NON-EXHAUSTIVE LIST OF ISSUES AND QUESTIONS TO FACILITATE PREPARATIONS FOR BILATERAL SCREENING MEETINGS WITH CROATIA AND TURKEY IN THE AREA OF:

Chapter 1: FREE MOVEMENT OF GOODS

GENERAL ASPECTS

I. GENERAL PRINCIPLES

Free Movement of Goods in the Non-Harmonised Area

1. Do measures exist in the laws, regulations or administrative provisions adopted at national or local level on the production, distribution and marketing of industrial products:

a. relating to the price of such products (e.g. fixing the prices above or below which the importation or marketing of a product is prohibited or restricted, laying down profit margins or the other price components, etc)?

As a general rule, the prices are determined under the free market conditions. Yet, for a limited number of products, special pricing mechanisms are in place.

Pricing on alcoholic beverages:

According to Article 1 of Law No.4250 on Alcohol and Alcoholic Beverages, authorization of pricing of the products except beer and wine in production, and except whiskey and natural sparkling wine in importation belongs to the Tobacco, Tobacco Products, and Alcoholic Beverages Market Regulatory Authority (Tobacco and Alcohol Authority).

Except beer and wine, on the condition that the alcoholic beverages producers that fulfil the production requirement by setting up the facility with at least one million litres (it is reduced to 600.000 litres in 2006) annual production capacity and receive production permit, in one calendar year do not reach the production quantity stated at the No. 4250 Law, the pricing and distribution authorization passes to the Authority. The retail sale price of each of the products in terms of brand and package whose pricing authorization is held by the Authority are determined.

Except whiskey and natural sparkling wine, the firms that reach the quantity that is stated at the No.4250 Law (for 2006, 600.000 litres) are able to freely price and distribute the alcohol and alcoholic beverages that they have imported within the concerned calendar year and the year following the year in concern.

The retail prices offered by firms in the form of tables are sent to the Authority. The evaluation is made by taking into consideration the portfolio data that is concerned with the subject and market conditions. From the prices that are determined, the firms, on the condition that they have literally notified to the Authority, may increase or decrease the price within the 10% limit. Concerning the changes beyond this proportion, firms re-arrange the selling price tables and notify to the Authority with the reasons of the change. Until today, all price offers that are received as firm offers are welcomed in the same manner.

Pricing for pharmaceuticals:

Pricing of medicinal products for human use is carried out according to the "Decree on the Pricing of Medicinal Products for Human Use", which was published in the Official Gazette No. 25373, dated 14.2.2004 and entered into force on the same day. This Decree establishes a reference pricing system. On the other hand, categorisation of profit margins for retail pharmacies and wholesalers are laid down in relevant Communiqué of 3 March 2004, which was published in Official Gazette No. 25391 (as amended by Communiqué of 22 April 2004 published in Official Gazette No. 25441). Sale of human medicinal products whose prices are above the stated retail prices is not allowed.

b. which require import licences or permits for imported goods (e.g. licence for import of automobiles)?

As a general rule, import licenses or permits are not required for imported goods. Yet, public authorities have the power to regulate and monitor the imports of certain goods on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants or the protection of industrial and commercial property.

I. Import licenses or permits required under the Import Regime Decree and Communiqués are as follows. Further explanation and product coverage of the Communiqués are provided in Annex I.

Import Communiqué	Product coverage	Rationale	Competent Authority
2006-2	War Weapons and parts thereof	Public security	Military and Security authorities
2006-3	Radioactive substances and apparatus using such substances	Public security / Public health	Turkish Atomic Energy Authority
2006-4	Certain communication apparatus	Public security	Telecommunications Authority
2006-5	Maps and similar documents	Public security/ Public policy	Turkish Naval Forces for imports of sea maps; Ministry of National Defence, General Command of Mapping
2006-6	Products which can only be imported with a guarantee certificate	Consumer Protection	Ministry of Industry and Trade
2006-7	Motor vehicles	Public security / Road safety	Ministry of Industry and Trade
2006-8	Products used in civil air crafts	Public security	General Directorate of Civil Aviation
Import	**Product coverage**	**Rationale**	**Competent Authority**

Communiqué			
2006-10	Banknotes and similar commercial papers	Public Security	Undersecretariat of Foreign Trade Board of Capital Market
2006-11	Some explosive substances, fire guns, knives and similar articles	Public Security	Ministry of Interior
2006-12	Solvents and certain petroleum products	Public policy, consumer protection	Energy Market Regulatory Authority
2006-13	Products which affect workers' health and work security	Public Security	Ministry of Labour and Social Security
2006-14	Ozone depleting substances	Vienna Convention for the Protection of the Ozone Layer and The Montreal Protocol on Substances That Deplete the Ozone Layer	Undersecretariat of Foreign Trade
2005-16	Fertilisers	Public policy	Ministry of Agriculture and Rural Affairs
2006-17	Substances listed in the annexes to the Convention on the Control of Chemical Weapons	"Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction" (CCW)	Undersecretariat of Foreign Trade
2006-22	Endangered Species of Wild Fauna and Flora.	"Convention on the International Trade of Endangered Species of Wild Fauna and Flora.	Ministry of Agriculture and Rural Affairs Ministry of Environment and Forestry
Import Regime Decree (Art.7)	Old, used, renovated, faulty (defective) goods	Public Policy	Undersecretariat of Foreign Trade

II. Under the Technical Regulations and Standardization Regime, the following certificates/permits are required at the importation stage.

For certain products, a control certificate is required. The relevant Ministries perform a documentary control prior to the import stage and issue a control certificate. These certificates are valid for a stated period from 4 to 12 months and for a stated quantity of imported goods. Within the limits of time and quantity the importer may use this control certificate for multiple imports.

Under Communiqué 2006/1, the Turkish Standards Institute (TSE) is designated to carry out conformity assessment for some industrial products at the import stage according to national mandatory standards. This means that the importer has to go to TSE upon his customs declaration. After testing or analysing (if necessary) the samples of products, TSE issues a certificate of conformity if the product complies with the relevant standard. There are exemptions from testing procedures, such as CE-marked products coming from the EU. When goods arrive at the border the custom officers check the presence of the required conformity or control certificates, if due, and release the goods for free circulation into Turkey.

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Communiqué No.	**Products Covered**	**Competent Authority**	**Implementation**
2006/1	Construction products; gasoline and diesel; automotive products; pressure equipments; gas appliances; lifts; batteries; lighters; feeding bottles; ethyl alcohol etc.	Undersecretariat of Foreign Trade Implemented by: TSE	- National standards or their equivalents (ISO, CEN, CENELEC or ETSI) applicable - Products from EU and certified according to EU legislation are exempt from physical checks (CE, "e" etc.) - Certificate of conformity is required
2004/9 and 2004/22	Products under Medical Devices, LVD, EMC, Machinery Directives	Ministry of Industry and Trade Ministry of Health Implemented by: TSE	- Only products coming from outside EU are subject to border controls - Certificate of conformity is required
2006/3, 2006/6 and 2006/7	Waste materials, chemicals, fuels	Ministry of Environment and Forestry	- Partly based on international agreements - Some products are prohibited from import - Control certificate is required

Communiqué No.	Products Covered	Competent Authority	Implementation
2006/4	Narcotic and psychotropic materials regulated with international agreements; Medicinal products (raw, semi-final and final) for human use; medical devices (in-vitro); baby foods; drinking water and relevant products	Ministry of Health	- Partly based on international agreements - Some products are prohibited from import - Control certificate is required
2006/5[1]	Biological products such as serum materials; livestock and veterinary products; phyto-sanitary products; feed products; medicinal products (raw, semi-final and final) for animal use; foodstuffs including spirit drinks; other agricultural and fishery products	Ministry of Agriculture and Rural Affairs	- Control certificate is required
2005/7 [2]	Alcoholic beverages, tobacco and tobacco products	Tobacco and Alcohol Authority	- To ensure market regulation in the sector - Certificate of conformity is required

1 The MARA issues control certificates for foodstuffs. Imports of food additives, aromas and the materials in contact with foodstuffs does not require control certificate. Both of these product groups (whether they require control certificate or not prior to the import stage) are subject to inspection at the customs by the MARA.

[2] In imports of alcoholic beverages, in addition to the Control Certificate issued by MARA, the Tobacco and Alcohol Authority issues "Certificate of Compliance for Import" based on the notification of the companies in order to ensure market regulation,

Communiqué No.	Products Covered	Competent Authority	Implementation
2005/23	Cosmetics	Ministry of Health	- No pre-market access control - Notification of products to be placed on the market for the first time
2005/32	Detergents	Ministry of Health	- No pre-market access control - Notification of products to be placed on the market for the first time
2002/6	Automotive Tyres	Ministry of Industry and Trade	- "e" or "E" marking is required - Guarantee certificate must be endorsed - Certificate of conformity is required

c. which make access to the domestic market conditional upon having a agent or representative in the territory of your country (e.g. legislation which provides for the sale of certain goods in your country subject to authorisation that may be obtained only by a person established in your country)?

There is no arrangement that requires having an agent or representative established in Turkey in order to have access to the domestic market.

Only as regards the pharmaceuticals (for human and animal use) and veterinary biological products, there must be an agent or representative established in Turkey having a distribution agreement with the manufacturer abroad.

d. which oblige to have storage facilities in the territory of your country (e.g. legislation applying only to imported goods which require these imported goods to be stored for some time before being marketed)?

There is no arrangement that requires having storage facilities in Turkey, which applies only to imported goods.

On the other hand, for certain products (imported or domestically produced) like pharmaceuticals or petroleum products, sufficient quantities should be stored for public health and safety purposes within the framework of the relevant legislation.

e. which impose on the marketing of imported products conditions (relating in particular to shape, size, weight, composition, presentation, identification and packaging, labelling) that are different from those imposed on domestic products or which require or encourage the use of certain type of packaging (shape, size, composition) for the marketing of a certain product, whether domestic or imported

(e.g. requirement that some goods may only be sold in a package with special form)?

Marketing conditions are the same for domestic and imported products.

There is a national mandatory standard "TS 4331 on The Marking and Labelling of Packages" which is still in force. However, this standard does not differentiate between domestic and imported products.

For foodstuffs, relevant provisions of the Turkish Food Codex are applied. These provisions also do not make any distinction between the domestic and imported products.

f. which oblige economic operators to label their product with the "Made in …" marking (obligatory origin marking)?

Article 5 of "Regulation Concerning Labels and Price Lists" which was issued on the basis of Article 12 of Law No.4077 on Consumer Protection as amended by Law No. 4822 regulates the origin marking of products. According to this provision, it is mandatory to indicate "the name of the country" in which the product was produced or the phrases "import", "imported product" or "foreign".

Goods are considered as domestic products:

a. in the absence of "the name of the country" in which the product was produced or the phrases "import", "imported product" or "foreign" on the label or,

b. in the presence of "domestic", "domestic good", "Made in Turkey" on the label.

For foodstuffs, it is obligatory to write the name of the origin country on the label of products.

g. which encourage or authorise the purchase (by individuals or public authorities) of domestic products alone or give preference to the purchase of such products in advertising campaigns (e.g. promotion actions with the participation of public authorities applying only to goods produced by producers in your country or from domestic raw materials)?

No.

h. which exclude imported products alone, in full or in part, from the possibility of using domestic facilities or equipment or which reserve the use of such facilities or equipment, in full or in part, for domestic products alone?

No.

i. which subject imported products to controls, other than those inherent in customs clearance procedures, that are not carried out on domestic products (e.g. veterinary, sanitary, phytosanitary and other controls)?

There are no controls carried out on imported goods other than those mentioned in paragraph 1(b).

j. which allow only traders holding a production licence or wholesale licence to import some goods (e.g. licensing system for the production and wholesale of some goods, which allow only the licence holder to import these goods)?

In order to produce alcohol and alcoholic beverages, Production Certificate is required. Producers and importers shall also receive "Distribution Competence Certificate" from the Tobacco and Alcohol Authority. Every producer or importer can place the product on the alcohol and alcoholic beverages market through the distribution channel established by himself. They distribute their products to certificated retailers and certificated public consumption places through the wholesalers having sales certificate issued by the Authority. Wholesalers and retailers are registered through issuing of "Sales Certificate" from the Authority. The aim of all the mentioned certificates issued by the Authority is to register the producer, importer and the products supplied to the market and to monitor the market.

For Veterinary Biological Products, firms are obliged to have operation licences to operate, production permits to manufacture, and sales authorizations to sell veterinary biological products on the market. Pursuant to the Communiqué on the Principles to be adopted in the Importation of Veterinary Biological Products (No. 2002-37), and as indicated in the question, import licences are granted to traders that hold production permits and sales authorizations. In addition to the conditions to be fulfilled by the importer firms that have distribution agreements, manufacturing firms are obliged to hold GMP and GLP certificates, free sales certificates and certificates that guarantee the inspection of the manufacturing firm in the territory of the country in which it is located.

As regards Veterinary Pharmaceuticals, imports of veterinary preparations are realised when a firm holding the authorization of a veterinary preparation imports this product, or transfers this right to another firm.

k. which creates monopolies of sale of some goods (e.g. tobacco products, alcohol products, etc)?

There is no monopoly on sale of the goods other than opium (Turkish Soil Products Office – TMO).

l. which reserve certain trade names for domestic products alone and, if so, on what conditions (e.g. rules which reserve the use of the description "mountain" to products prepared in Your country from domestic raw materials)?

Rakı is a traditional product of Turkey, whose production technique is defined in Law No.4250. The name Rakı is reserved exclusively for the products that are produced in conformity with only this production technique and produced by the usage of fresh and/or dry grapes and aniseed that are produced only in Turkey.

2. Do you have any information – albeit incomplete – which would make it possible to assess the number of times your authorities intervened to prohibit the marketing of products or withdraw products from the market during 2004 and 2005 for any reason whatsoever, e.g. health risk, incomplete labelling, inadequate consumer information, failure to comply with compulsory standards, etc.? Please describe the current status and the foreseen evolution with a precise timetable.

As a result of surveillance activities carried out by the MARA, 1,868 measures in 2004 and 4,268 measures in 2005 were taken. Accordingly, the products found non-compliant with the food legislation were destroyed or withdrawn from the market.

As regards fertilisers, in 2004, throughout the country, 5,439 premises were visited in the scope of production, purchase, storage conditions and product labelling control. During these visits, 1,041 samples were taken and 127 of them were found non-compliant. As a result, 741 tonnes of chemical

fertilisers were withdrawn from the market. In the year of 2005, 4,039 premises were visited and 634 samples were taken out of which 51 was found noncompliant. As a result, 389 tonnes of chemical fertilizers were withdrawn from the market.

For Veterinary Biological Products, in the last two years, 20 interventions took place, which resulted in withdrawal of the products due to the reasons including health risk, incomplete labelling, failure to comply with mandatory standards, and storage under unfit conditions.

In 2004–2005, the Telecommunications Authority performed 1,963 market surveillance activities out of which 109 cases were found to be non-compliant.

According to Regulation on the withdrawal of medicinal products for human use, which was published in Official Gazette No. 19196, dated 15 August 1986, 10 medicinal products (on the basis of active ingredients) were withdrawn from the market due to several reasons such as health risk, mis-labelling, and non-compliance with the product specifications. As a result of examinations carried out in 2005, 16 medicinal products were withdrawn from the market on the grounds of similar reasons.

For cosmetics, during the period of 30 March-31 December 2005, 115 investigations made out of which 79 cases found to be non-compliant (3 of them found unsafe).

3. **What are the general rules applicable in your country to non-food products? For example, is the marketing of products with a label and instructions written in a foreign language allowed? What particulars must be mentioned on the label of any industrial product intended for sale to consumers? Please describe the current status and the foreseen evolution with a precise timetable.**

Pursuant to the Article 14 of Law No.4077 on Consumer Protection as amended by Law No.4822, on the labels and instruction guides of non-food products, it is obligatory to write the information in Turkish. If this information is already given in Turkish, any other language can also be used.

According to first paragraph of Article 5 of "Regulation Concerning Labels and Price Lists", the obligatory information that must be written on the labels of goods is "production place", "distinctive features" and "sale price including all applicable taxes".

Moreover, certain pieces of legislation on products require additional information on labels.

4. **Do Candidate Countries have any information on steps to be taken to ensure that legislation and administrative practices are in accordance with Articles 28-30 of the EC Treaty and relevant case-law of the European Court of Justice? Did you already take any steps of legislative alignment and institution building in this area? If yes, please mention. Does that include among other elements the insertion of mutual recognition clauses in the legislation? What are your plans for the coming years for both legislation and implementation/enforcement capacity? Do you have already elaborated a timetable? Is there a central administrative unit responsible for the prevention and resolution of obstacles to the free movement of goods in the non-harmonised area?**

Articles 5-7 of Turkey-EC Association Council Decision (ACD) No. 1/95 correspond to Articles 28-30 of the EC Treaty. These obligations have been reflected into Turkey's;

- Import Regime,
- Export Regime, and

- Regime on Technical Regulations and Standardizations for Foreign Trade.

For example, according to Article 11 of the Decree on Technical Regulations and Standardization for Foreign Trade, which was published in the Official Gazette No. 25965, dated on 13.10.2005, 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 States of the EU in conformity with the relevant harmonised EU legislation and/or national legislation of Member States.

In addition, Turkey has prepared a draft regulation on mutual recognition in the non-harmonised area, which will provide a framework legal base for the implementation of Articles 5 and 7 of ACD No. 1/95. The draft was sent to the European Commission for its comments. The Commission has given its affirmative views on the draft.

Article 11 of the draft lays down the obligation of competent authorities to insert, whenever it is necessary, the mutual recognition clause, of which an example has been annexed to the draft, into the national technical regulations that they prepare.

Currently, there is no central administrative unit responsible for the prevention and resolution of obstacles to the free movement of goods in the non-harmonised area. However, the Undersecretariat of Foreign Trade (UFT) provides the necessary coordination between the respective institutions to this end.

Indeed, Article 5 of the Decree on Technical Regulations and Standardization for Foreign Trade states that "the coordination, monitoring, transparency and notification of technical regulations, standards, conformity assessment and inspection shall be carried out in accordance with this Decree in a uniform and harmonious way. Any regulation dealing with documents and signs indicating that an import or export product is in conformity with the applicable rules, such as control certificate, conformity certificate, type approval certificate, "CE" marking and "e" marking, shall be notified to the UFT to ensure uniformity in the system of foreign trade……."

Furthermore, the UFT is the central unit for the notifications of the draft technical regulations (in accordance with 98/34/EC, which was transposed into the Turkish internal legal system) and will be the central unit for the notifications of national measures derogating from the principle of free movement of goods as laid down in 3052/95/EC (which will be transposed by the above-mentioned draft). According to Article 7 of the above-mentioned draft, in case a competent authority requires a prior evaluation (as an exception), it will inform the UFT of its action together with the justifications for the necessity and the proportionality of the action.

Finally, representatives of the competent Turkish authorities have attended the seminars organized by the relevant EU institutions (i.e. TAIEX seminars) on the subject of free movement of goods, especially Articles 28-30 of the EC Treaty, and relevant case-law of the European Court of Justice. Furthermore, there have been a number of introductory meetings and seminars in Turkey on the same subject.

II. HORIZONTAL MEASURES

A. <u>Legal basis and administration</u>

1. What is the legal basis and administrative structure for technical regulations, standards, conformity assessment, accreditation, certification, metrology, and market surveillance?

- The main legal basis for technical regulations, conformity assessment, certification and market surveillance is Law No. 4703 on the Preparation and Implementation of Technical Legislation on Products, which was published in the Turkish Official Gazette on 11 July 2001 and entered into force on 11 January 2002. This Law is based on General Product Safety Directive No. 92/59/EEC and general principles identified in the New Approach Guide.

  Four implementing Regulations of Law No. 4703 were prepared and published in the Official Gazette. These Regulations are:

  - Regulation on Market Surveillance, which is based on General Product Safety Directive No. 92/59/EEC and on general principles identified in the New Approach Guide, chapter no. 8 (entered into force on 11 January 2002),
  - Regulation on the Affixing and Use of the CE Conformity Marking on Products, based on Council Resolutions of 7 May 1985 and 13 December 1989; Council Decisions of 21 December 1990 and 22 July 1993 on New Approach and Global Approach; and general principles identified in the New Approach Guide, chapter no. 5 (entered into force on 11 January 2002),
  - Regulation on Conformity Assessment Bodies and Notified Bodies, based on Council Resolutions of 7 May 1985 and 13 December 1989; Council Decisions of 21 December 1990 and 22 July 1993 on New Approach and Global Approach; and general principles identified in the New Approach Guide, chapter no. 6 (entered into force on 11 January 2002),
  - Regulation on the Exchange of Information on Technical Legislation on Goods and Standards between Turkey and the EU, based on Directive 83/189 of the EP and of the European Council laying down a procedure for the provision of information in the field of technical standards and regulations, repealed by 98/34/EC (entered into force on 3 May 2002).

- The main legal basis for standardization is Law No. 132 establishing Turkish Standards Institution (TSE), which was published in Official Gazette on 18 November 1960 and entered into force on 22 November 1960.

- The main legal basis for accreditation is Law No. 4457 on the Organisation and Functions of Turkish Accreditation Council (TÜRKAK), which was published in the Official Gazette and entered into force on 4 November 1999.

- The main legal basis for metrology is Law No. 3516 on Measurement and Metrology that was entered into force in 1989. (For a detailed explanation please see the information given in response to question II.F.)

- Decree of the Council of Ministers No 97/9196 for the Assignment of Public Institutions Responsible for the Preparation of Technical Legislation, published in the Official Gazette No. 22974, dated 29 April 1997.

- Decree on the Regime of Technical Regulations and Standardization for Foreign Trade, which was published in the Official Gazette No. 25965, dated 13 October 2005.

2. How are these functions organised, implemented and co-ordinated?

The institutions responsible for transposing the technical legislation of the EU, which are listed in ACD No. 2/97, were determined by the above-mentioned Decree No. 97/9196 of 29 April 1997. These institutions, such as Ministry of Industry and Trade, Ministry of Health and Ministry of Agriculture and Rural Affairs have been working on the harmonization of the legislation under their responsibility. According to the Decree, the UFT is responsible for the transposition of the horizontal legislation of the EU in the areas of general product safety, general principles of the New Approach, the notification procedures, etc., on the one hand, and for the coordination of the harmonisation of vertical legislation carried out by relevant public authorities, on the other.

In addition to the horizontal Regulation on Conformity Assessment Bodies and Notified Bodies, which was drafted by the UFT, each competent authority may publish its specific procedures for the designation of Notified Bodies for each of the new approach directives.

Following the recommendation of the UFT, different ministries have signed separate protocols with TÜRKAK to make a pre-assessment of candidate notified bodies before the application is forwarded to the UFT which, in turn, notifies the bodies to the European Commission.

A Conformity Assessment Board was set up on 23 September 2003 to form a consultation mechanism on conformity assessment in accordance with the objectives of the "Support to the Quality Infrastructure in Turkey" Project financed by the EU under the MEDA Programme. The main responsibilities of the Board are to discuss conformity assessment issues relevant to the Turkish situation, to set up Working Groups covering, for example, different directives for encouraging a wider range of players with interests in particular sectors to work together. The members of the Board are divided equally between public and private sectors and represent a selection of stakeholders, including government, TÜRKAK, TSE, UME (National Metrology Institute), conformity assessment practitioners, trade and professional associations and academic institutions, economic operators, consumers, and more generally any entity having an interest in conformity assessment. The Board is chaired by the UFT.

A Market Surveillance Coordination Board was established by the Regulation on Market Surveillance in 2002, with the representation of ministries and public authorities. This Board too is chaired by the UFT. The Board decisions are only advisory, but they are normally accepted. At the Board meetings, which are held once in every four months, the problems that the competent authorities face in relation to market surveillance and ways and methods for their solution are discussed. The competent authorities are also supposed to report to the Board their findings and data.

In addition to the horizontal Regulation on Market Surveillance of Products, which was prepared by the UFT, each competent authority may lay down its detailed procedures for its market surveillance activities in a specific legislation.

3. What is the basis for product conformity regulation and to what extent has your legislation moved towards the principles applied in European harmonised legislation, i.e. minimum requirements, absence of mandatory standards, self certification and the presumption of conformity?

All horizontal requirements, rules and procedures are laid down in the above-mentioned Law No 4703 and its four implementing Regulations, which are based on the corresponding EU Acquis and guides as shown in the answer to question II.A.1. The sectoral EU legislation, including New Approach Directives, are being transposed by specific Turkish regulations prepared by competent

public authorities such as Ministry of Industry and Trade and Ministry of Health. All principles applied in harmonised European legislation, i.e. minimum requirements, absence of mandatory standards, self-certification and the presumption of conformity have been, in principle, reflected into corresponding Turkish legislation.

4. Please describe any important recent developments.

- Work on the update of Law No 4703 to reflect "New Product Safety Directive" No. 2001/95/EC repealing 92/59/EEC continues. Turkish authorities have been closely following the process of the revision of the New Approach in the EU. The results of this process will also be taken into account in the revision of Law No 4703 and its implementing Regulations.

- As stated before, Turkey has prepared a draft regulation on mutual recognition in the non-harmonised area. The draft has been finalised and comments of the relevant Turkish authorities and of the European Commission have already been taken on board.

- Turkey is now about to transpose "Council Regulation No.339/93 on Checks for Conformity with the Rules on Product Safety in the Case of Products Imported from Third Countries". A draft legislation transposing the Regulation has been prepared and sent to the Commission for its views.

- An on-line system, namely the Product Safety System (PSS) was initiated in 2005. The system has been designed to facilitate on-line communication between customs, the UFT and market surveillance bodies. For a detailed explanation please see information given in II.G.4.

- MIT became an Associate member of European Cooperation in Legal Metrology (WELMEC) in 2005.

B. Regulation/Administrative capacity

Do the relevant ministries and technical organisations have sufficient numbers of adequately trained staff to master the technicalities of law-making and to ensure adequate co-ordination? Please specify.

Since the beginning of harmonization process of technical legislation in 1997, the relevant Ministries and technical organizations have been deploying all the efforts towards improving their administrative capacity. Accordingly, in the last decade, a great degree of progress has been recorded. For example, most institutions have established specialized units and recruited and trained experts, not only for transposition of the EU legislation but also for effective implementation. In addition, budgetary resources allocated to those activities have been significantly increased.

However, more budgetary resources and qualified personnel are still needed.

C. Standardisation

1. Is the standardisation body able to implement European and international standards? Has the standardisation body made a needs-assessment for investment and technical expertise required to participate in the European standards system?

TSE has sufficient capacity to adopt and implement the European and international standards.

TSE already takes part in the European standards development system as an affiliate member body. Technical experts of TSE regularly participate in and contribute to the working groups of the European Standardization Organizations (CEN/CENELEC).
Furthermore, a needs-assessment for investment and technical expertise is going on under the project on "Supporting the Standardization Infrastructure in Turkey" financed by the EU within the MEDA Programme. In this context, TSE is reorganizing and building up its capacity in line with the time schedule of the project.

2. Are staff numbers and financing adequate?

Yes. Currently 85 staff is working for the TSE Standards Preparation Department.

3. What percentage of national standards are in conformity with the European standards (give separate percentages for CEN, CENELEC and ETSI standards).

CEN : 89 %

CENELEC : 88 %

ETSI : 560 ETSI standards were published as Turkish Standards

4. Please indicate any (work towards) membership of European and international standards organisations (CEN, CENELEC, ETSI, others). Is there a timetable for achievement of full membership of CEN and CENELEC? What is the relationship with the international (IEC and ISO) standards bodies?

TSE is a full member of ISO-International Organization for Standards and IEC International Electrotechnical Commission, since 1955 and 1956, respectively.

TSE is also an affiliate member of CEN-European Standardization Committee and CENELEC-European Electrotechnical Standardization Committee, since 1991.

According to the project mentioned, it is planned to make the formal application of TSE for full membership of CEN and CENELEC at the end of March 2006.

The Telecommunications Authority became a full member of the ETSI as National Standard Organisation (NSO) in 2001. The Authority changed its status to observer (NSO) in 2005. Currently, the Authority is considering upgrading its membership status back to full membership.

D. Accreditation

1. Does your country have an accreditation system and an accreditation body? Is the body independent? Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting certification bodies in line with the European system?

Turkey has an operational accreditation system since 2001 based upon the Law No: 4457. The system is carried out by TÜRKAK, which is an independent body in terms of conducting accreditation activities and taking accreditation decisions.

TÜRKAK is equipped with all the necessary competencies for the purpose of accrediting conformity assessment bodies (CABs) in line with the European System.

2. Does it have agreements with European or other international standardisation organisations?

TÜRKAK has full membership agreement with European Cooperation for Accreditation (EA) and associate membership agreement with International Laboratory Accreditation (ILAC).

Furthermore TÜRKAK is an active member of Interregional Standardization Union (BASB), which includes standardization/accreditation bodies from Euro-Asian, Caucasus and Central Asian countries.

3. Is it a member or working towards membership of any such organisations?

TÜRKAK is working towards joining to Multilateral Agreements of EA. In January 2006 the peer-evaluation conducted by EA peer evaluators was finalized with positive results.

E. Certification / testing / inspection

1. What relevant bodies (and in which product sectors) does your country have in these areas? Have you made an assessment of these as regards laboratory practice, equipment and staff training needs?

Please see Annex II for a non-exhaustive list of Conformity Assessment Bodies established within the Project "Support to Conformity Assessment Bodies Activities, Turkey", financed by the EU under the MEDA Programme.

F. Metrology

1. What is the present metrology structure in your country?

Background

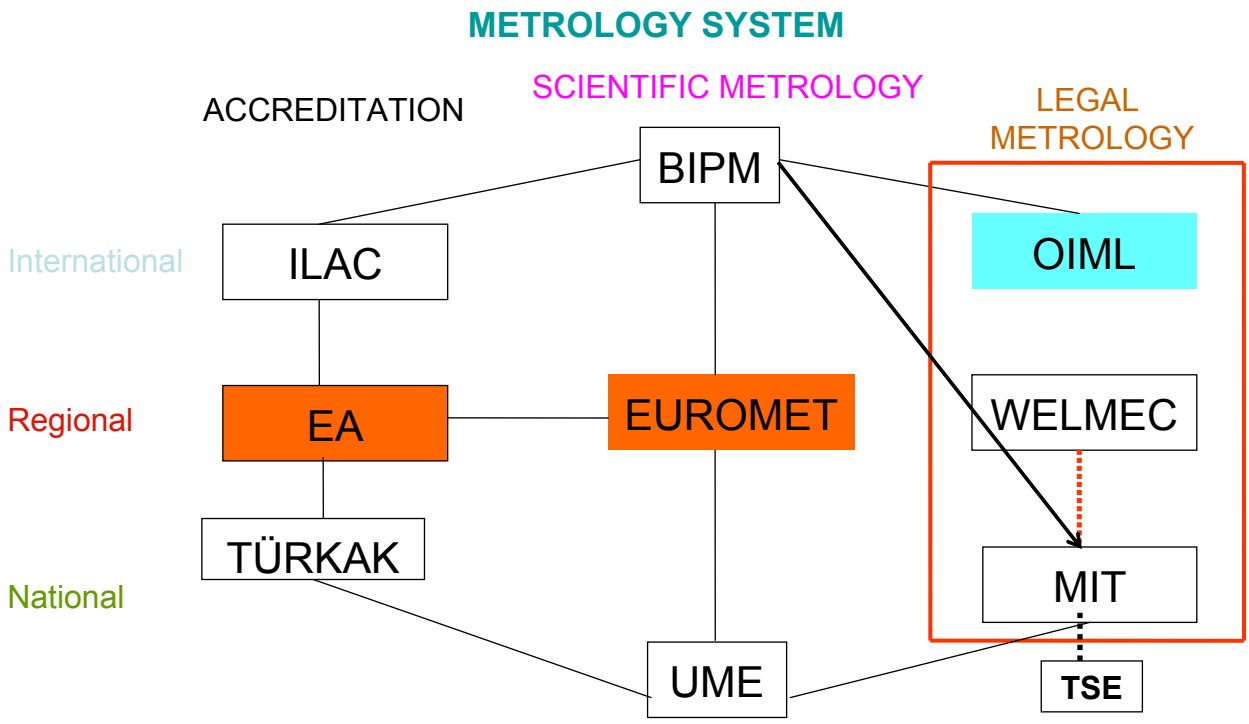
- Turkey accepted SI unit system by putting into force the Law No. 1781 on Weights and Measures on 26 March 1931.
- Law No. 3516 on Measurement and Metrology was put into force in 1989 and Directorate General for Measurement and Standards under the MIT was established.
- National Metrology Institute (UME) was founded in 1992.
- TÜRKAK was established in 1999.
- Law No. 4703 was put into force in 2002.

Present Structure

Scientific Metrology : TÜBİTAK National Metrology Institute (UME)

Legal Metrology : Ministry of Industry and Trade (MIT) – DG for Measurement and Standards

Industrial Metrology : Calibration Laboratories



Scientific Metrology

UME is responsible for scientific metrology. It was established in January 1992. UME is the member of EUROMET, MENAMET, EURACHEM, IMEKO and is active in 21 Technical Committees. It signed Mutual Recognition Agreement (MRA) with BIPM. Its objectives are as follows;

- To ensure traceability of measuring standards.
- To establish and maintain national measurements standards in accordance with the SI Units.
- To establish a national measurement system and provide services to the laboratories within this system in terms of calibration, training, consultancy and other mechanisms.
- To contribute to research and development in the areas of measurement techniques, calibration and basic metrology at the international level.

Legal Metrology

DG for Measurement and Standards of MIT is responsible for legal metrology together with its 81 provincial offices and municipalities.

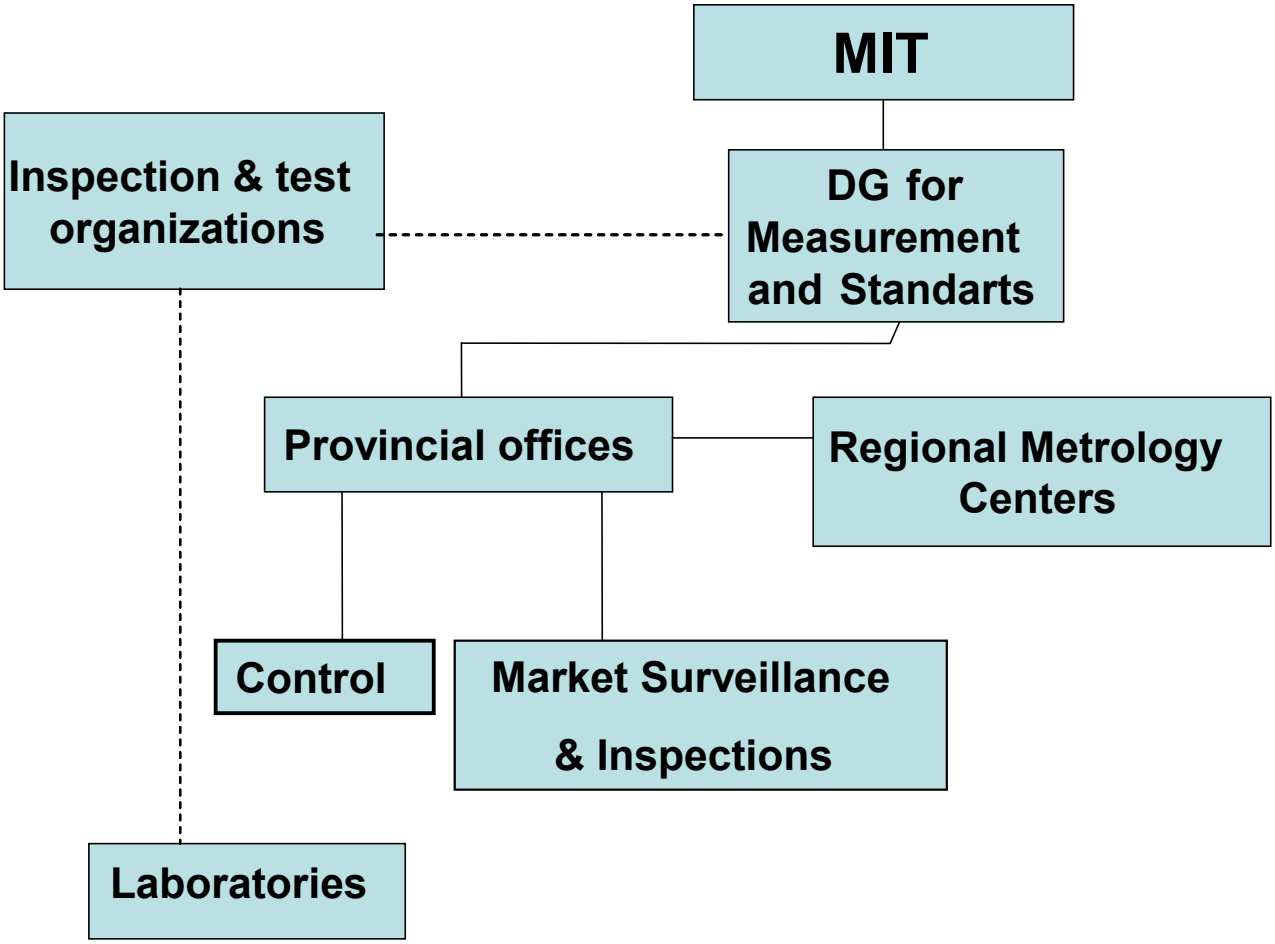
DG for Measurement and Standards was established by Law No 3516 on Metrology and Measurement in 1989. According to Law No. 3516, responsibilities of the MIT are as follows:

- To prepare and issue legislation on legal metrology,

- Inspection, verification, stamping of the measurement and measuring instruments,
- To issue type approval for measurement and measuring instruments,
- To register type approval and brands of the measurement and measuring instruments,
- To keep and control national etalons /or make them kept and controlled,
- To establish laboratories /or make them established,
- To organize training and technical courses,
- Verification of the measurement and measuring instruments.

MIT has currently 7 regional metrology labs equipped to handle the legal metrology related calibration. It has 81 provincial verification offices. In each municipality there is a verification bureau.

For type approval, MIT is the utmost authority. Actual measurements are performed by various laboratories authorized by MIT.



ORGANIZATION OF LEGAL METROLOGY IN TURKEY

Membership of MIT to International Organisations:

- "Bureau International des Poids et Mesures (International Metrology Centre) - BIPM"
  - Turkey has been a full-member since 1875.

- MIT participates to the meetings. (General Assembly)

- " International Organization of Legal Metrology - OIML"

  - Corresponding member in 1961 – 2005
  - Full-member since 2005.
  - MIT participate to the meetings. (General Assembly)

- "European Cooperation in Legal Metrology- WELMEC"

  - Associate member since 2005.

Industrial Metrology

There are 21 calibration laboratories accredited by TÜRKAK in Turkey. These calibration laboratories serve industrial metrology.

2. Is there a national programme for the development of the metrology structure?

Transposition of Measurement Instruments Directive (MID) of the EU is the most important development in the field of legal metrology and it requires the reorganisation of the existing system. Proper implementation of MID and following WELMEC documents will strengthen legal metrology structure in Turkey.

3. How is traceability to international measurements standards ensured?

The measuring and weighing instruments at the Provincial Offices are calibrated once in every two years by regional metrology labs.

Weighing and measuring instruments and ethalons at the provincial offices of MIT are calibrated by UME every two years in order to ensure traceability.

The traceability of the UME is provided by BIPM.

G. Market surveillance

1. How does your country ensure that products on the market throughout the country meet standard requirements? (Alternatively, do you have a reliable and standardised system of pre-marketing authorisation?)

According to Law No. 4703, producers, importers and distributors have to place only safe products on the market and responsible authorities must conduct surveillance activities to ensure that products on the market are in conformity with general safety requirement and specific requirements in vertical regulations such as the New Approach and Old Approach Directives transposed into the national legal order.

The Law leaves the principles of market surveillance to the Regulation on Market Surveillance, which particularly introduces essential tools for the enforcement of product-specific requirements. The surveillance activities are carried out for the products placed on the market and the authorities pay regular visits to the industrial, commercial and storage premises. They make also random and spot checks and, when necessary, visit work places. The information from complaints, accidents

etc. can also be used for investigation purposes. Visual checks as well as documentary checks are carried out during surveillance and, if required, the authorities take samples and test or analyse them.

When the surveillance authorities find that a product does not comply with the relevant requirements, they have to take action in order to establish conformity. Non-conformities are evaluated case-by-case and sanctions, which are laid down in the Law, depend on the level of non-conformity. For example, if non-conformity is substantial and the product is not safe, then the relevant national authority shall withdraw the product in question from the market.

More information on the activities of market surveillance authorities and their infrastructure can be found under sector-specific questions.

2. How is co-ordination ensured between sectors?

The Regulation on Market Surveillance (Article 9) requires close co-ordination and cooperation between market surveillance authorities when a product falls under various technical regulations and the responsibility of several public authorities.

The legislation also lays down provisions on the establishment of a co-ordination board, namely The Market Surveillance Coordination Board. Chaired by the UFT, the Board is composed of representatives from each national market surveillance authority. The Board is a platform where market surveillance authorities coordinate their activities with each other and discuss issues in the field.

The Board holds its meetings 3 times a year. Board's responsibilities include co-ordination among public authorities in order to ensure effective functioning of market surveillance, working out solutions to the problems that they face during the implementation, monitoring the preparation and implementation of technical legislation on products, and taking advisory decisions on relevant issues.

3. How is market surveillance co-ordinated between market surveillance authorities and customs as regards product conformity and safety checks at external borders?

Market surveillance as regards product safety and conformity checks at external borders is regulated under the Decree on Technical Regulations and Standardisation. The aim of the legislation is to ensure that the surveillance complies with international agreements as well as to prevent technical barriers to trade. According to this legislation, the UFT is designated as responsible body for co-ordination of external border controls while providing communication between market surveillance authorities and customs.

4. What information exchange network exists between the various authorities?

Communication between the various authorities in the country has taken place mainly through traditional means such as fax and correspondence. Besides, some Ministries- such as the Ministry of Agriculture and Rural Affairs (for foodstuffs)- have already put in place internal information-exchange networks between their central units and provincial directorates.

On the other hand, Turkey is very well aware of the fact that the exchange of information and close co-ordination between the authorities is indispensable for effective market surveillance. Therefore, a study was initiated in 2005 to develop a software program, namely the Product Safety System (PSS). This internet-based system, which is effective now in some sectors, provides an electronic

environment for the authorities where they can put information from their activities and monitor all these activities throughout the country on-line. It has been designed to facilitate on-line communication between the various authorities (customs, market surveillance bodies, etc.). The system also employs the new instrument of risk analysis method, which requires the evaluation of information from different sources such as the results of surveillance in the domestic market, notifications from different sources, complaints from consumers and users.

III. PROCEDURAL MEASURES

A. Directive 98/34: see country-specific questions

See country specific answers.

B. Return of unlawfully removed cultural objects

1. Do you have legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State?

Turkey attaches great importance to the return of cultural objects unlawfully removed from their territory. Turkey, as the EU, has as a fundamental aim to protect national treasures having artistic, historic or archaeological value and to prevent them from unlawful remove.

Currently, there is no national legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State.

A copy of preliminary draft text transposing the Council Directive No. 93/7/EEC was sent to the European Commission for comments. Technical studies on preparation of draft legislation are continuing regarding the abovementioned Directive and also the Council Regulation No. 3911/92/EEC.

2. What are the legal provisions ensuring the return of cultural goods, before or after their unlawful removal from the territory of your country?

Article 32 of Law No. 2863 on the Protection of Cultural and Natural Heritage, (Official Gazette No.18113, dated 7 July 1983) states that movable cultural property that has to be preserved inside the country cannot be taken out of Turkey.

However, taking into consideration national interest, such property can be temporarily sent outside the country for exhibitions, only on the conditions that after the temporary display period the property should be sent back to country and by establishing the necessary guarantee documents from the host state to protect the property against the probabilities of all kinds of damage, harm, threat or hazard as well as by providing the insurance of the property and by obtaining the favourable decision of a scientific commission to be set up by the Ministry of Culture and Tourism, consisting of the Heads of Department of Archaeology and History of Art at Universities and by receiving the approval of the Cabinet upon the request of Ministry of Culture and Tourism.

These procedures are listed in the “Regulation on the exporting and importing of movable cultural and natural property to be preserved (exhibitions)” (Turkish Official Gazette No. 18314, dated 16 February 1984).

Under this Law, there is no provision ensuring the return of cultural goods after their unlawful removal.

3. If such legislation exists what categories of cultural goods are covered?

There is no national legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State.

On the other hand, in Article 23 of Law No. 2863 movable cultural and natural properties to be conserved are defined as follows:

a. All kinds of cultural and natural properties that belong to geological, prehistoric or historic periods and that have documentary significance in terms of geology, anthropology, prehistory, archaeology and art history reflecting the social, cultural, technical and scientific characteristics and levels of their periods.

   All kinds of animal or plant fossils, human skeletons, flints (sleeks) obsidians, all kinds of bone or metallic tools, encaustic tile, ceramic, similar pots and pans, statues, figures, tablets, cutter, defender and striking weapons, icons, glass objects, ornaments, ring stones, earrings, needles, hooks, seals, bracelets and similar things, masks, diadems, leather, cloth, papyrus, documents written or depicted on parchment or metal, scales, coins, written or stamped slabs, handwritten or gilded books, miniatures, engravings which have artistic value, oil-paint or water colour paintings, relics, medallions, encaustic tile, soil, glass, wood, cloth and similar movable heritage and their pieces.

   The ethnographic cultural properties concerning science, religion and mechanical arts including human made tools and materials reflect social life of their citizens.

   Coins belonging to Ottoman Emperors Abdülmecit, Abdülaziz, Murat V, Abdülhamit II, Mehmet Reşat V and Vahidettin and the coins of the same period can be sold and bought in the country without being subject to registration according to this Legislation.

   Coins that are not in the scope of this Article are subject to the General Decrees of this Legislation.

b. For their significances in our National history, documents and other property with historical value that belong to the National War of Independence and the foundation of the Republic of Turkey and the personal belongings of Mustafa Kemal ATATÜRK, his documents, books, writings and similar movables.

   Studies of modifications of these categories accordance with the Annex of EU Directive 93/7 are continuing.

4. Is there a system of licenses, permits etc. for export or import of cultural goods?

The cultural goods having ethnographical value that cannot be removed from the territory of the country are laid down in Article 4 of "The Regulation on the Movable Cultural Goods Having the Ethnographical Value" (Official Gazette, No. 19803, dated 3 May 1988).

Article 5 of this Regulation states that cultural goods not defined in Article 4 can be removed from the country with the control of the museums affiliated with the Ministry of Culture and Tourism. These goods can be exported after receiving the approval (expert report) of the museums. When

deemed necessary, the Ministry may request the specialists from the museums to make physical checks of these goods at customs.

The imports of the cultural goods are free. However, an inventory list must be submitted to the customs point and a copy of it must be given to the museum affiliated with the Ministry of Culture and Tourism.

The procedures related with the temporary removal for international exhibitions of cultural property defined in Article 23 of Law No. 2863 are specified in the "The Regulation on the exporting and importing of movable Cultural and natural Property to be preserved" (Official Gazette No. 18314, dated 16 February 1984).

5. Which is the central authority, if any, responsible for dealing with the export of cultural goods and ensuring the return of cultural goods?

Ministry of Culture and Tourism, Directorate General for Cultural Heritage and Museums.

6. Do you have any plans to modify the existing legislation? Please give details and timetables.

Some modifications are considered in existing legislation. Studies are continuing to this end.

C. Control of the acquisition and possession of weapons

1. Do you have legislation providing for the control of the acquisition and possession of weapons?

Turkish legislation in this area:

- Law No. 6136 on Firearms, Knives, and other similar objects,
- Regulation No. 91 / 1779 on Firearms and Knives and similar objects,
- Law No. 2521on Manufacturing, transactions and possession of the hunting rifles, knives and target shooting rifles for sport,
- Law No. 6551 on Exclusion of gunpowder and explosives, Hunting Materials and Arms and their components from the Monopoly,
- Law No. 5201 on Supervision of Industries manufacturing arms, equipment and explosives.
- Import Communiqué No.2006/11 published in the Turkish Official Gazette dated 31.12.2005.

The above legislation lays down the lists of firearms, and the acquisition and conditions of possessing them.

2. Is there a legislation laying down the categories of firearms the acquisition and possession of which by private persons are either prohibited or subject to authorisation or declaration?

Acquisition and possession by private persons of all kinds of the firearms, which are not included within the scope of the Laws No. 6136 and 2521, are prohibited.

3. If the legislation is in force:

a. Which categories of firearms are covered?

- Law No. 6136 and the Regulation No. 91/1779 stipulate arrangement of procedures and fundamental principles regarding the importation, manufacturing, selling, purchasing, transportation and keeping of the firearms, bullets, knives and other tools which are particularly manufactured for the purpose of offensive and defensive use.

- Law No. 2521 regulates arrangements regarding manufacturing, purchasing, selling and owning guns, target pistols, hunting knives.

b. Which are the conditions necessary to be fulfilled in order to obtain the authorization?

There are two kinds of authorizations:

- First category: license to keep firearm either at workplace or at home.

- Second category: license to carry firearm.

The licences could be obtained by;

- Certain officials/ retired officials stipulated in Law No. 6136,

- Those entitled by the Council of Ministers through the Regulation,

- Citizens who have life risk due to the nature of the work they are doing through the prefects,

- Aliens with residence permit in accordance with the principle of reciprocity.

Requirements to obtain the licenses mentioned above:

- Turkish citizenship

- Over 21 years old,

- Not falling under one of the categories listed in the Regulation No. 91 / 1779,

- Not having any legal or health obstacles.

The permits for keeping and carrying are valid for five years. However, officials could only have these permissions during their work period, thus they should inform the authorities about their employment status.

c. What kind of information must be given in the declaration?

The applicant should provide following information:

- Petition,

- residence paper,
- judicial record,
- certificate for health condition,
- original and 3 copies of the identity card, four photos,
- application form.

Additionally, the professionals and civil servants who apply for carrying license should provide relevant documents about their employment status.

The application should be made to the Governorship of the city of residence.

On the other hand, according to Law No. 2521, in order to perform hunting with guns, excluding rifle, it is necessary to have "hunting certificate".

This certificate is issued by Governorships in the cities and Province Governorships in the provinces for a period of five years. The certificates are issued on a personal basis and they include the personal details such as name, surname, age, nationality, job and residence.

All the weapons, which are not registered by a hunting certificate or a possession document of guns, excluding rifle, are regarded as unlawful and they are confiscated by public authorities.

♦ Documents required for acquiring a gun without rifle:

- Document of judicial record,
- Official residence paper, two photos,
- Certificate for health condition,
- Petition,
- Hunting certificate.

♦ Issuing the Certificate for Right of Dealership and Documents Required

(Article 10 of the By- law concerning the application of the Law numbered 2521)

This certificate is exclusively issued by the Governorship (for 1 – 3 year time period) in the provinces.

Documents required during applications are;

- document proving that the workplace is either owned or rented,
- a health report on the mental and physical fitness of the applicant person for owning and selling guns,
- document of judicial report obtained from the office of director of public prosecutions,

- letter of undertaking stating that the applicant will comply to the Articles of Law No. 2521 and will be responsible for any possible outcome,

- official residence paper and a copy of identity card, two photos.

4. Are there any special rules for collectors and bodies concerned with the cultural and historical aspects of weapons? If so must these collectors and bodies be recognized by local authorities?

Article 11 of Law No. 6136 stating that it is mandatory to issue an ownership permit for the firearms that are of memory and antique character. However, no permit is sought for the swords, small swords or similar weapons that have been given by the State or owned by themselves for the same reason due to their duties and left in their homes after their duties ended or passed to their heritage. The permit that is given for the antique firearms and knives is only valid for to be inherited to the owner or for transportation purposes, not for carrying on.

5. Does the legislation, if any, exclude from its scope weapons and ammunition used for hunting or target shooting? In affirmative what rules are applied?

It is regulated by Articles 60, 61 and 62 of the Regulation No. 91/1779.

Persons, who want to establish a trap-skeet range and polygon for pistol and shotgun are compelled to obtain a prior permission certificate from the Ministry of Interior by a letter of application including information about properties of polygon or shooting range and project of the business and where it will be established.

If the promoter is a real person, he/she shall add confirmed sample of his/her identity card to the letter of application. If the promoter is a legal person it shall add confirmed sample of shareholders' and managers' identity cards. Certificate of prior permission shall be granted after the Ministry determines that the pretender is unexceptionable for public security.

In order to obtain Permission for Management, the promoter shall apply to the Governorship, which will submit these documents to the Ministry of Interior. "Permission Certificate for Management" shall be granted by the Ministry of Interior only after it is determined that the shooting polygon is suitable to the provisions of this regulation.

6. Do you have any plans to modify the existing legislation? Please give details and timetables.

The internal work is ongoing to modify the relevant legislation within the Ministry of Interior.

D. <u>Checks for conformity with the rules on product safety in the case of products imported from third countries</u>

1. Do you have legislation providing for conformity with the rules on product safety in the case of imported products? If so:

a. since when has it been in force?

The main legislation regulating external border conformity checks is Decree on Technical Regulations and Standardisation No. 2005/9454, which is under the responsibility of UFT. The Decree has been in force since 1995 and it was revised in 2005 according to the commitments

arising from the Customs Union, in particular for transposition of "Council Regulation No.339/93 on Checks for Conformity with the Rules on Product Safety in the Case of Products Imported from Third Countries".

The aims of the Decree are;

i. to prevent technical barriers to trade between Turkey and its trade partners,
ii. to provide conformity with the rules on product safety in the case of imported products,
iii. to designate national authorities responsible for conformity checks at import and export stages and to determine procedures for activities in the related field,
iv. to ensure human health and safety, animal and plant life or health, or environmental protection,
v. to adapt the technical legislation of the EU to the foreign trade applications,
vi. to regulate the responsibility of importer and relevant authorities with regard to product safety,
vii. to ensure an effective co-coordination between the relevant authorities.

b. please describe its broad outlines (which service is responsible for border controls and co-ordination regarding imported products, what is the procedure provided for etc?)

As regards to imported goods, Turkey follows a system that is based mainly on pre-market controls over goods at the importation stage. On the basis of national laws ministries and other designated governmental bodies may have the authority to regulate and monitor the domestic market for certain goods for reasons of human health and safety, animal and plant life or health, or environmental protection. For example, the Ministry of Health monitors pharmaceutical products, cosmetics, detergents, and toys placed on the market; the Ministry of the Environment and Forestry monitors dangerous chemicals and waste materials; the Ministry of Agriculture and Rural Affairs monitors the production, transport, storage, and processing of animal and plant products, foodstuffs, fertilizers etc. These rules are also applied to imported goods and no distinction is made among trading partners.

Having the central co-ordinating role in this process, the UFT prepares the legislation that applies to the imported goods. The Decree lays down the control procedures for imported goods, which are subject to controls in the domestic market. The goods are listed by their CN codes, the types of certificates that the Customs authorities have to check, the organisation that will issue those certificates, and how they are issued.

The conformity checks of the product with minimum safety requirements that are regulated in "vertical" legislation such as national standards or regulations transposed from European directives. Both domestic and imported products must be in compliance with that legislation.

TSE plays an important role in this process, because it is designated by UFT for the conformity assessment of some non-food products at import stage. This means that an importer has to go to TSE before the actual import takes place, having samples of his products tested or analysed. TSE issues a certificate of conformity. For some goods there are exemptions from the testing procedures, such as for CE or TSE marked products. In the case of CE marked products coming from the EU, for instance, TSE will limit itself to the examination of the (original) technical file, and than issue a "CE exemption certificate".

For some other product groups, not only a certificate of conformity but also a control certificate from different Ministries is necessary. The Decree is supplemented by various implementing

Communiqués, which divide the list of goods over the Ministries of Health, Agriculture and Rural Affairs, Environment and Forestry, etc. The Ministries will make a documentary control prior to the import stage and issue a control certificate. These control certificates are valid for a stated period (from 4 to 12 months) and for a stated quantity of imported goods. Within the limits of time and quantity the importer may use this control certificate for multiple imports.

When goods arrive at the border the main task of the custom officers is to check the presence of the required certificates, if due, and release the goods for free circulation into Turkey. Custom officers will not do physical checks on products; they have to be done before the stage of the import declaration. When a problem occurs about the import of goods, such as missing certificates, or non-conformity with the national technical regulations, the products shall not be released to the free circulation.

The present system of import control actually divides the imported goods into two groups, i.e. regulated and non-regulated. The non-regulated goods are the ones for which there exist no technical regulations. They may enter Turkey without any conformity certificate and/or control certificate. Of course, such goods are subject to the normal controls of the customs authorities when an import declaration is done, such as for import duties and illegal goods.

Turkey is now about to transpose the "Council Regulation No.339/93 on Checks for Conformity with the Rules on Product Safety in the Case of Products Imported from Third Countries" in order to carry out conformity checks at import stage as in the case of the EU. A draft legislation transposing the Regulation was prepared and submitted to European Commission for opinion. With the new system risk analysis method will be assumed as the basis for products to be checked at the borders. On the other hand, a study has already been initiated to revise the above-mentioned system according to the Regulation. Personal Protective Equipments and Toys, for example, have been effective as pilot implementations.

E. International Agreements

What mutual recognition or co-operation agreements in the field of standards, testing, certification and conformity assessment has your country signed? Do such agreements use international standards as a basis? Please provide copies (in English) of the relevant agreements.

There are a number of Protocols signed or platforms established with third countries with a view to building up the mutual cooperation in the area of technical regulations.

The Protocol on the Establishment of the Consultation and Cooperation Mechanism on Quality and Safety of Industrial Products between General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China and UFT is one of the initiatives to this end. This Protocol was signed on June 27, 2005. Currently, the approval and ratification procedure is under way.

Moreover, Free Trade Agreements signed by Turkey with third countries in line with Article 16 of Association Council Decision No: 1/95 include some provisions determining the rights and obligations of the Parties in respect of technical regulations, standards and conformity assessment. These provisions basically aim to strengthen the cooperation in the above areas, with a view to increasing mutual understanding of their respective systems and facilitating access to their respective markets. They refer to the WTO Agreement on Technical Barriers to Trade in terms of both governing the rights and obligations of the Parties as well as settling the disputes. The text of the relevant Article of the Free Trade Agreements is attached in Annex III.

IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

A. Standard questionnaire to be filled for each sector individually:

See Annex IV (a) for the answers given for each sector individually under this section.

The table showing the Ministries responsible for transposing new, global and old approach directives is given in Annex IV (b).

Annex IV (c) lists the Turkish Legislation harmonising New and Old Approach Directives of the EU which has been sent to the EC Commission for its opinion

B. Additional questions regarding chemicals

- **Civil Explosives**

1 Legislation

1.1 General Questions

- **Has EC legislation (Directive 93/15) been included in your legislation on explosives?**

Yes. It has been transposed and put into force.

- **When was your legislation on explosives adopted?**

The Regulation was published in the Official Gazette No. 24907, dated 15 October 2002.

- **When did it /will it enter into force?**

After the transitional period, the Regulation came into force on 1 July 2003.

- **Has there been any particular problem in the transposition process?**

No.

- **What has been your experience to date on applying the legislation?**

With the implementation of the new legislation, co-operation between the competent authorities and operators increased and market surveillance activities have become more effective.

- **Do you foresee making some changes to the legislation and if so, over what time frame?**

Amendments on the existing Regulation will be considered upon the developments to be recorded in the EU legislation.

1.2 Detailed Questions

- **What are the main differences you have identified from your legislation and that of the EC ?**

There are no differences between the transposed Regulation and the original Directive 93/15/EEC.

- **How are operators controlled – is there a specific licensing and registration system?**

Manufacturing of civil explosives is subject to permits issued by the DG for Public Security of the Ministry of Interior.

In Turkish legislation there are three different kinds of approvals concerning manufacturing of civil explosives:

1. Pre-approval for establishment
2. Approval for establishment
3. Approval for operation

Additionally, for imports of these products "Import Licence" issued by the DG for Public Security of the Ministry of Interior is required. (The Decree No. 87/12028, dated 29.09.1987 and Import Communiqué No.2006/11 published in the Official Gazette dated 31.12.2005.)

For exports of these products "Export Licence" issued by the DG for Public Security of the Ministry of Interior is required.

For buying, selling and using civil explosives, permission issued by the Governorships is required.

- **Do you require operators to keep track of explosives so that those holding explosives can be identified at any time?**

The manufacturer or the consumer of civil explosives is obliged to obtain permission from the local Directorate of Public Security of the region where the manufacturing premises are located, in order to be able to transport the explosives from the manufacturing premises.

- **Which preparations have been made for the CE marking of explosives?**

Workshops have been organized to inform the civil explosive manufacturers (there are only 5 manufacturers) in Turkey about the Regulation and its implementation. The potential conformity assessment bodies to serve under the Regulation have been invited to lodge an application for being appointed as Notified Bodies. However, no official application has been received so far.

- **What kind of information do you exchange with EU Member States on explosives and ammunition?**

There is no exchange of information.

- **Is there an explosives transfer document for internal and cross-border shipments?**

Yes. Manufacturer is obliged to obtain the bill of lading from the Local Directorate of Public Security where the manufacturer is located; otherwise, he/she is not allowed to transport explosives to other regions.

- **How do you control exports and imports? Are these consignment-based ?**

The products covered by the Regulation are subject to permission for each consignment by the Ministry of Interior for imports and exports.

- **Do you have specific controls on transit through your country?**

Transit of civil explosives through Turkey is subject to the permission of the Ministry of Interior (DG for Public Security), and the necessary controls are performed by the Customs authorities at the borders.

- **How do you apply border controls?**

Undersecretariat of Customs seeks the permit (e.g. for import) issued by the Ministry of Interior (DG for Public Security). If deemed necessary, Ministry of Interior has the authority to carry out on spot inspections at the borders.

- **What are the mechanisms in place to detect smuggled explosives?**

In addition to the regular controls which are carried out by the Commissions established within the Governorships, in order to prevent smuggling of civil explosives in the facilities of the operators, which possess necessary permits, in case of suspicion, information or complaints received, the individual controls are performed.

2 Administrative structure

- **What competent authority/authorities are responsible for explosives control tasks? Is there a lead authority?**

The Ministry of Industry and Trade (MIT) is responsible for the transposing the Directive 93/15/EC. Both the Ministry of Interior and MIT are responsible for implementation of the Directive 93/15/EC.

- **What are their resources in terms of number of personnel allocated to the task and their budget?**

Ministry of Interior controls the importation and smuggling actions with 150 personnel in the 81 provincial offices under the coordination of 3 personnel in Ministry of Interior at the Headquarters. On CE Marking, 70 personnel in the 81 provincial offices carry out market surveillance under the coordination of 4 personnel in Chemical Industry Division of DG for Industry of MIT.

A budget of approximately 200,000 Euros is allocated for the costs of testing under market surveillance activities for all Directives of DG for Industry of the MIT. All other costs (travel, daily allowances, training, etc.) are financed from the general budget.

- **What powers do the competent authorities have in relation to the control, monitoring, prevention or seizure of transactions or consignments?**

When circumstances contrary to the provisions of the Decree are determined during the controls carried out by the relevant authorities, a warning is made to the operator in order to correct the incompliance. When these infringements are repeated, the licences of the operator in question are

annulled by the Ministry of Interior or the Governorships temporarily or permanently. If the violation constitutes also a crime, the judicial authorities are reported about the situation.

All actions are taken and penalties are applied (including administrative fines, withdrawal from the market and disposal of product, granting time limit for remedying the nonconformity, informing the public through media of the nonconforming products as well as of the manufacturer) according to the provisions of the "Regulation on Procedures and Principles of Market Surveillance of the Products to be Performed by MIT" published in the Official Gazette No. 25103, dated 9.5.2003, the Regulation No. 2001/3529 on Market Surveillance of Products published in the Official Gazette No. 24643, dated 17.1.2002, and the Law No. 4703. In each case, such actions and penalties are applied considering level of nonconformity and the principle of proportionality.

- **How do authorities collaborate – is there an established system for exchange of information among authorities?**

There is not a specific information mechanism. Responsible authorities ensure necessary co-ordination and information exchange among themselves.

3 Partnership with operators

- **How many operators do you have manufacturing or using explosives?**

There are 5 manufacturers operating in the sector.

The explosives are used mainly by the mining and construction sector.

- **What steps have been taken to encourage a partnership between operators and competent authorities?**

Current approval mechanism already provides a close co-operation between operators and relevant official authorities.

- **How is the flow of information between the authorities and the operators organised, for example workshops, newsletters, training programmes?**

Sectoral meetings are organized annually to discuss the problems encountered by the manufacturers. The representatives of the sector are also invited to the training seminars delivered by the European experts.

Additionally, training seminars are organized by the Chamber of Mining Engineers.

- **How do you deal with suspicious transactions?**

Suspicious transactions are investigated within the framework of the Ministerial Decree No. 87/12028 and Law No. 4926.

- **What do you use to collect data on domestic and the export-import trade in explosives?**

The MIT is collecting domestic production data.

The Ministry of Interior records the permitted export and import figures. On the other hand, actual import and export data is provided by the Turkish Statistics Institute (TURKSTAT).

In 2005, 43 operators (3 individuals, 36 firms, 4 institutions) applied for import permission. In the same period 7 operators (6 firms, 1 institution) applied for export permission.

- **Does information flow in both directions i.e. from authorities to operators AND from operators to authorities?**

The applications for approvals of import, export and manufacturing constitute an interactive process by which information flow is ensured.

On the other hand, sectoral meetings are convened annually to discuss the problems encountered by the manufacturers.

Drug Precursors

1. Legislation

1.1 General Questions

a) What is the reference of the national legislation on drug precursors (title and date)? When did it /will it enter into force?

- Regulation transposing the provisions of the '1988 United Nations Agreement against the Smuggling of Drugs and Psychotropic Materials', which was published in the Official Gazette No. 22551, dated 11.02.1996.

- "Agreement on the Intermediate and Chemical Substances frequently used in the Illegal production of Drugs and Psychotropic Substances between the Republic of Turkey and the European Community", which was published in the Official Gazette No. 25446 dated 28 April 2004,

- Article 16 of Law No. 4208 amending Law No. 2313 on Control of Narcotic Drugs

- Circular No. 2005/56, dated 31.03.2005.

b) Has EC legislation (directive(s)/Regulation(s)) been included in your legislation on drug precursors?

The Regulation transposing "the Council Directive No. 92/109/EEC on the Production of Certain Materials used in the illegal Production of Narcotic and Psychotropic Materials and putting them on market" and "the Commission Regulation No. 1485/96/EC specifying the detailed rules in the application of the Council Directive No. 92/109/EEC on the Special Use of Certain Materials used in the illegal Production of Narcotic and Psychotropic Materials for Customer Notification" was published in the Official Gazette No. 25494, dated 16.06.2004. In addition, Circular No.2005/56 was issued on 31 March 2005.

c) Has there been any particular problem in the transposition process?

Yes. The Ministry of Health (MoH) has been facing problems with the categorization of the products.

d) What has been your experience to date on applying the legislation?

The MoH had no problem to date on applying the legislation.

e) Do you foresee making some changes to the legislation and if so, over what time frame?

Preliminary work has been just commenced to identify further alignment needs. Participation to the related technical committees/working groups operating under the Commission will provide Turkish administration with the opportunity to follow closely the developments in legislation and implementation in this area.

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f) What are the main differences you have identified from your legislation and that of the EC?

Turkish legislation has only one category while EC legislation has three categories.

1.2 Detailed Answers

a) How many controlled substances do you have? Which are these controlled substances? How are these substances grouped e.g. category 1, 2 and 3?

There are 23 controlled chemical substances, which are listed below:

1-phenyl-2-propanone	Lysergic acid
N-acetylanthranilic acid	Acetic anhydride
Isosafrole	Phenylacetic acid
3,4-methylenedioxyphenyl-2-propanone	Anthranilic acid
Piperonal	Piperidine
Safrole	Hydrochloric acid
Ephedrine	Sulphuric acid
Pseudoephedrine	Potassium permanganate*
Norephedrine	Toluene*
Ergometrine	Ethyl ether*
Ergotamine	Acetone*
	Methyl Ethyl Ketone*

*The salts of the substances listed under this category in places where the salts of these materials are available.

b) How are operators controlled? Is there a specific licensing and registration system?

The MoH has a registration system to monitor importers, exporters and manufacturers. Necessary controls including on-site audits are carried out on a regular basis. For the import and export procedures permits are issued on the basis of substances listed above.

c) Do you require customer declarations for monitoring trade and do you have a specific form for this purpose?

Yes. During the all kinds of movements of substances/precursors, which are subject to control "the end user declaration" which is issued by the MoH is required. This document should be kept for five years.

d) To which third countries do you send pre-export notifications?

Turkey sends pre-export notification to all countries.

e) How do you control exports and imports? Are these consignment-based or company based?

Permits are issued for import sand exports. Each consignment is controlled by the customs authorities, based on the control certificates issued by the MoH.

f) Do you have specific controls on transit through your country?

Yes.

g) How do you apply border controls?

Border controls are carried out by customs authorities in accordance with import / export permits issued by the MoH.

h) What are the mechanisms in place to detect smuggled consignments?

Permits are required for the import and export of chemical substances. Thus, chemical substances are not allowed to pass through the border if they do not have permits.

i) Do companies have to provide data at regular intervals on the legal trade or manufacture of drug precursors? Do you collect data on domestic and the export-import trade in drug precursors?

Particularly the invoice, cargo manifest, administrative documents, transport, stocking, production reports belonging to these substances and the product, which are manufactured using these substances and other commercial documents must be systematically kept by the operator for 5 years starting from the end of the year in which the procedures have been completed in order to ease the audit. Operators are responsible to prepare end user declarations in the trade of chemical

substances. The end user declaration should be kept for five years and shall be presented when requested by MoH. Importers, exporters and manufacturers are required to send the information and documents concerning the consumption and stocking of the chemical substances/precursors subject to control to the MoH regularly on a monthly basis.

j) Do companies have to inform authorities about suspicious orders or transactions?

Yes. Relevant operators should immediately inform the MoH on the amount, packaging, payment terms, transportation means and other details regarding the chemical substances/precursors subject to control in order to prevent smuggling.

2. Administrative structure

a) What competent authority/authorities are responsible for managing the drug precursor control regime? Is there a lead authority?

The MoH is responsible for setting up the control measures on the audit of the legal use and legal trade of chemical substances. Security forces and judicial authorities are responsible for monitoring/dealing with the illegal transactions/activities.

b) What are their resources in terms of number of personnel allocated to the task and their budget?

7 persons are allocated to this task in the MoH. The expenses are financed from the general budget of the MoH..

c) What powers do the competent authorities have in relation to the control, monitoring, prevention or seizure of transactions or consignments?

According to the control measures taken by the MoH, if it is found and believed that the permit holder uses the permit unlawfully or permit holder is not meeting the criteria anymore, then the permit is cancelled or suspended by the Ministry. Prevention or seizures of the transactions or consignments are possible measures if an infringement constitutes a crime under law.

d) Are companies audited by the competent authorities?

Yes. The MoH may survey and audit the premises, where any kind of activity is carried out regarding chemical substances/precursors subject to control.

e) Which authority/ministry is responsible for the monitoring of drug precursors?

The MoH is responsible for the monitoring of drug precursors.

f) How do authorities collaborate? Is there an established system for exchange of information among authorities within the country?

Authorities (Customs, Security Forces, Ministry of Health) collaborate by electronic means. There is no established system for exchange of information among authorities.

g) How do the authorities deal with suspicious transactions notified by operators?

Operators are required to inform the suspicious transactions to the MoH. Necessary controls and investigations are carried out with the coordination and cooperation of all relevant authorities, if an unlawful situation is determined then the case is referred to the security forces and the judiciary.

3 Partnership with operators

a) How many operators do you have manufacturing or using drug precursors?

There is a total of 332 companies, as importers, exporters and manufacturers.

b) Are there companies from sectors other than chemical companies dealing with drug precursors? For example pharmaceutical companies, perfume companies?

Yes. There are companies from pharmaceutical, perfume, food and other industrial sectors (e.g. paint, metal industry, fertilizer).

c) Is there particular initiatives taken to encourage a partnership between operators and competent authorities?

The operators are informed and encouraged to co-operate with public authorities at various platforms in order to ensure the proper functioning of the system established in line with the provisions of the legislation.

d) How are companies informed about drug precursors, illegal trade of drug precursors, risks of diversion? Were there for example workshops, newsletters, training programmes organised?

They are informed through national and international meetings (e.g. TAIEX and meetings of cities' health departments) and various publications of the MoH, including the web site of the Ministry (www.saglik.gov.tr).

e) How many suspicious transactions are reported by companies to the authorities per year?

There were two suspicious transactions in 2005 and there has been one suspicious transaction in 2006.

Good Laboratory Practice

Implementation of Directive 2004/9/EC, Directive 2004/10/EC and the OECD 1989 Council Decision-Recommendation on Compliance with GLP - C(89)87(Final)

1. **Country: Turkey**

Name(s) of the government body(ies) in charge of the designation of the GLP monitoring authority(ies).

Government bodies in charge of designation of the GLP monitoring authorities are:

- Ministry of Health (MoH) (responsible for registration and control of pharmaceutical products, cosmetics and pesticides for household use)

- Ministry of Environment and Forestry (MoEF) (responsible for registration and control of dangerous chemicals within the scope of the Dangerous Chemicals Regulation.
- Ministry of Agriculture and Rural Affairs (MARA) (responsible for registration and control of pesticides used in agriculture, veterinary drugs, food and feed additives)

Identify the body(ies) in charge of monitoring GLP compliance for the various fields of testing specified under 2.1.

GLP compliance monitoring requires legislative, administrative and technical infrastructure to be set up by political decisions and the necessary human resources. Currently there is no a central body responsible for monitoring GLP compliance. This issue has also been discussed within the Twinning Project "Support for the Alignment of Turkey with the EU Veterinary Acquis" (Project No. 02.03.05, duration: 13.11.2003-31.10.2005) between the MARA and Germany as MS Twinning partner. The Project outputs emphasized the necessity of creating a GLP monitoring authority in Turkey.

The national GLP Monitoring Authority will be established within the scope of the Twinning Project: "Strengthening the MoH, the MoEF, and the MARA to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection" (Project No. TR 0402.03). The Project, to be carried out in cooperation with the Slovak Republic as MS Twinning partner, aims at strengthening the institutional and administrative capacity of the related Ministries to adopt and implement the EU Directives on GLP, and covers the following components:

Component 1: The enforcement of the EU Directives 2004/9/EC and 2004/10/EC, by the way of transposition of the Directives into Turkish Law (transposition-and implementation of the EU Directives and other relevant GLP documents into Turkish law)

Component 2: The establishment of a Monitoring, Auditing and Inspection Body **(**training of members, auditors and inspectors of the Turkish national monitoring authority)

Component 3: The establishment of an agreed framework for GLP procedures in the field of Chemicals **(**training of personnel of the test facilities, potential study directors, principal investigators, quality managers, organization of seminars and workshops for potential sponsors of GLP studies, technical assistance for 5 laboratories from participating ministries to prepare for GLP compliance)

Final Draft of the Twinning Contract is being prepared for comments of the Steering Committee. The project is expected to start, following the positive opinion of the European Commission and will be concluded by 30 November 2007.

2. National Legal Requirements to Apply GLP:

2.1 Specify legislative and regulatory documents requiring the application of GLP for testing of the following product groups:

2.1.1 industrial chemicals

The Dangerous Chemicals Regulation needs to be revised and amended to achieve full transposition of the 4 EU Chemicals Directives (67/548/EEC, 99/45/EC, 93/67/EEC, 91/155/EEC). There is a Technical Assistance Project in the Field of Chemicals (TeACH - EUROPEAID/120220/D/SV/TR) for Turkey to harmonize the 4 EU Chemicals Directives. Completion date of project is 2007.

2.1.2 pharmaceuticals

Regulation on Licensing of Medicinal Products for Human Use, transposing Directive No. 2001/83/EC of EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, published in the Official Gazette No. 25705, dated 19 January 2005.

Annex 1: "Documents to be submitted in applications for licensing of medical products" (Introduction and General Principles), states that:

Non-clinical (pharmacotoxicological) studies will be carried out in accordance with the "Regulation on Good Laboratory Practice Principles and Certification of Test Laboratories" and the "Regulation on the Inspection and Verification of Good Laboratory Practice", both published in Official Gazette No. 24796 of 25 June 2002.

Annex 1: "Documents to be submitted in applications for licensing of medical products" (Section 3-2. Radiopharmaceuticals and precursors), states that:

With respect to single dose and repeated dose toxicity, results of studies carried out in compliance with provisions of the "Regulation on Good Laboratory Practice Principles and Certification of Test Laboratories" and the "Regulation on the Inspection and Verification of Good Laboratory Practice", was published in Official Gazette No. 24796 of 25 June 2002, are provided and verified.

2.1.3 veterinary medical products

No corresponding national legislation.

2.1.4 pesticides

No corresponding national legislation.

2.1.5 food additives

No corresponding national legislation.

2.1.6 feed additives

No corresponding national legislation.

2.1.7 cosmetics

Regulation on Cosmetics**,** transposing the Directive No. 76/768/EEC of the European Council of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products and the Commission Decision 96/335/EC, published in the Official Gazette No. 25823 dated 23 May 2005.

Article 12 (Principles for control and inspection) states that:

For market surveillance and control, upon the request of the Ministry, the manufacturer will provide product information including safety evaluation of the final product regarding human health. For this evaluation, the manufacturer will take into consideration the toxicological characteristics, chemical structure and susceptibility levels of the product constituents. This evaluation will be

carried out in conformity with the "Regulation on Good Laboratory Practice Principles and Certification of Test Laboratories" published in the Official Gazette No. 24796, dated 25 June 2002.

2.1.8 Biocides

National Regulation on Biocidal Products transposing Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market will be prepared within the scope of the Twinning Project "Strengthening the Ministry of Health to Harmonise and Implement Legislation in the Field of Biocides (Biocidal Products Directive) and Water (for Public Health Protection) (Project no. TR 0402.10). The project carried out in cooperation with Austria as MS twinning partner started on 23 November 2005 will be completed by 30 November 2007.

2.1.9 other products (specify) and provide appropriate links to any documents available in English or English translation, if available.

Regulation on Good Laboratory Practice Principles and Certification of Test Laboratories, transposing the GLP Directive No. 87/18/EEC as amended by 1999/11/EC, published in the Official Gazette No. 24796, dated 25 June 2002.

This Regulation lays down the GLP principles to be applied by laboratories involved in physical-chemical, toxicological and eco-toxicological testing of substances or organisms of synthetic chemical, natural or biological origin, for products and substances within the scope of cosmetics, pesticides, pharmaceutical products, veterinary drugs, food and feed additives and dangerous chemicals.

Regulation on the Inspection and Verification of Good Laboratory Practice, transposing the GLP Directive 88/320/EEC as amended by 1999/12/EC, published in the Official Gazette No. 24796, dated 25 June 2002.

This Regulation lays down the principles and procedures to be applied for the inspection and verification of GLP applications.

2.2 For each group listed in 2.1 above, specify the type of testing that has to be carried out under GLP, using the table given in Appendix A.

For pharmaceuticals: non-clinical (pharmacotoxicological) studies – as stated in the Regulation (pharmacology, pharmacokinetics, toxicology)

For cosmetics: safety evaluation for human health– as stated in the relevant Regulation (toxicology, chemical structure)

The table given in Appendix A was not filled as the studies towards establishing a GLP Monitoring Authority as well as determining a GLP Monitoring Programme are still going on.

3. GLP Compliance Monitoring Authorities

Provide answers for each of the questions below for each of the product groups specified under 2.1 above.

3.1 Starting date for the monitoring programme.

Currently, there is no GLP Monitoring Programme since a GLP Monitoring Authority is yet to be established. Nevertheless, within the scope of the Twinning Project: "Strengthening the MoH, the MoEF, and the MARA to harmonise and implement legislation in the field of Good Laboratory Practice for Non Clinical Health and Environmental Protection" (Project No. TR 0402.03), it is planned to establish a GLP Monitoring Authority, and accordingly prepare a monitoring programme. Details regarding the Project can be found in the answer to the first question of this section.

3.2 Give name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the GLP compliance monitoring authority(ies) and the responsible person(s).

N/A

3.3 Give name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the authority(ies) and the person(s) responsible for the international communication on GLP inspection and audit procedures if different from those given under 3.2.

N/A

3.4 What is the complete (national) legal basis for conducting GLP compliance monitoring?

N/A

Answer all further questions for each of the authorities mentioned under 3.2 above:For each of the authorities mentioned under 3.2., above, answer all of the following questions.

3.5 Describe the powers of the inspectors to access the test facilities and testdata. [If GLP requirements monitored by one authority have different legal bases (seequestion 2), specify the powers granted under each of these cases].

N/A

3.6 List the number of inspectors in each compliance monitoring authority (specify full-time or part-time), the level of education, training and additional qualifications required to fill the position. Then list the qualifications (including discipline in which qualification was gained), GLP and other relevant training and relevant professional experience for each inspector.

N/A

3.7 What percentage of their work load do the inspectors spend on inspections and study audits and GLP related activities? How many full-time equivalents does this represent?

N/A

3.8 What is the inspectors contractual relationship with the compliance monitoring authority (employee, external contractor, etc.)?

N/A

3.9 Describe what actions are taken to ensure adequate access to expertise when the scope of GLP coverage of the monitoring authority (ies) is extended, or when new areas within the current scope are encountered. The answer should address such issues as additional training for inspectors, access to external expertise, analysis of current competencies, preparation of new documents, cooperation with domestic regulators and other compliance monitoring authorities.

N/A

4. Explanation of Organisation and Management of GLP Compliance Monitoring

4.1 Give a detailed written description of how the GLP compliance monitoring in your country is organized, including a description of the relationship between monitoringauthority(ies) and the receiver of the test data (i.e. ., regulatory authority(ies)), and whether testfacilities are required to be registered in the monitoring programme in order for studies they carry out to be recognised as being compliant with GLP.

N/A

4.2 i) How does the monitoring programme determine if the test facility should be inspected?

N/A

ii) How many test facilities are inspected per year?

N/A

iii) How many studies are audited upon request per year?

N/A

iv) What is the frequency (a range is acceptable) of inspections of each test facility?

N/A

4.3 i) What are the criteria for performing the first inspection and reinspection of a test facility?

N/A

ii) What are criteria for performing study audits?

N/A

4.4 i) Describe the actions that may be taken if non-compliances with GLP requirements are found during a test facility or during a study audit.

N/A

ii) Detail the nature and number of actions taken in the last four years.

N/A

iii) What are the criteria for giving a test facility the status of "not in compliance"?

N/A

iv) What is the procedure used to inform other Member countries about facilities or studies found to be non-compliant?

N/A

4.5 How are the records of, inspections and study audits documented?

N/A

a. How are the test facility(ies) informed about the result of an inspection or a study audit?

N/A

4.7 How does your programme react to requests from other national GLP authorities to conduct inspectors or study audits, or to release inspection reports?

N/A