EUSIP NEWSLETTER

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Establishment of a common platform for the new expert teams

On the 27th of April 2010, the Committee for Technical Regulations appointed the members of the 5 new expert teams, which will be responsible for the transposition of 5 EU directives into BiH legislation in 2010. Only two days after the meeting, the new members – 42 in total – were invited to a kick-off seminar in Hotel Europe in Sarajevo, where the participants were introduced to the task they are facing.

The presentations at the seminar were made by one International expert and two representatives of BiH authorities and focused on the rules and principles for the transposition of EU Directives into BiH legislation.

There are various legal instruments used in the EU system and the ways they can be applied in the member states are different. As regards the directives, the member states have the freedom to choose how to implement the directives. In practice this means that the member states – or candidate countries – shall ensure equivalence. However, it does not mean that the legal text in the BiH legislation shall be 100% identical to the text of the directive. This means that the deviations must be done within very narrow limits since they must not lead to protectionism, discrimination against foreign firms, a lower security level than in other countries, etc. Therefore, it is always subject to some risk to deviate from the text of the directive and in BiH it is a rule that the text in the ordinance transposing the directive is as close to the directive text as possible.

The legal framework for the work of the expert teams is laid down in the Instruction on Method of Development and Procedure of Enforcement of Technical Regulations. Besides a clear description of the role of different authorities involved in the transposition process, the Instruction also introduces the so-called Regulatory Impact Analyses.

The reason why such an analyses shall be prepared as a part of the transposition process is that the analyses put light on the legal and economic consequences and impacts of the new legislation. The concept of these analyses was presented by Ms. Radmila Urta, Advisor from the Directorate for European Integration.

Regulatory Impact Analyses will, together with the draft ordinance, be presented to the public in connection with the "Public Discussion" of the new legislation. Therefore, the analyses represent an important contribution to the public debate which takes place when new technical legislation is introduced and at the same time the analysis can also result in the implementation of measures to mitigate adverse impacts.

With this common platform for the new expert teams, the work of the teams has now been launched.

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Impact Analyses – why do we need them?

The transposition of EU technical regulation into BiH legislation includes a number of steps described in the Instruction on Method of Development and Procedure of Enforcement of Technical Regulation. One of these steps is the preparation of impact analyses which shall identify important economic consequences of the adoption of the EU legislation into BiH legislation.

Within the framework of the Safety Infrastructure Project five impact analyses will be prepared. The impact analyses vary in the depth depending on the economic importance of the field regulated by the new regulations. As for the five impact analyses, only one full impact analysis is prepared and the rest are so-called initial impact analyses, which only more superficially describe the consequences of the regulations.

The full impact analysis is prepared for the regulation transposing the Construction Product Directive into BiH legislation. The construction area is characterized by being one of the economically most important areas - not only in BiH, but in economies around the world.

The preparation of an impact analysis consists of a series of steps where the first one is to identify all significant stakeholders. In this context, ministries, agencies, private companies, conformity assessment bodies and institutions directly involved in the implementation of the new legislation are obvious stakeholders. The latter category includes, for example, the market surveillance authorities and the national standards body. Furthermore, statistical material from all available sources is gathered to get as much quantitative information as possible.

Based on the interviews with the stakeholders and statistical materials, the team carrying out the impact analysis will establish a knowledge base that will put the light on both the positive and the negative consequences of the legislation seen from different angles.

The challenge in the Safety Infrastructure Project is to prepare impact analyses which provide information to the ministries and the politicians so that the negative consequences can be minimized by concrete initiatives. Therefore, the results of the work are of great importance since the smooth implementation of the new legislation is the criterion of success in all countries adapting their legislation to the EU system.

BAS staff prepared for the future

In parallel with the preparation for EU membership, BiH is also negotiating with the World Trade Organization (WTO) about membership. This calls for the establishment of an organizational structure to ensure openness and transparency of national technical regulation in relation to both the members of EU and WTO.

Besides the political importance of becoming a member of the EU, the access to the Single Market is probably the most important incitement for EU membership. This requires a comprehensive change of the legislative framework so that it is based on EU directives, but is also requires openness about the pure national legislation which must not be in conflict with the overall principles of free trade within Europe.

The same is the situation in the WTO. Members must inform other WTO members of new national legislation to ensure that new barriers to trade are not established.

In the EU, the obligations with respect to openness and transparency are regulated in the Directive 98/34/EC, which is laying down a procedure for the provision of information in the field of technical standards and regulations. Similar obligations are stated in the WTO/Technical Barriers to Trade Agreement (TBT).

In short, the directive and the agreement shall first and foremost ensure that a notification process of other members of the EU and the WTO respectively is initiated when a new technical regulation is in pipeline. This gives other members an opportunity to make objections against the regulation if it may create technical barriers to trade.

Secondly, the directive and the agreement ensure openness regarding the development of pure national standards. Even though the standards are voluntary, they can play an important role for the international trade. Finally, the WTO/TBT Agreement requires that all members of the WTO establish a WTO/TBT Enquiry Point, which provides information on technical regulation both to domestic companies and to foreign WTO/Enquiry Points seeking information on technical regulation.

National standards bodies host the WTO/Enquiry Points and this is also the case in BiH. Therefore, the Safety Infrastructure Project has carried out 4 half-day seminars at the Institute for Standardisation of Bosnia and Herzegovina – BAS – where all aspects of the directive, the WTO agreement and the operation of the Enquiry Point were discussed. With this introduction the BAS staff is now prepared for the future.

Safety Infrastructure Project EUSIP) Expert Group for Conformity Assessment

As already described in the previous newsletter, the project supports three fields: 1) Transposition and Implementation of EU Directives, 2) Establishment of Conformity Assessment System at the State Level, and 3) Development of Capacities of the Market Surveillance System in BiH. Close cooperation of the Project Team with beneficiaries – the Ministry of Foreign Trade and Economic Relations and the Market Surveillance Agency BiH - is essential for achieving the expected results of the Project. Moreover, as regards the establishment of conformity assessment system, the Project Team has recognized the need for the establishment of an expert group com-

prised of representatives from relevant ministries, institutions and stakeholders with a direct interest in this field.

At the invitation of the EU Delegation, the following authorities participate in the Project Expert Group for Conformity Assessment: MoFTER, Directorate for European Integration BiH, Ministry of Economy, Energy and Development of RS, Ministry of Energy, Mining and Industry of FBiH, Ministry of Transport and Communications BiH, Ministry of Civil Affairs BiH, Market Surveillance Agency BiH, Institute for Accreditation, Institute for Metrology, BiH Foreign Trade Chamber.

The expert group will serve as a panel for presentation and discussion of documents related to conformity assessment; shall act as an advisory board during the Project implementation and shall participate in various trainings and awareness campaigns organized by the Project.

The first meeting of the group was held on 14 July 2010 in Sarajevo. Mr. Ljubiša Ćosić, Advisor of the Minister of Foreign Trade and Economic Relations BiH, opened the meeting. Mr. Ćosić mentioned that the Progress Report 2009 of the European Commission pointed to problems with the establishing of conformity assessment system in BiH. Hence, the work of both, the EUSIP and PEG, is important for achieving more positive results in this area.

Mr. Zoran Bilbija, Head of Conformity Assessment Department within MoFTER, summarized the situation in conformity assessment in BiH as a fragmented one and emphasized the necessity to build up the new system based on accreditation.

Mr. Vitomir Fister, EUSIP legal expert, presented the experience with building up the EU system in Slovenia. He stressed the importance of interministarial cooperation in the process.

EUSIP key expert for conformity assessment informed about the activities and expected results of the Project and its crucial part – the preparation of an Action Plan for the signing of the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) between the EU and BiH.

The participants then discussed the various subjects of mutual cooperation and support to EUSIP's progress. Identification of technical legislation that could create technical barriers to the adoption of the ACAA and potential sectors of interest for its conclusion were the main topics.

Next PEG meeting is supposed to be held in late September.

A strategy will be the framework for the development of the BiH market surveillance system

The EU requirements to the market surveillance systems in EU member states are defined in the regulation published in 2008. Therefore, these requirements are benchmarks for the development of market surveillance system in BiH. Representatives of the inspectorates in the entities and Brcko District and the Market Surveillance Agency met in Banja Luka on the 29th June 2010 to discuss and clarify how well the present system is prepared to meet the EU requirements.

Market surveillance strategy in the field of industrial products will be prepared within the framework of the Safety Infrastructure Project. The challenge is that the strategy shall not only cover one organization but three Inspectorates and the Market Surveillance Agency BiH. However, these organizations together form the market surveillance system in BiH, which shall ensure that the products covered by Community harmonization legislation are effectively surveilled.

To establish an effective market surveillance system a number of different mechanisms and systems shall be in place so that the Inspectorates and the Agency can follow up on complaints, monitor accidents, and ensure that the penalties in the case of violations are proportionate. Most of these issues are already addressed in the existing laws, but the seminar in Banja Luka showed that the implementation of the words written in the laws is not in place yet.

The strategy process includes different stages and at present the project is still in the analysis and fact finding stage. This includes a comprehensive analysis of the current legislation; the seminar in Banja Luka; analysis of daily cooperation between the Inspectorates and the Market Surveillance Agency, which has a coordinative role; analysis of capacities of the laboratories and interviews. These activities will together with the studies of market surveillance systems in the EU form the basis for the strategy that will be prepared by the international experts.

"When the strategy is approved by the involved organizations the hard work will start, but organizational development is a necessity in all countries which want to be a part of the EU", Team Leader Carsten Kudahl says.

Laboratory capacity

Consumer protection is the most immediate outcome of market surveillance activities, when dangerous products are removed from the hands of consumers. The ultimate purpose of market surveillance is to ensure the safety of products placed on the market and to allow the elimination of unfair competition. Moni-

toring the market involves taking product samples and investigating those samples in order to determine their safety. For this purpose, sufficient laboratory capacity must be available.

The core of market surveillance is a chain of interdependent processes such as inspections, sampling, laboratory testing, interpretation of results, decision making, intervention and execution of ensuing legal processes, which may culminate in imposing sanctions or other interventions.

All products which are placed on the EU market must be equipped with proper documentation, e.g. Declaration of Conformity and markings. However, declarations of conformity can be easily falsified and CE-marking can be affixed unlawfully. It is not therefore possible to rely on document checks alone to assess the safety of the products for which self certification is allowed. Further investigations are thus needed, including sampling and laboratory testing of the products themselves. The GPSD recognizes this by imposing an obligation for market surveillance to include sampling and safety testing.

The Market surveillance authority decides to test products that could be suspicious. Essentially, two kinds of tests could be foreseen for market surveillance purposes: “simple tests” and “other tests”.

There is no clear definition for “simple” tests, but in general they can be performed by market surveillance inspectors, taking into consideration certain quality items (e.g., measurement of dimensions, basic electrical quantities, etc.). Due to the complexity of this standard and the number of requirements it imposes to the laboratory performing the test, in general, we can say that testing is not a task for the market surveillance authority. “Other” testing requires a specific test equipment/infrastructure usually only available to accredited laboratories.

Monitoring the market involves taking product samples and investigating those samples in order to determine their safety. For this purpose, sufficient laboratory capacity must be available. Laboratory facilities can be part of the infrastructure of the authority itself or can be subcontracted.

Therefore, one of the essential task of the Safety Infrastructure Project of BiH was to evaluate the laboratories operating in BiH and to assess their capability to act as conformity assessment bodies in the technical fields of New Approach Directives and General Product Safety Directive.

Questionnaires were sent to 36 laboratories and the Project succeeded to gather information for 19 laboratories, two additional laboratories informed the Project that they do not provide testing or inspection. Out of those 19 laboratories, 13 laboratories have already been accredited according to standards BA EN ISO /IEC 17025, BA EN ISO /IEC 17020 or BA EN 45011.

All accredited Conformity Assessment Bodies, visited during the missions, are at reasonable technical and scientific level. The staff is competent and has a high educational background. The equipment is calibrated, well maintained and up to date. Laboratory facilities for testing, calibration or inspection are adequate. The laboratories which have not established the quality system yet, generally do not guarantee the traceability of their test results.

The accredited conformity assessment bodies have close contacts with conformity assessment bodies abroad and they regularly participate in inter-laboratory comparisons or proficiency-testing programs.

There were three laboratories identified that already provide testing according to the harmonized standards. Two are working in the field of Construction Products Directive and one in the field of Personal Protective Equipment. Other assessed laboratories do not carry out testing or inspection or certification in the frame of considering directives.

“Laboratories are essential part of the market surveillance system and we cannot imagine effective market surveillance without them”, Market Surveillance Expert Borut Matkovic says.

Contact information

Delegation of the European Union to Bosnia and Herzegovina

Address: Skenderija 3A, 71000 Sarajevo
Phone: + 387 (0)33 254 700
Fax: + 387 (0)33 666 037
Website: www.europa.ba

BiH Ministry of Foreign Trade and Economic Relations

Address: Musala 9
71000 Sarajevo
Phone: +387 (0)33 445 193
Fax: +387 (0)33 206 141
Website: www.mvteo.gov.ba

BiH Market Surveillance Agency

Address: Karadjordjeva 8
71123 Istocno Sarajevo
Phone: +387 (0)57 343 503
Fax: +387 (0)57 343 502
Website: www.annt.gov.ba

Safety Infrastructure Project Office

Address: Obala Isa-bega Isakovica 6/I
71000 Sarajevo
Phone: +387 (0)33 236 173
Fax: +387 (0)33 441 548

Team Leader: Mr. Carsten Kudahl
E-mail: ckudahl@eusip.ba, info@eusip.ba

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