

# SEE QI Newsletter 8

## Regional Consultancy Fund for Quality Infrastructure (QI) in South East Europe (SEE)

The SEE QI Fund is a demand-driven project implemented by the German national metrology institute, Physikalisch-Technische Bundesanstalt (PTB). It supports initiatives that foster the increased recognition of QI services in the Western Balkan (WB6) countries and thus facilitates their integration into the European Union (EU) common market and other markets. This newsletter provides updates on recent developments in the SEE QI Fund and the ongoing SEE QI projects with the aim of motivating QI stakeholders to take advantage of the opportunities and benefits of regional cooperation in this field.

### 1. Interview with Marina Janković, Market Inspector – Coordinator for Technical Surveillance from the Administration for Inspection Affairs of Montenegro

The personal protective equipment (PPE) component of the SEE QI 4 project on market surveillance kicked off in summer 2020 with an exchange of experience on market surveillance of Covid-19 PPE equipment and a training session on the EU PPE regulation ((EU) 2016/425) and its practical implications for WB6 countries. In 2021, the practical components of the SEE QI 4 project, namely a joint testing of PPE equipment and a visit to a laboratory, were converted into a virtual joint action on reflective vests. Based on the laboratory results, the market inspectors' group undertook the risk assessment of reflective vests sampled in five Western Balkan countries. Marina Janković, market inspector – coordinator for technical surveillance from Montenegro, was one of the participants who attended all PPE market surveillance activities of the project.

*How did you and your colleagues benefit from the participation in the SEE QI 4 project activities on market surveillance of personal protective equipment?*

Despite the Covid-19 pandemic conditions, the PPE component was realized very successfully. In the course of several virtual trainings and exchanges of



Marina Janković

experiences we had the opportunity to witness the best European practice. The trainings were led by the Croatian expert Ante Fuzul. He has been an inspector in this area for many years now, so he transferred his experience to us in a very pragmatic way.

Given the rapid spread of the coronavirus, the demand for protective and medical equipment was huge. Guided by the EU countries' experience, inspectors from the Montenegrin market found protective masks which had no certificates on type

review or had fake certificates. Immediately, Market Inspection ordered a withdrawal and a permanent ban on circulation of 10,590 protective masks.

Soon after this exchange of experience, a virtual training on the PPE regulation ((EU) 2016/425) was also held, covering its content and a comparison with the previous PPE directive (89/686/EEC). Representatives from Western Balkan countries presented examples of protective equipment which they had inspected on their markets. Furthermore, the SEE QI 4 project team agreed to conduct the control of reflective vests in a joint action. As part of the joint action, a virtual training was held, during which checklists for reflective vests were presented in accordance with the standard and the regulation as well as a complete course of inspection with conducted sampling and product testing.

*Due to the virtual implementation of the activities and the fact that the trainings were offered in Croatian with Albanian interpretation, around 50 market inspectors could participate, more or less continuously, in the last year. What was the added value of bringing market inspectors from six Western Balkan countries together?*

The trainings were very rich in content. The trainer gave his best to show all the details regarding the personal protective equipment surveillance, examples, differences between the original and fake products, risk assessment, undertaking measures depending on the risk level; he submitted all the necessary materials for surveillance. Keeping in mind that the trainings were offered in languages accessible to everyone present, all participants individually contributed through questions and comments to making this topic better understood.

*Due to travel restrictions, the WB6 joint action on reflective vests was implemented virtually. What results have been achieved so far for your country and the region?*

As mentioned before, all the activities for preparing the joint action on reflective vests were conducted virtually: meeting on the standard and regulation, preparation of checklists, the sampling method, etc. After the inspectors took samples with minutes on sampling and non-commercial invoice, the samples were sent to a laboratory which is a notified body for PPE in Croatia. Out of five samples taken by inspectors in Montenegro, three samples did not pass the testing. At the virtual training, all the individual test reports were analyzed. Risk

assessment was also conducted together. In Montenegro all the products not fulfilling safety requirements, which in total were 3 types out of 2,223 pieces, were withdrawn from the market and destroyed. In two cases a recall from the end users was ordered.

*For you personally, what were the most useful aspects of the SEE QI 4 project? Can you provide one example of what you will do differently in the future as a result of your participation in the project?*

Each training brings along specific benefits and one can always learn new things. As for me, risk assessment and the Risk Assessment Guide (RAG) form available on the RAPEX website of the EU was a very useful aspect. In the future, I will use the RAG in conducting risk assessment.

## 2. WB6 Regulators Learn from Montenegrin Transposition of Regulation (EU) 2019/1020

On June 9, 2021 the PTB SEE QI 4 project organised a three-hour workshop in which WB6 experiences and questions regarding the transposition of the new EU legislation on market surveillance were discussed. The workshop was attended by 39 participants from WB6 countries.

This workshop was the follow up to an e-conference on the new EU legislation on market surveillance organized by the SEE QI 4 project in May 2020. WB6 regulators benefitted from Montenegro's frontrunner position in the region: Montenegro has intensively worked on the transposition of Regulation (EU) 2019/1020 with support from a bilateral EU technical assistance project and was ready to share all experiences with its Western Balkan neighbors.

The workshop opened with a theoretical introduction into the legislative transposition process by Ms Vera Despotović from the Serbian Ministry of Trade, Tourism and Telecommunications. Afterwards, Ms Marina Janković from the Montenegrin Administration for Inspection Affairs presented the development process and content of the Montenegrin draft market surveillance law. Mr. Joachim Geiss from the German Federal Ministry for Economic Affairs and Energy commented on some key presentation points and addressed questions from the WB6 countries regarding the table of concordance of the Montenegrin draft law with Regulations (EU) 2019/1020 and (EU) 2019/515.

Additionally, the current status of the Law on Market Surveillance in Bosnia and Herzegovina was presented by Ms Gordana Krsmanović Kusmuk from the Market Surveillance Agency of Bosnia and Herzegovina.

The PTB SEE QI 4 project will provide further support with the transposition process on national level, if needed, and with a toolbox for the development of national strategies as required by the new Regulation (EU) 2019/1020.

### 3. Closing Event of the SEE QI 8 Project (WB6 QI Response to Covid-19)

The closing conference of the SEE QI 8 project on 16 June 2021 combined an overview of the project highlights and main achievements with interactive training sessions on business resilience.

The SEE QI 8 project on quality infrastructure (QI) response to Covid-19 related challenges came to an end. To share the achievements of the project with stakeholders in the WB6 countries, a closing conference was held on 16 June 2021. The virtual event was attended by approximately 50 people, namely project partners, representatives of quality infrastructure institutions, relevant ministries and the private sector.



Useful outputs were presented such as a [Guide to Quality for Medical Laboratories Performing Molecular Tests for Covid-19](#), which is available in Albanian and English. Moreover, participants from WB6 QI institutions shared their impressions from the activities, reported on impact of the activities on their work and provided

concrete advice on how to address Covid-19 related challenges based on their learnings and experiences made in the framework of the project. The second session of the event was dedicated to the trainers on business resilience who were trained in the framework of the SEE QI 8 project.

After a short overview of the most relevant standards and an introduction of the experts involved in the training, two parallel training sessions were offered by participants in the training of trainers, namely Vesna Vulić and Ivana Mišković.

### 4. Wrap-up and Outputs of Five-Month Training of Trainers on Business Resilience Standards

Western Balkans businesses and other institutions can now benefit from a hands-on booklet and access to trained experts in their countries to increase their business resilience by drawing on established international standards.

The Training of Trainers (ToT) on Business Resilience Standards, attended by more than 30 participants with diverse professional backgrounds from Montenegro, BiH, Serbia, North Macedonia, Kosovo and Albania, was part of the SEE QI 8 project “WB6 QI response to Covid-19.” The course covered a comprehensive package of international standards related to business resilience, leadership and practical application in case studies. An interactive virtual training approach and lectures by Western Balkan trainers who are familiar with the local context guided the participants to become trainers themselves and built a regional network of future trainers.

A substantial output delivered by the ToT programme is a Business Resilience Standards booklet, giving the reader a detailed insight into topics such as Risk Management, Business Continuity Management and Leadership. [Compiled in a publication of 182 pages](#) the booklet is available in English, Bosnian and Albanian.

The ToT programme encouraged the trainees to conduct a free pilot training, consultancy or webinar, which would improve their marketing skills and increase the tangible benefit of the ToT programme for Western Balkan businesses. The SEE QI Fund compiled in the brochure [Trained Experts of Business Resilience](#) the professional profiles of the six regional trainers and those of 17 trainees, who conducted such pilot trainings.

While the ToT course officially ended on July 1<sup>st</sup>, this marks only the beginning for the newly trained trainers, consultants and advisors in business resilience standards. We wish them all the best!



Dr Andreas Kalisch from the German national accreditation body (Deutsche Akkreditierungsstelle GmbH (DAkkS)) and was moderated by Rózsa Ring. There was a strong interest in the topic: 42 persons participated from the six SEE countries.

Heidelinde Fiege summarized the CPR's specificities and the "Assessment and Verification of Constancy of Performance" (AVCP) systems of the CPR, describing the tasks of and requirements from the notified bodies in each system. Then she explained the notification process in the EU when notification is based on accreditation covering all CPR requirements and when notification is not based on accreditation or based on accreditation partly covering all CPR requirements.

Dr Andreas Kalisch provided a comprehensive interpretation of EA-2/17 EA Document on Accreditation for Notification Purposes and on how this mandatory document is implemented by DAkkS in the field of CPR. Then Andreas Kalisch presented the DAkkS accreditation process in the field of CPR, showing several examples from DAkkS's practices. Special attention was paid to the competence requirements for assessors and technical experts, the specific accreditation criteria for conformity assessment bodies involved in the AVCP, the general and sector specific assessment reports/checklists used by DAkkS assessment teams and the scope of accreditation in this specific regulated field.

The participants welcomed the German example of accreditation as a prerequisite for notification as a model to be followed.

## 5. Training on Accreditation and Notification

A one-day virtual training on accreditation and notification related to the EU Construction Product Regulation (CPR) was held on 29 September 2021 as the last activity in the framework of SEE QI project 6 dealing with EU best practices in accreditation.

The training was conducted by Heidelinde Fiege from the German notifying authority for CPR (Deutsches Institut für Bautechnik (DIBt)) and



## Annex: Overview of ongoing SEE QI Projects

Name	Coordinator	Timeframe	Objective
<b>1. Interlaboratory comparison for small volumes</b>		Finalised	National Metrology Institutes achieve mutual and international recognition of their calibration services for small volumes.
<b>2. Adjustment of certification programs in organic production to the modified EU legal basis 2018/848</b>	Mersida Musabegović, Organska Kontrola, BiH	10/2019–03/2022	SEE certification bodies acquire competence about the new EU Regulation 2018/848 and are able to implement the changes required and know how to work with the new list of compliant CBs
<b>3. National normative aspects (NNA) for standardization of overhead electrical lines</b>	Tatjana Bojanić, Institute for Standardization, Serbia	09/2019–10/2021	Standardisation institutes and technical experts develop specifications for a regionally harmonized draft NNA document for overhead electrical lines (EN 50341-1 09/2019–08/2021)
<b>4. New EU legislation on market surveillance</b>	Samir Bekto, Market Surveillance Agency, BiH	10/2019–11/2021	Market surveillance authorities build capacity and exchange knowledge on the safety requirements resulting from newest horizontal and vertical EU legislation: Regulation (EU) 2019/1020, Regulation (EU) 2019/515, Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) and Machinery Directive 2006/42/EC
<b>5. Metrology for medical devices</b>	Bianka Mangutova Stoilkovska, Bureau of Metrology, North Macedonia	04/2020–12/2021	The capacities of NMIs for calibration / verification / control of the most relevant types of medical devices with measuring function in WB6 countries are strengthened
<b>6. Capacity building for harmonization of accreditation activities with the European rules in selected areas</b>	Dejan Stojkovski, Institute for Accreditation of the Republic of North Macedonia (IARNM)	04/2020–10/2021	WB6 region implements, on market demand, accreditation schemes (policies, requirements, procedures) in compliance with the practices of the national accreditation bodies that are members of EA
<b>7. Capacity building for the implementation of interlaboratory comparisons (ILC) and proficiency tests (PT)</b>	Stilian Habibi, National Metrology Institute DPM, Albania	04/2020–11/2021	The goal of the project is to support the applying NMIs in gaining knowledge on the ISO 17043:2010 standard requirements and enable them to develop competence in the complementary operation of ILC/PT schemes at national and regional level
<b>8. QI response to Covid-19 challenges</b>		Finalised	QI institutions in the Western Balkan countries proactively tackle Covid-19 challenges related to QI

October 2021 | This newsletter is published about 3–4 times each year. Please subscribe or unsubscribe [here](#).

**Published by**  
International Cooperation  
Physikalisch-Technische Bundesanstalt  
Bundesallee 100  
38116 Braunschweig, Germany

**Responsible**  
Susanne Wendt  
+49 531 592-9030  
[susanne.wendt@ptb.de](mailto:susanne.wendt@ptb.de)

**Editors**  
Stefan Wallerath  
Suzana Lange