

SEE QI project 4: New EU legislation on Market Surveillance

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

Main result: Market surveillance authorities built 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

Duration: October 2019 – December 2021



SEE QI 4 planning workshop September 2019

Coordination team:

Albania: Stela Bita, Julian Lleo, State Inspectorate of Market Surveillance
Bosnia and Herzegovina (BiH): Samir Bekto (project leader), Market Surveillance Agency
Montenegro: Marina Jankovic, Administration for Inspection affairs
Kosovo: Artan Demolli, Ministry of Industry, Entrepreneurship and Trade
Serbia: Vera Despotovic, Ministry of Trade, Tourism and Telecommunications – Market Inspection Sector
North Macedonia: Tina Temovska, State Market Inspectorate
PTB: Suzana Lange (external project manager)

External experts:

Horizontal EU legislation: Joachim Geiss, Johann Dietrich
Personal protective equipment: Ante Fuzul
Machinery: Johann Dietrich, Janez Furlan
(Online) facilitation: Suzana Lange

Background

Representatives from Western Balkans (WB6) market surveillance authorities and PTB met for a SEE QI planning workshop on September 4-5, 2019 in Podgorica. After a needs assessment, the project coordinators decided to focus the activities of Project 4 on adapting to the two new horizontal EU market surveillance regulations and the new regulation on personal protective equipment (PPE) as well as the new product types regulated by the Machinery Directive. They decided to build on achievements of previous WB6 cooperation projects with GIZ ORF and SIDA/ CEN and continue the WB6 Network on Dangerous Product Notification System and the joint actions for specific product groups. The WB6 workshop participants selected Mr Samir Bekto from BiH as project leader. All WB6 countries designated contact persons to facilitate the coordination of the project and to reach out to national market inspectors.

Component 1 focused on the **new EU horizontal legal framework** in the field of market surveillance.

The activities under this component started with a regional conference which introduced the development of the EU legal framework over time and the implementation of the new EU Regulations (EU) 2019/1020 and (EU) 2019/515 on market surveillance. Originally scheduled for mid-March 2020 in Montenegro, the event took place online as e-conference on May 27-28, 2020 due to the Covid-19 pandemic. Two German experts presented the EU legislation. In addition to the training material, they developed a Q&A document that was shared with all

TABLE OF CONCORDANCE

Accession Country: Republic of Serbia

REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance); Official Journal of the European Union L 218, 13/08/2008 p. 0030-0047		Accession Country's Legislation			
CELEX code of EU legislation 32008R0765		01. Law on Market Surveillance, Official Journal of the Republic of Serbia 92/2011			
1	2	3	4	5	6
Article	Text	Reference	Article	Content	Remarks

Example table of concordance EU legislation – national legislation

participating market inspectors. Within the e-conference, the WB6 Network on Dangerous Product Notification System met and decided to rotate the leadership of its coordination in an alphabetical order: after Albania in 2020 and BiH in 2021, Kosovo will take over the coordination in 2022. The CEFTA Secretariat was invited as well to further discuss the acquisition of a common electronic database for the exchange of market surveillance information.

As a follow-up, the German Federal Ministry responsible for market surveillance invited all SEE market inspectors to its annual market surveillance conferences in 2020 and 2021, both held online. Germany shared its draft law on market surveillance (translated into the local language by the BiH Market Surveillance Agency), which transposes the new EU legislation. Montenegro is the first Western Balkan country to begin transposing Regulation (EU) 2019/1020. Other WB6 countries, such as Serbia, are planning to do it in 2022. On June 9, 2021, the SEE QI 4 Project organised a regional workshop for regulators in which Montenegrin, German, Bosnian and Serbian experts shared with their WB6 peers their experience in the development process and content of their new/planned draft laws on market surveillance. One of the main results was a table of concordance between the Montenegrin draft law and Regulations (EU) 2019/1020 and (EU) 2019/515 that can be used by other Western Balkan

countries when developing their own legislation. As a final activity, the SEE QI 4 Project developed a toolbox for the development of national strategies as required by Regulation (EU) 2019/1020.

VRSTA MASKI I RESPIRATORA I STUPANJ ZAŠTITE OD COVID-19*

MASKA ¹	RESPIRATOR ²			
KIRURŠKA MASKA	N95	FFP2	FFP3	P100
2 mikrona 2000 nm	0.3 mikrona 300 nm	0.3 mikrona 300 nm	0.023 mikrona 20 nm	0.02 mikrona 20 nm
NE	NE	NE	DA	DA

Koronavirus COVID-19
0.12 mikroni (0.06 - 0.14)
120 nm (80 - 140)

* - prema aerosolnom prijenosu
1 - štite druge od osobe koja nosi masku
2 - štite osobu koja nosi respirator

MedicinskaSestra.eu

Exchange of experience on market surveillance of PPE used in Covid-19

Component 2 focused on market surveillance of items covered by the **Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)**.

The initial activity under this component was in response to a spontaneous request from a SEE partner for an exchange of experience on the topic of market surveillance of PPE used against Covid-19. On July 15, 2020, market inspectors discussed how to monitor the conformity of protective masks to detect and remove from the market defective or

fraudulent products and therefore to contribute to ensuring the health and safety of medical staff and citizens in the pandemic. The component continued with a training held on September 28-29, 2020, on the content of Regulation (EU) 2016/425 on PPE and its differences to previous / parallel EU legislation and guidelines. Experts from BiH, Serbia, Montenegro, Albania and Kosovo shared their own best practices on products such as hearing protectors and protective masks.

A joint action was organised in order to harmonise the correct interpretation of standards and regulation, make a checklist out of them, use it in market surveillance controls, sample and test products, and decide on follow up actions based on the test results and risk assessments. The SEE QI 4 project team selected the PPE item of high visibility vests, which is covered by the standard "EN ISO 20471:2013/A1:2016 High visibility clothing - Test methods and requirements". The virtual kick-off training of the joint market surveillance action on high visibility vests took place on February 3-4, 2021. The trainer connected the formal letter of the legislation and standards to the actual practice of implementing market surveillance by presenting his country's approach and discussing how to overcome challenges when applying the market surveillance procedures.

Following the training, market inspectors from five WB6 countries sampled reflective vests on their markets and sent the samples to an accredited laboratory in an EU country. The study visit to the laboratory, which was originally foreseen in the SEE QI 4 Project, was replaced by a short movie and several videoclips that the laboratory staff presented and discussed with the participants during the second training. During the subsequent training on May 11 and June 9, 2021, the group of participating market inspectors undertook a risk assessment of high-visibility vests, based on the results from the test reports, using the so called Risk Assessment Guide (RAG) form available on the Risk Assessment for Safety Gate (ex RAPEX) website of the European Commission. It resulted in detecting several high-visibility vests which presented a serious risk to the user and therefore had to be withdrawn from the WB6 markets.



Training on market surveillance of electric drills

Component 3 addressed challenges of market surveillance of new products covered by the **EU Machinery Directive 2006/42/EC**.

The initial activity was a regional training, held on November 26-27, 2019 in Tirana, on the requirements of the EU Machinery Directive 2006/42/EC and challenges related to new products such as e-scooters, drones and hoverboards. Kosovo invited all SEE QI 4 market inspectors working on machinery to join a two-day training which covered the implementation of the EU Machinery Directive on EU and national level as well as the role of market surveillance in verification of

compliance for machinery. It was organized on March 30-31, 2021 in the framework of its bilateral Free Movement of Goods project.

To deepen the training on market surveillance in the area of machinery, the SEE QI 4 project team decided to focus on the product of electric drills. An online training was organized on September 14-15, 2021. After a short overview of Directive 2006/42/EC, the trainer presented the standards EN 62841-2-1:2018 and EN 62841-1:2015 and their practical translation into a checklist for market inspections. Pre-shot videos and online tutorials demonstrated how to properly implement hands-on tests to verify compliance with the requirements of the standards. The participants discussed how to do the risk assessment of electric drills, using again the RAG website, and what measures to take as a response in the local context.

Impact

After two years of SEE QI 4 project implementation, the coordination team from WB6 market surveillance institutions and the PTB management came together for a final wrap-up meeting on December 7, 2021. One of the objectives of the meeting was to receive feedback from the market surveillance institutions on the extent to which the implemented trainings and activities have contributed to concrete changes or innovations in the market surveillance practices and documented processes. The coordination team members from all WB6 countries reported that the exchange of information in the region contributed to facilitation of efficient market surveillance. All project events and the joint action had a positive impact on the improvement of market surveillance processes and harmonization of the sampling procedure as well as the approximation of the risk assessment methodology. The successfully implemented joint action on market surveillance of PPE has shown especially active participation of inspectors and good transfer of knowledge by experts. The items selected for the development of checklists, such as electric drills, were included to be covered by WB6 national



SEE QI 4 planning workshop November 2019

programmes for market surveillance. As a result of the exchange of experiences on solving different challenges related to EU legislation, legislators will be able to apply a more practical approach to transposition and harmonization of legislation. In general, the SEE QI 4 Project contributed to the goal of harmonizing general market surveillance practices of the WB6 countries with those of the EU, e.g. by developing and using common checklists for market surveillance and by exchanging results of market surveillance campaigns using well-proven methodology for risk assessment and information exchange.

To give an example of impact on national level: During the implementation of market surveillance of high-visibility vests in Bosnia and Herzegovina, 11 inspections were performed. A total of 8 different models of high-visibility vests were controlled. 5 models of vests had non-conformities, of which 4 models posed a serious risk to consumers. Companies voluntarily or by order of inspection bodies withdrew from the market 5 non-conformity models of high-visibility vests in the amount of 10733 pieces. In 2022, the control of electric drills is planned using knowledge and the checklist developed in this project.

Lessons learned

- The peer-to-peer exchange of experience worked very well in the SEE QI 4 Project: WB6 experts could complement presentations by EU trainers with valuable practical examples and share material developed in their countries.
- Joint regional market surveillance achieves better results because it involves the control of large regional companies that distribute their products in several countries.
- Harmonization of market surveillance procedures and information exchange prevents the distribution of unsafe products from one country to another.
- Due to the online implementation of activities the project conducted more activities and included more participants than originally foreseen. When an issue related to quality infrastructure was raised on regional level, the possibility to organize spontaneous online regional meetings through a video conferencing platform in order to discuss and resolve it was very useful.
- Capacity development activities in the field of market surveillance should include practical topics, e.g. how to carry out inspections not only by checking the conformity of the equipment on paper but also conducting indicative physical checks.
- To successfully include a broader variety of participants from WB6 countries, interpretation during events and translation of training material into local languages is necessary.
- WB6 and PTB team members actively created synergies with other ongoing processes and projects, e.g. opening national trainings to participants from other countries and sharing draft laws.