

## EUSIP conference put light on the challenges

In order to boost the awareness of the new technical regulations based on EU directives, the Safety Infrastructure Project organized a conference “New Technical Regulation - A revolution for free trade and safe goods”, which took place the 29th September at the Hotel Europe in Sarajevo.

The transposition of the new technical regulations is gaining momentum and in December 2011 the first ordinance covering low voltage products enters into force. This is only the first of a number of ordinances which will enter into force – most of them covering important economic sectors. The conference was organized within the framework of the Safety Infrastructure Project with the overall objective of putting a light on the consequences of the new regulations seen from different angles. Several international speakers were invited to the conference.

David Norris, Project Manager of the IPA 2008 Regional Program, gave an overview of the situation in the neighboring countries within the quality infrastructure. In general, Croatia has the most advanced level in comparison with Macedonia, Albania, Montenegro, Serbia, Kosovo and Bosnia and Herzegovina. Furthermore, it is typically in the standardization and accreditation that the most progress has been made, while market surveillance is the weakest sector.

Ms Vinka Soljagic from the Ministry of Economy in Slovenia outlined the process Slovenia went through when it prepared itself for the EU membership in the field of free movement of goods. One of her points was that it takes a lot of efforts

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from the involved authorities to succeed. And the organization and coordination must be in place when such comprehensive changes are implemented.

At the end of the day, Mr Ahmed Zalic from the Bosnian company Saniteks explained the process they went through when they should introduce their medical products on the EU market in the mid nineties. Even though the company had worked with quality and quality management for years and although their prices were competitive, the requirements in the European legislation forced them to identify the right conformity assessment procedure, prepare technical files for each product and affix the CE mark, before they could export to Europe. It was a demanding and complicated process but today Saniteks is fully competitive and exports to countries like Australia and Italy.

Around 50 participants participated at the conference. Most of the participants represented the authorities and institutions involved in the implementation of the new technical regulation but the representatives of private companies participated at the conference as well.



## Quality Infrastructure in the Western Balkans

**The regional project Quality Infrastructure in the Western Balkans and Turkey financed by IPA 2008 has for several years carried out assessments of the state of quality infrastructure to check progress made in the different countries. And there are many similarities in the various countries.**

Most progress has been made in the national standardization and accreditation functions. However, apart from those in Croatia, the organizations have not yet reached a sufficient level with regard to implementation of the European standards so there is still a lot to do in these fields.

Of the various national measurement fields, the most advanced is legal metrology, which comprises all activities for which legal requirements are prescribed on measurement. These activities are performed by governmental authorities, in order to ensure an appropriate level of credibility of measurement results in the national regulatory environment. An immediate explanation for the rather advanced level is that there is a long tradition for such systems in the assessed countries.

“The weakest sector is Market Surveillance. The market surveillance authorities are having to change their mindset from pre-market control to post market surveillance. This is something which changes the daily work of the inspectors radically and a new “culture” has to be introduced. It is not easy – sometimes it is impossible” says Mr. David Norris, Team Leader for Quality Infrastructure in the Western Balkans and Turkey.

Mr. Norris adds “In general Croatia is a step ahead of the other countries, but given the great emphasis placed on EU accession by successive Croatian governments, I would be surprised if it was otherwise”.

The current IPA 2008 project ends in February 2011, but already negotiations between beneficiary countries and the European Commission are well underway for a further regional project, which might start as early as spring 2011. The potential new project will begin with a further series of assessments into the latest progress made in quality infrastructure fields. It will also provide intensive “hands-on” training, mainly in market surveillance, accreditation and conformity assessment; inter-laboratory comparisons for more than 50 conformity assessment bodies; and a networking component to intensify links with CEFTA and other key players in the region and in the field, such as OECD and UN-ECE.

### Accreditation in BiH as part of quality infrastructure

By Miloš Marković, deputy director of BATA

**One famous quality guru once said: “If the mankind on our planet has so far not been united by politics or religion, maybe quality will succeed in this”**

This may be especially valid for Bosnia and Herzegovina.

Quality is a global phenomenon today, which in its full meaning won Europe, after Japan and the USA, and in the past two decades it is trying to win Bosnia as well. In that process, accreditation is an active participant, as an unavoidable pillar of quality infrastructure, through which confidence can be invested into results of Conformity Assessment Bodies on the international market of goods and services, in accordance with equal conditions, accepted in Europe and worldwide.

Accreditation means an official recognition that a Conformity Assessment Body (CAB) as a laboratory, a certification body (for products, management systems or persons), or an inspection body (control body) is competent to undertake specific activities of conformity assessment.

In Bosnia and Herzegovina, the Institute for Accreditation (BATA), in accordance with the laws of BiH and EC Regulation 765/2008, is the only accreditation body designated by the state that works in accordance with European and international standards. In this regard, BATA has established its own system of accreditation in BiH, harmonized with the requirements of the standard BAS ISO/IEC17011 and European or international requirements.

### Most important achievements and institutional framework of BATA

BATA today has eighteen full-time well-trained employees. The number of external associates of the Institute (assessors and experts) is about 50. The Institute has so far accredited approximately 40 CABs in different areas (see: [www.bata.gov.ba](http://www.bata.gov.ba)).

Cooperation agreements have been signed with accreditation bodies of Serbia, Croatia, Turkey, Montenegro, Norway, Macedonia and Hungary, and these agreements resulted with numerous activities that are very important for BATA. For instance, a project of technical assistance on institutional and expert level, strengthening BATA's capacities was successfully realized in 2009 with the Norwegian Accreditation Body.

Negotiations are underway for continuation of this project in 2011.

Furthermore BATA signed the Cooperation Agreement with the EA in 2005 and is an associated member of ILAC since 2009.

### Priority task

The priority task of BATA is to sign the Multi-Lateral Agreement (MLA) on recognition of documents issued by accredited CABs with the EA. In March of 2010, BATA submitted an application for signing of the MLA EA in the area of calibration and testing laboratories and inspection bodies. We will try to complete this very huge task to be a full MLA member by the end of the first quarter of 2012, which will depend mostly on capacities of EA.

The key project for realization of this goal is IPA-2007 project “Strengthening of the Accreditation System in BiH”, funded by the EC. An extremely successful implementer of this project is a consortium consisting of several European institu-

tions from the area of accreditation, led by the German Federal Institute for Materials Research and Testing - BAM.

## Study tour to Spain for BiH delegation

The on-going transposition of the New Approach Directives into BiH legislation is supported by the Safety Infrastructure Project. However, the transposition cannot be an isolated activity. It has to go hand in hand with the implementation of quality infrastructure system that consists of a number of different organizations and institutions which must cooperate closely in order to establish the right framework for the private operators.

With this in mind the Safety Infrastructure Project organized a study trip to Spain for nine representatives of authorities from the state and entity level. The overall purpose of the study trip was to give the full overview of how the different institutions and bodies who are involved in the implementation of the EU technical legislation are operating.

The participants had the chance to exchange views and experience through extensive discussions and question and answer sessions with representatives of the Spanish organizations dealing with metrology, accreditation, market surveillance and standardization. Furthermore, the participants got valuable knowledge on how the system can be organized.

The study trip took place in the period 25-29 October and the host was the Spanish standardization organization AENOR.



## Conformity Assessment Seminar

Seminar "Establishment of Conformity Assessment system at the state level" organized by EUSIP took place in Sarajevo on 28th September 2010. Experience of the lately acceding EU Member States (Slovenia, Czech Republic) in the transformation of pre-market attestation of products into the EU system of conformity assessment were presented by experts from the respective countries. At the same time, participants received detailed information on the EU New Legislative Framework adopted in 2008 and its impact on building up quality infrastructure elements – accreditation, market surveillance. Requirements which have to be fulfilled by notifying authorities and notified conformity assessment bodies were highlighted.



Project Director, Mr. Evangelos Vardakas, former Director of DG Enterprise, European Commission, informed the audience how the project contributes to the establishment of conformity system in BiH, which shall be aligned with the EU system in near future.

40 representatives of ministries (both state and entities level), quality infrastructure bodies, Foreign Trade Chamber and few conformity assessment bodies took participation. The seminar was evaluated as very useful by the vast majority of participants. Transfer of "know how" from the EU Member States which have profound transformation experience was appreciated.

## Market Surveillance Systems must be customized to the markets

**Market Surveillance has been the subject of much discussion in Europe over the years and despite a clearer legislation in this field than ever before, the EU member states live up to their obligations in very different ways.**

The technical regulation in BiH is gradually adapted to the EU requirements and in parallel a market surveillance system is established which can fill the role as it is intended to fill in. In this context it is tempting to draw inspiration from the EU member states in order to make the transformation process easier. However, there is not only one correct model, but rather an infinite number of possibilities.

Since the introduction of the New Approach in the mid-1980s, market surveillance has been given very different attention in many of the so-called "old" EU member states. And quite often it has not been given as much attention as

required. However, this was changed when 10 "new" Member States joined the EU in 2004. These member states faced very clear requirements to their market surveillance systems which were largely built on the former pre-marketing system.

The result today is that very efficient and resourceful market surveillance systems are established in many of the "new" Member States, while the market surveillance systems in several of the "old" Member States are not at the same level. However, this does not mean that more people are injured by products in the latter countries.

"One explanation could probably be that the so-called old Member States have a long tradition of taking prompt actions when specific products or product groups cause problems. This often causes lots of fuss and creates a bad-will against the affected company, which in turn means that all companies will do extra efforts to adhere to the requirements," says Torben Rahbek, who has experience from the Danish Safety Technology Authority where he headed the Market Surveillance Department for a couple of years. "Furthermore consumers are so well educated and aware of the risks that they promptly report unsafe products to the authorities and the economic operators. This means that the market to some extent is self-regulating in the sense that unsafe products rarely survive in the tough competition and the authorities can do away with less efforts to keep it clean."

"You will appreciate that it takes a couple of years' hard work to clean up a market and to achieve this level. Therefore BiH is not in a situation where an approach like the Danish one will be useful" Torben Rahbek continues "but it is likely that the BiH market surveillance system will eventually adapt to the market it operates on, so that there is a balance between the resources used and the results generated."

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