.2005
- Number of Official Gazette: 25705
- Date of entry into force: 19.07.2005 (mandatory enforcement 19.07.2009)

If possible, please provide with a copy of the Turkish regulation in English.

The draft text of the Regulation has been sent to the Commission for opinion in February 2006.

- ✓ **Please provide updated information regarding the:**

- **present status**
- **forecast (implementation plans during the transitional phase -from 19.07.2005 to 19.07.2009- with detailed timetables if possible).**

A detailed industrial inventory survey is currently in progress. During the transitional period, the Communiqué on basic Criteria for Notified Bodies will be published in 2006, and the manufacturers and the operators of cableway installations will be informed of the Regulation. Furthermore, a Technical Subcommittee on Cableway Installations will be established under the Technical Committee on Lifts. The potential conformity assessment bodies will also be determined during the transition period.

Standards, testing, certification, conformity assessment, accreditation and market surveillance

- ✓ Please provide information on the relevant regimes for the products covered by Directive 2000/9/EC relating to cableway installations
 - short description and
 - further evolution

▪ Notified bodies

- ✓ Does Turkey have any relevant bodies which could be designated as notified bodies under Directive 2000/9?
- ✓ If yes,
 - Do those bodies comply with the minimum criteria contained in Annex VIII of Directive 2000/9?
 - Do those bodies have enough knowledge to apply all conformity assessment procedures described in Annex V and VII of Directive 2000/9/EC? If not, which of those conformity assessment procedures would they be able to apply?

The potential notified bodies will be determined during the inventory survey for conformity assessment bodies to be carried out during the transitional period.

▪ Standardisation

All of the 24 harmonised European standards under 2000/9/EC have been transposed by TSE.

Transposed EN standards

| | | |
|----|--------------|----------------|
| 1 | EN 1709 | TS EN 1709 |
| 2 | EN 1908 | TS EN1908 |
| 3 | EN 1909 | TS EN1909 |
| 4 | EN 12385-8 | TS EN12385-8 |
| 5 | EN 12385-9 | TS EN12385-9 |
| 6 | EN 12397 | TS EN12397 |
| 7 | EN 12927-1 | TS EN12927-1 |
| 8 | EN 12927-2 | TS EN 12927-2 |
| 9 | EN 12927-3 | TS EN 12927-3 |
| 10 | EN 12927-4 | TS EN12927-4 |
| 11 | EN 12927-5 | TS EN12927-5 |
| 12 | EN 12927-6 | TS EN12927-5 |
| 13 | EN 12927-7 | TS EN12927-7 |
| 14 | EN 12927-8 | TS EN 12927-8 |
| 15 | EN 12929-1 | TS EN12929-1 |
| 16 | EN 12929-2 | TS EN12929-1 |
| 17 | EN 12930 | TS EN 12930 |
| 18 | EN 13107 | TS EN13107 |
| 19 | EN 13223 | TS EN13223 |
| 20 | EN 13243 | TS EN13243 |
| 21 | EN 13243 /AC | TS EN13243 /AC |
| 22 | EN 13796 -1 | TS EN13796 -1 |
| 23 | EN 13796 -2 | TS EN13796 -2 |
| 24 | EN 13796 -3 | TS EN13796 -3 |

- **Is the National Standards Institute able to implement the harmonised standards in support of Directive 2000/9/EC**

All harmonized EN standards have been adopted by TSE as national standards. The Turkish versions of all EN standards which are referred to in the Directive will be published during the transition period.

- **Are staff numbers and financing adequate to participate in standardisation activities related to cableways directive?**

Yes. In terms of the standardization activities at the international level, TSE is already an affiliated member of CEN and CENELEC, and an application will be made for full membership upon completion of the MEDA Project aimed at reorganising and upgrading the standardisation infrastructure.

▪ **Market surveillance**

- ✓ **Pl. provide the name, function and contact details of the authority responsible for market surveillance for Directive 2000/9 in Turkey.**

Ministry of Industry and Trade
 DG for Industry
 Ankara / TURKEY

- ✓ **How would Turkey ensure that safety components and subsystems of cableway installations placed on the market continue to meet essential requirements of Directive 2000/9/EC?**

This will be ensured by trained market surveillance staff employed in 81 provincial offices.

- ✓ **Do the relevant ministries have sufficient numbers of adequately trained staff to master the technicalities of such a specific directive and to ensure adequate co-ordination?**

Currently, the personnel both in the headquarters and provincial offices, especially in the regions where tourist and ski centres are located need special training regarding technicalities and market surveillance issues under 2000/9/EC.

- ✓ **Does the Turkish system resemble the EU system? Are there plans to develop the Turkish system towards the EU system? e.g.:**

- to designate authorities competent to monitor the conformity of safety components and subsystems of cableway installations with the directive and arrange for such authorities to have the necessary powers to take the measures incumbent upon them i.e. to carry out their duties with the speed required, in cases where the non-conformity of a component product poses a risk; to ensure the follow-up of complaints or reports concerning non-compliant components, monitor accidents and damage to health involving components of cableway installations etc..
- to define the organisation of the national market surveillance system and the tasks of the competent authorities.
- to organise an effective communication and co-ordination between their market surveillance authorities and the other organisations which intervene in the field of safety of products.

Please describe any important recent developments.

The MIT is responsible for carrying out market surveillance for the installations, subsystems and safety components not put into service yet. The market surveillance envisaged under the Directive No. 2000/9/EC will be carried out by 81 Provincial Offices of the Ministry under the coordination of the Lifts and Cableway Installations Division of DG for Industry. 600 personnel employed in 81 provincial offices carry out market surveillance of all products falling under Regulations, which the MIT is responsible for implementation, including Regulation on Cableway Installations.

Currently, there is no authority to monitor the conformity of safety components and subsystems, to take action in case the nonconformity of a component poses a risk, and to follow-up of complaints or reports on nonconformities. However, preparation of legislation on operation and maintenance of existing installations is considered. By this way it can be possible to organise an administrative mechanism based on cooperation between the provincial offices and local administrations.

APPENDIX A

| Identity of Chemicals (Categories) | Industrial Chemicals | Pharmaceuticals | Veterinary Medical Products | Pesticides | Food Additives | Feed Additives | Cosmetics | Biocides | Other Products (specify) |
|--|-----------------------------|------------------------|------------------------------------|-------------------|-----------------------|-----------------------|------------------|-----------------|---------------------------------|
| physical-chemical testing | | | | | | | | | |
| toxicity studies | | | | | | | | | |
| mutagenicity studies | | | | | | | | | |
| Environmental toxicity studies on aquatic and terrestrial organisms | | | | | | | | | |

| | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|
| studies on behaviour in water, soil and air; bioaccumulation | | | | | | | | | |
| residue studies | | | | | | | | | |
| studies on effects on mesocosms and natural ecosystems | | | | | | | | | |
| analytical and clinical chemistry testing | | | | | | | | | |
| other studies, specify | | | | | | | | | |

- + **GLP required by legislation**
- **GLP not required by legislation**
- N/C **Not covered by programme**