1. Basic Information

1.1 CRIS Number:

1.2 Title: Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of New Hot Boilers, Gas Appliances, Cosmetics, IVD, Veterinary Pharmacy and Construction Products (Fire Testing)

1.3 Sector: Internal market

1.4 Location: Turkey

1.5 Duration: 22 Months

2. Objectives

2.1 Overall Objective(s):

The overall objective of the project is to contribute to the implementation of the EU *acquis communautaire* in the area of internal market, specifically focusing on the effective functioning of market surveillance support laboratories.

2.2 Project purpose:

Strengthening of the national system of market surveillance support laboratories in the selected priority areas: New Hot Boilers, Gas Appliances, Cosmetics, IVD, Veterinary Pharmacy and Construction Products (Fire Testing), ensuring that they are equipped and capable autonomously to carry out the relevant testing services related to market surveillance.

2.3 Accession Partnership and NPAA priority

A short-term priority under the free movement of goods heading of the Accession Partnership (AP) 2003 in terms of removing technical barriers to trade, accelerating alignment and application of European standards and ensuring effective in-market control and free movement of goods in line with internal market legislation. The AP, under its short-term priorities, explicitly includes starting implementation of certification and conformity assessment with the New and Global Approach Directives, reinforcing existing market surveillance and conformity assessment structures with equipment and training and creating compatible administrative infrastructure. AP gives the completion of alignment with the acquis and the completion of strengthening existing certification and market surveillance structures as a medium-term priority. The National Programme for the Adoption of the Acquis (NPAA) 2003 gives the establishment and functioning of conformity assessment and market surveillance structures as a short-term priority. The completion and operation of the whole system together with the required infrastructure is a medium-term priority.
**AP 2003**

**Short Term Priorities**

**Free Movement of Goods**

Start implementing certification and conformity assessment and CE marking in compliance with the new and global approach Directives; reinforce existing market surveillance and conformity assessment structures with equipment and training and and create compatible administrative infrastructure.

**Medium Term Priorities**

Complete alignment with the acquis; complete strengthening of existing certification, market surveillance and conformity assessment structures.

**NPAA 2003**

Priority 1.1. New Approach Directives;

“For the New Approach Directives, the short term targets are;

- Complete alignment with the acquis,
- Establishment of market surveillance and conformity assessment system and their implementation.

In the middle term it is envisaged to,

- Complete necessary infrastructure, and full enforcement of the system”

Priority 1.6. Veterinary Medicinal Products

“Strengthening the infrastructure of the laboratories on quality control and analysis of veterinary preparations”

Priority 1.7. Cosmetics

“With the administrative measures subject to the Draft Law, the following short term measures are envisaged:

- Defining the substances that may be used in the production of cosmetics,
- Establishment of the necessary infrastructure for the market control system”

2.4 Contribution to National development plan (and/or Structural Funds Development Plan/SDP)

*Not applicable.*

2.5. Cross border impact

*Not applicable.*
3. Description

3.1 Background and justification

3.1.1 General Background on Market Surveillance

The conclusions of the Helsinki European Council in December 1999 recognised Turkey as a candidate for membership to the European Union. The European Council agreed in December 2004 to start accession negotiations with Turkey after October 2005. As a candidate country Turkey has to approximate the whole body of EU legislation known as the acquis communautaire.

For the approximation of legislation in the area of Free Movement of Goods, Turkey has a head start due to the existence, since 1996, of the Customs Union between Turkey and the EU. According to Decision 1/95 of the EC-Turkey Association Council, completing the Customs Union, Turkey had to finalise, before the end of 2000, the harmonisation of its technical legislation, in areas of direct relevance to the Customs Union.

In line with the Association Council Decisions no 1/95 and 2/97, a Framework Law relating to the preparation and implementation of the technical legislation regarding products has entered into force on 11 January 2002. The Law was adopted by the Parliament on 29.06.2001 and published in the Official Gazette on 11 July 2001. This Framework Law establishes the legal basis for full harmonisation with the EC legislation, and it lays down the basic principles for product safety and the implementation of Old and New Approach Directives. It sets out the conditions of the placing on the market of the products, the liabilities of the producers and distributors, the conformity assessment bodies, notified bodies, market surveillance and inspection, the prohibition of the placing on the market of certain products, the withdrawal and destruction of the marketed products as well as the notifications relating to these arrangements.

The Framework Law is complemented by five pieces of secondary legislation (by-laws) in order to become operational on the ground: market surveillance and control of the products, use and affixing of the CE conformity mark, working principles and procedures for the conformity assessment bodies and notified bodies and their assignments, exchange of information on national measures derogating from the principle of the free movement of goods, notification procedures between Turkey and the EC regarding technical legislation.

This horizontal legal framework is in force since 2002. From that date onwards, the Ministries accelerated their work regarding the harmonization of technical legislation which had started with the Customs Union Decision of 1995 and also have taken steps in order to establish the necessary mechanisms for its implementation, especially with regards to market surveillance and conformity assessment.

A central agency for market surveillance in Turkey or any other centralized responsibility for market surveillance does not exist, nor is the creation of such an agency on Turkey’s political agenda.

In Turkey, there is no coordinating authority for market surveillance other than the Market Surveillance Co-ordination Board, which was established by regulation issued by the Undersecretary of Foreign Trade, in 2002. This Board is composed of authorities involved in surveillance related issues including the technical Ministries. The main functions of this Board are to monitor developments and recommend changes required in the enacted laws and improve
co-operation between ministries and institutions in surveillance work. The Board met six times for 2002 and 2003, and two more meetings held in 2004.

Market surveillance is performed more as pre-market control and is centralized at the Ministries and their local offices. The Municipalities and authorized public institutions such as the Chamber of Mechanical Engineers also carry out surveillance activities.

Although progress has been made in terms of the alignment of technical legislation, enforcement of the new conformity assessment and market surveillance systems is still to be achieved. This is partly due to the need for technical assistance on these complicated issues and also due to the lack of laboratory infrastructure and trained laboratory staff.

3.1.2 Ministry of Health, Ministry of Industry and Trade, Ministry of Agriculture and Rural Affairs and Ministry of Public Works and Settlement.

Apart from harmonizing the legislation in the field of New Hot Boilers, Gas Appliances, amongst others (full list of legislation in Annex 5), the Ministry of Industry and Trade has finalized its overall market surveillance strategy and notified body criteria.

Throughout Turkey, 15 pilot provincial offices are selected as pilot areas for a first step on the basis of intensity of industrial production. Depending on the market products to survey priorities on types of devices to be monitored, within the new market surveillance platform have also been defined.

The Ministry does not have its own laboratories, or the intention of establishing these. In the sector of NHWB 3 public or private laboratories have been pre-selected by the Ministry of Industry in view of Market Surveillance tasks:

- Istanbul Technical University
- Turkish Standards Institute
- TUBITAK

For the purposes of this project and following expert assessment, the Ministry will use the 3 laboratories for testing products on the market, for which these laboratories would be used as CABs.

These laboratories already have test systems working on similar technologies including NHWBs and they will be extended specifically by this project fiche for Market Surveillance tasks.

As large national institutions, the 3 laboratories already have high level expertise and are planning to upgrade their conformity assessment know-how, as they have been all providing testing and certification services in Turkey for many years.

In the area of Gaseous Appliances, TUBITAK and TSE again have been pre-selected to provide market surveillance services to the Ministry if they can benefit from EC funding for upgrading their test laboratories.

For Explosives Atmosphere products, the Ministry has also engaged a well experimented laboratory, TSE-Izmir which has already been performing market surveillance and inspection tasks for several years at the Ministry of Industry; another possibility is a coal mine laboratory.
organization depending of the Ministry of Energy. An initial period of about 12 months is needed for upgrading the coal mine laboratory and training its experts to modern technical investigation techniques.

TÜRKAK will carry out preliminary assessment of market surveillance laboratories and conformity assessment bodies in accordance with ISO 17025 requirements.

The strategy is to use the already available network of 15 delegations of the Ministry for an efficient national coverage.

The Ministry of Agriculture and Rural Affairs is harmonizing its relevant EU legislation on veterinary pharmacy and its control (full list in Annex 5).
The Ministry intends to use the Pendik laboratory for performing in-market surveillance tasks, knowing that this laboratory is already performing drugs pre-market control and inspections for the Ministry.

The level of knowledge and competence of the technical personnel working at the Pendik laboratories has been assessed “good” by the European experts.

The Ministry of Health designated Refik Saydam Hygiene Center as its Market Surveillance laboratory for Cosmetic Directive as well as for the IVD Directive.

The Ministry of Public Works and Settlement harmonized the Construction Products Directive CPD (details in Annex 5). Specific CPD sector rules have resulted in communiqués:

- Technical and ad hoc decisions from the European Commission transposed for Turkish sector information purposes
- Communiqué that describes the procedure for designating the notified bodies and approval bodies: published 31.08.2003.
- Communiqué regulating the activities of market surveillance: ready to be published.

The Ministry intends to use its central laboratory for testing of products for market surveillance. There is also consideration of using well-qualified support laboratories run by the industry, the Turkish Cement Producers Cooperation (TÇMB) and the Scientific and Research Council of Turkey (TÜBİTAK).

The Ministry is aware of the wide coverage of the construction products directive and has a staged approach in terms of its equipment needs and implementation. It is also clear to the Ministry that an integrated market surveillance approach covering all sub-sectors has not been possible in EU MS.

Fire safety of buildings and limitation of damages in case of earthquakes are considered as high priorities. The effective implementation of the CPD is essential for Turkey for combating earthquake risks in works of buildings and for getting CE marking of their components. The new installation of a fire testing laboratory is also close connected to this priority.

3.2. Sectoral rationale
3.2.1 Identification of the project

As in previous years, during the programming exercise 2004, the issue of strengthening the capacity of Ministries responsible for the harmonisation of technical legislation, for market surveillance has been identified as a priority for funding. This would be the continuation of the previous exercises for the remaining product groups.

The previous programming efforts of 2002 and 2003 had enabled the Ministries to have a closer look at their needs and deficiencies through various assessment and pre-feasibility exercises undertaken during that process. The Ministry of Health and the Ministry of Industry and Trade have participated in these exercises and have produced projects for funding. These projects were mainly investment-related, except the Twinning sub-component of the Support to Turkish Conformity Assessment Bodies and Ministry of Industry and Trade in the implementation of some New Approach Directives.

The Ministry of Agriculture and Rural Affairs had submitted a project on chemical fertilizers, which came late in the programming cycle and could not be assessed by experts and therefore not accepted for 2003.

The assessment methodology of the projects was a detailed scrutiny process where the harmonization of legislation, existence of a market surveillance strategy and notified body criteria were looked at amongst other issues. The Ministries were asked to fill in a questionnaire as in previous years and provide information and economic data on the product group, related technical legislation and policy/strategy papers on market surveillance.

This revealed the fact that the EC legislation was generally harmonized and what the Ministries needed was starting the implementation of these Directives as accompanied with some hands-on training on market surveillance which is being addressed by a Twinning project under 2004 funds. In the first assessment of the situation, the sectors of fertilizers, non-automatic weighing instruments, construction products, textiles and lifts were identified as priority sectors in terms of their readiness and urgency for implementation. 6 other sectors have been assessed for the second stage: NHWB, Gas Appliances, Cosmetics, IVD, Veterinary pharmacy and Construction Products (Fire Testing).

3.2.2 Sequencing

Although all the projects in this field are related to the free movement of goods area, a sequencing is not possible as each project relies on one compact product group or a combination of these groups under one Ministry and the requirements of EC legislation as related to that product group.

A sequencing in terms of technical assistance followed by investment does not seem feasible either, as the major TA program in this field is outside the pre-accession framework and continues to give services. Hence, some of TA have already been engaged or planned in some sectors.
Within the scope of this fiche, the Ministry of Industry and Trade will indirectly benefit from equipment support in the area of NHWB, Gas Appliances through support to its choice of market surveillance support laboratories from 2005 funding.

The Ministry of Industry and Trade, Ministry of Health and the Ministry of Agriculture are planned to receive support from a Twinning project in these fields (Strengthening the capacity of Turkish Ministries for market surveillance in selected areas). The equipment support scheme under the current project should be considered in conjunction with these Twinning actions.

3.3 Results

3.3.1 Component 1: Ministry of Industry and Trade: Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of New Hot Boilers, Gas Appliances

3.3.1.1. Results

Results expected from this project component are:

- The necessary equipment for testing laboratories with regards to market surveillance on new hot boilers and gas appliances, supplied and operational.
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Industry and Trade for new hot boilers and gas appliances increased and updated to EU compatible level.

3.3.2 Component 2: Ministry of Health: Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of Cosmetics, IVD

3.3.2.1. Results

Results expected from this project component are:

- The necessary equipment for testing laboratories with regards to market surveillance on cosmetics and IVD supplied and operational.
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Health for cosmetics and IVD increased and updated to EU compatible level.

3.3.3 Component 3: Ministry of Agriculture and Rural Affairs: Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of Veterinary Pharmacy

3.3.3.1. Results

Results expected from this project component are:

- The necessary equipment for testing laboratories with regards to market surveillance on Veterinary Pharmacy supplied and operational.
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Agriculture and Rural Affairs for Veterinary Pharmacy and updated to EU compatible level.
3.3.4 Component 4: Ministry of Public Works and Settlement: Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of Construction Products (Fire Testing)

3.3.4.1. Results

Results expected from this project component are:

- The necessary equipment for testing laboratories with regards to market surveillance on Construction Products (Fire Testing) supplied and operational.

The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Public Works and Settlement for Construction Products (Fire Testing) and updated to EU compatible level.

3.4 Activities:

3.4.1 Component 1: Ministry of Industry and Trade: EU Directives on Gas Appliances and New Hot Boilers:

- Procurement of equipment for test laboratories of Market Surveillance according to the technical specifications prepared.

- Training of laboratory staff on the use of equipment and analysis, when necessary (as a part of supply contract)

3.4.2 Component 2: Ministry of Health: Cosmetics and In Vitro devices

- Procurement of equipment for test laboratories of Market Surveillance according to the technical specifications prepared.

- Training of laboratory staff on the use of equipment and analysis, when necessary (as a part of supply contract)

3.4.3 Component 3: Ministry of Agriculture and Rural Affairs: Veterinary Pharmacy products:

- Procurement of equipment for test laboratories of Market Surveillance according to the technical specifications prepared.

- Training of laboratory staff on the use of equipment and analysis, when necessary (as a part of supply contract)

3.4.4 Component 4: Ministry of Public Works and Settlement: Construction products (fire testing):

- Procurement of equipment for test laboratories of Market Surveillance according to the technical specifications prepared.

- Training of laboratory staff on the use of equipment and analysis, when necessary (as a part of supply contract)
3.5 Linked activities

“Administrative Cooperation Programme”

This EU funded project has become operational in 2000 and aims at providing short-term technical assistance support to Turkish authorities in its accession efforts to the EU, by facilitating transfer of know-how and best practice from European authorities and administrations through a variety of activities and sub-projects. There are a series of study visits for the officials of the Ministry of Industry and Trade (MIT) foreseen under the Program on electrical risk and equipment and pressure vessels.

From the same program, MIT has received technical assistance for the establishment of a market surveillance strategy for the Ministry. The result of that study has also been taken into account in this project.

"Support to the Quality Infrastructure in Turkey" Project

This EU funded project, with a duration of 5 years, started in August 2002, was envisaged as a technical assistance programme. The programme provides, in a broad way, expertise, either for training, consultancy for training awareness. This is achieved by providing a framework for technical assistance that will consist of four components:

- Legal and technical advice, on the design of legislative instruments,
- Institution building support, for the strengthening of the application and enforcement of the legal instruments in question,
- The transfer of know-how to both the public and private sector,
- Awareness campaign on the implications of the Customs Union Agreement and the Free Movement of Goods for the public and private sector.

The project has supported the Ministry of Health with a short-term TA action in the drafting of its market surveillance strategy on toys, detergents and medical devices. The results of that TA action is also taken into account in the preparation of this project fiche.

“Support to the Turkish Conformity Assessment Bodies and the Ministry of Industry and Trade in the implementation of some New Approach Directives”

The project is funded under the 2003 Pre-Accession Funds. It consists of three components: Feasibility Study including a call for expression of interest for conformity assessment bodies, a kick-off equipment support scheme for those bodies and a twinning action for the Ministry of Industry and Trade. The first two components relate to the areas of medical devices, toy safety, foodstuffs and detergents, machinery, electrical equipment, pressure vessels, motor vehicles and, telecommunications technology and equipment and oriented towards investment only with no technical assistance support to the involved Ministries and institutions. The last component, twinning, addresses only three areas machinery, electro-technical equipment and pressure vessels.

“Strengthening the capacity of Turkish Ministries for market surveillance in selected areas”

This project is funded under the 2004 Pre-Accession funds. It provides technical assistance on market surveillance to the Ministry of Agriculture and Rural Affairs, Ministry of Construction
and Public Works and Ministry of Industry and Trade on several areas. It will be implemented through Twinning. The project should be seen as a complementary action to the equipment support project.

“Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of fertilizers, lifts, non-automatic weighing instruments, textiles and construction products”

The project is funded under the 2004 Pre-Accession Funds. It consists investment for equipment support for several sectors under the responsibility of the relevant ministries.

3.6. Lessons Learned

The above mentioned technical assistance projects have been helpful in terms of self-defining the needs and the deficiencies at the beneficiary ministries and formulating market surveillance strategies on the basis of these assessments. It has been evident from these projects that the ministries were now knowledgeable on the general principles of EC directives, but they were lacking hands on information regarding the implementation of such directives. Therefore any project designed from now on should help the ministries to implement EC legislation especially in terms of market surveillance.

The equipment support schemes financed in the previous years are not yet under full implementation considering the progressing adaptation period in terms of the use of pre-accession funds and the de-centralised implementation system. One lesson learned from this process is that the technical specifications of the equipment should be fully ready at the start of the projects in order not to delay the procurement exercise.

4. Institutional framework

The lead beneficiary for this project will be the Ministry of Health. However the project will be implemented in partnership with the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Affairs.

The Ministry of Industry and Trade is responsible for the harmonisation and enforcement of the EU technical legislation in the area of NHWB and Gas Appliances. It is also responsible for market surveillance in this area. The Ministry does not have laboratories and subcontracts these activities usually to public or semi-public laboratories.

The Ministries of Health and Agriculture and Rural Affairs have the same responsibilities for Cosmetics, In Vitro Devices and for Veterinary pharmacy as well as Ministry of Public Works and Settlement for Construction Products (Fire Testing).

The present investment project together with other TA actions in this field will help the Ministries to implement the requirements of Directives effectively.
5. **Detailed Budget**

<table>
<thead>
<tr>
<th>Year 2005- Investment Support Jointly Co Funded</th>
<th>Phare/Pre-Accession Instrument Support</th>
<th>Co-financing</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>National Public Funds (*)</td>
<td>Other Sources (**)</td>
<td></td>
</tr>
<tr>
<td>C1-1a Istanbul Tech Univ Gas, Electrical, Fuel Appliances laboratory</td>
<td>153 000 €</td>
<td>51 000 €</td>
<td>204 000 €</td>
</tr>
<tr>
<td>C1-1b TUBITAK Gas Appliances Boliers analysis laboratory</td>
<td>377 625 €</td>
<td>125 875 €</td>
<td>503 500 €</td>
</tr>
<tr>
<td>C1-2 TUBITAK Lab Gas Appliances Dir laboratory analysers</td>
<td>213 750 €</td>
<td>71 250 €</td>
<td>285 000 €</td>
</tr>
<tr>
<td>C2-1 Chromatographs and Spectrometer for labs (Refik Saydam)</td>
<td>229 500 €</td>
<td>76 500 €</td>
<td>306 000 €</td>
</tr>
<tr>
<td>C2-2 Virology, Tuberculosis, Communicable Deseases labs (Refik Saydam)</td>
<td>586 500 €</td>
<td>195 500 €</td>
<td>782 000 €</td>
</tr>
<tr>
<td>C3 Chromatography and residues control for Veterinary (Pendik Inst)</td>
<td>270 000 €</td>
<td>90 000 €</td>
<td>360 000 €</td>
</tr>
<tr>
<td>C4. TUBITAK Construction Products- Fire Laboratory</td>
<td>643 500 €</td>
<td>214 500 €</td>
<td>858 000 €</td>
</tr>
<tr>
<td><strong>Investment Support –Total</strong></td>
<td><strong>2 473 875 €</strong></td>
<td><strong>824 625 €</strong></td>
<td><strong>3 298 500 €</strong></td>
</tr>
<tr>
<td><strong>% of total public funds</strong></td>
<td><strong>max 75 %</strong></td>
<td><strong>min 25 %</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total Project 2005</strong></td>
<td><strong>2 473 875 €</strong></td>
<td><strong>824 625 €</strong></td>
<td><strong>3 298 500 €</strong></td>
</tr>
</tbody>
</table>

(*) contributions from National, Regional, Local, Municipal authorities, FI's loans to public entities, funds from public enterprises
(**) private funds, FI's loans to private entities

The government of Turkey will provide 25% co-financing in cash of the project budget. The national co-financing will be covered from the national budget. Please see 11.2. All operating and maintenance costs of the equipment purchased under this project will be provided by the beneficiary.

1. All investment sub-projects supported by the pre-accession fund must receive co-financing from national public funds. Minimum requirement for co-financing from national public funds is 25% of the combined PHARE and national contributions to the overall investment support.

2. Many Institution building projects will also have a degree of co-financing – this should be quantified and included wherever possible.
3. Expenditure related to equipment (regulatory infrastructure or ESC-related) and to Technical Assistance supporting investment (e.g. pre feasibility study / supervision of works / technical specifications) should be considered as Investment support in the project fiche.

4. All co-financing must be provided on a joint basis. Parallel co-financing will, in a principle, not be accepted. Exceptions to this rule have to be agreed with the Commission in advance.

5. All co-financing should be clearly quantified, also the degree of certainty of such co-financing (i.e. for National Public Funds: is it already earmarked in local or national budget, for FIs Loans, private funds: are they already approved/ under appraisal, etc.).

6. Where parallel co-financing is accepted and justified per exception to the normal rule it should be provided in monetary form. If this is not possible there should be clear criteria set out for the valuation of any non-monetary contributions (that should be quantified in the table).

7. If twinning is involved, clearly state the expected budget of the twinning covenant

8. The financial engineering of the project should be closely monitored against actual delivery during implementation and against the objectives that were set in the project fiche so that corrective actions may be taken where required.

6. Implementation Arrangements

6.1 Implementing Agency

The Central Financing Contracting Unit (CFCU) will be the Implementing Agency and will be responsible for all procedural aspects of the tendering process, contracting matters and financial management (including payments) of the project activities. The Head of the CFCU is Mr. Nuri Ercan Tortop (tel: 90 312 4723700, fax: + 90 312 4723744).

6.2 Twinning

Not applicable.

6.3 Non-standard aspects

Not applicable.

6.4 Contracts

There will be six contracts under the project:

<table>
<thead>
<tr>
<th>Contract</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1-1a</td>
<td>204 000 €</td>
</tr>
<tr>
<td>C1-1b</td>
<td>503 500 €</td>
</tr>
<tr>
<td>C1-2</td>
<td>285 000 €</td>
</tr>
<tr>
<td>C2-1</td>
<td>306 000 €</td>
</tr>
<tr>
<td>C2-2</td>
<td>782 000 €</td>
</tr>
<tr>
<td>C3</td>
<td>360 000 €</td>
</tr>
<tr>
<td>C4</td>
<td>858 000 €</td>
</tr>
</tbody>
</table>

TOTAL euros 3 298 500 €

7. Implementation Schedule

7.1 Start of tendering/call for proposals
December 2005

7.2 Start of project activity
September 2006

7.3 Project completion
September 2007
Component 1: MIT Directives Gas Appliances (GAD), NHWBoilers:

- C1-1a  Istanbul Tech Univ Gas, Electrical, Fuel Appliances laboratory  
  déc-05  sept-06  sept-07

- C1-1b  TUBITAK Gas Appliances Boliers analysis laboratory  
  déc-05  sept-06  sept-07

- C1-2  TUBITAK Lab Gas Appliances Dir laboratory analysers  
  déc-05  sept-06  sept-07

Component 2: MoH Dir: Cosmetics and In Vitro Devices (IVD):

- C2-1  Chromatographs and Spectrometer for labs (Refik Saydam)  
  nov-06  juin-07  sept-07

- C2-2  Virology, Tuberculosis, Communicable Diseases labs (Refik Saydam)  
  déc-05  sept-06  sept-07

Component 3: Veterinary pharmacy:

- C3  Chromatography and residues control for Veterinary (Pendik Inst)  
  févr-06  nov-06  sept-07

Component 4: TUBITAK Construction Products - Fire Laboratory  

- C4. TUBITAK Construction Products - Fire Laboratory  
  déc-05  sept-06  sept-07

8. **Equal Opportunity**

Participation in this project will be open to both males and females involved in the sector. Records of professionals' participation in all project-related activities will reflect this and will be kept with the project documentation.

9. **Environment**

The project consists of supplying laboratory equipment to market surveillance laboratories and will not have a detrimental impact on the environment.

10. **Rates of return**

Supply of equipment for laboratory testing is to assist the beneficiaries in supporting the assessment and monitoring of the *acquis* compliance. The investment is not of commercial or profit-oriented character. The ultimate Beneficiaries of the project are the Ministries implementing the *acquis communautaire* in the related fields.

11. **Investment criteria**

11.1  Catalytic effect:
The EU pre-accession investments under this project will contribute to the strengthening of the necessary market surveillance system and its functioning at the required EU level.

The overall objective of the project is to support the application and enforcement of the Acquis in the area of free movement of goods, which is an accession priority stressed both in the Accession Partnership and the NPAA.

11.2 Co-financing:

In addition to the EU pre-accession fund the investment will receive co-financing from State budget (25%).

Although the ultimate beneficiaries are the Ministries that would receive services from a network of laboratories, the direct recipients of equipment support would be the following laboratories:

**Component 1:**
- Contract C1-1: boilers and gas appliances
  Istanbul Technical University and TUBITAK, 25 % of co-financing
- Contract C1-2: Gas appliances
  TUBITAK, 25 % co-financing

**Component 2:**
- Contracts C2-1, 2-2: cosmetics and In Vitro Devices,
  Refik Saydam Hygiene Centre, 25 % co-financing

**Component 3:**
- Contracts C3: Veterinary pharmacy
  Pendik Institute, 25% co-financing

**Component 4:**
- Contract C4: Construction Products (Fire Testing)
  TUBITAK, 25% co-financing

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<table>
<thead>
<tr>
<th>Project – Components - Contracts</th>
<th>Total Cost</th>
<th>Public/Private</th>
<th>Co-Financed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ministry of Industry:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Component 1 MIT Directives Gas Appliances (GAD), NHWBoilers:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1-1a  Istanbul Tech Univ Gas, Electrical, Fuel Appliances laboratory</td>
<td>204 000</td>
<td>25%</td>
<td>51 000</td>
</tr>
<tr>
<td>C1-1b  TUBITAK Gas Appliances Boliers analysis laboratory</td>
<td>503 500</td>
<td>25%</td>
<td>125 875</td>
</tr>
<tr>
<td>C1-2  TUBITAK Lab Gas Appliances Dir laboratory analysers</td>
<td>285 000</td>
<td>25%</td>
<td>71 250</td>
</tr>
<tr>
<td><strong>total MIT Dir</strong></td>
<td>992 500</td>
<td>248 125</td>
<td></td>
</tr>
<tr>
<td><strong>Ministry of Health:</strong></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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### Component 2 MoH Dir : Cosmetics and In Vitro Devices (IVD):

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Amount</th>
<th>Percentage</th>
<th>Ex 1000</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2-1 Chromatographs and Spectrometer for labs (Refik Saydam)</td>
<td>306 000</td>
<td>25%</td>
<td>76 500</td>
<td></td>
</tr>
<tr>
<td>C2-2 Virology, Tuberculosis, Communicable Diseases labs (Refik Saydam)</td>
<td>782 000</td>
<td>25%</td>
<td>195 500</td>
<td></td>
</tr>
<tr>
<td><strong>Total MoH Dir</strong></td>
<td>1 088 000</td>
<td></td>
<td>272 000</td>
<td></td>
</tr>
</tbody>
</table>

### Ministry of Agriculture and Rural Affairs

### Component 3 : Veterinary pharmacy:

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Amount</th>
<th>Percentage</th>
<th>Ex 1000</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3 Chromatography and residues control for Veterinary (Pendik Inst)</td>
<td>360 000</td>
<td>25%</td>
<td>90 000</td>
<td></td>
</tr>
<tr>
<td><strong>Total MARA Dir</strong></td>
<td>360 000</td>
<td></td>
<td>90 000</td>
<td></td>
</tr>
</tbody>
</table>

### Ministry of Public Works and Settlement

### Component 4 : Construction Products (Fire Testing):

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Amount</th>
<th>Percentage</th>
<th>Ex 1000</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>C4: TUBITAK Construction Products - Fire Laboratory</td>
<td>858 000</td>
<td>25%</td>
<td>214 500</td>
<td></td>
</tr>
<tr>
<td><strong>Total MoPWS Dir</strong></td>
<td>858 000</td>
<td></td>
<td>214 500</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL** 3 298 500 | 824 625

### 11.3 Additionality:

The EC grants will not displace other financiers especially from the private sector. The operations cover only market surveillance support to the Ministries and the recipients of equipment are either public laboratories or already designated laboratories by the Ministry for market surveillance purposes.

### 11.4 Project Readiness and Size:

All technical specifications will be completed by December 2005. The legislation is already harmonised in these areas and there is a clear government policy.

### 11.5 Sustainability:

The project supports the implementation and enforcement of the *acquis*. All equipment will be required to comply with the applicable European directives. Maintenance of the equipment, in particular the cost for spare parts and supplies will be borne by the budget of the beneficiaries.
11.6 Compliance with state aids provisions

Not applicable

12. Conditionality and sequencing

- Project beneficiaries should exclusively perform market surveillance activity and should not be involved in conformity assessment activities.

- Project beneficiaries should not be subject to Court proceedings (or be the object of negative Court rulings since 01.01.2002) in relation to their market surveillance activities.

Prior to the start of procurement (launch of tenders):

- All relevant legislative alignment and harmonisation of EN standards must be completed.

- Suitable physical infrastructure must exist to install and use the procured equipment.

- Beneficiary laboratories must fulfil the technical criteria in Annex 7

- Qualified human resources must be available to operate the equipment for the implementation of EC Directives
Annexes to Project Fiche

1. Logframe in standard format for each project.
2. Detailed Implementation Chart
3. Contracting and Disbursement Schedule
5. Reference list of relevant Laws and Regulations.
6. Reference List of relevant strategic plans and studies.
7. Criteria For Equipment Support to Laboratories
8. Some Sector Economic Data.
ANNEX 1: Logical framework matrix in standard format

<table>
<thead>
<tr>
<th>Programme name and number</th>
<th>Support to the Market Surveillance Laboratories for the Implementation of EC Directives in the areas of New Hot Boilers, Gas Appliances, Cosmetics, IVD, Veterinary Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracting period expires:</td>
<td>11/2007</td>
</tr>
<tr>
<td>Disbursement period expires:</td>
<td>11/2008</td>
</tr>
<tr>
<td>Total budget:</td>
<td>3 298 500 €</td>
</tr>
<tr>
<td>EU Contribution:</td>
<td>2 473 875 €</td>
</tr>
</tbody>
</table>

### Overall objective

The overall objective of the project is to contribute to the implementation of the EU *acquis communautaire* in the area of internal market, specifically focusing on the effective functioning of market surveillance support laboratories.

<table>
<thead>
<tr>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increased number of products offered for export to EU;</td>
<td>• NPAA</td>
</tr>
<tr>
<td>• Industrial products in compliance with the provisions of the applicable Directives placed on the market;</td>
<td>• EC regular report;</td>
</tr>
<tr>
<td></td>
<td>• Manufacturers association information.</td>
</tr>
</tbody>
</table>

### Project purpose

Strengthening of the national system of market surveillance support laboratories in the selected priority areas: New Hot Boilers, Gas Appliances, Cosmetics, IVD, Veterinary Pharmacy, Construction Products (Fire Testing) ensuring that they are equipped and capable autonomously to carry out the relevant testing services related to market surveillance.

<table>
<thead>
<tr>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Market Surveillance labs operational in the respective fields and performing tests in accordance with the requirements</td>
<td>• EC regular report;</td>
<td>• Development of the industrial sectors continue on a favourable economic environment.</td>
</tr>
<tr>
<td>• Ministries and Authorities carrying out market surveillance activities at EU standards</td>
<td>• Registry of accreditations at TURKAK;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reports on the progress of the project (Interim evaluation and monitoring reports).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Yearly M.S. Reports of Ministries/Authorities</td>
<td></td>
</tr>
</tbody>
</table>
### Results

<table>
<thead>
<tr>
<th>Component</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| Component 1: Ministry of Industry and Trade: | - Types of tests performed;  
- Number of tests performed;  
- Number of inspection reports issued.  
- Increased number of CE conforming products | - Registry of inspections and test reports at labs;  
- Reports on the progress of the project.  
- Manufacturers association information | - Use of the testing facilities by regulators (Ministries or Authorities);  
- Successful implementation of twinning/Tech Assistance projects for training Turkish experts  
- Achievement of competent and qualified staff to carry out the relevant tests. |
| Component 2: Ministry of Health: | - The necessary equipment for testing laboratories with regards to market surveillance on cosmetics and IVD supplied and operational.  
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Health increased and updated to EU compatible level | - Registry of inspections and test reports at labs;  
- Reports on the progress of the project.  
- Manufacturers association information | - Use of the testing facilities by regulators (Ministries or Authorities);  
- Successful implementation of twinning/Tech Assistance projects for training Turkish experts  
- Achievement of competent and qualified staff to carry out the relevant tests. |
| Component 3: Ministry of Agriculture and Rural Affairs: | - The necessary equipment for testing laboratories with regards to market surveillance on veterinary pharmacy supplied and operational.  
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Agriculture and Rural Affairs for veterinary pharmacy increased and updated to EU compatible level | - Registry of inspections and test reports at labs;  
- Reports on the progress of the project.  
- Manufacturers association information | - Use of the testing facilities by regulators (Ministries or Authorities);  
- Successful implementation of twinning/Tech Assistance projects for training Turkish experts  
- Achievement of competent and qualified staff to carry out the relevant tests. |
| Component 4: Ministry of Public Works and Settlement: | - The necessary equipment for testing laboratories with regards to market surveillance on construction products (fire testing) supplied and operational.  
- The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Public Works and Settlement for construction products (fire testing) increased and updated to EU compatible level | - Registry of inspections and test reports at labs;  
- Reports on the progress of the project.  
- Manufacturers association information | - Use of the testing facilities by regulators (Ministries or Authorities);  
- Successful implementation of twinning/Tech Assistance projects for training Turkish experts  
- Achievement of competent and qualified staff to carry out the relevant tests. |
<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Costs</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| **Component 1: Ministry of Industry and Trade:** | • Funds allocation for contracting:  
  - EC: 2 473 875 €  
  - Turkey: 824 625 €  
  - Call for proposals  
  - Equipment purchase contract.  
  - Training on equipment delivery | Component 1  
  - € 992 500 | • Logistics assistance is made available for customs, transportation, calibration and maintenance of project equipment, or any other similar problems. |
| Component 2: Ministry of Health: | | Component 2  
  - € 1 088 000 | • Personnel able to absorb training on test systems is available |
| Component 3: Ministry of Agriculture and Rural Affairs: | | Component 3  
  - € 360 000 | • Achievement of Proficiency testing – Laboratory inter-comparison campaign contracts with EU partners (see Quality Support Programme for TA) |
| Component 4: Ministry of Public Works and Settlement: | | Component 4  
  - € 858 000 | |
| | | | |

- Logistics assistance is made available for customs, transportation, calibration and maintenance of project equipment, or any other similar problems.
- Personnel able to absorb training on test systems is available
- Achievement of Proficiency testing – Laboratory inter-comparison campaign contracts with EU partners (see Quality Support Programme for TA)
**Pre-Conditions:**

- Suitable physical infrastructure to place the procured laboratory equipment and availability of basic equipment to interconnect with the procured equipment.
- Beneficiary laboratories fulfil the technical criteria in Annex 7
- Qualified human resources to operate the equipment for the implementation of EC Directives
## ANNEX 2: Detailed implementation chart

Support to the Turkish Conformity Assessment Bodies and the Ministry of Industry and Trade, Ministry of Health, Min of Agriculture

<table>
<thead>
<tr>
<th>Component 1 MIT Directives Gas Appliances (GAD), NHWBoilers:</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1-1a Istanbul Tech Univ Gas, Electrical, Fuel Appliances laboratory</td>
<td>T T T T T T T T T P P P I O O O O O O O O O O O O O O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1-1b TUBITAK Gas Appliances Boliers analysis laboratory</td>
<td>T T T T T T T T T P P P I O O O O O O O O O O O O O O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1-2 TUBITAK Lab Gas Appliances Dir laboratory analysers</td>
<td>T T T T T T T T T P P P I O O O O O O O O O O O O O O</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component 2 MoH Dir : Cosmetics and In Vitro Devices (IVD):</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2-1 Chromatographs and Spectrometer for labs (Refik Saydam)</td>
<td>T T T T T T T P P I O O O O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2-2 Virology, Tuberculosis, Communicable Deseases labs (Refik Saydam)</td>
<td>T T T T T T T P P P I O O O O O O O O O O O O O O</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component 3 : Veterinary pharmacy:</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3-1 Chromatography and residues control for Veterinary (Pendik Inst)</td>
<td>T T T T T T T T T P P P I O O O O O O O O O O O O O O</td>
<td></td>
<td></td>
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</tbody>
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<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>C4. TUBITAK Construction Products- Fire Laboratory</td>
<td>T T T T T T T T T P P P I O O O O O O O O O O O O O O</td>
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<td></td>
</tr>
</tbody>
</table>

T : tendering  
P : Procurement  
I: Installation
ANNEX 3: Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period)
Support to the Turkish Conformity Assessment Bodies and the Ministry of Industry and Trade, Ministry of Health, Min. Agriculture

<table>
<thead>
<tr>
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<td>122 400</td>
<td>183 600</td>
<td>183 600</td>
<td>183 600</td>
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<td>0</td>
<td>0</td>
<td>122 400</td>
<td>183 600</td>
<td>183 600</td>
<td>183 600</td>
</tr>
<tr>
<td>C1-1b</td>
<td>TUBITAK Gas Appliances, Boilers analysis laboratory</td>
<td>427 500</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>302 100</td>
<td>453 150</td>
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<td></td>
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<td>0</td>
<td>302 100</td>
<td>453 150</td>
<td>453 150</td>
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<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>453 150</td>
<td>453 150</td>
</tr>
<tr>
<td>C1-2</td>
<td>TUBITAK Lab Gas Appliances, Dir laboratory analyzers</td>
<td>265 000</td>
<td>Contracted</td>
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<td>0</td>
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<td>0</td>
<td>0</td>
<td>171 000</td>
<td>256 500</td>
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<td>0</td>
<td>0</td>
<td>171 000</td>
<td>256 500</td>
<td>256 500</td>
<td>256 500</td>
</tr>
<tr>
<td>C2-1</td>
<td>Chromatographs and Spectrometer for labs (Refik Saydam)</td>
<td>270 000</td>
<td>Contracted</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>183 600</td>
<td>306 000</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>306 000</td>
<td></td>
</tr>
<tr>
<td>C2-2</td>
<td>Virology, Tuberculosis, Communicable Diseases labs (Refik Saydam)</td>
<td>699 361</td>
<td>Contracted</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>469 200</td>
<td>703 800</td>
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<td>469 200</td>
<td>703 800</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>306 000</td>
</tr>
<tr>
<td>C3-1</td>
<td>Chromatography and residues control for Veterinary (Pendik Inst)</td>
<td>320 000</td>
<td>Contracted</td>
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<td>0</td>
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<td>216 000</td>
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<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>216 000</td>
<td>324 000</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>216 000</td>
<td>324 000</td>
</tr>
<tr>
<td>C4.</td>
<td>TUBITAK Construction Products-Fire Laboratory</td>
<td></td>
<td>Contracted</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 579 500</td>
<td>2 585 250</td>
<td>2 693 250</td>
<td>2 876 850</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 795 500</td>
<td>2 693 250</td>
<td>2 693 250</td>
<td>2 876 850</td>
</tr>
<tr>
<td>TOTAL</td>
<td>Contracted</td>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 579 500</td>
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<td>2 876 850</td>
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<td>0</td>
<td>1 795 500</td>
<td>2 693 250</td>
<td>2 693 250</td>
<td>2 876 850</td>
</tr>
</tbody>
</table>

NB: 1. all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
2. all disbursements must be completed within 36 months of signature of the FM
ANNEX 4 : Reference List of Feasibility Studies.

- Results of the Pre-feasibility Study (for 8 sectors within the Ministry of Industry, the Ministry of Health and the Telecom Authorities), study performed in May 2003 by EOTC under the frame of contract: Assistance for upgrading the physical infrastructure regarding Conformity Assessment and Market Surveillance in Turkey – "Reassessment of Sectors and Conditionalities in Ankara"

- Revision 23/12/03 of the Pre-feasibility Study, extended for 9 sectors

- Assessment of the sectors by EOTC in February-March 2004, expert reports available.
### ANNEX 5: List of relevant Laws and Regulations

#### 1. List of relevant Laws and Regulations - Ministry of Industry

**NHWB**

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>19.03.2003, No. 25053</td>
<td>(mandatory from 01.01.2004 on)</td>
</tr>
</tbody>
</table>

**GAD**

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Implementing Regulation Adding an Interim Article in the Implementing Regulation on Appliances Burning Gaseous Fuels (90/396/EC)</td>
<td>19.03.2003, No.25053</td>
<td>19.03.2003 (mandatory as of 01.01.2004)</td>
</tr>
</tbody>
</table>

**Cosmetics**

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Commission Decision 96/335/EC of 8 May 1996 establishing an</td>
<td>Law on Cosmetics</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Implementing Regulation on Cosmetics

A common nomenclature of ingredients employed in cosmetic products (Text with EEA relevance) and a common nomenclature of ingredients employed in cosmetic products (Text with EEA relevance)

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
</table>

#### IVD

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
</table>

#### Veterinary

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products</td>
<td>Communiqué on Colouring Matters Which may be added to Human and Veterinary Medicinal Products And Preparations</td>
<td>10.01.2005 / 25704</td>
<td>10.01.2005</td>
</tr>
<tr>
<td>3</td>
<td>Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products</td>
<td>Implementing Regulation on Controlling of Veterinary Medicinal Products And Preparations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Title of the EU Legislation</td>
<td>Corresponding Turkish Legislation</td>
<td>Date and Number of the Official Gazette</td>
<td>Date of entry into force</td>
</tr>
<tr>
<td>----</td>
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<td>-----------------------------------------------------------------</td>
<td>---------------------------------------</td>
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</tr>
</tbody>
</table>
ANNEX 6 : Reference List of relevant strategic plans and studies.

MARKET SURVEILLANCE STRATEGY OF THE MINISTRY OF INDUSTRY AND TRADE,
document available : Market Surveillance Strategy, MIT

MARKET SURVEILLANCE STRATEGY OF THE MINISTRY OF HEALTH
document available : Market Surveillance Strategy, MoH

MARKET SURVEILLANCE STRATEGY OF THE MINISTRY OF PUBLIC WORKS AND SETTLEMENT
document available : Market Surveillance Strategy, MoPWS
ANNEX 7: Criteria for the Equipment Support to Laboratories

- The laboratory will use the investment to fulfil the requirements to obtain the status of market surveillance support laboratory
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- The laboratory can raise the required funds to participate in the investment
- The laboratory is able to establish the appropriate sinking funds for the amortisation of the invested equipment.
- There shall be no duplication of equipment procured.
ANNEX 8 : Economic data on some sectors

(documents available)

- Cosmetic sector Market data.doc
- IVD sector data: see report from EOTC expert
ANNEXES TO PROJECT FICHE

1. Logframe in standard format for each project.
2. Detailed Implementation Chart.
3. Contracting and Disbursement Schedule
5. Reference list of relevant Laws and Regulations.
6. Reference List of relevant strategic plans and studies.
7. Criteria For Equipment Support to Laboratories
8. Some Sector Economic Data.
ANNEX 1: Logical framework matrix in standard format

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
</table>
| The overall objective of the project is to contribute to the implementation of the EU *acquis communautaire* in the area of internal market, specifically focusing on the effective functioning of market surveillance support laboratories. | • Increased number of products offered for export to EU;  
• Industrial products in compliance with the provisions of the applicable Directives placed on the market; | • NPAA  
• EC regular report;  
• Manufacturers’ association information. |

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| Strengthening of the national system of market surveillance support laboratories in the selected priority areas: New Hot Boilers, Gas Appliances, Cosmetics, IVD, Veterinary Pharmacy, Construction Products (Fire Testing) ensuring that they are equipped and capable autonomously to carry out the relevant testing services related to market surveillance. | • Market Surveillance labs operational in the respective fields and performing tests in accordance with the requirements  
• Ministries and Authorities carrying out market surveillance activities at EU standards | • EC regular report;  
• Registry of accreditations at TURKAK;  
• Reports on the progress of the project (Interim evaluation and monitoring reports).  
• Yearly M.S. Reports of Ministries/Authorities | • Development of the industrial sectors continues on a favourable economic environment. |
<table>
<thead>
<tr>
<th>Component 1: Ministry of Industry and Trade</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| • The necessary equipment for testing laboratories with regards to market surveillance on New Hot Boilers and Gas Appliances: supplied and operational.  
• The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Industry and Trade for the Directives increased and updated to EU compatible level | • Types of tests performed;  
• Number of tests performed;  
• Number of inspection reports issued.  
• Increased number of CE conforming products | • Registry of inspections and test reports at labs;  
• Reports on the progress of the project.  
• Manufacturers association information | • Use of the testing facilities by regulators (Ministries or Authorities);  
• Successful implementation of twinning/Tech Assistance projects for training Turkish experts  
• Achievement of competent and qualified staff to carry out the relevant tests. |
| Component 2: Ministry of Health | | | |
| • The necessary equipment for testing laboratories with regards to market surveillance on cosmetics and IVD: supplied and operational.  
• The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Health increased and updated to EU compatible level | | | |
| Component 3: Ministry of Agriculture and Rural Affairs | | | |
| • The necessary equipment for testing laboratories with regards to market surveillance on veterinary pharmacy supplied and operational.  
• The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Agriculture and Rural Affairs for veterinary pharmacy increased and updated to EU compatible level | | | |
| Component 4: Ministry of Public Works and Settlement | | | |
| • The necessary equipment for testing laboratories with regards to market surveillance on construction products (fire testing) supplied and operational.  
• The testing capabilities of market surveillance support laboratories and the inspection capabilities of the Ministry of Public Works and Settlement for construction products (fire testing) increased and updated to EU compatible level | | | |
<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Costs</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| **Component 1: Ministry of Industry and Trade:** | • Funds allocation for contracting:  
  • EC: **2 473 875 €**  
  • Turkey: **824 625 €**  
  • Call for proposals  
  • Equipment purchase contract.  
  • Training on equipment delivery | Component 1  
  € **992 500** | • Logistics assistance is made available for customs, transportation, calibration and maintenance of project equipment, or any other similar problems.  
• Personnel able to absorb training on test systems is available  
• Achievement of Proficiency testing – Laboratory inter-comparison campaign contracts with EU partners (see Quality Support Programme for TA) |
| **Component 2: Ministry of Health:** | | Component 2  
  € **1 088 000** |
| **Component 3: Ministry of Agriculture and Rural Affairs:** | | Component 3  
  € **360 000** |
| **Component 4: Ministry of Public Works and Settlement:** | | Component 4  
  € **858 000** |
| | | | • Funds allocation for contracting:  
  • Training of laboratory staff on the use of equipment and analysis, when necessary (as a part of supply contract) |
Pre-Conditions:

- Suitable physical infrastructure to place the procured laboratory equipment and availability of basic equipment to interconnect with the procured equipment.
- Beneficiary laboratories fulfil the technical criteria in Annex 7
- Qualified human resources to operate the equipment for the implementation of EC Directives
**ANNEX 2: Detailed implementation chart**

*Support to Market Surveillance Laboratories*

<table>
<thead>
<tr>
<th>Component 1 MIT Directives Gas Appliances (GAD), NHWBoilers:</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1-1b TUBITAK Gas Appliances Boilers analysis laboratory</td>
<td>T T T T T T T T T T T T P P P I</td>
<td>O O O O O O O O O O</td>
<td>O O O O O O O O O O</td>
</tr>
<tr>
<td>C1-2 TUBITAK Lab Gas Appliances Dir laboratory analysers</td>
<td>T T T T T T T T T T T T P P P I</td>
<td>O O O O O O O O O O</td>
<td>O O O O O O O O O O</td>
</tr>
</tbody>
</table>

| Component 2 MoH Dir : Cosmetics and In Vitro Devices (IVD): |
|-------------------------------------------------------------|------|------|------|
| C2-1 Chromatographs and Spectrometer for labs (Refik Saydam) | | | T T T T T T T T P P I O O O O |
| C2-2 Virology, Tuberculosis, Communicable Diseases labs (Refik Saydam) | | | T T T T T T T T P P P I O O O O O O O O O O |

| Component 3 : Veterinary pharmacy: |
|-------------------------------------|------|------|------|
| C3-1 Chromatography and residues control for Veterinary (Pendik Inst) | | | T T T T T T T T T T T T P P P I O O O O O O O O O O |

| Component 4: Construction Products (Fire Testing): |
|----------------------------------------------------|------|------|------|
| C4. TUBITAK Construction Products- Fire Laboratory | | | T T T T T T T T P P P I O O O O O O O O O O O |

**Notes:**
- T: tendering
- P: Procurement
- I: Installation
## ANNEX 3: Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period)

### Support to Market Surveillance Laboratories

<table>
<thead>
<tr>
<th>Contracting</th>
<th>Disbursement</th>
<th>C1-1a Istanbul Tech Univ Gas, Electrical, Fuel Appliances laboratory</th>
<th>C1-1b TUBITAK Gas Appliances Boilers analysis laboratory</th>
<th>C1-2 TUBITAK Lab Gas Appliances Dir laboratory analysers</th>
<th>C2-1 Chromatographs and Spectrometer for labs (Refik Saydam)</th>
<th>C2-2 Virology, Tuberculosis, Communicable Diseases labs (Refik Saydam)</th>
<th>C3-1 Chromatography and residues control for Veterinary (Pendik Inst)</th>
<th>C.4. TUBITAK Construction Products-Fire Laboratory</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracted</td>
<td>Contracted</td>
<td>171 000 0 0 0 0 122 400 183 600 183 600 183 600 204 000</td>
<td>427 500 0 0 0 302 100 453 150 453 150 453 150 503 500</td>
<td>265 000 0 0 0 171 000 256 500 256 500 256 500 285 000</td>
<td>270 000 0 0 0 0 183 600 306 000</td>
<td>699 361 0 0 0 0 183 600 782 000</td>
<td>320 000 0 0 0 216 000 324 000 324 000 324 000 360 000</td>
<td>514 800 0 0 0 514 800 772 200 772 200 772 200 858 000</td>
<td>0 0 0 0 1 579 500 2 585 250 2 693 250 2 876 850 3 298 500</td>
</tr>
<tr>
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<td>Disbursed</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
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<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
</tr>
<tr>
<td>Sept-06</td>
<td>Sept-07</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
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<tr>
<td>Oct-06</td>
<td>Oct-07</td>
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<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
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<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
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<tr>
<td>Nov-06</td>
<td>Nov-07</td>
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<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
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<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td>
</tr>
</tbody>
</table>

**NB:**
1. All contracting should normally be completed within 6-12 months and **must** be completed within 24 months of signature of FM
2. All disbursements **must** be completed within 36 months of signature of the FM
ANNEX 4: Reference List of Feasibility Studies.

- Results of the Pre-feasibility Study (for 8 sectors within the Ministry of Industry, the Ministry of Health and the Telecom Authorities), study performed in May 2003 by EOTC under the frame of contract: Assistance for upgrading the physical infrastructure regarding Conformity Assessment and Market Surveillance in Turkey – “Reassessment of Sectors and Conditionalities in Ankara”

- Revision 23/12/03 of the Pre-feasibility Study, extended for 9 sectors

- Assessment of the sectors by EOTC in February-March 2004, expert reports available.
### ANNEX 5: List of relevant Laws and Regulations

#### 1. List of relevant Laws and Regulations—Ministry of Industry

**NHWB**

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>19.03.2003, No. 25053</td>
<td>19.03.2003 (mandatory from 01.01.2004 on)</td>
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</table>

**GAD**

<table>
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<tr>
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<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Implementing Regulation Adding an Interim Article in the Implementing Regulation on Appliances Burning Gaseous Fuels (90/396/EC)</td>
<td>19.03.2003, No. 25053</td>
<td>19.03.2003 (mandatory as of 01.01.2004)</td>
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</table>

**Cosmetics**

<table>
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<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Implementing Regulation on Cosmetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Commission Decision 96/335/EC of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (Text with EEA relevance)</td>
<td>Law on Cosmetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Title of the EU Legislation</td>
<td>Corresponding Turkish Legislation</td>
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</tbody>
</table>

**IVD**

<table>
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<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
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</thead>
</table>

**Veterinary**

<table>
<thead>
<tr>
<th>No</th>
<th>Title of the EU Legislation</th>
<th>Corresponding Turkish Legislation</th>
<th>Date and Number of the Official Gazette</th>
<th>Date of entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products</td>
<td>Communiqué on Colouring Matters Which may be added to Human and Veterinary Medicinal Products And Preparations</td>
<td>10.01.2005 / 25704</td>
<td>10.01.2005</td>
</tr>
<tr>
<td>3</td>
<td>Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products</td>
<td>Implementing Regulation on Controlling of Veterinary Medicinal Products And Preparations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Title of the EU Legislation</td>
<td>Corresponding Turkish Legislation</td>
<td>Date and Number of the Official Gazette</td>
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    Document available:  Market Surveillance Strategy, MoH

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- The laboratory is able to establish the appropriate sinking funds for the amortisation of the invested equipment.
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/Documents available/

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- IVD sector data: see report from EOTC expert