



The Government of the  
Republic of Serbia



HALFWAY:  
ACHIEVEMENTS AND RESULTS  
IN THE PERIOD  
JANUARY 2019 – AUGUST 2020

POLICY AND LEGAL  
ADVICE CENTRE  
(PLAC III) PROJECT



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## INTRODUCTION

The Policy and Legal Advice Centre (PLAC III) project is one of the projects funded by the European Union in Serbia that significantly contributes to the improvement of Serbia's European integration process. After the opening of accession negotiations, the Republic of Serbia entered the most demanding phase on its path to membership in the European Union, which includes the harmonisation of the national legislation with Union *acquis* and the conduct of the negotiations themselves. Since its inception in January 2019, the PLAC III project is providing support to the Government of Serbia in both processes – the harmonisation of legislation and conducting accession negotiations. The project priority areas have been agreed upon and implemented in close cooperation with the Ministry of European Integration, the Negotiation Team for Accession of the Republic of Serbia to the European Union and national institutions. Serbia's accession to the European Union is ultimately for the benefit of all Serbian citizens to whom the European standards are gradually becoming closer even now, also through the support of the PLAC III project.

This brochure presents an overview of the results achieved by the PLAC III project during the first 16 months of its actual implementation. The outbreak of the Covid-19 pandemic affected the project implementation flow and after a short pause (from 18 March to 8 June 2020), PLAC III has resumed its activities on a full scale with some adjustments to the extraordinary circumstances created by the pandemic situation in order to fulfil the main goal – achieving a high level of effective alignment of national legislation with Union *acquis* and its implementation.

## ABOUT THE PROJECT

The Policy and Legal Advice Centre (PLAC III) project, an EU-funded project managed by the Delegation of the European Union to the Republic of Serbia, is implemented by a consortium led by DMI Associates in cooperation with GIZ and ECG. The assistance provided by the Project shall contribute to an enhanced compatibility of the national legislation with EU legislation and its effective implementation and further strengthening of the capacities of relevant national structures to successfully carry out accession negotiations.

The project provides legal assistance to the Serbian Government in the process of the harmonisation of the national legislation with Union acquis through amending the existing and drafting new legislation. That entails providing a legal basis for the introduction of European standards in all spheres of life and work in Serbia – from financial and market regulations, health and energy to environmental protection. The project also assists in the process of accession negotiations. This assistance is comprehensive and is provided, among others, through seminars, study tours, workshops and trainings organised within the framework of the project.

By achieving a high level of effective alignment of the national legislation with Union acquis and its implementation, the Serbian administration will be enabled to effectively conduct accession negotiations and successfully manage overall EU integration and pre-accession assistance geared towards EU membership.

The project started in January 2019. The planned project duration of 30 months is likely to be amended due to the pause caused by the outbreak of the Covid-19 pandemic. After the pause lasting from 18 March to 8 June 2020, the implementation of project activities resumed on full scale but adapted to the pandemic circumstances that entail remote work on the part of the project team and expert online performance.

# BENEFICIARIES

The main beneficiaries are the Ministry of European Integration and the Negotiating Team for Accession of the Republic of Serbia to the European Union. The immediate project beneficiaries are line ministries and institutions involved in legal harmonisation in specific areas under different negotiating chapters.

## **PLAC III covers 9 negotiation chapters as the project's priority areas:**

Chapter 3: Right of establishment and freedom to provide services; Chapter 8: Competition policy; Chapter 9: Financial services; Chapter 12: Food safety, veterinary and phytosanitary policy; Chapter 15: Energy; Chapter 16: Taxation; Chapter 27: Environment and climate change; Chapter 28: Consumer and health protection; Chapter 33: Financial and budgetary provisions.

Additionally, a horizontal issue of human rights in legislative development is addressed.

## **The project results that should be achieved are as follows:**

1. Enhanced compatibility of national legislation with EU legislation and its effective implementation;
2. Enhanced capacities of relevant national structures for successful carrying out of accession negotiations.

# PLAC III IMPLEMENTATION

PLAC III is the fifth project in Serbia providing legal assistance to the process of association with the EU and to the negotiation process. In this line, it is the third one financed through the Instrument for Pre-Accession Assistance (IPA). The total budget of the project is EUR 2,763,300.

The Project's work plan envisages the engagement of project experts in various areas under the negotiating chapters and more than 2,135 expert working days will be spent working with beneficiary institutions in providing support to the harmonisation of the national legislation with Union acquis and the institutional capacity-building of relevant national structures for a successful carrying out of accession negotiations. The allocation of the number of working days to a particular chapter corresponds to the project priorities which were agreed upon in consultations with the beneficiary institution. At the same time, it is a reflection of the current state of play of accession negotiations between Serbia and the EU. The project team management demonstrated flexibility in the course of implementation, adapting to the beneficiary needs.

Chapter	Total number of available working days	Number of experts engaged in the period I/2019 – VIII/2020	Number of working days spent in the period I/2019 – VIII/2020
Chapter 3	219	9	118
Chapter 8	170	6	85
Chapter 9	195	3	50
Chapter 12	575	14	310
Chapter 15	143	2	28
Chapter 16	35	2	10
Chapter 27	530	19	296
Chapter 28	194	9	144
Chapter 33	20	0	0
Horizontal (HR)	50	0	0
Sub-total	2,131	64	1,041
Visibility & capacity building	165	3	89
Unallocated	4		
<b>Total</b>	<b>2,300</b>	<b>67</b>	<b>1,130</b>

The Project work plan envisages the realisation of results planned through 64 activities. In the period January 2019 – August 2020, 18 activities were finalised:

Chapter	Number of activities planned	Number of activities finalised in the period January 2019 – August 2020
Chapter 3	7	2
Chapter 8	4	1
Chapter 9	8	3
Chapter 12	12	4
Chapter 15	8	1
Chapter 16	2	0
Chapter 27	15	4
Chapter 28	7	3
Chapter 33	1	0
Horizontal (HR)	1	0
<b>Total</b>	<b>64</b>	<b>18</b>

## OVERVIEW OF PROJECT ACTIVITIES

Project activities are diverse and include the following:

- Assisting relevant institutions in the preparation of laws, by-laws, regulations, strategies, action plans and guidelines as well as in developing the necessary implementation follow-up measures in monitoring the implementation of harmonised legislation;
- Preparing the national administration for the practical aspects and challenges in the implementation of harmonised regulations and supporting the establishing of functional coordination mechanisms to facilitate implementation;
- Assisting institutions in assessing the effects of the pieces of legislation to be harmonised and to accurately anticipate the financial implications of their implementation;
- Providing support to relevant institutions and structures in different phases of the negotiation process for accession to the EU;
- Horizontal activities covering issues related to all negotiation chapters and the entire EU accession process.

Activities are designed after thorough discussion with the project beneficiaries according to their needs, taking into account the current state of play of accession negotiations as well as NPAA priorities. They incorporate the transfer of the know-how from recent accession experiences and the use of examples from the best European practices. For that reason, the PLAC III project gathers experts from all over Europe to be involved in the implementation of project activities, along with their Serbian colleagues.

# MAIN ACHIEVEMENTS AND RESULTS

In the period January 2019 – August 2020

During this period of the implementation, PLAC III project has already finalised 18 activities in areas related to 9 negotiation chapters. Beneficiary institutions were line ministries, government agencies and regulatory bodies. In addition, 17 public events of various types, with some 650 participants, were organised, as well as one study trip (to Slovenia).



Activities implemented in 9 negotiation chapters **9**



pieces of national legislation analysed **109**



project experts engaged **67**



Study trip to Slovenia organised **1**



workshops and trainings held **13**



media briefings held **2**

**40** EU legal acts transposed/harmonised



**79** Laws, bylaws and strategic documents drafted



**1,130** working days spent



**17** public events:

**2** conferences organised



**650** Total number of participants



## CHAPTER 3

# RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES

Negotiation Chapter 3 envisages that Member States (and aspirant countries that have opened accession talks) must ensure the right of the establishment of EU nationals and legal entities in any Member State as well as the freedom to provide cross border services. The acquis also harmonises the rules ensuring the mutual recognition of qualifications and diplomas between Member States, while for certain regulated professions a common minimum training curriculum must be followed in order to have the qualification automatically recognised. Thus, PLAC III project support focuses on the harmonisation of sectoral laws with the Directive on Services and the Directive on the mutual recognition of professional qualifications.

# 1. EXPERT SUPPORT IN HARMONISATION WITH THE DIRECTIVE ON SERVICES

The freedom to provide services is one of the four freedoms on which the EU single market is based. The umbrella document in Union acquis in this area is the Directive on Services 2006/123/EC, which allows the removal of obstacles to the full freedom of services in the EU. The full implementation of the Directive makes it easier for entrepreneurs to set up businesses and provide services in the EU, and for citizens to have a wider choice of services.

In Serbia, services falling within the scope of the Directive are not regulated by a single legal act but by a number of sectoral laws and regulations. The harmonisation of legislation in this area is implemented through the Draft Law on Services that transposes the Directive and through the harmonisation of sectoral laws. The PLAC III project provided support in analysing the current level of alignment of sectoral legislation with the Directive on Services.

**Beneficiary institution:** Ministry of Trade, Tourism and Telecommunications

**Number of experts engaged:** 1

**Number of working days:** 28

## **Project outputs:**

- The analysis covered sectors that are crucial for the country's economy: trade, tourism, construction as well as a number of business services (real estate agents, driving schools, representatives of intellectual property rights agencies, secondary vocational education, etc). In total, 65 legal acts (27 laws and 38 bylaws) that were identified as falling under the scope of the Directive of Services were analysed. It was determined that 44 legal acts (22 laws and 22 by-laws) must be amended in order to achieve compliance with the Directive. The analysis covered as many as 128 services and professional activities. Recommendations were made on how to achieve harmonisation.
- The capacities of the Ministry of Trade, Tourism and Telecommunications as well as other ministries/authorities were built up to recognise the importance of the Directive and challenges in its implementation.

## **Recommendations:**

Establishment of a multi-year technical support project for the implementation of the Directive on Services in order to achieve full harmonisation is recommended, based on the experience of a candidate country which already went through this process (Montenegro).

**Harmonisation with Union acquis:** Directive on Services 2006/123/EC; Directive on Mutual Recognition of Professional Qualifications 2013/55/EC

## 2. RECOGNITION OF PROFESSIONAL QUALIFICATIONS AND SERVICES IN THE FIELD OF CONSTRUCTION

The strategy for harmonising, transposing and implementing acquis in the field of mutual recognition of professional qualifications is implemented in Serbia since its adoption in November 2017. The strategy covers all reforms necessary in terms of legislative alignment and institutional capacity-building for the mutual recognition of professional qualifications. Additional support is required in the process of harmonisation of legislation for the profession of architects and the provision of architectural services. Services and professional qualifications in the planning and construction sector are regulated by the Law on Planning and Construction that has to be harmonised with relevant Union acquis, i.e. the Directive on Services and the Directive on Mutual Recognition of Professional Qualifications.

**Beneficiary institution:** Ministry of Construction, Transport and Infrastructure

**Number of experts engaged:** 2

**Number of working days:** 40

### **Project outputs:**

- A legal gap analysis of alignment of the Law on Planning and Construction with Union acquis was prepared;
- Based on the analysis, draft amendments to the Law on Planning and Construction were prepared. The amendments referred to architects and other regulated professions in the field of construction (their professional title, training, examinations, licensing, etc). Also, the Law was amended so that services could be provided by individuals and legal entities, while it also contains the new section enabling foreign nationals (individuals and companies) to carry out professional activities;
- Tables of Concordance on the Directive on Services and the Directive on Mutual Recognition of Professional Qualifications which provide a comparison between the provisions of two Directives and corresponding provisions of the Law on Planning and Construction were prepared, thus indicating the level of the harmonisation of national legislation in the field;
- An analysis was prepared of the need for further additional drafting of legislation regarding services and regulated professions in the field of planning and construction as the basis for draft recommendations on how to achieve full alignment with the directives;
- A workshop was held for representatives of relevant ministries, professional organisations, chambers and the interested public in order to inform them of the changes enacted by the amendments to the Law on Planning and Construction.

### **Recommendations:**

Related to the system of licensing, it is necessary to assess the need for such a number of licenses for individuals and legal entities. Considering the facilitation of the administrative procedures, a reduction of requirements and burden is recommended, as the administrative facilitation in all EU Member States has led to an increase of economic activities.

**Harmonisation with Union acquis:** Directive on Services 2006/123/EC; Directive on Mutual Recognition of Professional Qualifications 2013/55/EC

## CHAPTER 8

### COMPETITION POLICY

Negotiation Chapter 8 is one of the most crucial and demanding chapters in the process of Serbia's accession negotiation with EU, especially in the area of state aid. Union acquis in this chapter covers both anti-trust and state aid control policies. It includes rules and procedures to fight anti-competitive behaviour by companies (restrictive agreements between undertakings and the abuse of authority), to scrutinise mergers between undertakings, and to prevent governments from granting state aid that distorts competition on the internal market. Serbia has not yet opened this chapter: in the Screening Report for Chapter 8, the European Commission set six opening benchmarks that are to be met before negotiations are opened. One of the benchmarks is for Serbia to ensure the State Aid Authority's operational independency and assign it the powers and the resources necessary for the full and proper application of state aid rules in line with the obligations under the Stabilisation and Association Agreement. PLAC III assistance is focused on enhancing the harmonisation with relevant EU regulations and their proper implementation and providing support in meeting the opening benchmarks set for Chapter 8, especially regarding the alignment of the existing fiscal aid schemes such as the Law on Free Zones harmonisation.

# 1. ANALYSIS OF THE POSITION OF FREE ZONES, INDUSTRIAL AND TECHNOLOGY PARKS IN RELATION TO THE STATE AID RULES

In Serbia, the Commission for State Aid Control is a national competent authority. It is an operationally independent body established by the Government in 2010. The Department for State Aid Control, an independent organisational unit within the Ministry of Finance, carries out specialist, administrative and technical activities for the Commission and is also responsible for the harmonization of national legislation in the field of state aid. By signing the SAA (in 2007), Serbia accepted obligations in the field of state aid. In order to meet these obligations, it is necessary to harmonise the national laws with Union acquis that include, among others, the articles of the Treaty on the Functioning of the EU, GBER (General Block Exemption Regulation) and the De minimis Regulation. Appropriate state aid control enables strengthening free competition, establishing better market conditions and determining the manner of granting subsidies and other state aid types to certain economic operators. Fair competition in the market is secured in that way, as well as free access to the market for new companies and conditions for economic development. The final beneficiaries are Serbian citizens, both as consumers and businessmen.

An analysis of the position of Free Zones, Industrial and Technological Parks is of a great importance, having in mind their role in the economic development of the country and the rising trend of opening new technological parks in Serbia as the focus for state-of-the-art research and development. PLAC III project experts' assistance encompassed a comparative analysis of how public support to free zones in Serbia is financed and organised as well as a comparison with the practice in EU countries. In addition, an overview of existing state aid schemes was carried out and recommendations made for alignment with the relevant EU laws. The assistance resulted in proposals for the harmonisation of the Law on Free Zones and Regulation on Rules for State Aid Granting with EU regulations that will contribute to a faster opening of the benchmark related to state aid.

**Beneficiary institution:** Ministry of Finance's Department for State Aid Control; Commission for State Aid Control

**Number of experts engaged:** 2

**Number of working days:** 30

## **Project outputs:**

- A draft comparative analysis was prepared of the organisation, financing and public support to the Free Zones in EU Member States and the Republic of Serbia. It was concluded that it was necessary to harmonise the Law on Free Zones and Regulation of Rules on State Aid Granting, as the Regulation is not entirely in line with EU legislation especially for regional state aid, investments in local infrastructure and in research infrastructure, as well as training aid;
- Proposals were made of amendments to the Law on Free Zones in terms of state aid for its alignment with Union acquis;
- Draft Guidelines on the financing of free zones, industrial and technological parks in the Republic of Serbia were prepared, containing proposals of amendments to the Law on Free Zones and Regulation on State Aid Granting, and comments on the Law on Investments and the Law on Innovation Activities.
- A workshop was held for the Ministry of Finance's Department for State Aid Control representatives as well as the representatives of the Free Zone Administration, Commission for State Aid Control and Ministry of Education, Science and Technological Development, with a presentation of proposals for the harmonisation of relevant national legislation with EU state aid rules.

### **Recommendations:**

The basic state aid categories should be harmonised with EU GBER; the Republic of Serbia should adopt the Regional State Aid Map, which is a precondition for granting regional aid; new investments schemes should be adopted for granting state aid to industrial and technological parks.

**Harmonisation with Union acquis:** Commission Notice on the notion of State aid as referred to in Article 107(1) of the Treaty on the Functioning of the European Union; General Block Exemption Regulation (GBER) 2014; De minimis Regulation; Guidelines for Regional State Aid.

## CHAPTER 9

### FINANCIAL SERVICES

Financial services are of a great importance for the functioning of the EU internal market, which is one of the foundations of European integration. The most important objectives of Union acquis in the field of financial services are to ensure financial stability and an adequate protection of consumers, investors and insured persons. The acquis comprises of rules for the authorisation, operation and supervision of financial institutions in the areas of banking, insurance, supplementary pensions, investment services and securities markets. Financial institutions can operate across the EU in accordance with the “home country control” principle either by establishing branches or by providing services on a cross-border basis. Negotiating Chapter 9 – Financial services is of a crucial importance to the Republic of Serbia, as it is to ensure financial stability and adequate consumer and investor protection. Serbia has opened negotiations on Chapter 9, which means that it has reached a satisfactory level of alignment for securities markets and investment services to open negotiations and that it is partly applying acquis in this area. The European Commission 2019 Country Report states that Serbia is moderately prepared in the area of financial services and that some progress was made, especially in the area of banks and financial conglomerates, although more work is required to implement the financial services acquis.

# 1. TRANSPOSITION OF THE EU REGULATION ON THE PROSPECTUS

Regulations in the field of financial services have been evolving rapidly in the EU during the last years. The phasing-in of the new acquis is an ongoing process to which accession countries like Serbia must adapt. The EU has encouraged Serbia to continue the process of alignment with the acquis and its effective implementation and enforcement. In order to fully align with relevant EU regulations, Serbia has to include cross-border activities and foreign issues, as well as the incrimination of the attempt to act unlawfully. The new EU Regulation on the prospectus, in force as of July 2019, introduced substantial changes. PLAC III project's assistance focused on providing technical and legal advice on the substantial changes made by the new acquis and the drafting of amendments to the relevant prospectus by-law (or drafting a new one) in order to transpose the Regulation on the prospectus. The national legislation that regulates the field is the Law on Capital Markets, which was the subject of a project expert analysis, along with the by-laws. After a gap analysis of the national legislation and the level of its alignment with relevant Union acquis, it was concluded that the draft Law and two Rulebooks should be aligned with the latest amendments to the Prospectus Regulation.

**Beneficiary institution:** the Securities Commission

**Number of experts engaged:** 1

**Number of working days:** 15

## **Project outputs:**

- A Legal Assessment Report was prepared, summarising the current status of alignment of national legislation (Draft Law on Capital Markets) with Union acquis in the prospectus area;
- The Draft Law on Capital Market is fully aligned with the latest consolidated version of the Prospectus Regulation (amendments made through Regulation (EU) 2019/2115);
- A Draft Rulebook on the content of an application for approving a prospectus aligned with the Delegated Regulation (EU) 2019/980 was prepared; a Draft Rulebook was prepared on the format, minimum information contained in prospectuses, and base prospectuses as well as advertisements were aligned with Delegated Regulation (EU) 2019/979.
- A workshop was held for Securities Commission representatives, with the presentation of aligned documents.

## **Recommendations:**

Having in mind that Union acquis is still developing, it is necessary to monitor advancements in the adoption of all delegated acts under the Prospectus Regulation as well as the revisions and amendments to two Delegated Regulations (2019/980 and 2019/979). The changes will require amendments to the two Rulebooks.

**Harmonisation with Union acquis:** Regulation (EU) 2017/1129 on the prospectus to be published when securities are offered to the public or admitted to trading and repealing Directive 2003/71/EC (shortened - Regulation (EU) 2017/1129 on the prospectus); Regulation (EU) 2019/2115; Delegated Regulation (EU) 2019/980; Delegated Regulation (EU) 2019/979.

## 2. CAPITAL MARKETS AND INVESTMENT SERVICES; HARMONISATION OF LEGISLATION ON EUROPEAN LONG-TERM INVESTMENT FUNDS

Serbia's legislation in the area of securities markets and investment services is specified by the Law on the Capital Market, the Law on Alternative Investment Funds and the by-laws issued by the Securities Commission, which supervises the implementation of the laws. At present, investment services and funds are regulated by the Law on Open-Ended Investments Funds with a Public Offering and the Law on Alternative Investment Funds, which are in force as of October 2019. PLAC III assistance focused on the alignment of national legislation with EU legislation pertaining to European long-term investment funds and fostering capacities of Securities Commission. The *acquis* in the field consists of Regulation (EU) 2015/760 on European Long-Term Investment Funds (ELTIF).

**Beneficiary institution:** the Ministry of Finance and the Securities Commission

**Number of experts engaged:** 1

**Number of working days:** 20

### **Project outputs:**

- A gap analysis was prepared of the Law on Alternative Investment Funds with Regulation (EU) 2015/760 on European Long-Term Investment Funds (ELTIF). The analysis identified a small number of drafting changes to be aligned with ELTIF and included a proposal for full harmonisation;
- The Table of Concordance of ELTIF with the Law on Alternative Investment Funds was drafted; the Table of Concordance of the Law with Commission Delegated Regulation (EU) 2018/480 was also drafted;
- Amendments to the Law were drafted;
- A workshop for Ministry of Finance and Securities Commission representatives was held, with a presentation of ELTIF. To reinforce Securities Commission capabilities, an implementation checklist for adapting its procedures to ELTIF was prepared.

**Harmonisation with Union *acquis*:** Regulation (EU) 2015/760 on European Long-Term Investment Funds; Commission Delegated Regulation (EU) 2018/480.

## 3. MARKET ABUSE AND CRIMINAL SANCTIONS FOR MARKET ABUSE

In its Screening Report for Serbia in part related to Chapter 9, the European Commission states that in the field of securities markets and investment services, “the Market Abuse Directive (MAD) together with its amendments and implementing instruments is to introduce a harmonised and comprehensive administrative regime for prohibiting and prosecuting insider dealing and market manipulation.” Directive 2003/6/EU on insider dealing and market manipulation has been largely implemented in Serbian national law through the Law on the Capital Market and its by-laws. The EU has observed that the Republic of Serbia needs to take steps forward toward full alignment with Directive 2014/57/EU (MAD) on criminal sanctions for market abuse and to align with Regulation 596/2014 on market abuse (MAR). Alignment is

envisioned no later than six months prior to Serbia's EU accession. The PLAC III project provided support in achieving the full implementation of the Union acquis in the area, e.g. of the Directive of criminal sanctions of market abuse (MAD) and the Regulation on market abuse (MAR), having in mind that acquis is quickly evolving. At the request of the beneficiary, expert work focused on public disclosure of inside information, as well as on market soundings and a sanctioning regime. Assistance included on-the-job training for Securities Commission employees.

**Beneficiary institution:** the Ministry of Finance and the Securities Commission

**Number of experts engaged:** 1

**Number of working days:** 15

#### **Project outputs:**

- Gap analyses were drafted on public disclosure of inside information, on market soundings and a sanctioning regime;
- Drafts of procedures were prepared for conducting oversight related to the topic of public disclosure of inside information and market soundings for the Securities Commission in accordance with MAD and MAR;
- On-the-job training was held for Securities Commission staff on the substantial changes made by the new acquis in accordance with criminal sanctions for MAD and MAR;
- A working session was held for Securities Commission employees with a presentation and an overview of the best practices from various EU countries.

#### **Recommendations:**

The Securities Commission should adopt written procedures, at least for its main work-lines.

**Harmonisation with Union acquis:** Directive 2014/57/EU on criminal sanctions for market abuse (MAD); Regulation 596/2014 on market abuse (MAR).

## CHAPTER 12

### FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY

Negotiation Chapter 12 covers the rules in the area of food safety. The general foodstuffs policy sets hygiene rules for foodstuff production. Furthermore, Union acquis provides detailed rules in the veterinary field essential for safeguarding animal health, animal welfare and safety of food of animal origin on the internal market. In the phytosanitary field, EU rules cover issues such as quality of seed, plant protection material, harmful organisms and animal nutrition. The European Commission 2019 Country Report states that Serbia is moderately prepared in areas related to Chapter 12 and has yet to define a strategy and action plan for full transposition of acquis. One of the three opening benchmarks set by the Commission is the adoption of the framework legislation that complies with acquis. Serbia needs to increase the effectiveness of controls, in particular by strengthening its administrative capacity for inspections, and applying risk-based checks. The Republic of Serbia is intensively preparing for negotiations with the EU regarding Chapter 12.

The PLAC III project singled out Chapter 12 as one of the most important of all chapters, allocating around one quarter of all working days to it. Assistance focused on enhancing the harmonisation of national legislation and its proper implementation that will foster meeting of opening benchmarks.

# 1. HARMONISATION OF LEGISLATION IN THE AREA OF MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

The full compliance in the area of food contact materials (FCM) with Union acquis has to be ensured in order to guarantee the high level of protection of health and consumers in Serbia. The Ministry of Health is a competent authority for establishing policy, legislative and official control functions in the FCM and articles intended to come into contact with food. The national legislative framework regulating this area is contained in the Law on Food Safety, the Law on Health and Safety of Products of General Use and in a by-law - the Rulebook on Conditions in relation to Health and Safety of Products of General Use that can be placed on the Market. Further harmonisation with EU laws required drafting a by-law in the field of FCM and articles intended to come into contact with food, including products intended for infants and children for facilitation of feeding and sleeping, as well as packaging. The PLAC III project provided support to the Ministry of Health's Sanitary Inspection in completing the work of drafting a Rulebook and a Guideline for proper implementation of official controls of FCM. The Law on Products for General Use, which is a legal basis for adopting a Rulebook, has already transposed relevant EU directives in the field of FCM and the Rulebook should further specify provisions of the Law.

**Beneficiary institution:** the Ministry of Health (Sanitary Inspection Directorate)

**Number of experts engaged:** 2

**Number of working days:** 55

## Project outputs:

- A report was prepared containing a legal analysis of the national legislation in relation to the relevant EU laws in the area of FCM and articles intended to come into contact with food, after detailed consultations between the project experts and the beneficiary institution representatives;
- A Rulebook on Materials and Articles Intended to Come into Contact with Food, Including Products Intended for Infants and Children for Facilitation of Feeding and Breastfeeding, Calming and Sleeping as well as Packaging for Food and Articles of General Use was drafted. It transposes the remaining EU legislation in the field of FCM and thus represents a good starting point for implementation;
- 13 Tables of Concordance were prepared, presenting the level of the compliance of the Rulebook with Union acquis comprising of 7 European Commission's Regulations and 6 Directives of the European Council (Regulation EC 1935/2004; Commission Regulations EC 2023/2006; 10/2011; 450/2009; 282/2008; 284/2011; 1895/2005; Directive 2007/42/EC; Council Directive 84/500; Commission Directive 93/11/EEC; Council Directive 78/142/EEC; Council Directive 85/572/EEC and Council Directive 82/711/EEC).
- A Guideline was drafted for the proper implementation of official control of FCM and articles intended to come into contact with food. Templates for declarations of conformity for different categories of FCM were created as an integral part of the document;
- A workshop was held with presentations of the draft Rulebook and examples of the good practice in Croatia as the selected EU Member State regarding the implementation of relevant EU Regulations. The Workshop was attended by more than 80 representatives of the beneficiary institution and different stakeholders – regulatory authorities, economic operators, laboratories and sanitary inspectors (at central, regional and border levels).

### Recommendations:

The Republic of Serbia should consider amendments to the Unique Methodological Rules for legislation drafting with the aim to secure a coherent and consistent transposition of EU rules and principles. Strengthening the administrative capacities should be done by employing new sanitary inspectors in regional offices (50), border inspections posts (3) and in the Autonomous Province of Vojvodina (8) together with training sessions for civil servants at all levels (central, border and regional).

**Harmonisation with Union acquis:** Regulation EC 1935/2004; Regulation EC 2023/2006.

## 2. HARMONISATION OF LEGISLATION ON NATURAL MINERAL WATERS AND SPRING WATERS

In Serbia, the Ministry of Health is the body responsible as regards to safety of water for human consumption, more precisely, water in its original packaging. At present, the Draft Law on Water for Human Consumption and the Draft Rulebook on the Health Safety of Drinking Water have been prepared and are undergoing additional amendments through PLAC III assistance under Negotiating Chapter 27. Since the Draft Law on Water for Human Consumption includes water in its original packaging (bottled water), it provides a legal basis for the adoption of the Proposal for a Rulebook on Health and Water quality in the Original Packaging. Both pieces of legislation need to be aligned with the Union acquis relevant for Chapter 12, namely Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for constituents of natural mineral and spring waters and Directive 2009/54/EC on the exploitation and marketing of natural mineral waters. PLAC III provided assistance in drafting a Rulebook on Health and Water Quality in the Original Packaging aligned with acquis. The Rulebook will ensure safety and the quality of natural mineral waters and spring waters as the main legal tool for all public authorities in the sector. It contains detailed procedural provisions for public authorities, laboratories and the institutes of public health as well as detailed technical annexes on norms and standards. Its adoption will contribute to the further harmonisation with relevant EU legislation and to the fulfilment of a benchmark set for Chapter 12 – the adoption of a framework legislation.

**Beneficiary institution:** the Ministry of Health;  
Negotiation group for Chapter 12

**Number of experts engaged:** 2

**Number of working days:** 35

### Project outputs:

- A legal gap analysis in the mineral water sector was conducted identifying the gaps where alignment with EU Directives is necessary. A report was drafted;
- A Table of Concordance between national Serbian legislation on natural mineral waters and spring waters (the Law on Mineral Waters and Rulebook on Mineral Waters) and two EU Directives were prepared;
- A Rulebook on Health and Water quality in the Original Packaging was drafted. During the drafting process, needs for amendments and revisions of the Draft Law on Human Consumption were identified; the needed changes were considered and included into the Draft Law;
- A workshop on the presentation and implementation of the Draft Rulebook was held, with the participation of representatives of beneficiary institutions and of stakeholders – institutes for public health, Ministries, local governments, government inspectorates and mineral water associations.

### Recommendations:

Any water-related law drafting should be closely liaised with all Ministries dealing with the water sector, including the Ministry for Environmental Protection.

**Harmonisation with Union acquis:** Directive 2003/40/EC establishing the list of concentrations and labelling requirements for constituents of natural mineral waters and the conditions for the use of ozone-enriched air for the treatment of natural mineral waters and spring waters; Directive 2009/54/EC on the exploitation and marketing of natural mineral waters.

## 3. HARMONISATION OF LEGISLATION RELATED TO NUTRITION AND HEALTH CLAIMS MADE ON FOOD

In the European Union, rules on nutrition and health claims have been established by Regulation (EC) No 1924/2006, in force as of July 2007, which represents the legal framework used by food business operators when they wish to highlight the particular beneficial effects for health and nutrition of their products on the product label or in its advertising. The objective of the rules is to ensure that any claim made on food labelling, presentation or advertising in the EU is clear, accurate and based on scientific evidence. Food claims that could mislead consumers are prohibited on the EU market. A public EU Register of Nutrition and Health Claims lists all permitted nutrition claims and all authorised and non-authorised health claims as a source of reference so that full transparency for consumers and food business operators is ensured. In Serbia, the Rulebook on nutrition and health claims made on food is already in force; PLAC III project's assistance focused on drawing up a guideline for a proper implementation of the Rulebook. The National Guide for implementation of the Rulebook is intended for food safety inspectors in performing official controls of food placed on the market, as well as for food business operators in the aim of delivering correct, truthful and complete information to consumers.

**Beneficiary institution:** the Ministry of Health (Sanitary Inspection Directorate)

**Number of experts engaged:** 1

**Number of working days:** 15

### Project outputs:

- A draft National Guide for the implementation of the Rulebook on nutrition and health claims made on food was prepared and presented to the beneficiary institution and stakeholders (Ministry of Agriculture, Chamber of Commerce, National Alliance for Local Economic Development (NALED), consumer associations' representatives). The document included "gluten-free" claims, "lactose-free" claims, "trans-free" claims, vegetarian/vegan free claim and "fasting-free" claims, as per suggestions of some stakeholders.
- A workshop was held, with a presentation of the Guide as well as examples of the best practices in the selected EU Member States regarding the implementation of relevant EU Regulations.

### Recommendations:

The beneficiary – the Ministry of Health should work on creating a printed document with good graphics and food label examples in line with similar documents published in Ireland, Finland and the Netherlands. The document should be distributed among government Ministries and agencies, as well as stakeholders in the food sector; it should be also made public on the Ministry of Health's website.

**Harmonisation with Union acquis:** Regulation (EC) No 1924/2006 on nutrition and health claims made on foods; Commission Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and proper implementation.

## 4. 1. SUPPORT IN ASSESSING THE NEW ACQUIS IN THE FIELD OF PLANT HEALTH – ORNAMENTAL PLANTS FOR PLANTING

Plant health is very important for plant production, forests, natural and planted areas, natural ecosystems, ecosystem services and biodiversity. Plant health is threatened by species injurious to plants and plant products, which now present a greater risk due to the globalisation of trade and climate change. In the EU, Regulation (EU) 2016/2031 as a new EU Plant Health Law establishes the rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products and measures to reduce those risks to an acceptable level. The Regulation introduces a concept of “high risk plants, plant products and other objects” in relation to the presence of a pest risk of an unacceptable level for Union territory. The Regulation also stipulates that professional operators shall not introduce a Union-regulated non-quarantine pest into, or move that pest within Union territory on the plants for planting through which it is transmitted, as specified in the list. The European Food Safety Authority (EFSA) defined the information required and developed a format for the preparation and submission of technical dossiers to support demands for import of high-risk plants, plant products and other objects. According to EFSA Guidelines, this information must be supported by appropriate references, and the search methodology and its results must be documented in detail. The PLAC III project provided assistance to the competent Serbian institutions in assessing the Regulation and in its proper implementation. The project also provided professional advice on the substantial information required for submitting a comprehensive and suitable technical dossier for certain planting materials, in line with the new EU rules.

**Beneficiary institution:** the Ministry of Agriculture, Forestry and Water Management (Plant Protection Directorate)

**Number of experts engaged:** 1

**Number of working days:** 50

PLAC III project's expert support included the analysis of the present situation in Serbia related to pests potentially associated with ornamental plants for planting, young plants for propagation and reproductive material as well as phytosanitary measures for mitigation and drafting technical dossiers according to EFSA guidelines. In total, scientific data on pests on 11 ornamental woody plant species were collected and assessed.

### **Project outputs:**

- A draft technical dossier for ornamental plants propagating material: an extensive collection of 353 scientific papers was compiled, describing the presence of harmful organisms recorded to be present in Serbia. A collection of 532 bibliographic units (papers and articles) on harmful organisms of 9 ornamental plant woody species was prepared for the first time in Serbia.

### **Recommendations:**

A comprehensive database has been established in Serbia for the first time and could have a much wider and stronger impact on growers and especially research on pests, including pathogens of ornamental woody plants in Serbia.

**Harmonisation with Union acquis:** Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against plant pests.

## 4.2. SUPPORT IN ASSESSING NEW ACQUIS IN THE FIELD OF PLANT HEALTH – FRUIT PLANTS

Plant health is very important for plant production, forests, natural and planted areas, natural ecosystems, ecosystem services and biodiversity. Plant health is threatened by species injurious to plants and plant products which now present a greater risk due to the globalisation of trade and climate change. In the EU, Regulation (EU) 2016/2031 as the new EU Plant Health Law establishes rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products and measures to reduce those risks to an acceptable level. The Regulation introduces a concept of “high risk plants, plant products and other objects” in relation to the presence of a pest risk of an unacceptable level for the Union territory. The Regulation also stipulates that professional operators shall not introduce a Union regulated non-quarantine pest into, or move that pest within the Union territory on the plants for planting through which it is transmitted, as specified in the list. The European Food Safety Authority (EFSA) defined the information required and developed a format for the preparation and submission of technical dossiers to support demands for import of high-risk plants, plant products and other objects. According to EFSA Guidelines, this information must be supported by appropriate references, and the search methodology and its results must be documented in detail. The PLAC III project provided assistance to the competent Serbian institutions in assessing the Regulation and in its proper implementation. The project also provided professional advice on the substantial information required for submitting a comprehensive and suitable technical dossier for certain fruit plant propagation material for planting, in line with the new EU rules.

**Number of expert engaged:** 1

**Number of working days:** 50

PLAC III project's expert support included the analysis of the present situation in Serbia related to pests potentially associated with the fruit plant propagation material as well as phytosanitary measures for mitigation and drafting technical dossiers for certain plant commodities according to EFSA guidelines. In total, scientific data on 8 fruit species were collected and assessed.

### **Project outputs:**

- A draft technical dossier was prepared for fruit plant propagating material and other necessary documentation for the risk assessment: formation of a broad collection of published papers and bibliographic units including 532 scientific papers describing the presence of all harmful organisms registered in Serbia on 8 fruit species (including stone and nut fruits).

### **Recommendations:**

A comprehensive database has been established in Serbia for the first time and could have a much wider and stronger impact on fruit production and especially research on pests and pathogens of stone and nut fruits in Serbia. The database should be published on the Ministry of Agriculture official web site and as such could be a valuable resource for many interested parties, including producers, traders, scientists in Serbia and wider.

**Harmonisation with Union acquis:** Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against plant pests.

## CHAPTER 15

### ENERGY

Energy is traditionally the most important field of operations of the European Union. Today, management of the energy sector is one of the most important activity areas of EU institutions. EU energy policy objectives include the improvement of competitiveness, security of energy supplies and the protection of the environment. The energy acquis consists of rules and policies, notably regarding competition and state aids (including the coal sector), the internal energy market (opening up the electricity and gas markets, promotion of renewable energy sources), energy efficiency, nuclear energy and nuclear safety and radiation protection. The EU assists with implementation of energy efficiency so as to ensure competitiveness, safety of supply and assumption of obligations foreseen under the Kyoto Protocol. The benefits that the country will have from harmonising its regulations with those of the EU are safe energy supply, orientation towards renewable energy sources and use of European funds for sustainable energy. According to the European Commission's report for 2019, Serbia is moderately prepared in this field. Serbia's legislation is partially in line with the relevant acquis regarding nuclear energy, nuclear security and radiation protection. The PLAC III project provided assistance in further harmonisation of national legislation with key Directive 2013/59/Euratom, laying down Basic Safety Standards for Protection against the Dangers arising from Exposure to Ionising Radiation. The Directive stipulates, inter alia, an establishment of the system of management of disused radiation sources.

# ASSISTANCE IN DRAFTING A GUIDELINE FOR MANAGEMENT OF DISUSED SOURCES IN RADIATION PRACTICES

The Law on Radiation and Nuclear Safety and Security, in force in Serbia as of December 2018, is partially harmonised with Council Directive 2013/59/Euratom. According to the National Programme for the Adoption of the Acquis, full harmonisation is expected in the next two years. The Law introduced the definition of disused radiation sources and provided a legal basis for the further establishment of the system of management of disused sources. A regulatory body – the Serbian Radiation and Nuclear Safety and Security Directorate - shall specify the requirements concerning the management of disused sources and thus transpose/implement the Directive.

**Beneficiary institution:** the Serbian Radiation and Nuclear Safety and Security Directorate (SRBATOM)

**Number of experts engaged:** 1

**Number of working days:** 8

## Project outputs:

- A draft Guidance for the management of Disused Sources in radiation practices was prepared.

In close cooperation with representatives of SRBATOM and the Public Company Nuclear Facilities of Serbia, the national legislative regime and its implementation regarding safe and secure management of sealed radiation sources and disused sealed radiation sources were discussed. A field visit of the storage of PC Nuclear Facilities by a PLAC III project expert was realised.

The Guidance provides information on the management of both types of radiation sources, as well as of orphan sources; requirements and a graded approach for all types of radiation sources; source identification and declaration; source inventory; funding mechanisms; authorisation and inspection for disused sources; compatibility of disused radioactive sources with radioactive waste management strategy; the decision-making process for designating radioactive source as disused and radioactive waste and subsequent consequences to the regulatory control and management options.

## Recommendations:

SRBATOM should consider creating a national registry of radiation sources. The declaration of the source type should be formulated in a consistent manner, according to a graded approach. The authorisation and inspection, as well as requirements for safety and security, should apply similarly for both types of radiation sources. A regulatory inspection should be conducted for all sealed radiation sources and disused radiation sources. Campaigns for the identification and discovery orphan sources should be implemented. As regards to disused radiation sources, since a disposal facility and relevant infrastructure do not exist, their return to a manufacturer abroad should be the preferred option. Recycling of disused radioactive sources should be justified before being applied in practice.

**Harmonisation with Union acquis:** Council Directive 2013/59/Euratom laying down the Basic Safety Standards for Protection against the Dangers arising from Exposure to Ionising Radiation.

## CHAPTER 27

### ENVIRONMENT AND CLIMATE CHANGE

Environmental protection is recognised as one of the most challenging and complex acquis when it comes to the harmonisation of national legislation with EU standards and norms. Moreover, the implementation of the legislation in the environmental sector requires significant investments. EU environment policy aims to promote sustainable development and protect the environment for present and future generations. It is based on preventive action, the “polluter pays” principle, fighting environmental damage at source, shared responsibility and the integration of environmental protection into other EU policies. Union acquis comprises over 200 major legal acts covering horizontal legislation, water and air quality, waste management, nature protection, industrial pollution control and risk management, chemicals and genetically modified organisms (GMOs), noise and forestry. A strong and well-equipped administration on a national and local level is imperative for the application and enforcement of environment acquis.

The Republic of Serbia is intensively preparing for negotiations with the EU regarding Chapter 27.

# 1. DRINKING WATER LEGISLATION

In the area of drinking water legislation, Serbia has achieved a high level of alignment with Union acquis, but has yet to make progress in complying with the drinking water acquis by transposing Council Directive 98/83/EC on the quality of water intended for human consumption – the so-called Drinking Water Directive (DWD) and its amended version of 2015 (Directive 2015/1787). In addition, the existing Serbian drinking water legislation needs to consider that the European Commission on 1 February 2018 adopted a proposal for a revised drinking water directive to improve the quality of drinking water and provide greater access and information to citizens. The DWDs will be transposed into Serbian legislation by means of one Law and one Rulebook. The Serbian Draft Law on Water intended for Human Consumption was prepared in 2019 by a working group under the Ministry of Health. Currently, this draft law is under consultation with stakeholders and members of the working group regarding drafted provisions. For full transposition of the DWD, based on the abovementioned law, the subsequent step is drafting a Rulebook on Drinking Water Health Safety. The legislation aligned with Union acquis will ensure safe drinking water and better drinking water management in Serbia. PLAC III project's support included assistance in drafting both pieces of legislation – the Law and the Rulebook.

**Beneficiary institution:** the Ministry of Environmental Protection

**Number of experts engaged:** 1

**Number of working days:** 8

## Project outputs:

The Ministry of Health is responsible partly for the transposition of DWD and partly for its implementation. The project's expert worked in close cooperation with the Ministry of Health's working group in analysing the national drinking water legislation and the level of its alignment with relevant Union acquis. During the drafting of the Rulebook, needs for amendments and revisions of the Law were identified and subsequently included in the draft Law. Drafting activities considered the anticipated changes in a proposal of a revised DVD as much as possible; however, since its legal adoption is still under way, the transposition is based on the DVD in force.

- A draft Table of Concordance on Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive) identified gaps in national legislation was prepared;
- A Draft law on water for human consumption and a draft Rulebook on drinking water were fully harmonised with relevant EU law;
- A workshop was held with the presentation of a Draft law and Draft Rulebook, with the participation of the representatives of the beneficiary institutions and stakeholders – institutes for public health, water supply managements, and local governments.

## Recommendations:

Serbian legislation on drinking water may need to be amended and brought in line with the European Commission's proposal of a new DWD upon its adoption expected in the third quarter of 2020; it is recommended that Serbia ensures that the law on waters is fully compliant with the EC Water Framework Directive. Any water-related law drafting should be closely liaised with all Ministries involved in the sector (the Ministry of Health and Ministry of Agriculture), including the Ministry for Environmental Protection.

**Harmonisation with Union acquis:** Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive); Commission Directive (EU) 2015/1787 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption (DWD).

## 2. CIRCULAR ECONOMY

In 2015, the European Commission adopted the first Circular Economy Action Plan which includes measures that will help stimulate Europe's transition towards a circular economy, boost global competitiveness, foster sustainable economic growth and generate new jobs. In March 2020, the new Action plan for the Circular Economy was published as a comprehensive set of initiatives along the entire life-cycle of products that aims to "make the EU economy fit for a green future" and one of the main blocks of the European Green Deal. The Plan establishes a concrete and ambitious programme of action, with measures covering the whole cycle: from production and consumption to waste management and the market for secondary raw materials and a revised legislative proposal on waste. The revised legislative framework on waste, in force as of July 2018, sets clear targets for waste reduction and establishes an ambitious and credible long-term path for waste management and recycling. Since Serbia is a candidate country for EU accession, this implies full harmonisation of regulations and compliance with standards existing in EU countries. Serbia should prepare the appropriate public policy paper for the circular economy that will provide guidelines for the direction of action. As a necessary step to that, under the Law on the Planning System of the Republic of Serbia, an ex-ante impact assessment must be done before determining the type of public policy document. An ex-ante impact assessment is a process providing for the timely identification of potential positive and negative, direct and indirect effects that may be generated by the measures contained in a public policy document, and/or regulation, so that the public policy document and regulation could be formulated so as to minimize the potential negative impact and achieve the desired change. The PLAC III project provided assistance in preparation of an ex-ante impact assessment in the field of circular economy, which will serve as a starter document in the determination process of relevant public policy so Serbia could achieve the goals set in the EU Circular Economy Action Plan.

**Beneficiary institution:** the Ministry of Environmental Protection

**Number of experts engaged:** 2

**Number of working days:** 40

### **Project outputs:**

A range of consultations with beneficiary institutions and stakeholders as well as data collection and legislation analysis preceded the drafting of the document. Feedback from industries, civil society organisations and financial institutions/banks was gathered through tailor-made questionnaires and during a public presentation held at the Belgrade Eko-fair. The document was drafted under RIA (Regulatory Impact Assessment) procedures, as the first of its kind in Serbia. In the EU, RIA is the main instrument used by governments and regulators to appraise the likely effects of their policy proposals.

- A draft ex-ante impact assessment report in the field of circular economy was prepared in accordance with guidelines from the Serbian Regulation on the methodology of public policy management, impact assessment of public policies and regulations, and the content of individual public policy documents;
- Two public presentations of the draft ex-ante impact assessment report in the field of circular economy were held: at the Belgrade Eko-Fair and at the "Circular Economy – how to Get to It" conference.

### **Recommendations:**

Serbia should create a public policy package, the National Programme for Circular Economy. It is recommendable, among others, to obtain a full harmonisation of the legal framework with EU legislation and to set up a special government Agency for circular economy.

# 3. TRANSPOSITION OF LEGISLATION RELATED TO TRANSPORT OF HAZARDOUS WASTE AND DANGEROUS GOODS

In its Serbia 2019 Country Report, the European Commission states that Serbia has some level of preparation in the area of environment and climate change, but that no progress has been made on medical and hazardous waste. In the European Union, shipments of waste across borders are regulated by the Waste Shipment Regulation, which implements the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. The relevant EU legislation includes the Waste Framework Directive (2008/98/EC) with its basic “polluter pays” principle. In Serbia, the Law on Waste Management regulates transport of hazardous waste; its amendments adopted in 2016 have enabled the transposition of a large number of Waste Framework Directive provisions. The adoption of by-laws is ongoing. The dangerous goods transport is regulated by the Law on Transport of Dangerous Goods, which is in accordance with three ratified international agreements. To achieve a more efficient implementation of laws and regulations related to the transport of dangerous goods and waste management, it is necessary to determine the relationship between UN numbers of dangerous goods and hazardous waste index numbers, especially those which are directly connected and described as substances potentially harmful to the environment (liquid and/or solid). The PLAC III project provided assistance in the harmonisation of national laws in the area of hazardous waste in relation to dangerous goods and the inspection/control with the Union acquis and ratified international agreements in the field.

**Beneficiary institution:** the Ministry of Environmental Protection (Waste Management Department); the Ministry of Construction, Transport and Infrastructure (Group for transport of dangerous goods); competent authorities (enforcing border, inspection, traffic police, fire-fighter controls)

**Number of experts engaged:** 2

**Number of working days:** 30

## Project outputs:

An analysis of relevant national laws and by-laws was held in close cooperation with beneficiary institutions; the level of compliance was assessed in three Tables of Concordance. Consultations with private sector operators were organised by the PLAC III project. The Project experts’ work on the Harmonisation of the European Waste Catalogue and Hazardous Waste Lists with Hazardous Goods Numbers (UN numbers) was presented firstly at the Sixth regional conference “Towards Sustainable Transport” held in Zlatibor and then during the workshop for beneficiaries, stakeholders and competent authorities’ representatives held in Belgrade.

- A Manual was drafted on the transport of dangerous goods (including waste) containing procedures for the competent authorities in line with the best practices in EU Member States;
- A review of national legislation on transport of dangerous goods was drafted;
- Tables of Concordance were drafted for Directive 2008/68/EC on the inland transport of dangerous goods, for Directive 2010/35/EU on transportable pressure equipment and for Regulation (EC) No 1013/2006 on shipment of waste;
- A report was prepared on the analysis of records of inspection controls of transport on dangerous good and hazardous waste in the territory of Republic of Serbia;
- A workshop was held for beneficiary institutions, competent authorities and relevant waste operators.

## Recommendations:

Regulation (EC) No.1013/2006 on shipments on waste (Waste Shipment Regulation); Directive 2008/68/EC on the inland transport of dangerous goods; Directive 2010/35/EU on transportable pressure equipment.

**Harmonisation with Union acquis:** Regulation (EC) No. 1013/2006 on shipments of waste (Waste Shipment Regulation); Regulation (EC) No. 1013/2006 on shipments of waste (Waste Shipment Regulation); Directive 2008/68/EC on the inland transport of dangerous goods; Directive 2010/35/EU on transportable pressure equipment.

## 4. REGULATORY IMPACT ASSESSMENT OF THE DRAFT LAW ON ENVIRONMENTAL LIABILITY

In the EU, in the field of environmental protection, the horizontal sector is concerned with environmental legislation on various matters that cut across different environmental areas. Rather than to regulate a specific area, these items of legislation are more procedural. They provide for methods and mechanisms aimed at improving decision-making and legislative development and implementation through e.g. environmental impact assessment directive (EIA), environmental liability, infrastructure for spatial information (INSPIRE) directive and regulations, etc. According to the European Commission's Report for 2019, Serbia, in the area of horizontal legislation, has achieved a high level of alignment with the acquis, but the legislation needs to be further aligned and its implementation strengthened. That entails transposing and implementing the remaining horizontal legislation, in particular the Environmental Liability Directive 2004/35 EC. The Draft Law on Environmental Liability is developed with the support of the PLAC I project. The Ministry of Environmental Protection also formed a working group for the preparation of the Draft Law on Environmental Liability. Currently, this draft law is under consultation with stakeholders and the members of the working group. The PLAC III project provided support in developing the Regulatory Impact Assessment (RIA) of the Draft Law on Environmental Liability as aligned with the Environmental Liability Directive 2004/35 EC (EDL). That included assessing the effects and overall impact of the Law transposing EDL to be fully harmonised and to accurately anticipate the financial implications of its implementation.

**Beneficiary institution:** the Ministry of Environmental Protection

**Number of experts engaged:** 2

**Number of working days:** 40

### **Project outputs:**

The Regulatory Impact Assessment was implemented in accordance with the Law on the Planning System in the Republic of Serbia and included an analysis of the financial and economic effects of the Law on Environmental Liability, as well as an analysis on the effects on society, on environment and analysis of management's effects and risks. To collect reliable data, a questionnaire was developed by project experts and distributed to the Ministries and stakeholders. The Regulatory Impact Assessment report was prepared together with an explanatory note.

- A draft RIA applied to the Draft Law on Environmental Liability was prepared, containing an analysis on who will be affected and how with the solutions proposed by the Law and an analysis on whether the positive effects of the adoption of the Law justify the costs of its implementation;
- An Explanatory note accompanying the Draft Law on Environmental Liability was drafted.

**Harmonisation with Union acquis:** Environmental Liability Directive 2004/35 EC.

## CHAPTER 28

### CONSUMER AND HEALTH PROTECTION

EU rules protect consumers in relation to product safety, dangerous imitations and liability for defective products. The EU also ensures high common standards for tobacco control, blood, tissues, cells and organs, patients' rights in cross-border healthcare, and serious cross-border health threats, including communicable diseases, as well as medicines for human and veterinary use. The European Commission's Country Report for 2019 states that the Republic of Serbia is moderately prepared for consumer and health protection. Some progress was made, including the adoption of the Law on the transplantation of cells and tissues and the Law on human organ transplantation, but Serbia should strengthen the administrative capacity of relevant authorities for consumer protection, market surveillance and sanitary inspection as well as overall managerial capacity, human resources and financial sustainability of the public health insurance fund. The PLAC III project's assistance was focused on the further harmonisation of the national legislation with the relevant Union acquis and strengthening the capacities of relevant authorities in the area of biomedicine and public health management.

# 1. ALIGNMENT WITH UNION ACQUIS IN THE FIELD OF THE TRANSPLANTATION OF CELLS AND TISSUES

The national Law on the Transplantation of Cells and Tissues and the Law on Human Organ Transplantation were adopted and both were designed to be fully aligned with Union acquis. However, according to the European Commission report, EU-level quality, safety standards and inspection services have yet to be developed. In order to organise healthcare institutions operating in the field of cells and tissues according to relevant EU Directives, and in order to regulate this area, a clear distinction was made between the bank of tissues and the healthcare institution to perform the activity of testing of cells and tissues, and the healthcare institutions to perform the activity of obtaining cells and tissues. In addition to that, inpatient healthcare institutions with an intensive care unit are defined as donor hospitals. The Ministry of Health has established a Working Group for the preparation of regulations in the field of transplantation of cells and tissues. The PLAC III project provided assistance in drafting harmonised by-laws in the field of Transplantation of Cells and Tissues in accordance with the Union acquis, which will accurately anticipate implications of its implementation.

**Beneficiary institution:** the Ministry of Health (Directorate of Biomedicine)

**Number of experts engaged:** 2

**Number of working days:** 35

## Project outputs:

Project experts performed an analysis of the draft by-laws in tissues and cells and compatibility check of the national legislation against the relevant Union acquis; in total, 7 pieces of EU legislation (Directives, Decisions) were the subject of the comparative work. Tables of Concordance of the level of compliance of drafted national by-laws with relevant EU Directives were prepared. Four by-laws (Ordinances) were drafted to be fully aligned with Union acquis.

- A draft report was created on the gap analysis of the existing relevant legislation of the Republic of Serbia (Law on Transplantation of Cells and Tissues) and on recommendations regarding the further implementation of the Law;
- Tables of Concordance were drafted of the level of compliance of draft by-laws with four EU regulations;
- Four by-laws according to the Law on Transplantation of Cells and Tissues were drafted: 1. Ordinance on minimal requirements regarding personnel, premises, equipment and the quality system for performing tissues and cells banking activities; 2. Ordinance on traceability and serious adverse effects and notifications; 3. Ordinance on Hematopoietic Stem Cells Registry; 4. Ordinance on Bio-medicine inspection;
- A workshop presenting the drafts of the new legislation was held, with the participation of representatives of the beneficiary institution, clinical centres and hospitals from cities across Serbia.

## Recommendations:

To strengthen the capacity of the Directorate of Biomedicine to perform its role in line with EU requirements, particularly monitoring, inspection and vigilance activities; to start promoting a voluntary unpaid donation of tissues and cells under the principle already set by the Law, in order to improve the present situation of a significant tissue shortage in Serbia.

**Harmonisation with Union acquis:** Directive 2010/45/EC; Directive 2012/39/EC; Directive 2012/39/EU, Directive 2015/565/EC; Directive 2015/566/EC, Directive 2004/23/EC, Directive 2006/17/EC, Directive 2006/86/EC.

## 2. HARMONISATION OF LEGISLATION IN THE FIELD OF HUMAN ORGAN TRANSPLANTATION

The National Law on Human Organ Transplantation is harmonised with Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation and Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange between Member States of human organs intended for transplantation. Further alignment is necessary to fully implement the requirements from the Law and the Directives. The PLAC III project provided assistance in drafting the harmonised by-laws in the field of human organs transplantation.

**Beneficiary institution:** the Ministry of Health  
(Directorate of Biomedicine)

**Number of experts engaged:** 2

**Number of working days:** 34

### Project outputs:

Together with the beneficiary institution, project experts performed an analysis of the legislative and institutional framework in the field of organs transplantation. It was concluded that there is a necessity to draft three by-laws and to create Tables of Concordance for 13 by-laws (10 already created by the Ministry of Health and three to be drafted by project experts) to be aligned with Union acquis.

- Three Rulebooks based on the Law on Human Organ Transplantation and aligned with Union acquis were drafted: 1. The Rulebook on detailed conditions and the manner of conducting the programme of cross-donation between two or more couples; 2. The Rulebook on the manner of national cooperation as well as cooperation with international bodies or European organisations for organ exchange; 3. The Rulebook on the detailed conditions for professional training as well as guidelines related to performing inspection surveillance;
- Report on recommendations highlighting the most important issues for an efficient implementation of the Law on organ transplantation;
- A gap analysis report was prepared of the existing relevant legislation of the Republic of Serbia in the area of biomedicine;
- A Table of Concordance of the level of compliance of 13 by-laws drafted with Directive 2010/53/EU was prepared. A Table of Concordance of the level of compliance of 13 by-laws drafted with Directive 2012/25/EU was prepared;
- A workshop presenting the drafts of the new legislation was held with the participation of the Directorate of Biomedicine representatives and health professionals from across Serbia.

### Recommendations:

Training of health professionals and Directorate of Biomedicine personnel covering all aspects of organ donation and transplantation will be needed to ensure a smooth implementation of the legislative requirements into practice.

**Harmonisation with Union acquis:** Directive 2010/53/EU; Commission Implementing Directive 2012/25/EU.

### 3. IMPLEMENTATION OF ACQUIS (DIRECTIVE 2014/40 EU ON TOBACCO PRODUCTS): STUDY TOUR

**Beneficiary institution:** the Ministry of Health (Sector for Public Health and Program Health Care, Inspection Sector), Institute of Public Health “Milan Jovanović Batut”, the Ministry of Trade, Tourism and Telecommunications (Sector for Trade Inspection), the Ministry of Finance (Sector for Fiscal System), the Customs Administration and Tobacco Administration.

Expert assistance was realised through the organisation of a 4-day study tour to Slovenia for 15 representatives of beneficiary institutions. Key officials of relevant Slovenian institutions involved in legislative activities and implementation of the legal order in identified areas participated in presenting Slovenian experience in the field.

**Harmonisation with Union acquis:** Directive 2014/40 EU on tobacco products.

### 4. HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health Technology Assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process aimed to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology. With awareness that the transparent and transferable information on the short- and long-term effectiveness of health technologies is essential for the decision-making procedures for a better outcome for patients and society in the coming years, Serbia should in particular work on strengthening the overall sustainability of the public health system. EU accession in the field of medicines and other technologies implies the acceptance of Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (the Transparency Directive 89/105/EEC) and the principles of evidence-based decision-making, so HTA returns to the focus of interest of health policy makers. HTA improvements should aim that Serbia is to become equal in collaboration with other EU countries as regulated in Directive 2011/24/EU on the application of patient rights in cross-border healthcare. The PLAC III project provided support in drafting new regulations on HTA in line with Union acquis - by giving a proposal for amendments to the existing regulations and a proposal for drafting new regulations on HTA performance.

**Beneficiary institution:** the Ministry of Health

**Number of experts engaged:** 1

**Number of working days:** 10

**Project outputs:**

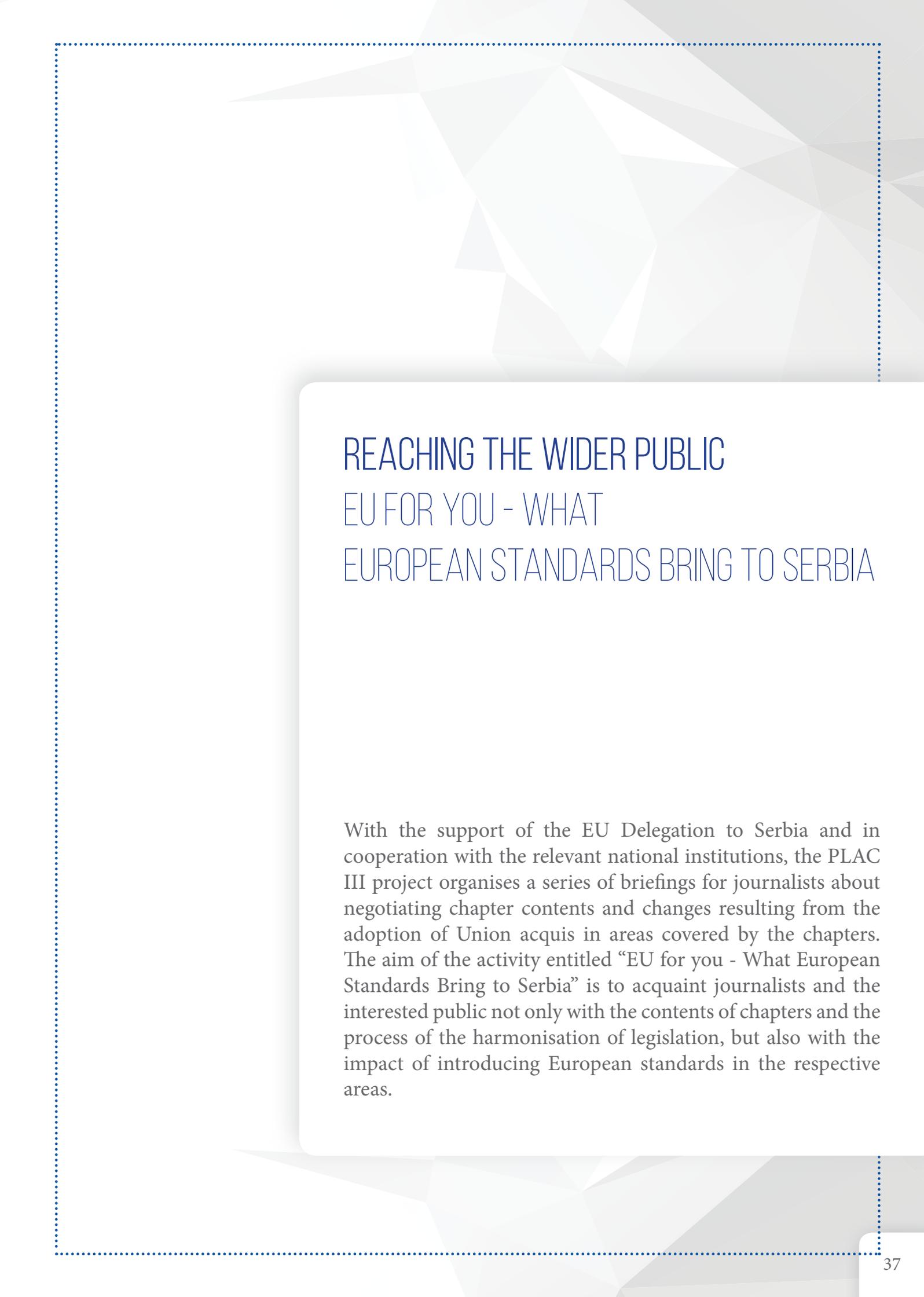
An analysis of the national legislation (laws, by-laws) regulating HTA and market access of all health technologies was carried out by project experts. At the request of the beneficiary institution, an additional analysis was carried out on legislation gaps in the field of medical devices and procedures. A gap analysis was prepared in order to make suggestions for the necessary improvements to strengthen the HTA system with regards to the procedures, tools, evidence-based reports and decisions as well as for the necessary

capacity-building of relevant Serbian institutions and their collaboration with EU HTA bodies in other countries.

- A HTA legal gap analysis report was prepared;
- A guide to the application dossier (in French and English) was created;
- An evidence submission template was made;
- A HTA pharmaceuticals evidence submission template was made;
- A Dossier type for the evaluation of a drug by the Transparency Commission was prepared.

**Recommendations:**

Apart from the legal gap analysis report, all other documents produced within the scope of PLAC III project assistance will serve as tools for further transposition and drafting in the field.



## REACHING THE WIDER PUBLIC

### EU FOR YOU - WHAT EUROPEAN STANDARDS BRING TO SERBIA

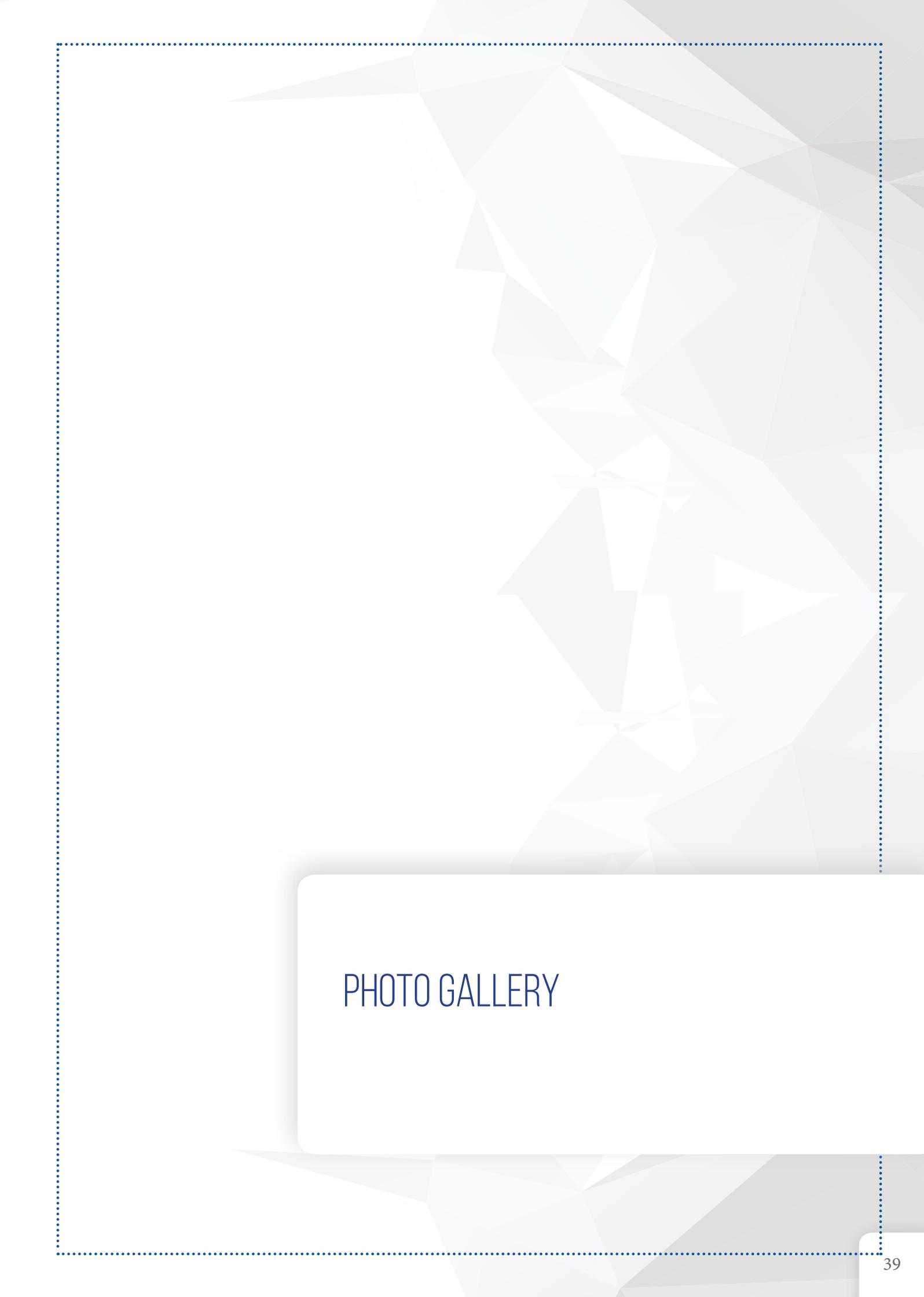
With the support of the EU Delegation to Serbia and in cooperation with the relevant national institutions, the PLAC III project organises a series of briefings for journalists about negotiating chapter contents and changes resulting from the adoption of Union acquis in areas covered by the chapters. The aim of the activity entitled “EU for you - What European Standards Bring to Serbia” is to acquaint journalists and the interested public not only with the contents of chapters and the process of the harmonisation of legislation, but also with the impact of introducing European standards in the respective areas.

# 1. TOBACCO AND THE EU – EXPECTATIONS, CHALLENGES AND MEMBER STATES' EXPERIENCES

The first in a series of “EU for You - what European Standards Bring to Serbia” briefing session was held in Belgrade on Thursday, 31 October 2019. The session “Tobacco and the EU – expectations, challenges and Member States’ experiences” focused on tobacco control; the EU Delegation to Serbia Chief of Operations Yngve Engstroem gave the opening remarks, while project experts Mrs. Vesna Kerstin Petrič and Mrs. Uliana Bakh presented the EU’s Tobacco Products Directive to journalists, along with an overview on the health consequences, economic costs and projections. Each year, 700,000 people in the EU die from smoking-related diseases; EUR 517 billion is the amount of economic losses in the Union related to tobacco smoking and the health consequences, Mrs. Kerstin Petrič said. She added that Serbia should do more to enforce the ban on smoking in public places, advertising at points of sale, on TV and in films. If stricter laws are adopted, as many as 545,000 deaths in Serbia could be prevented in the next 40 years, Mrs. Kerstin Petrič claimed, quoting WHO projections. In the Q & A session with journalists, Kerstin Petrič and Uliana Bakh stressed that efforts are being made at the EU level to discourage young people from smoking, and that a country’s tobacco control strategy, in order to be successful, needs to be a long-term one.

# 2. WHAT EUROPEAN STANDARDS BRING TO SERBIA – TOWARDS FOOD AND WATER SAFETY

The improvement of national water legislation and the implementation of European food labelling rules were the topics of the briefing “What European standards bring to Serbia - towards Food and Water Safety” which was held in the EU Info Centre in Belgrade on Wednesday, 4 March 2020. The Head of Operations III at the Delegation of the EU to Serbia Mr. Sakellaris Hurdas opened the session with an overview of EU assistance to the sectors relevant to Negotiation Chapters 12 and 27. Project expert Mr. Raymond O’Rourke presented the EU legislation on food labelling and contents of health and nutrition statements. According to him, companies now use the EU register of health claims, while rules are set to define what must be stated on nutrition declarations. Serbia has a Rulebook on Health and Nutrition Statements, and within the PLAC III project, drafting a Rulebook on Implementation is currently under way. The improvement of water legislation was discussed by project expert Mr. Robert Seelig, who introduced the Water Framework Directive as well as the Drinking Water and Bathing Water Directives and presented experiences of EU Member States in legislation implementation. Through the PLAC III project, expert support was provided to the Serbian Ministry of Health in drafting the Law on Water Intended for Human Consumption, which has transposed relevant EU directives. Apart from journalists, the briefing was attended by representatives of the relevant civil society organisations.



## PHOTO GALLERY

# PROJECT LAUNCH CONFERENCE BELGRADE, 17 APRIL 2019



# CONFERENCE CIRCULAR ECONOMY – HOW TO GET TO IT BELGRADE, 6 NOVEMBER 2019



# CHAPTER 3 WORKSHOP ON RECOGNITION OF PROFESSIONAL QUALIFICATIONS IN THE FIELD OF CONSTRUCTION BELGRADE, 24 OCTOBER 2019



## CHAPTER 8

WORKSHOP ON FREE ZONES, INDUSTRIAL AND TECHNOLOGICAL PARKS FINANCING IN ACCORDANCE WITH STATE AID RULES  
BELGRADE, 26 JULY 2019



## CHAPTER 12

WORKSHOP ON HARMONISATION OF LEGISLATION ON FOOD CONTACT MATERIALS AND ARTICLES  
BELGRADE, 28 NOVEMBER 2019



WORKSHOP ON LEGISLATION ON NATURAL MINERAL WATERS AND SPRING WATERS  
BELGRADE, 7 FEBRUARY 2020



# WORKSHOP ON NUTRITION AND HEALTH CLAIMS MADE ON FOOD BELGRADE, 10 MARCH 2020



# CHAPTER 27 WORKSHOP ON DRINKING WATER LEGISLATION BELGRADE, 6 SEPTEMBER 2020



# WORKSHOP ON HAZARDOUS WASTE AND DANGEROUS GOODS LEGISLATION BELGRADE, 9 MARCH 2020



## CHAPTER 28

### WORKSHOP ON ALIGNMENT OF LEGISLATION IN THE FIELD OF BIOMEDICINE BELGRADE, 4 SEPTEMBER 2019



### WORKSHOP ON HUMAN ORGAN TRANSPLANTATION LEGISLATION BELGRADE, 12 DECEMBER 2019



### STUDY TOUR TO SLOVENIA LJUBLJANA, MARIBOR, 10 – 13 MARCH 2020



# MEDIA BRIEFING TOBACCO AND THE EU – EXPECTATIONS, CHALLENGES AND MEMBER STATES' EXPERIENCES BELGRADE, 31 OCTOBER 2019



# MEDIA BRIEFING WHAT EUROPEAN STANDARDS BRING TO SERBIA – TO- WARDS FOOD AND WATER SAFETY BELGRADE, 4 MARCH 2020



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Resavska 27, 11 000 Belgrade  
t: + 381 11 407 32 82  
e: [plac3office@gmail.com](mailto:plac3office@gmail.com)  
w: <https://euinfo.rs/plac3>



Resavska 27, 11 000 Belgrade  
t: + 381 11 407 32 82  
e: [plac3office@gmail.com](mailto:plac3office@gmail.com)  
w: <https://euinfo.rs/plac3>