

Project Fiche
IPA Decentralised National Programmes
Project number: TR 07 02 10

1. Basic Information

1.1. CRIS Number:

1.2. Title: Establishment of an Accredited Calibration Laboratory

1.3. Sector: Internal Market

1.4. Location: Ankara / TURKEY

Implementing Arrangements

1.5. Implementing Agency:

The CFCU will be the implementing agency and will be responsible for all procedural aspects of the tendering process, contracting matters and financial management including payment of project activities. The Director of the CFCU will act as Programme Authorizing Officer (PAO) of the project.

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1.6. Beneficiary: The principal beneficiary of the “**Establishment of an Accredited Calibration Laboratory**” is Refik Saydam Hygiene Center (Ministry of Health)

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2007/ Calibration 11062007

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The project will be coordinated by Poison Research Department of RSHC. Interim Quarterly Reports will be prepared and discussed at the Steering Committee (SC) meetings to be held on a quarterly basis. The Project Steering Committee will be chaired by SPO, Assoc. Prof. **Mustafa** Ertek, President of RSHC and will be composed of :

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Representatives of the Delegation, CFCU and EUSG will participate in the SC meetings as observers.

1.7. Overall cost: 1.130.000 €

1.8.EU contribution: 1,035,000 €

1.9.Final date for Contracting: 2 years after the signature of the Financing Agreement

1.10. Final date for execution of contracts: 4 years after the signature of the Financing Agreement

1.11. Final date for disbursements: 5 years after the signature of the Financing Agreement

2. Overall Objective and Project Purpose

2.1. Overall Objective: To further strengthen the quality infrastructure in the field of market surveillance of chemical safety, food safety and nutrition, toys, water quality, drugs and cosmetics, environmental health, and public health.

2.2. Project Purpose: To increase the quality and effectiveness of the services provided by RSHC in accordance with quality standards TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice by June 2010.

2.3.1. Link with AP: The Accession Partnership 2003 sets out the principles, priorities intermediate objectives and conditions decided by the European Council and Turkey.

In short term, the priorities are

-Free movement of goods

‘Start implementing certification and conformity assessment and marking in compliance with the New and Global Approach directives, reinforce existing market surveillance and conformity-assessment structures with equipment and training and create compatible administrative infrastructure; complete work relating to mutual recognition in sectors that are not harmonized;’

-Consumer protection and health

‘Further align legislation with the acquires and develop infrastructure for effective implementation, in particular with regard to market surveillance,’

In medium term, the priorities are

-Free movement of goods

‘Complete alignment with acquires; complete strengthening of existing certification, market surveillance and conformity-assessment structures’

-Agriculture

‘Re-organize and strengthen the food safety and control system and upgrade human, technical and financial resources to ensure that EC food safety standards, and further establishment of testing and diagnostic facilities’

2.3.2.Link with NPAA: The Turkish Government has adopted the NPAA 2003 and in line with the ‘New Approach Directives’, ‘Foodstuffs’ and ‘Chemical Substances’ sections have the priorities as follows:

Priority 1.1. New Approach Directives

‘For the proper implementation of the directives it is essential to establish a market surveillance and assessment system, and develop the accreditation, and certification and testing bodies and laboratories which will operate within this system in conformity with European Union requirements.’

‘The institution building schedule for the implementation of the legislation gives priority to accreditation of Refik Saydam hygiene Center laboratories in the fields of medical devices and toys.’

Priority 1.3. Foodstuffs

‘Food control in Turkey is carried out by the Ministry of Agricultural and Rural Affairs and the Ministry of Health.’

‘The institution building schedule for the implementation of the legislation gives priorities to accelerate accreditation studies of the official food control.’

Priority 1.4. Chemical Substances

‘For the inspection of chemical substances the administrative structure has to be recognized according to the needs of the new system. Moreover for proper monitoring and verification

during the implementation, Good Laboratory Practices (GLP) has to be established and the related administrative structure has to be reorganized accordingly

2.4. Link with MIPD: In Multi-annual Indicative Planning Document (MIPD) for Turkey: Component I- Transition Assistance and Institution Building has main priorities and objectives. One of the priorities for assistance under this component is Transportation and implementation of acquits and its sub priority is:

Transposition and implementation of the acquis

Agriculture (including veterinary and phytosanitary issues, as well as the fisheries sector): ‘Administrative structures to operate Common Agricultural Policy, particularly in the area of rural development, and Common Fisheries Policy instruments; Animal identification and registration; Eradication of main animal diseases, continuing on-going programs related to the eradication of rabies, FMD and the control of avian influenza; Implementation of EU health and food safety related standards in food production and food-processing establishments, in particular targeting sectors and sub-sectors identified under component V; Implementation of residues and zoonosis control programs; Veterinary and phytosanitary border controls;’

Addition to above sub priority, Institution Building support in the areas of the acquits:

‘Free Movement of Goods (support for quality assurance at testing and calibration laboratories)’

2.5. Link With EU Legislation: The project is closely linked with the EU legislation in the field of Free Movement of Goods concerning toys, medical devices, medicinal products, cosmetics, chemicals, detergents, GLP, foodstuffs, plastics, rubber, natural mineral waters and also water for human consumption and biocides. The relevant EU legislation is given in Annex 4.

3. Description of Project

3.1. Background and justification: Refik Saydam Hygiene Center was established as a National Reference Laboratory. It has 7 regional institutes and is the coordinator of 115 **provincial** Public Health Laboratories. With its mission, it carries out laboratory analysis for,

and provides consultancy and expertise to the Ministry of Health and the other Ministries, institutions, customs offices, private companies, individuals and stakeholders including the Ministry of Environment and Forestry, Ministry of Agriculture and Rural Affairs.

Due to the wide range of responsibilities, it is involved in a variety of activities which are decentralized in ten departments **in the center**. Departments of **RSHC** directly related to internal market and consumer **safety** and their responsibilities are as follows:

a) Drugs& Cosmetics Research Department

- laboratory studies and quality control tests within the system of National Drug and Cosmetics Quality Control
- physical, chemical, pharmaceutical, microbiological and pharmacological tests on the officially sent samples of locally produced or imported human and veterinary drugs, raw material, drug products, some medical devices and cosmetics for the preregistration and post marketing control
- to follow the guidelines of the harmonization studies among European union and recent studies to guarantee safety and quality of drugs on the market

b) Food Safety and Nutrition Research Department

- control of food products, food supplementary products and food packaging materials physically, chemically and bacteriological
- analysis of the imported medically aimed baby food and internal products
- analysis of drinking water, spring water, mineral water and packaging materials used in contact with water for registration purposes

c) Poison Research Department

- analysis of residual pesticides, phenols in bottled water drinking water, mineral water and thermal water for registration purposes
- implementation of conformity assessment procedures in the field of toxic and hazardous chemicals in food, water, consumer products and biological products, to investigate complaint samples for chemical safety
- analysis of chemicals poisoning agents in food, water and biological materials in case of poisoning

d) Environmental Health Research Department

- studies on control, monitoring and analysis at national and international level in order to protect environmental and public health
- control and research industrial waste and waste water
- control and research cleaning materials like detergents
- control and research air pollution, noise control and soil pollution

In addition to these departments, RSHC also has Biological Products Control & Research Laboratory, Virology Laboratory, Tuberculosis Reference & Research Laboratory, Vaccine & Sera Production & Research Department, Department of Communicable Diseases and Research, Blood & Blood Products production & Research Department in the headquartes working in the

field of public health. Moreover, in the seven regional institutes of RSHC physical, chemical and bacteriological controls of food products, food supplementary products, food packaging materials, drinking water, spring water, mineral water and bottled water are currently being carried out. In the 115 Public Health Laboratories, coordinated by RSHC, mostly analysis of drinking water, spring water, mineral water, packaging materials used in contact with water, food products, food supplementary products and food packaging materials are conducted.

RSHC is in the process of establishing its quality infrastructure. Application for certification of RSHC according to the ISO 9001 Quality Management System was submitted to the Turkish Standardization Institute (TSE), the certifying institution, in June 2007 and an audit will be performed at RSHC by TSE in August 2007. For the ISO 9001 Quality Management System and the EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories, the first four requirements for the administrative issues are similar, however as the laboratory is a technical issue, there are further requirements for accreditation (EN ISO/IEC 17025) and the certifying agency is the Turkish Accreditation Agency (TÜRKAK). The aim of RSHC is to be accredited accordingly and for this aim, ISO 9001 certification is the first step. Furthermore, there are steps taken by RSHC to provide consultance service from the National Metrology Institute (UME) on the placement and infrastructural requirements of the calibration laboratory to be established within RSHC. This initiative is yet at the discussion stage.

RSHC is coordinating a twinning project on Good Laboratory Practice (TR 0402. 03) which is involving assistance and training, provided by the Slovak Twinning Partner, for GLP compliance in three laboratories of RSHC working in the field of Free Movement of Goods, namely Pharmacology Laboratory, Pesticides Formulation Laboratory and Biological Control and Research Laboratory. The project aims enforcement of the EU Directives related to GLP in accordance with their transposition into Turkish Law, establishment of the GLP Monitoring Authority and establishment of an agreed framework for GLP in the field of chemicals.

Another EU funded Twinning Project on Biocidal Products (TR 0402.10) is also assisting in the ISO EN 17025 accreditation of the related laboratories of RSHC, with Austria as the Twinning Partner. Support to the Quality Infrastructure in Turkey Program has supported the Ministry of Health with a short term TA action in drafting of its market surveillance strategy for toys, medical devices and detergents and RSHC has participated in this activity. Furthermore, the Health Transition Project, supported by the World Bank, is also providing assistance and training to RSHC for achieving its goal towards establishment of the quality infrastructure.

In Turkey, 37 calibration laboratories from different sectors are accredited by TÜRKAK. Some of them only provide internal service and others are private companies in different fields. However, accredited sector for calibration is new in Turkey and this causes some inadequacies; mostly the scope of calibration is limited to volume calibrations for pipettes and burettes only. For the scope of RSHC, there are many experiments and analysis done whose limits and uncertainties are important. At this point, due to the important role of RSHC for Turkey, the calibration issue gains importance again. The aim of this project is to close this gap, firstly for RSHC itself and then for others effecting the internal market and consumers.

Calibration of the laboratory equipment is crucial for quality systems such as ISO EN 17025 and GLP that lead to international recognition of test results generated by the laboratories. RSHC either has to pay for external calibration service or set up its own accredited calibration laboratory which can also serve external laboratories and sectors.

As a pre-condition of the EC, RSHC (attached as an annex to the PF) carried out a feasibility study to assess cost effectiveness of setting up an accredited calibration laboratory, by

investigation and comparison of the financial aspects of procurement of this service from the market, versus the cost of establishment of a calibration laboratory. With this respect, research was done on the cost of external calibration services and the number of equipment and glass materials that need calibration, taking into consideration calibration periods and calibration fees. With the basic information already available from the feasibility study, a second study was carried out to identify the calibration equipment, training and consultancy requirements to determine the cost of setting up a new calibration laboratory.

The yearly cost of calibration for RSHC laboratories with 7 regional institutes and 115 Public Health Laboratories for balance and volume calibrations is 381,120 €, for temperature calibration one point temperature measurement is 44,824 € and plane temperature distribution measurement is 190,080 €. As total cost for only **external** calibration is 616,024 € and the amount of money **required for establishment of the calibration laboratory** from this project is 1,130,000 €, in two years money paid for only calibration will be higher than the project budget. **It is understood that, for RSHC to purchase the equipment and establish a calibration laboratory is more cost effective than buying services from the market for a laboratory of this size.**

It is unfortunate that there is no sectoral investment plan for Chapter 1 of the acquis which consists of several different pieces of legislation from automotive to detergents, to frame the supply of equipment envisaged in this project. There have been some feasibility studies under the 2003 programming for identification of equipment needs. As a result of these studies, RSHC received equipment support on medical devices and detergents.

RSHC is also a beneficiary of four twinning projects concerning GLP, medical devices, biocides and water. In order to obtain better and more efficient results of the past and the current assistance, and as the sole public laboratory/market surveillance authority for medical devices, in-vitro medical devices, pharmaceuticals, detergents, cosmetics and toys and as a candidate GLP-compliant laboratory for chemicals, RSHC will need to be accredited and use calibration services.

3.2. Assessment of project impact, catalytic impact, sustainability and cross border effect:

The project will contribute to Chapter 1 of the acquis by enabling reinforced conformity assessment/market surveillance capacity of the Ministry of Health and RSHC in the area of medical devices, in-vitro medical devices, pharmaceuticals, detergents, cosmetics, toys and chemicals.

Financial sustainability: When the project is completed, the money paid to the private sector by RSHC for repairing, measuring sterility and calibration will be less than the amount for now. **Continuity of trainings, in service training, maintenance of the equipment, accreditation costs and supply of additional equipment, as needed, will be provided by RSHC.**

Institutional sustainability: The accredited calibration laboratory will be established under the structure of RSHC to provide service to all laboratories of RSHC and MOH firstly, then **to external laboratories of** the market which need calibration services of volume, mass-balance, and temperature like markets related with cosmetics, drugs, medicines, toys, foods, detergents, vaccines, poisoning, blood production, environmental issues like water quality services.

RSHC has to carry out some laboratory studies (especially in Drugs and Cosmetics Research Department, Food Safety and Nutrition Research Department, Poison Research Department) in laminair and biosafety cabinets to protect the staff from the dangerous gases occurring during the experiments and to protect products from the contamination caused by dust or air. The clean room and sterility control laboratory conducts standard tests like air velocity, smoke test and particule counter on laminair and biosafety cabinets, to check whether these equipment work effectively. In Turkey there is only one company (branch office of an international company) that has the certificate of doing these special tests **for validation**, however it is not accredited yet.

Electronic and Biomedical Equipment Maintenance and Repair Laboratory of RSHC has the responsibility of all the equipment maintenance and repair. Due to the fact that calibration and maintenance laboratories must be in cooperation, as when the calibration of equipment are done and the uncertainty limits are so high according to the analysis and experiments, **the equipment must be checked to see what is wrong, why it does not work efficiently and the maintenance and/or repair is to be done accordingly.** After repairing, the equipment must be calibrated again before beginning to use to confirm that it works effectively.

As a result, strengthening and accreditation of the ‘Electronic and Biomedical Equipment Maintenance and Repair Laboratory’ and the ‘Clean Room and Sterility Control Laboratory’ of RSHC will strengthen the structure and services of RSHC in the field of Free Movement of Goods and public health .

The staff of the calibration laboratory will be composed of a medical physicist, an electronic engineer, an electronic-electricity engineer and an electricity technician currently employed by RSHC. This team will be responsible for calibration for the whole institute and getting the accreditation certificate for this laboratory firstly, then, supported with additional personnel, it will serve external laboratories. The laboratory will report to the President of the institute.

3.3. Results and Measurable indicators: The following three results are expected from the Project:

1. An accredited calibration laboratory is established within the Ministry of Health to assist RSHC laboratories in meeting quality standard TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice by June 2010.

2. Electronic and Biomedical Equipment Maintenance and Repair Laboratory of RSHC is strengthened and accredited. As the duty of this laboratory is to serve all the laboratories for repair and maintenance, it acts as a supplier for RSHC laboratories and it is an obligation of ISO EN 17025 that this laboratory must also be strengthened and accredited.

3. The Clean room and Sterility Control Laboratory of RSHC is strengthened and accredited.

The laboratory conducts some standard tests on laminair and biosafety cabinets to check whether these equipment work effectively. The aim of the Clean Room and Sterility Control laboratory is to gain ability to apply all the necessary standard tests for validation of laminair

and biosafety cabinets and to be accredited in this field to serve RSHC and external laboratories.

According to these results the measurable indicators are follows:

- 1.1. At least 4 people trained about the accreditation and calibration by May 2009.
- 1.2. The needed equipment for calibration laboratory supplied by second quarter half of 2010.
- 1.3. Certification of accreditation of the calibration laboratory achieved by third quarter of 2010.

- 2.1. At least 4 people trained on maintenance and repairs about the equipments used in RSHC by August 2009.
- 2.2. The quality of given services at least 40% by laboratory to the RSHC laboratories is increased by August 2010.
- 2.3. Certification of accreditation of the Electronic and Biomedical Equipment Maintenance and Repair Laboratory by August 2010.

- 3.1. At least 3 people trained on Clean room and Sterility Control by August 2009.
- 3.2. The needed equipment for Clean Room and Sterility Control Laboratory supplied by second half of 2010.
- 3.3. The quality of given services at least 40% by laboratory to the RSHC laboratories is increased by August 2010.
- 3.4. Certification of accreditation of the Clean room and Sterility Control Laboratory

3.4. Activities:

1. An accredited calibration laboratory is established within the Ministry of Health to assist RSHC laboratories in meeting quality standard TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice by June 2010.

1.1. Two study tours of five days each for 6 persons arranged to the members of European Accreditation

1.2. A counseling service from primary level of accreditation and calibration.

1.3. Accreditation and calibration trainings from 'Accreditation Monitoring Authority' for 8 personnel

1.4. Supply of equipment

1.5. Training on the equipment supplied

1.6. Certification of accreditation.

2. Electronic and Biomedical Equipment Maintenance and Repair Laboratory of RSHC is strengthened and accredited.

2.1. Theoretical training on maintenance and repairs of electronic and biomedical equipment for one month in RSHC.

2.2. Practical training on maintenance and repairs of electronic and biomedical equipment for one month in RSHC.

2.3. Accreditation training for 4 personnel.

2.4. Certificate of accreditation.

3. The Clean room and Sterility Control Laboratory of RSHC is strengthened and accredited.

3.1. Theoretical training on clean room and sterility control for 15 days in RSHC.

3.2. Practical training on clean room and sterility control for 15 days in RSHC.

3.3. Accreditation training for 4 personnel.

3.4. Supply of the equipment

3.5. Trainings on equipment supplied.

3.6. Certificate of accreditation

3.5. Conditionality and sequencing: The tender of this project can be launched by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s).

Laboratory infrastructure where the supplies will be installed are fully prepared and ready to receive, install and operate the equipment.

The sequence of activities:

For Accredited Calibration Laboratory:

Two study tours seven days of each for 8 persons arranged to the members of European Accreditation

A counseling service from primary level of accreditation and calibration.

Accreditation and calibration trainings from 'Accreditation Monitoring Authority' for 8 persons

Supply of the equipment

Training on the equipment supplied.

Certification of accreditation.

For Electronic and Biomedical Equipment Maintenance and Repair Laboratory:

Theoretical training on maintenance and repairs of electronic and biomedical equipment for one month in RSHC.

Practical training on maintenance and repairs of electronic and biomedical equipment for one month in RSHC.

Accreditation trainings for 4 persons.

Certificate of accreditation.

For Clean Room and Sterility Control Laboratory:

Theoretical training on clean room and sterility control for 15 days in RSHC.

Practical training on clean room and sterility control for 15 days in RSHC.

Accreditation trainings for 4 persons.

Supply of the equipments

Trainings on equipment supplied.

Certificate of accreditation.

3.6. Linked Activities:

Good Laboratory Practice (GLP) twinning project (Project No.TR 0402.03) **is providing training and assistance for setting up the national GLP system in Turkey, also assisting three RSHC laboratories to achieve GLP compliance.** According to GLP principles, calibration and

validation have to be made regularly to be sure about the reliability and the validity of the results.

Market Surveillance Support on Medical Devices EU Twinning Project (TR/04/IB/EC/02) had a seminar about the Quality Systems: ISO EN 17025 and ISO EN 15189 between the dates of 15-17 January of 2007 . In this seminar general knowledge about technical and administrative requirements for calibration and experimental laboratories according to ISO EN 17025 is learnt with the help of this activity.

Biocidal Products and Water Project (Project No. TR 0402.10) (Twinning and supply of equipment); **Training and assistance on : ISO EN 17025 accreditation is provided within the project.** Calibration of equipment like pipettes, burettes, balances, incubators, deepfreeze and the validation of equipment are important for this project again.

Cosmetics and Invitro Diagnostics Project (Supply of equipment and training) the importance of uncertainty calculations and the calibration is learnt from the seminars.

Support to Quality Infrastructure in Turkey Program (Training) provided training about conformity assessment and quality management systems, Internal Quality Inspection, Quality System Documentation and ISO EN 17025 .

3.7. Lessons Learned:

Support to Conformity assessment Bodies (CABs) Project (Project No.TR 0302.01) was breaking the ice at RSHC for the EU projects; its steps are important to follow what is happening next. **A business plan was prepared by RSHC for this project in 2004. However, it needs to be revised and updated and this can be accomplished within the scope of the project on the “Establishment of an Accredited Calibration Laboratory”, to justify the need for the equipment supply envisaged in the PF.**

Good Laboratory Practice (GLP) project (Project No.TR 0402.03) is the first twinning project coordinated by RSHC and has provided an extensive experience in coordinating a wide-scope project involving MOH, MOEF, MARA, TÜRKAK, the industry and the Slovak Republic as the MS Twinning Partner. It has also formed the basis to improve coordination and

cooperation skills and capacity of the beneficiaries, contributing highly to the success and the sustainability of the project results.

RSHC has received equipment supply from the EU funded CABs, Air Quality, Water and Biocides Projects and gained experience in the preparation of tender documents, tendering and evaluation processes. On the other hand, the institute has also benefited from training and assistance within the scope of these projects in addition to other projects and programmes such as the Medical Devices Twinning Project, Travel Facilities Project, the Health Transition Project of the World Bank, MATRA Programme, the Administrative Cooperation Programme (2003 and 2005), TAIEX and the Support to the Quality Infrastructure in Turkey Programme that assisted RSHC to strengthen its technical and administrative capacity and to install a quality management system.

The experience gained by RSHC through the activities of these past and current projects will facilitate the management of the project on the “Establishment of an Accredited Calibration Laboratory” and will lead to successful and sustainable project results.

4. Indicative Budget:

The project works including infrastructure will be done by Refik Saydam Hygiene Center before the equipment will come to institute. Within the structural design of the institute, the

place of the calibration laboratory is decided. On the other hand, the Electronic and Biomedical Equipment Maintenance and Repair Laboratory needs minor changes; redesign of its work component will also be done by institute. The Clean Room and Sterility Control Laboratory serves with mobile equipment, it only needs a room for the equipment and the staff.

	<u>TOTAL PUBLIC COST</u>	<u>SOURCES OF FUNDING</u>								
		<u>EU CONTRIBUTION</u>				<u>NATIONAL PUBLIC CONTRIBUTION</u>				
		<u>Total</u>	<u>% *</u>	<u>IB</u>	<u>INV</u>	<u>Total</u>	<u>Type of cofinancing (J/P) **</u>	<u>% *</u>	<u>Central</u>	<u>Region</u>
<u>Activities</u>										
<u>Activity 1</u>										
<u>Supply Contract</u>	<u>380.000</u>	<u>285.000</u>	<u>75</u>		<u>285.000</u>	<u>95.000</u>	<u>J</u>	<u>25</u>	<u>95.000</u>	
<u>Activity 2</u>										
<u>Service Contract</u>	<u>750.000</u>	<u>750.000</u>	<u>100</u>	<u>750.000</u>						
<u>TOTAL</u>	<u>1.130.000</u>	<u>1.035.000</u>				<u>95.000</u>				

** compulsory for INV (minimum of 25 % of total EU + national public contribution) : Joint cofinancing (J) co financing (P) per exception

* expressed in % of the Total Public Cost

5. Indicative Implementation Schedule

Contracts	Start of Tendering	Signature of Contract	Contract Completion
Contract 1(supply contract including equipment for laboratories)	Q1 2008	Q 3 2008	Q 4 2009
Contract 2 (service contact including trainings and consultancy)	Q1 2008	Q 3 2008	Q 4 2009

Duration of the project: 24 months

6. Cross Cutting Issues:

6.1. Equal Opportunity: Equal participation of women and men will be secured through appropriate information and publicity material, in the design of projects and access to the opportunities they offer. An appropriate men/women balance will be sought on all the managing bodies and activities of the programme and its projects.

6.2. Environment: This project has no negative impact on environment.

6.3. Minority and vulnerable groups: According to the Turkish Constitutional System, the word minorities encompasses only groups of persons defined and recognized as such on the basis of multilateral or bilateral instruments to which Turkey is a party. Moreover, Turkish Law put an obligatory of engaging disabled person in the amount of defined. Within the scope of Refik Saydam Hygiene Center disabled persons have the opportunity of working and earning their own money.

ANNEX 1: Logframe Matrix

Proje Referans No: 148

Proposal Title: Establishment of an Accredited Calibration Laboratory

LOGFRAME PLANNING MATRIX FOR	Programme name and number	IPA
	Contracting period expires : 2 years after the signature of the Financing Agreement	Disbursement period expires: 5 years after the signature of the Financing Agreement
	Total budget : 1.130.000 €	IPA budget : 1.035.000 €

Overall objective	Objectively verifiable indicators	Sources of Verification	
To further strengthen the quality infrastructure in the field of market surveillance of chemical safety, food safety and nutrition, toys, water quality, drugs and cosmetics, environmental health, and public health.	<p>1. Increased the trustworthiness of the public at least 50 % about the quality of services given by RSHC by August 2010.</p> <p>2. Increased at least 50 % understanding of the public about the importance of the quality infrastructure for and consumer safety in the field of toys, food, drugs and cosmetics and public health. By August 2010.</p>	<p>1.1. Statistics which are applied to the public about the health services.</p> <p>2.1. Evaluation reports after getting services and using goods.</p>	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions

<p>To increase the quality and effectiveness of the services provided by RSHC in accordance with quality standards TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice by June 2010.</p>	<p>1. An increase of at least 50 % in the quality of the test data product by August 2010.</p> <p>2. An increase of at least 25 % in the international recognition of test data produced.</p>	<p>1.1. Results of inter laboratory proficiency tests.</p> <p>1.2. Certification of test laboratories according to TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice</p> <p>2.1. GLP Compliance certificates</p> <p>2.2. Applications by the industry for health and environmental safety testing chemicals.</p>	<p>Political continuity about the public health and consumer safety.</p> <p>Continuous interest of health care services, public and private laboratories and the industry to cooperate with RSHC for calibration services.</p>
<p>Results</p>	<p>Objectively verifiable indicators</p>	<p>Sources of Verification</p>	<p>Assumptions</p>
<p>1. An accredited calibration laboratory is established within the Ministry of Health to assist RSHC laboratories in meeting quality standard TS EN ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories and Good Laboratory Practice by June 2010.</p>	<p>1.1. At least 4 people trained about the accreditation and calibration by May 2009.</p> <p>1.2. The needed equipment for calibration laboratory supplied by second quarter half of 2010.</p>	<p>1.1.1. List of trained persons.</p> <p>1.1.2. Certificated of the calibration and accreditation trainings.</p> <p>1.2.1. Tender dossier</p> <p>1.2.2. Certificate of warranty</p> <p>1.2.3. Receiving report</p>	<p>Continuity of commitment and will of RSHC at the management level.</p> <p>Good co-operation and collaboration between RSHC and TURKAK.</p>

<p>2. Electronic and Biomedical Equipment Maintenance and Repair Laboratory of RSHC is strengthened and accredited.</p>	<p>1.3. Certification of accreditation of the calibration laboratory achieved by third quarter of 2010.</p> <p>2.1. At least 4 people trained on maintenance and repairs about the equipments used in RSHC by August 2009.</p> <p>2.3. The quality of given services at least 40% by laboratory to the RSHC laboratories is increased by August 2010.</p> <p>2.4. Certification of accreditation of the Electronic and Biomedical Equipment Maintenance and Repair Laboratory by August 2010.</p>	<p>1.2.4. List of the bought equipments. 1.2.5. Receipts of the bought equipments.</p> <p>1.3.1. Accreditation certificate from accreditation agency.</p> <p>2.1.1. List of taken trainings. 2.1.2. Certificates given to the trainers</p> <p>2.3.1. Questionnaires after given repairing services. 2.3.2. Documents that show the amount of paid money to the private sector before and after strength laboratory.</p> <p>2.4.1. Accrediation certificate</p>	
<p>3. The Clean room and Sterility Control Laboratory of RSHC is strengthened and</p>	<p>3.1. At least 3 people trained on Clean room and Sterility Control by</p>	<p>3.1.1. List of taken trainings.</p>	

<p>accredited.</p>	<p>August 2009.</p> <p>3.2. The needed equipments for infrastructure of Clean Room and Sterility Control Laboratory supplied by second half of 2010.</p> <p>3.3. The quality of given services at least 40% by laboratory to the RSHC laboratories is increased by August 2010.</p> <p>3.4. Certification of accreditation of the Clean room and Sterility Control Laboratory</p>	<p>3.1.2. Certificates given to the trainers</p> <p>3.2.1. List of bought equipments</p> <p>3.2.2. receipts of bought equipments</p> <p>3.3.1. Questionnaires after given repairing services.</p> <p>3.3.2. Documents that show the amount of paid money to the private sector before and after strength laboratory.</p> <p>3.4.1. Accrediation certificate</p>	
<p>Activities</p>	<p>Means</p>	<p>Cost</p>	<p>Assumptions</p>

1.1. Two study tours five days each for 6 persons arranged to the members of European Accreditation	1* Services	750,000 €	Good communication between calibration laboratory and the other laboratories of RSHC.
1.2. A counseling service from primary level of accreditation and calibration.	1*Supply	380,000 €	
1.3. Accreditation and calibration trainings from 'Accreditation Monitoring Authority' for 8 personnel	TOTAL	1,130,000 €	Good co-operation between Electronic and Biomedical Equipment Maintenance and Repair Laboratory of RSHC within the other laboratories.
1.4. Supply the equipments			
1.6. Certification of accreditation.	2.1. Theoretical training on maintenance and repairs electronic and biomedical equipment for one month in RSHC.	2.2. Practical training on maintenance and repairs electronic and biomedical equipment for one month in RSHC.	Good co-operation between Clean Room and Sterility Control Laboratory RSHC within the other laboratories
2.3. Accreditation trainings for 4 personals.	2.4. Certificate of accreditation.	The continuity of the personnel.	

<p>3. 1.Theoretical training on clean room and sterility control for 15 days in RSHC.</p> <p>3.2. Practical training on clean room and sterility control for 15 days in RSHC.</p> <p>3.3. Accreditation trainings for 4 personals.</p> <p>3.4. Supply of the equipments</p> <p>3.5. Trainings on equipments supplied.</p> <p>3.6. Certificate of accreditation</p>			
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	<p>Preconditions</p> <p>The tender this project can be launched on the project that, by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s).</p>
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