#### **Standard Summary Project Fiche – IPA centralised programmes**

# Quality Infrastructure in the Western Balkans and Turkey

# 1. Basic information

- 1.1 CRIS Number: 2008/020-320
- 1.2 Title: Quality Infrastructure in the Western Balkans and Turkey
- 1.3 ELARG Statistical code: 03.01
- 1.4 Location: Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo¹ and Turkey

# **Implementing arrangements:**

- 1.5 Contracting Authority (EC): The European Community represented by the Commission of the European Communities
- 1.6 Implementing Agency: not applicable
- 1.7 Beneficiaries: Western Balkans: Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo

Turkey

In each location: ministry responsible for transposition and implementation of technical regulations; national standards body; national metrology institute; national accreditation body; bodies responsible for market surveillance; conformity assessment bodies.

# **Financing:**

1.8 Overall cost (VAT excluded):	EUR 2 100 000
1.9 EU contribution:	EUR 2 000 000
1.10 Final date for contracting:	30.11.2009
1.11 Final date for execution of contracts:	30.11.2011
1.12 Final date for disbursements:	30.11.2012

# 2. Overall Objective and Project Purpose

#### 2.1 Overall Objective:

To facilitate intra-regional trade and the free movement of goods with a view to improving the competitiveness of the economy in the region and preparing the Beneficiaries for future accession negotiations with the EU.

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<sup>&</sup>lt;sup>1</sup> under UNSCR 1244/99

#### 2.2 Project purpose:

To improve the capabilities of quality infrastructure<sup>2</sup> bodies, needed to comply with the areas of the acquis communautaire, especially in Chapter 1, but also needed in other areas of the acquis (environment, consumer protection, agriculture, customs, etc.) enabling them to offer better services to economic operators, to facilitate trade in the EU and EFTA market, as well as in the markets of the beneficiaries.

The main specific common areas of quality infrastructure (QI) have been identified and are based on the results from previous and current assistance programmes and assessments. This project builds on the results of and continues the work carried out under the previous CARDS regional quality infrastructure project.

#### 2.3 Link with AP/EP/ SAA/NPAA

The European and Accession Partnership documents point out the need to complete the establishment of the legal and institutional set-up of quality infrastructure, including market surveillance and certification. This is particular relevant in view of the new EU legislative framework.

The SAAs stipulate that Beneficiaries shall take the necessary measures in order gradually to achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures. To this end the Beneficiaries shall seek:

- To promote the use of Community technical regulations and European Standards, tests and conformity assessment procedures;
- To conclude, where appropriate, European Conformity Assessment Protocols;
- To foster the development of the quality infrastructure;
- To promote participation in the work of specialised European Organisations [European Committee for Standardisation (CEN), European Committee for Electro-technical Standardisation (CENELEC), European Telecommunications Standards Institute (ETSI), European Co-operation in Legal Metrology (WELMEC), European Co-operation in Measurement Standards (EURAMET), European Co-operation for Accreditation Laboratory (EA), etc.].

#### 2.4 Link with MIPD

The Multi-beneficiary MIPD is designed to complement and be consistent with National MIPDs. Areas of intervention are addressed through the Multi-Beneficiary MIPD where there is a clear

<sup>&</sup>lt;sup>2</sup> Quality infrastructure refers here to metrology, standardization, accreditation, market surveillance, testing, quality management, inspection and certification that have a bearing on conformity assessment (abbreviated as MSTQ). This includes both public and private institutions and the regulatory framework within which they operate.

comparative advantage to be gained, for instance through tackling cross-border problems or - as is the case for this project - in obtaining efficiencies through establishing harmonised approaches, leveraging established instruments or facilitating networks of experts.

The Multi-Beneficiary MIPD 2008-2010 identifies (chapter 2.3.3) *Ability to assume the obligations of Member States and approximation to European Standards* as a priority area and in particular *quality infrastructure* as one of the particular "areas of focus".

2.5 Link with National Development Plan (where applicable)

Not applicable

2.6 Link with national/sectoral investment plans (where applicable)

Not applicable

# 3. Description of project

# 3.1 Background and justification:

Regional cooperation is a principle of the highest importance for the political stability, the security and economic development of the Western Balkans. The development of regional cooperation corresponds to a commitment made by the Beneficiaries of the region at the EU–Western Balkans Summits of Zagreb (2000) and Thessaloniki (2003). Coordination and coherence is fundamental importance in this region, given the large number of players involved.

The close connection of regional cooperation with European integration is particularly evident in the area of trade. The European Commission quickly identified the removal of barriers to trade as a priority for intervention and one where many challenges remain. The first regional programme in the field of Quality Infrastructure dates from early 1990s.

In the 1990s some of the beneficiaries had already received assistance under the Phare Multi-Country programme for Quality Infrastructure (PRAQ). More recently, the Regional Quality Infrastructure project under the CARDS programme and the Support to the Quality Infrastructure in Turkey project under the MEDA programme, both carried out by the European Committee for Standardisation (CEN), assisted the beneficiaries to develop quality infrastructure to broaden the basis for mutual confidence between beneficiaries and with the European Union. By working together Beneficiaries have begun to pool their expertise, sharing knowledge and resources in a variety of fields including technical regulations, standardisation, accreditation, testing-certification-inspection, metrology and market surveillance.

The Country Report (2006-2007) for Turkey and the Assessment Report (2007) for the Western Balkans show many similarities in the challenges in the quality infrastructure field and provide the core content for this project in their recommendations. Whilst there are a number of national peculiarities, which are better supported by national projects, there are sufficient common issues to justify a regional approach both in terms of the support provided and the common solutions being

sought. It will be more straightforward for existing EU and EFTA member states to integrate further up to eight more member states if they have adopted common systems and approaches.

## 3.2 Assessment of project impact, catalytic effect, sustainability and cross-border impact

#### **Impact**

The removal of technical barriers to trade is a precondition for the completion of the internal market. Since the adoption of the *New Approach to technical harmonisation and standards* in 1985, the harmonisation of European industrial standards in the areas covered by European technical legislation has become an essential instrument in completing the single market. This approach was subsequently complemented by a coherent policy on conformity assessment (the *Global Approach to certification and testing* of 1989), setting out clear, consistent and transparent principles which apply to the product certification procedures to be used at Community level. The renewed European policy on a common framework for the marketing of products, including specific requirements for accreditation and market surveillance complement the EU *acquis* in the field. The objective is to help to establish a policy on quality in cooperation with national and international standardisation bodies. This programme will assist in developing the comparable framework and administrative capacity required in the Beneficiaries. Through the project, the various state institutions are expected to further evolve into institutions that primarily see themselves as service providers.

# Catalytic effect

The system for certification and testing needs to be truly open and transparent to have mutual recognition and confidence by all major interested parties and applied in a uniform way through the EU and candidates and potential candidates. This project will strengthen the system of accreditation in the beneficiaries, which is known to be the best way to achieve mutual recognition and technical trust between all actors.

Delays in producing standards should be reduced, hence the importance of increasing the efficiency and accountability of the standardisation process that this programme intends to foster. This programme should prove its catalytic effect on increased competitiveness of the region's industry, as well as better and wider trade regimes with the EU, EFTA, CEFTA and the global economy in general.

In terms of multiplier effects, many other negotiating chapters of the *acquis* require reliable quality infrastructure, not only free movement of goods but also regional development, agriculture, environment, food safety, consumer protection, customs, etc. The prospect of becoming an EU Member State requires the capacity to measure, test and inspect with a view of enforcing legislation in all these areas. A concrete and harmonised common approach and clearly defined range of support measures for these priority areas should be developed into this project in an effective way.

#### *Sustainability*

Sustainability is of vital importance in establishing regional cooperation and networks in the quality infrastructure fields. In order to maintain the objectives achieved in the long term, training for senior staff and managers at the technical level must go hand in hand with awareness-raising measures at the higher political level. This includes also the EC Delegations' strong involvement. At least a common launch event should be organised. Similarly, the activities organised for the beneficiary institutions should include participants from economic operators.

#### Cross-border impact

Greater use should be made of the sector's potential to foster regional integration processes. Action will be demanded from partner Beneficiaries in terms of spreading and implementing regional trade agreements (CEFTA 2006). The best way to this is the planned regional cooperation. The EU is already promoting the common approach and the joint use of national structures that have been

developed in a complementary way. The fact that regional coordination processes take more time should be taken into account while planning common actions.

#### 3.3 Results and measurable indicators:

# Results and measurable indicators in relation with activity 1 - Assessments

#### Results

A focused report containing a summary of progress made towards harmonisation of quality infrastructure systems with those of the EU/EFTA and recommendations for next steps and training and support required to complete the harmonisation process.

Participating organisations will have the chance to benchmark their performance with that of their neighbours, introducing an element of competition and stimulating further progress.

#### Measurable Indicators

- An assessment report on the QI situation for each of the Beneficiaries;
- A general overview report on QI in the region.

# Results and measurable indicators in relation with activity 2 - Proficiency Testing

#### Results

This builds on the ambitious proficiency testing exercises in Turkey and the Western Balkans and will result in a further group of laboratories being able to demonstrate their competence to deliver testing and calibration services to European standards. The group training sessions will enhance the laboratory networks being created and will encourage the sharing of resources cross-borders. The common approach used by national accreditation bodies, metrology institutes and future proficiency testing providers in the beneficiaries will ease access to the beneficiaries' market in the preaccession period for EU/EFTA exporters. The common approach will also help the beneficiaries to meet their CEFTA 2006 obligations.

# Measurable indicators

- The number of Proficiency Tests done;
- The number of participating laboratories
- The number of laboratory staff trained.

# Results and measurable indicators in relation with activity 3 - Training

## Results

Quality infrastructure bodies will be provided with the skills necessary to fulfil their roles at European levels and thus offer industry services which will facilitate intra-regional trade and trade with the EU/EFTA. The common approach engendered will make it more straightforward for quality infrastructure bodies to integrate into the EU/EFTA system.

EU technical legislation will be implemented in a more uniform manner and this will reduce technical barriers to trade within the region and between the region and the EU/EFTA.

Quality infrastructure will be better prepared to operate according to the new EU legislative framework linked to the requirements for accreditation and market surveillance relating to the marketing of products.

# Measurable indicators

• The number of training events organised;

• The number of staff participating in the trainings.

# Results and measurable indicators in relation with activity 4 - Network-building

# Results

In the Beneficiaries, each with limited resources, the networks created will enable the sharing of resources and eventually of facilities.

Confidence will be achieved in high quality training courses, information to industry and improved access of industry to quality standards to enhance their competitiveness, in conjunction with the improved services offered to them by the main quality infrastructure bodies.

#### Measurable indicators

- The development of training course certification programme;
- The number of information CD-ROM distributed;
- The number of delegates at information seminars;
- Number of shared facilities;
- The number of topical regional networks created.

#### 3.4 Activities:

#### Activity 1 Assessments

Assessments have been conducted annually (2003-2007) for Turkey and bi-annually (2005 and 2007) for the Western Balkans in each of the main fields of quality infrastructure: implementation of technical regulations, metrology, accreditation, standardization, market surveillance, testing-certification-inspection. The *Country Reports* for Turkey were a very large exercise with specific objectives which served a useful purpose at the time. In the likely period for implementation of this project (2009-2011) the more limited approach of the Western Balkans' *Assessment Reports* would be more appropriate. By means of questionnaires and on-site audits, EU/EFTA experts in each field will report on progress since 2007 towards harmonisation of quality infrastructure systems with those of the EU/EFTA and recommend training and support required to complete the harmonisation process.

# **Activity 2 Proficiency Testing**

Organisations wishing to export to the EU/EFTA market need to be able to demonstrate the compliance of their product to the EU *acquis*. One way to do this is to comply with the relevant European Standards. There are a number of laboratories in the beneficiaries able to offer testing and calibration services. However, very few of the laboratories are accredited and the few accreditations which exist are frequently done by bodies not having signed the European Cooperation for Accreditation multilateral agreement, which means that the testing and calibration certificates are not recognised in the EU/EFTA and re-testing is required. In addition, there are only very limited networks of laboratories in existence, and these partly result from the past EC/EFTA regional support. Proficiency testing by means of inter-laboratory comparison enables laboratories in priority sectors to demonstrate their competence compared to European Standards.

Representatives of beneficiaries' accreditation bodies and metrology institutes, together with the technical managers of the laboratories will be trained by an accredited EU/EFTA proficiency testing provider in appropriate techniques. They will then conduct, under carefully supervised conditions, a number of proficiency testing exercises in the target sectors. The results of the exercise will be analysed by the EU/EFTA proficiency testing provider and all representatives will then be provided with further training in fields where the results demonstrate weaknesses. The approach will also

create new networks and strengthen existing ones. This approach was used very effectively in the CARDS 2006 Regional Quality Infrastructure project.

## **Activity 3 Training**

The recommendations contained in the *Country Report* (2006-2007) for Turkey and the *Assessment Report* (2007) for the Western Balkans show many similarities in the challenges in the quality infrastructure field. Whilst some areas are best dealt with at national level, there are a number where the regional systems approach is perfectly suited. The project will provide practical, handson training in the EU/EFTA and in the beneficiaries in all fields of quality infrastructure. Each training course will be designed to meet a need/needs identified as existing in more than three beneficiaries. In particular, it is anticipated that practical, hands-on training will be provided in:

*Metrology* – to enable technical staff at national metrology institutes to fulfil the requirements of the European Association of National Metrology Institutes;

Accreditation – to enable technical staff at national accreditation bodies to fulfil the requirements of the European Cooperation for Accreditation and in particular its multilateral agreement, as well as meet the requirements of the new EU regulation setting out inter alia the requirements for accreditation; to enable managerial staff improve their capabilities in order to attract business and to improve their place on the market;

Standardisation – to enable technical staff at national standards bodies to fulfil the requirements of the main European standardization bodies;

*Market surveillance* – to enable technical staff in bodies responsible for market surveillance to meet the requirements of the new EU regulation setting out inter alia the requirements for market surveillance;

Technical regulations – to enable ministry staff responsible for transposition and implementation of technical regulations to adopt wherever possible a common approach in line with the obligations contained in the Stabilisation and Association Agreements, as well as to deliver effective public awareness campaigns;

Testing-certification-inspection – in addition to that contained in Activity 2 above, to enable technical staff of testing, certification and inspection bodies in priority fields to prepare for accreditation.

# Activity 4 Network-building

In support of improved confidence amongst beneficiaries, the project will provide regional training for trainers in the quality infrastructure sectors and creation of a regional network of quality infrastructure training providers and develop training course certification programme linked to existing EU schemes;

A regional quality infrastructure information programme for industry will be provided, to support established quality for ain the region, via internet, via an information CD-ROM and seminars;

A regional strategy for stimulation of competitiveness and exports will be provided that can be used to create awareness in industry and public authorities.

# 3.5 Conditionality and sequencing:

The project includes the following conditions:

• Cooperation of authorities in the beneficiaries and QI bodies with CEN in the implementation of the project;

- Availability of motivated counterpart personnel during the implementation period;
- Avoiding overlapping with national and other donor programmes;
- Provision of expertise from EU/EFTA experts.

In terms of sequencing, assessments should be conducted first. Preparations for the three other activities can begin and they can take place simultaneously, though their final detailed content will rely in part on the findings and recommendations of the assessments.

#### 3.6 Linked activities

The project will complement initiatives taken at national and/or by other donors. Analysis of past, present and future national programming has been conducted (summary attached at Annex 5) to ensure no overlap with this regional project and that the content of this regional project could not be delivered more effectively at national levels.

#### 3.7 Lessons learned

Managing a multi-beneficiary, multi-institution project is always challenging, with various interests and rivalries frequently present. Doing so in a region that in the very recent past has been the victim of mistrust and wars between re-emerging nations is likely to be extremely difficult. However projects have been marked by an astonishing degree of co-operation and dialogue between individuals and institutions.

This is due in part to the policy of remaining scrupulously balanced in terms of the opportunities to participate in project activities to experts in each beneficiary, the locations selected for project activities and the degree of support offered to delegates in obtaining the necessary documentation to visit those destinations.

It has to be underlined that the visa regimes of many Beneficiaries and EU member states are unnecessarily onerous and it is frequently difficult to see what purpose they have. Many EU member states require visas for citizens of certain Beneficiaries but do not have consulates in those Beneficiaries and have not made arrangements with the consulates of others to facilitate the process. In future programmes, visa requirements should be taken into account in the choice of locations for events (training, steering committee meetings, etc.) to minimise problems.

It is important to keep not only the members of the project cooperation committee informed of project actions, even though they have all been very good at disseminating information, but also heads of quality infrastructure bodies and other relevant people to ensure as wide a possible benefit. It is also important to maintain contacts at Government level, often in the ministry for industry, as this is where high-level decisions are taken about policy in this field. A number of ministries transposing EU technical legislation have still not understood the role of quality infrastructure bodies and continued efforts to inform are essential.

It is obvious that hands-on training and awareness-raising events which were designed and provided under two previous regional CARDS, have given a remarkable opportunity to all concerned beneficiaries to create a first large network between the quality infrastructure field operators. The existing proficiency testing activities managed jointly with national laboratories already received a large participation and very positive publicity.

Besides technical, legal, organisational etc. aspects of setting up quality infrastructure, economic and financial aspects should be included. Sustainable development after EU support, based on national resources, should be considered from the initial stage of development of all quality infrastructure in all Beneficiaries.

The idea of creation of regional joint facilities in terms of joint ownership was unrealistic and a premature expectation. But the regional cooperation already underway has stimulated sharing of available resources and joint use.

Coordination with national programming must be improved and regional cooperation could be used to prevent duplications and to give a common and harmonised programming approach.

# **4.** Indicative Budget (amounts in €)

		SOURCES OF FUNDING										
		TOTAL EXP.RE	IPA COMMUN CONTRIBUTI		D	OMES	TIC CONTI	RIBUTION		PRIVATI CONTRIBUT		
ACTIVIT IES	IB	IN V	EUR	EUR	%( 1)	Total EUR	% (1)	Central EUR	Regional/ Local EUR	IFIs EUR	EUR (2)	% (1)
All activities	X		2,100,000	2,000,000	95						100,000	5
TOTA	L IB		2,100,000	2,000,000	95						100,000	5
TOTAL INV												
TOTAL P	ROJ	ECT	2,100,000	2,000,000	95						100,000	5

# Amounts net of VAT

(1) Expressed in % of the **Total** Expenditure

# (2) EFTA Contribution

A service contract will be signed via a negotiated procedure with the European Committee for Standardisation (CEN) in conformity with Article 242(1) (b) IR whereby "services may be entrusted to public-sector bodies ......... and relate to activities of an institutional nature".

# 5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1	N/A	January 2009	January 2011

All projects should in principle be ready for tendering in the  $1^{\rm ST}$  Quarter following the signature of the FA

# **6.** Cross-cutting issues (where applicable)

# 6.1 Equal Opportunity:

The principles and practice of equal opportunity will be guaranteed so as to ensure equitable gender participation in the project.

6.2 Environment:

Not applicable

6.3 Minorities:

Not applicable

# **ANNEXES**

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3- Description of Institutional Framework per beneficiary
- 4 Reference to relevant EU legislation, basis of the regional programme
- 5- National TA quality infrastructure projects summary

# **ANNEX 1: Logical framework matrix in standard format**

LOGFRAME PLANNING MATRIX	Programme name and number Quality	
FOR Project Fiche	Infrastructure in the Western Balkans &	
	Turkey	
	G	D: 1
	Contracting period expires 30.11.2009	Disbursement period expires 30.11.2012
	Total budget :	IPA budget:2,000,000
	2,100,000	

Overall objective	Objectively verifiable indicators	Sources of Verification
Facilitate intra- regional trade and free movement of goods to improve competitiveness of regional economy pre- accession	Inter regional export rates increased	National and Regional Statistics in the relevant fields
Project purpose	Objectively verifiable indicators	Sources of Verification

Improve capabilities of QI bodies, enabling them to offer industry services to provide tools to trade in EU/EFTA market, as well as in markets of beneficiaries.	Common tools and approach exists  Ratio of income earned from industry vs. state.	Strategies in the beneficiaries , SAA reports , experts reports  Financial reports of QI bodies;  National accounts.	Strong governmental political and financial support  Stability in the region
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
Activity 1 Focused report containing summary of progress made towards harmonisation of QI systems with those of EU/EFTA & recommendation s for next steps, training and support required to complete	An assessment report on the QI situation for each of the Beneficiaries; A general overview report on QI in the region.	Project reports.  Project reports.	Continued commitment of national governments to EU harmonisation and to regional co-operation.

Participating organisations will have chance to benchmark performance with that of their	Availability of reports to participating organisations.	PT report.	
neighbours.	Number of PTs done;		Continued support of lab development by national administrations.
Activity 2 Labs able to demonstrate competence to deliver testing and calibration services to European standards.	Results analysis of PT.  Number of lab staff trained.	PT report.  National statistics.	
Group training sessions to enhance lab networks and cross-border sharing of resources.  Common approach used by	Increased exports in target sectors in years after completion of project.		Willingness of NABs and NMIs to work together and to agree common approach.

NABs, NMIs and future PT providers in beneficiaries will ease access to beneficiaries' markets in preaccession period for EU/EFTA exporters.		Project reports.	Willingness of QI bodies to participate; Availability of EU/EFTA bodies to provide training.
Common approach will help beneficiaries meet CEFTA 2006 obligations.	Number of training events organised;		
Activity 3 QI bodies will be	Number of staff participating in trainings;	Data from European organisations.	Commitment of QI bodies to common approach.
provided with skills necessary to fulfil their roles at European level and thus	Feedback analysis.  Applications to	National statistics.	Commitment of beneficiaries to EU harmonisation.
offer industry services which will facilitate intra-regional trade and trade with the EU/EFTA.	join European organisations.	rational statistics.	

Common approach engendered will make it more straightforward for QI bodies to	Trade flows.	Data from European organisations.	Commitment of beneficiaries to EU harmonisation.
integrate into EU/EFTA system.			
EU technical legislation will be implemented in a more uniform manner and this will reduce technical barriers to trade within the region and between the region and the	Applications to join European organisations.		
EU/EFTA.		Project reports.	
Quality infrastructure bodies will be better prepared to fulfil their obligations		Statistics from QI training providers;	Willingness of QI training bodies to participate.  Willingness of industry to invest in training and third party certification.

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contained in	Web site including
(likely) new EU	a list of training
legislation e.g.	providers is
the proposed	created
regulation of the	
European	
Parliament and	Development of
of the Council	training course
setting out the	certification
requirements for	programme
accreditation and	
market	
surveillance	Number of visits
relating to the	to information
marketing of	website
products.	
	Number of
l	delegates at
Activity 4	information
Networks created	seminars
will enable	Schillars
sharing of	
resources and	
eventually of	
facilities.	
Confidence will	
be achieved in	
high quality	
training courses,	
information to	

industry and improved access of industry to quality standards to enhance competitiveness, in conjunction with improved services offered to them by main QI bodies.			
Activities	Means	Costs	Assumptions
1. Assessments in main fields of QI: - technical regulations - metrology - accreditation - standardization - market surveillance - testing-certification-inspection to report on	Questionnaires and on-site audits conducted by EU/EFTA experts.		Availability of appropriate experts; Willingness of QI bodies to participate.

2007 towards harmonisation of quality infrastructure systems with those of EU/ EFTA and recommend training and support required to complete the harmonisation process	Accredited EU/EFTA based PT provider.	Availability of appropriate PT provider; Willingness of labs to participate.
2. Proficiency testing by means		
of inter-		
laboratory		
comparison		
enabling		
laboratories in		
priority sectors to		
demonstrate their		
competence		
compared to		
European		
Standards and to		
create networks.		
Representatives		
of beneficiaries'		
national		

results of the exercise will be co	EN member odies and other ompetent bodies a EU/EFTA.		Availability of appropriate Hands-on-training providers; Willingness of QI bodies to participate.
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3. Practical,			
hands-on training			
in EU/EFTA and			
in beneficiaries			
in QI. Each			
training course			
designed to meet			
needs applicable			
in more than			
three			
beneficiaries.			
Hands on			
training will be			
provided in:			
Metrology –			
enable technical			
staff at NMIs to			
fulfil			
requirements of			
EURAMET;			
Accreditation – enable technical			
staff at NABs to			
fulfil			
requirements of			
EA and its MLA,			
as well as new			
regulation setting			
out requirements			
for accreditation;			
to enable NAB			
to chable IVAD			

managerial staff to improve their capabilities to attract business and improve their place on the market;		
Standardization – to enable technical staff at NSBs to fulfil the requirements of ESOs;		Willingness of QI training providers to participate;
Market surveillance – enable technical		Availability of EU/EFTA experts.
staff in bodies responsible for MS to meet requirements of	EU/EFTA experts.	
new regulation setting out requirements for	Seminars, training.	
MS; Technical	EU/EFTA experts.	
regulations – enable ministry staff responsible		
for transposition and implementation	EU/EFTA experts.	

•		7	
of ToRs to adopt a common approach in line with obligations contained in SAAs, as well as deliver effective public awareness campaigns.  Testing-certification-inspection – to enable technical staff of T-C-I bodies in priority fields to prepare for accreditation.	EU/EFTA experts in implementing EN ISO 9000.		
4. Regional training for trainers in QI;			
Creation of regional network of QI training providers;			
Development of training course certification programme linked to existing			

EU schemes;		
Regional QI information programme for industry, to support offering of established EU information providers in region, via internet, CD-ROM and seminars;		
Regional strategy for stimulation of competitiveness and exports will be provided by introduction of Quality Standards in Companies.		

ANNEX 2: Amounts (in €) Contracted and disbursed by quarter for the project

Contracted	1/09	2/09	3/09	4/09	1/10	2/10	3/10	4/10	1/11	2/11	3/11
Contract 1	2,000,000										
Cumulated	2,000,000										
Disbursed											
Contract 1		500,000		500,000		500,000			300,000		200,000
Cumulated		500,000		1,000,000		1,500,000			1,800,000		2,000,000

A service contract will be signed via a negotiated procedure with the European Committee for Standardisation (CEN) in conformity with Article 242(1) (b) IR whereby "services may be entrusted to public-sector bodies ......... and relate to activities of an institutional nature".

# **ANNEX 3: Description of Institutional Framework**

The **Albanian** quality infrastructure system is overseen by the Ministry of Economy, Trade and Energy, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. There are functioning bodies responsible for metrology, accreditation and standardisation. There are a number of testing, certification and inspection bodies, some of which are accredited. Market surveillance is being developed.

The quality infrastructure system of **Bosnia and Herzegovina** is overseen by the Ministry of Foreign Trade and Economic Relations, which is also the only body able to coordinate implementation of directives based on the New Approach and Global Approach. There are functioning bodies responsible for metrology, accreditation and standardisation at state level. There are a number of testing, certification and inspection bodies, some of which are accredited. Market surveillance is being developed. There are also quality infrastructure bodies operating at entity level in the fields of metrology, standardisation (Republika Srpska only) and market surveillance. Coordination between state and entity levels in this field has been greatly enhanced by CARDS regional quality infrastructure projects.

The **Croatian** quality infrastructure system is overseen by the Ministry of Economy, Labour and Entrepreneurship, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. There are functioning bodies responsible for metrology, accreditation and standardisation. There are a large number of testing, certification and inspection bodies, many of which are accredited. Market surveillance is being developed.

The quality infrastructure system of **Kosovo** is overseen by the Ministry of Trade and Industry, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. There are new bodies responsible for metrology, accreditation and standardisation. There are a very small number of testing, certification and inspection bodies, none of which are accredited. Market surveillance is not developed.

The quality infrastructure system of the **former Yugoslav Republic of Macedonia** is overseen by the Ministry of Economy, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. There are functioning bodies responsible for metrology, accreditation and standardisation. There are a number of testing, certification and inspection bodies, some of which are accredited. Market surveillance is being developed.

The **Montenegrin** quality infrastructure system is overseen by the Ministry for Economic Development, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. New bodies have been set up with responsibility for metrology, accreditation and standardisation. There are a small number of testing, certification and inspection bodies, some of which are accredited. Market surveillance is being developed.

The **Serbian** quality infrastructure system is overseen by the Ministry of Economy and Regional Development, which is responsible for coordinating implementation of directives based on the New Approach and Global Approach. There are functioning bodies responsible for metrology, accreditation and standardisation. There are a large number of testing, certification and inspection bodies, many of which are accredited. Market surveillance is being developed.

Given **Turkey's** size it is worth going into a little more detail:

**Harmonisation** of legislation has been concluded in at least 230 fields in accordance with the 1997 Decision of the EC-Turkey Association Council, including all "New and Global Approach Directives". The number of mandatory standards decreased from 1,250 in 2003 to fewer than 200.

- The Turkish **Accreditation** Agency (TÜRKAK) is a signatory of 4 (out of 7) Multi-Lateral Agreements of EA, with remaining MLAs to be signed by mid-2008. TÜRKAK is also a full member of ILAC and discussions are underway for full membership of IAF.
- The Turkish Association of **Testing and Calibration** Laboratories (TÜRKLAB) is a member of EUROLAB, and is taking the lead, together with TÜRKAK, in the development of the Turkish network of Proficiency Testing and Inter Laboratory Comparisons providers.
- The Turkish **Standards** Institution (TSE) has been completely re-structured, and its different activities are now clearly split and independent (standardisation, certification, testing, metrology, etc.). Some issues, beyond TSE's control, remain for TSE to reach the 9 criteria for accession to full membership of CEN-CENELEC.
- The Ministry of Trade & Industry is responsible for **Legal Metrology**. They have taken the opportunity of the adoption of several directives (Non-Automatic Weighing Instrument Directive (NAWI), Pre-Packaging Directive, Measurement Instrument Directive (MID), etc...) for re-organising their Legal Metrology system. Implementation of the new system remains to be done.
- The Turkish Metrology Institute (UME) is responsible for **fundamental**, **scientific and industrial metrology**.

Although it is estimated that more than 120 **notified bodies** are currently operating in Turkey, those notified by Turkish authorities are only 3 in number covering 7 Directives. This figure should increase as soon as TÜRKAK becomes a signatory of the EA MLA regarding Product Certification. This is foreseen to take place by mid-2008. From this date Turkey will be allowed to notify NBs to Brussels without any additional checking from the Commission.

# ANNEX 4: Reference to relevant EU legislation, basis of the regional programme

The relevant EU legislation which is the basis for this project is as follows:

- 1. Council Resolution 85/C 136/01 of 07.05.1985 on a New Approach to technical harmonization and standards;
- 2. Council Resolution 90/C 10/01 of 21.12.1989 on a Global Approach to certification and testing;
- 3. Council Decision 93/465/EEC of 22.07.1993 setting guidelines and procedures for conformity assessment to be used in New Approach directives;
- 4. Twenty-one Directives based on the principles of the *New Approach* which provide for CE marking;

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		Number of directive amendment	Reference in OJ EC (corrigendum) amendment
1	Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits	73/23/EEC 93/68/EEC	OJ L 77 of 26/03/73 (OJ L 181 of 04/07/73) OJ L 220 of 30/08/93
2	Council Directive 87/404/EEC of 25 June 1987 on the harmonisation of the laws of the Member States relating to simple pressure vessels	87/404/EEC 90/488/EEC 93/68/EEC	OJ L 220 of 08/08/87 (OJ L 31 of 02/02/90) OJ L 270 of 02/10/90 OJ L 220 of 30/08/93
3	Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys	88/378/EEC 93/68/EEC	OJ L 187 of 16/07/88 (OJ L 281 of 14/10/88) (OJ L 347 of 16/12/88) OJ L 37 of 09/02/91) OJ L 220 of 30/08/93
4	Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products	89/106/EEC 93/68/EEC	OJ L 40 of 11/02/89 OJ L 220 of 30/08/93
5	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility	89/336/EEC 92/31/EEC 93/68/EEC	OJ L 139 of 23/05/89 (OJ L 144 of 27/05/89) OJ L 126 of 12/05/92 OJ L 220 of 30/08/93
6	Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective	89/686/EEC 93/68/EEC 93/95/EEC	OJ L 399 of 30/12/89 OJ L 220 of 30/08/93 OJ L 276 of 09/11/93

	equipment	<u>96/58EC</u>	OJ L 236 of 18/09/96
7	Council Directive 90/384/EEC of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments	90/384/EEC 93/68/EEC	OJ L 189 of 20/07/90 ( OJ L 258 of 22/09/90) OJ L 220 of 30/08/93
8	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices	90/385/EEC 93/42/EEC 93/68/EEC	OJ L 189 of 20/07/90 (OJ L 7 of 11/01/94) (OJ L 323 of 26/11/97) OJ L 169 of 12/07/93 OJ L 220 of 30/08/93
9	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels	90/396/EEC 93/68/EEC	OJ L 196 of 26/07/90 OJ L 220 of 30/08/93
10	Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	92/42/EC 93/68/EEC	OJ L 167 of 22/06/92 (OJ L 195 of 14/07/92) (OJ L 268 of 29/10/93) OJ L 220 of 30/08/93
11	Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses	93/15/EEC	OJ L 121 of 15/05/93 (OJ L 79 of 07/04/95)
12	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	93/42/EEC 98/79/EC 2000/70/EC	OJ L 169 of 12/07/93 (OJ L 323 of 26/11/97) (OJ L 61 of 10/03/99) (OJ L 125 of 19/05/99) (OJ L 72 of 14/03/01) OJ L 331 of 07/12/98 (OJ L 313 of 13/12/00)
13	Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres	<u>94/9/EC</u>	OJ L 100 of 19/04/94 (OJ L 257 of 10/10/96) (OJ L 21 of 26/01/00) (OJ L 304 of 05/12/00)
14	Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the	94/25/EC	OJ L 164 of 30/06/94 (OJ L 127 of

	approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft	2003/44/EC	10/06/95) (OJ L 17 of 21/01/97) (OJ L 41 of 15/02/00) (OJ L 214 of 26/08/03)
15	European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts	95/16/EC	OJ L 213 of 07/09/95
16	Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment	97/23/EC	OJ L 181 of 09/07/97 (OJ L 265 of 27/09/97) (OJ L 250 of 23/09/99
17	Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery	98/37/EC 98/79/EC	OJ L 207 of 23/07/98 (OJ L 16 of 21/01/99) (OJ L 80 of 25/03/99) OJ L 331 of 07/12/98
18	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices	98/79/EC	OJ L 331 of 07/12/98 (OJ L 22 of 29/01/99) (OJ L 74 of 19/03/99) (OJ L 124 of 25/05/00) (OJ L 6 of 10/01/02)
19	Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity	1999/5/EC	OJ L 91 of 07/04/99
20	Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons	2000/9/EC	OJ L 106 of 03/05/00
21	Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments	2004/22/EC	OJ L 135 of 30/04/2004

5. Four Directives based on the principles of the *New Approach* or the *Global Approach*, but which do not provide for CE marking;

	Number of	Reference in OJ EC
	directive	(corrigendum)

		amendment	amendment
1	European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	94/62/EC	OJ L 365 of 31/12/94
2	Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system	96/48/EC	OJ L 46 of 17/02/97 (OJ L 246 of 10/09/97) (OJ L 241 of 29/08/98)
3	Council Directive 96/98/EC of 20 December 1996 on marine equipment	<u>96/98/EC</u>	OJ L 46 of 17/02/97 (OJ L 246 of 10/09/97) (OJ L 241 of 29/08/98)
4	Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system	2001/16/EC	OJ L 110 of 20/04/01 (OJ L 334 of 18/12/01)

# 6. Four Directives and proposals based on the principles of the Global Approach;

		Number of directive amendment	Reference in OJ EC (corrigendum) amendment
1	Directive 1996/57/EC of the European Parliament and of the Council of 3 September 1996 on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof	1996/57/EC	OJ L 236 of 18/09/96
2	Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment	1999/36/EC	OJ L 138 of 01/06/99 (OJ L 250 of 23/09/99)
3	Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors	2000/14/EC	OJ L 162 of 03/07/00
4	Directive 2000/55/EC of the European Parliament and of	2000/55/EC	OJ L 279 of

the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting		01/11/00
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7. Two proposals for directives based on the principles of the New Approach or the Global Approach;

		Number of COM document	Reference in OJ EC
1	Proposal for a Council directive on articles of precious metal	COM(1993)322	OJ C 318 of 25/11/93
2	Proposal for a European Parliament and Council directive on marking of packaging and on the establishment of a conformity assessment procedure for packaging	COM(1996)191	OJ C 382 of 18/12/96

8. Proposed regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products [COM (200)) 37]

# **ANNEX 5: National TA quality infrastructure projects summary**

Information detailed hereafter results from the assessments done through the regional CARDS 2006 Quality Infrastructure project. Related data concerns 2006-2008 programming, validated by Beneficiaries, but still subject to EC validation.

Most of the EU support in the quality infrastructure field is steered into institution building, including completion of the legislative and regulatory framework, and the purchase of metrology equipment.

There is some modest national bilateral support, the total value of which in the Beneficiaries concerned amounts to €0.7m in this period.

However some strong World Bank support (principally in the form of loans aimed for the most part for the metrology equipment purchase) exists in Albania (€5.4m) and the former Yugoslav Republic of Macedonia (€3.5m).

#### **ALBANIA**

CARDS 2006 "Support on accreditation, standardization and certification" (€0.8m) Objective: facilitate EU/international trade and investment opportunities in Albania by increasing quality and safety of Albanian products, through adoption of EU market regulations and standards in line with SAA requirements.

CARDS 2006 "Technical Regulations, Market Surveillance, Consumer Protection" (€0.9m) Objective: facilitate EU/international trade and investment opportunities in Albania through increased quality and safety of Albanian products and ensuring a high level of consumer protection.

CARDS 2006 "Legal Metrology" (€0.3m)

Purchase of measurement equipment, enabling establishment/enforcement of laboratories in Fieri, Lezhe and Korca, within the General Directorate of Metrology and Calibration.

#### **BOSNIA AND HERZEGOVINA**

# FRAMEWORK CARDS (€0.4m)

Two short term assignments ITR and impact analyses of implementation of directives.

IPA 2007 "Safety Infrastructure" (€1.7m)

Objectives: develop capacity for legal drafting and implementation of technical regulations, provide technical assistance in transposition of priority technical regulations in compliance with corresponding EU New Approach Directives, establish conformity assessment system and develop market surveillance capacity.

IPA 2007 "Strengthening of Metrology System (€1.7m including €0.7m equipment) Objective: develop distributed metrology system.

IPA 2007 "Strengthening of Accreditation System" (€1 m)

Objective: establish conditions for future international recognition of testing, certification and calibration results.

#### **CROATIA**

PHARE 2006 "Support to the Croatian Accreditation Agency (HAA)" (€0.2m)

Objective: establish assessment system of CABs' competence according to EU New Approach Directives.

PHARE 2006 "Support to Development of Time and Frequency Measurement System in Croatia" (€0.25m).

IPA 2007 "Support to Standardization and Accreditation" (€2.4m).

IPA 2008 "Development and Strengthening of the Institutional and Operational Aspects of the Croatian Metrology Institute" (€3.0m - project not yet accepted).

The former Yugoslav Republic of MACEDONIA

CARDS 2006 "Technical Assistance to Market Surveillance" (€0.98m).

IPA 2007/2008: In process of definition.

#### **KOSOVO**

CARDS 2006 "Technical assistance in the development of the MSTQ infrastructure" (€1.5m)

CARDS 2006 "Support basic metrology equipment for the creation of a metrology laboratory in Pristina (€0.5m).

## **MONTENEGRO**

CARDS 2006 "Development of Quality Infrastructure in Montenegro" (€0.184m) Framework contract includes some TA and preparation of IPA TOR and PF.

CARDS 2006 "Development of Quality Infrastructure in Montenegro (€0.18m) Second planned Framework contract covering urgent training needs of officials in accreditation, metrology and standardisation institutions.

IPA 2007 "Development of Quality Infrastructure in Montenegro" (€2.0m including €1 m TA, €0.5m metrology equipment and €0.5m works

Global institution-building project covering all MSTQ sectors.

#### **SERBIA**

CARDS 2006 "Technical Assistance to Key Institutions and Bodies in the Field of Standardisation, Accreditation, Metrology and Conformity Assessment" (€2.9m including €1.7m in equipment).

CARDS 2006 "Market Surveillance" (€4.0m - planned).

IPA 2008: in process of definition.

# **TURKEY**

IPA 2007 "Establishment of an Accredited Calibration Laboratory" (€1.035m)

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

IPA 2007 "Establishment of laboratory for personal protective equipment (PPE) tests" (€1.05m)

Objective: contribute to implementation of the *acquis communautaire* in area of internal market, specifically focusing on effective functioning of market surveillance support laboratories.

IPA 2007 "Support to Quality Infrastructure in Turkey" (€5.55m)

Objective: strengthened institutional and infrastructural framework to enable better implementation of *acquis* regarding free movement of goods.