SERBIA EMERGENCY COVID-19 RESPONSE PROJECT

TORLAK INSTITUTE BIOSAFETY LEVEL 3 SUBPROJECT

ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT REPORT (ESIA) SCOPING REPORT

March 2023

ANKARA

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ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT REPORT (ESIA)

SCOPING REPORT

Version	Revision	Date	Prepared By					Quality Management By	Checked By	Approved By
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Final Draft	B0	January 2023	Celal Denizli Biology, B.Sc.	Onur Ali Taşkın Sociologist, B.Sc.	Eray Özen Environmental Engineer, B.Sc.	Z. Leyla Demirçin Environmental Engineer, B.Sc.	Prof. Dr. Ahmet Çarhan Senior Biosafety Expert	Esra Okumuşoğlu Geological Engineer, B.Sc.	Günal Özenirler Environmental Engineering, M.Sc.	D. Emre Kaya Environmental Engineer, B.Sc.
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Revision Codes: A: Draft, B: Final Draft, C: Final

Project No: 22 / 013

March 2023

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ABBREVIATIONS

ABSL	Animal Biosafety Level
AF	Associated Facility
AoI	Area of Influence
BAT	Best Available Techniques
BSC	Biosafety cabinet or Biological Safety Cabinet
BSL	Biosafety Level
EC	European Commission
EHS	Environment, Health, and Safety
EIA	Environmental Impact Assessment
ESF	Environmental and Social Framework
ESIA	Environmental and Social Impact Assessment *see also "Glossary"*
ESMMP	Environmental and Social Management and Monitoring Plan
ESMP	Environmental and Social Management Plan
ESMS	Environmental and Social Management System
ESS	Environmental and Social Standards
EU	European Union
EUNIS	European Nature Information System
Euratom	European Atomic Energy Community
GHG	Greenhouse Gas
GIIP	Good International Industry Practice
HEPA	High-Efficiency Particulate Air
HVAC	Heating, Ventilation, and Air Conditioning
IBRD	International Bank for Reconstruction and Development
IFC	International Finance Corporation
JV	Joint Venture
KBA	Key Biodiversity Area
KPI	Key Performance Indicator
LBM	Laboratory Bio-Safety Manual
LMP	Labor Management Procedure
MoH	Ministry of Health
MPA	Multiphase Programmatic Approach
OHS	Occupational Health and Safety
OP	Operational Policy

PAD	Project Appraisal Document
PAP	Project Affected People
PCU	Project Coordination Unit
PID	Project Information Document
PPE	Personal Protective Equipment
PS	Performance Standard
RoS	Republic of Serbia
SECRP	Serbia Emergency COVID-19 Response Project
SEP	Stakeholder Engagement Plan
SS	Suspended Solids
ToR	Terms of Reference
WBG	World Bank Group
WHO	World Health Organization

GLOSSARY

Implementing Agency	Ministry of Health
Associated Facility	Facilities or activities that are not funded as part of the project and, in the judgment of the Bank, are: (a) directly and significantly related to the project; and (b) carried out, or planned to be carried out, contemporaneously with the project; and (c) necessary for the project to be viable and would not have been constructed, expanded or conducted if the project did not exist. For facilities or activities to be Associated Facilities, they must meet all three criteria.
AoI	The area likely to be affected by the project, including all its ancillary aspects, such as power transmission corridors, pipelines, canals, tunnels, relocation and access roads, borrow and disposal areas, and construction camps, as well as unplanned developments induced by the project (e.g., spontaneous settlement, logging, or shifting agriculture along access roads).
Borrower	Republic of Serbia
Project Owner	The Project Coordination Unit of the Ministry of Health of Republic of Serbia
ESIA	Environmental and Social Impact Assessment
Lender	WBG or World Bank Group
Project / Subproject (Subproject of SECRP)	Torlak Institute Biosafety Level 3 Subproject under the Serbia Emergency COVID-19 Response Project (SECRP)
Project Area	The area where the Project will be constructed within the existing Torlak Institute of Virology, Vaccines and Sera, Belgrade and potential locations used for construction works such as mobilization area.

1 INTRODUCTION

The Project Coordination Unit (PCU) of the Ministry of Health of Republic of Serbia, (hereinafter "the Project Owner") intends to design and construct a new diagnostic laboratory building with Biosafety Level 3 (BSL-3) named Torlak Institute BSL-3 Subproject (hereinafter "Project") within the existing Torlak Institute of Virology, Vaccines and Sera, Belgrade. The Project will be located on the state-owned land already within Torlak Institute. The new diagnostic laboratory building will consist of 4 floors with a total area of approximately 4,500 m^2 in which the BSL-3 laboratory will be established in a total area of approximately 150 m^2.

the Project will be financed under the one of its subcomponents as the Subcomponent 1.1 of the Serbia Emergency COVID-19 Response Project (SECRP) financed by the World Bank Group.

Establishing the BSL-3 laboratory will help:

a) strengthen disease surveillance systems, national reference and public health laboratories, and epidemiological capacity for early detection and confirmation of cases;
b) combine detection of new cases with active contact tracing;
c) support epidemiological investigation;
d) strengthen risk assessment;
e) and provide on-time data and information for guiding decision-making and response and mitigation activities.

The Ministry of Health (MoH) of Serbia would like to use the proceeds of the World Bank Group (IBRD) loan to undertake the ESIA study required to assess potential risks and propose appropriate mitigation measures. According to the scoping study results the risk category of Torlak BSL-3 Subproject (Project) is suggested as "Substantial". Therefore, it is necessary to conduct a detailed Environmental and Social Impact Assessment (ESIA) as per the provisions of the Bank ESF and Serbian legislation, including Environmental and Social Management Plan (ESMP) for construction and operation phases of the Project. The potential environmental and social impacts of the Project will be addressed with defined mitigation measures through ESIA studies. Mitigation measures implementation will be managed and monitored through the ESMP and other related management plans that will be developed for the Project. The risk category of the Project will be reviewed during the ESIA studies and confirmed. The Stakeholder Engagement Plan (SEP) and the Labor Management Procedure (LMP) have already bene developed for SECRP. SECRP SEP and LMP will be used for tailoring the Project specific SEP and LMP Relevant actions and provisions from the Project SEPmust be integrated into the Project's ESMP and be presented in a stand-alone action plan. This includes adequate outreach to neighbouring units who will be impacted by the construction works and dialogue with any residential communities in range. Similarly, risks related to workforce will also be addressed in the ESIA,

appropriate aspects of the LMP will be integrated into the ESMP to ensure adequate safety for labor including worker safety on site, occupational health and safety. Provisions detailed in management plans such as ESMP, LMP, SEP etc. will be integrated into the bidding documents by MoH for selection of design/works third parties. If needed, and depending on the scope of the issue, the ESMP can include integrated plans in the area of but not limited to:

1. Chemical and Hazardous Materials Management Plan
2. Air Quality and Noise Management Plan
3. Waste and Wastewater Management Plan (including Medical Waste Management Plan)
4. Pollution Prevention Plan
5. Construction site Traffic Management Plan
6. Operation Traffic Management Plan
7. Human Resources Management Plan
8. Community Health and Safety Plan
9. Occupational Health and Safety Plan
10. Resource Efficiency Management Plan
11. Labor Management Plan
12. Emergency Response and Action Plan
13. Biosafety Management Plan
14. Biosecurity Management Plan
15. Security Management Plan
16. Communication Plan

In this context, the environmental and social impacts of the Subproject will be assessed by Joint Venture (JV) of “Enacta Ltd. (Serbia) and 2U1K Engineering and Consultancy Inc. (Türkiye) and 2U1K International Ltd. (UAE) during the Scoping Stage and detailed in the ESIA.

The above-mentioned plans will be separately prepared for construction and operation phases. Related plans will also specify mitigation measures addressing to COVID-19 risks particularly for workers and communities.

This JV will conduct 2 (two) Public Participation Meetings, one for the disclosure of this Scoping Report before ESIA preparation process, and another after preparation of draft ESIA. The engagement and consultations with stakeholders will not be limited by the disclosure and consultations on this Scoping Report and draft ESIA, ESMP, LMP and SEP, but will also be held by MoH throughout the entire stages of construction and operation, as per the procedures specified in Torlak Institute BSL-3 SubprojectSEP. The consultations will adhere with the COVID-19 measures introduced by the MoH at that time.

The JV will also conduct required environmental and social baseline measurements, analyses and surveys which include but are not limited to social and biodiversity surveys, air quality, noise measurements, soil, surface water and ground water analysis. Then, JV of Enacta and 2U1K shall prepare the ESIA document, available in both languages (English and Serbian), meeting both WB's Environmental and Social Standards- (ESSs) requirements, GIIP, relevant international standards and guidelines and Serbian legal requirements. ESIA Report will not be prepared according to Serbian regulation since the Project is not included in List 1 (projects that require EIA) or List 2 (projects that may require EIA) in the "Regulation on the List of Projects Requiring a Mandatory Impact Assessment and List of Projects that May Require an Environmental Impact Assessment of Official Gazette of RS, no. 114/2008. For the financing of the Project, ESIA report is being prepared in line with WB ESSs.

1.1 Project Background

The Republic of Serbia has received a loan from the World Bank Group in the amount of EUR 92 million equivalent for the implementation of SECRP. The objectives of the SECRP are: (a) to respond to the threat posed by COVID-19 and (b) to strengthen the national health system for public health preparedness in Serbia.

Part of the loan proceeds will be applied to payments for goods, works, related services and consultancy services to be procured under this project.

The SECRP consists of the following components:

Component 1: Emergency COVID-19 Response

Component 2: Implementation Management and Monitoring and Evaluation

Component 1

Component 1 will provide immediate support to Serbia to enable limiting the local transmission of SARS-CoV-2 through containment strategies. This component has three subcomponents.

Subcomponent 1.1 Case Detection, Confirmation, Contact Tracing, Recording, Reporting

This subcomponent will, inter alia, help strengthen national reference and public health laboratories and epidemiological capacity for early detection and confirmation of cases and support the establishment of a BSL-3 laboratory.

Establishing a BSL-3 laboratory: The capacity at the Torlak Institute of Virology, Vaccines and Sera will be strengthened by establishing a laboratory which fulfils requirements for handling pathogens such as SARS-Cov2, since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher. Having appropriate laboratory would enable

widening the research related to detection of viral presence in air, wastewater, soil and elsewhere. Most importantly, such a laboratory would enable handling of many other pathogens that require such a level of biosafety, like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also different bacterial, fungal and rickettsia pathogens, thus greatly strengthening Serbia's national laboratory system.

The new diagnostic laboratory building with BSL-3 at the Torlak Institute facility will not be used for research on animals.

Subcomponent 1.2. Physical Distancing Measures and Communication Preparedness

This subcomponent combines activities listed in Component 1 of the global Multiphase Programmatic Approach (MPA) Project Appraisal Document (PAD) under Social Distancing Measures and Communication Preparedness. Communication preparedness activities will include developing and testing messages and materials to be used in a pandemic.

Subcomponent 1.3: Health System Strengthening

Assistance will be provided to the health care system for preparedness planning to provide optimal medical care, maintain essential community services, and minimize risks for patients and health personnel. Strengthened clinical care capacity will be achieved, inter alia, through the procurement of ambulances and other vehicles, hospital beds, X-ray devices, computed tomography (CT) scanners and (e) X-ray devices to be installed in community health centres.

Component 2

Component 2: The project will cover the costs associated with project management and coordination.

Relevant World Bank Group Environmental and Social Standards (ESS) applied to the SECRP

According to the WB ESF, SECRP falls under the World Bank Group's Standards (ESS). In addition to the applicable national regulation, the following WB ESSs are considered relevant in managing the environmental and social impacts of the SECRP and sets out the requirements for the Ministry of Health (MoH) relating to the identification and assessment of environmental and social risks and impacts associated with the Project:

- ESS1 Assessment and Management of Environmental and Social Risks and Impacts
- ESS10 Stakeholder Engagement and Information Disclosure
- ESS2 Labor and Working Conditions
- ESS3 Resource Efficiency and Pollution Prevention and Management
- ESS4 Community Health and Safety

The environmental risks are considered Substantial due to concerns on disposal and management of medical waste and biohazards, and the resource constraints in responding to epidemics and the medical, environmental, and social impacts that come with these types of operations.

Social risks have been determined as Substantial, as they may pose a risk to public health and safety and may trigger social unrest. The risks and impacts are considered temporary, predictable and can be readily managed through the instruments designed within the Project.

The risk of the Subproject is categorized as Substantial. The Subproject's risk category will be reconsidered based on the results of the ESIA study, as needed.

1.2 Project Justification

Torlak Institute BSL-3 Subproject is one of the subcomponents to be implemented under the scope of Component 1 of Serbia Emergency COVID-19 Response Project that the Republic of Serbia has received a loan from the World Bank Group for the implementation.

The objective of the Serbia Emergency COVID-19 Response Project is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness in Serbia.

Torlak Institute Biosafety Level 3 Laboratory will be newly constructed in the Serbian capital Belgrade, within the existing complex of the Torlak Institute of Virology, Vaccines and Sera.

The construction of the Project will be covered under the World Bank Group Loan. The objective of establishing a new diagnostic laboratory building with BSL-3 is to strengthen the capacity at the Torlak Institute of Virology, Vaccines and Sera. The BSL-3 laboratory will fulfil requirements for handling pathogens that require such a level of biosafety, like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also different bacterial, fungal and rickettsia pathogens.

The Project will strengthen Serbia's national laboratory system since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher.

In order to provide laboratory support to the system of epidemiological surveillance, warning and rapid response to possible threats to public health at the national and global level, it is necessary to develop capacities for detection through the isolation of the above-mentioned microorganisms and the implementation of in-house (internal) diagnostic tests.

The establishment of a BSL3 laboratory opens the possibility of developing in-house tests and their use, both for diagnostic purposes and for scientific research, as well as the introduction of new diagnostic procedures that could not be carried out in the existing space of BSL2 laboratory.

Unlike commercial tests, the development and use of in-house (internal) diagnostic tests allows the laboratory to be independent in diagnosing pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the appearance of a new "threatening" infectious agent. This is especially important given that in times of high global demand, there can be enormous difficulties in obtaining commercial diagnostic kits.

The prerequisite for the development of in-house (internal) diagnostic tests, for the analysis of the virus genome and the determination of the sensitivity of the virus to antiviral drugs, is the isolation of the virus from patient samples. To begin with, isolation of viruses such as West Nile virus, dengue virus, SARS-CoV-2, hantaviruses and others which are from the Risk Group 3 of pathogenic microorganisms is planned. Cultivation of Risk Group 3 bacterial infectious agents and determination of sensitivity to drugs are also planned. All these analyzes contribute to the improvement of the quality of the health system's response to the threat of infectious diseases because they enable more efficient prevention of the spread of the epidemic and better treatment of the consequences of infectious diseases. Also, the safety of healthcare workers is significantly improved.

The BSL-3 laboratory will be available not only to the "Torlak" Institute, whose primary activity is in the field of virology, but also to other diagnostic and scientific research institutions in Serbia. It will support Serbia's infrastructure and human resources with BSL3 training in order to address the challenges and threats to the country's public health.

1.3 Purpose of the Environmental and Social Impact Assessment

The purpose of the Environmental and Social Impact Assessment (ESIA) that will follow this Scoping is to identify and assess the severity of potential environmental and social impacts on receptors and identified resources; develop and describe mitigation measures that will be taken to prevent or minimize any potential negative effects and maximize the potential benefits for the construction and operation phases of the Project. This Scoping Report is prepared based on the review of the available Project documentation provided by the Project Owner, environmental and social information collected through secondary sources and field surveys, and the review of international standards.

The following documents are fundamentally used regarding the design and planning of the proposed Project:

- PID for the SECRP,
- ToR for the ESIA and Environmental and Social Management Plan (ESMP) for New diagnostic laboratory building with BSL-3 at the Torlak Institute of Virology, Vaccines and Sera, Belgrade.

In addition to WB ESSs and Serbia's own the national legislation, to develop Project relevant standards to be followed GIIP and relevant standards are reviewed. The legislative framework, guidelines and standards that will be met/followed during the lifetime of the

Project are detailed in Section 3. In addition to local legislation and World Bank Group Environmental and Social Standards, ESIA will be developed in compliance with the World Bank Group's applicable Environment, Health and Safety (EHS) guidelines, WHO Laboratory Bio-Safety Manual (LBM) (2020), Biorisk Management: Laboratory Biosecurity Guidance (2006) and other relevant international guidelines.

The Project's ESIA will not only delineate the boundaries and relevant standards that the Project should meet, but also will assess the positive and negative impacts, address the appropriate methods to prevent or reduce the negative impact and increase or achieve positive outputs of the Project, and develop a monitoring plan to ensure the compliance with these standards through the construction and operation phases of the Project.

This Scoping Report is prepared to present the findings from the Scoping study conducted as a part of the ESIA procedure of all stages of the Project. The objectives of this Scoping Report include, but are not limited to, the following:

- to define the Project area and potential spatial and temporal boundaries of influence (i.e., impact area and durations), associated facilities, project phases, and potential stakeholders
- to review relevant national and international regulations, standards, guidance, and guidelines on Best Available Techniques (BAT) and WBG ESSs regarding the design, planning and certification of the Project within the scope of ESIA
- to delineate potential issues to be studied in detail in the subsequent ESIA
- to provide an indication of baseline environmental and social conditions and relevant relationships and relevant vulnerabilities to be focused on in the ESIA works
- to initiate the stakeholder engagement activities and dissemination of Project information to facilitate relevant consultations and communications with stakeholders.
- to identify potentially affected communities and other stakeholders with an interest in the Project

The following subsections provide details of the Scoping Stage within the framework of ESIA procedure and relevant methodologies followed. Additionally, the description of the structure of this report is also given in the following sections.

2 ESIA PROCESS AND SCOPING

2.1 Key Steps in the ESIA Process and Scoping's Place

The integration of environmental and social considerations into the project cycle is an essential part of all projects that aim to contribute to sustainable development. The ESIA process is accepted as being the most effective way of achieving this integration. ESIA is a systematic process that predicts and evaluates the impacts of a project on various aspects of the physical, biological, and socioeconomic environment. The ESIA process identifies measures that the project will take to avoid, reduce, remedy, offset or compensate for adverse impacts, and also to provide benefits, to the extent these are technically feasible and cost-effective. The first step in the ESIA process is the screening stage which determines whether an ESIA is required to be undertaken for a project. This is in general determined by referring to the FIs categorization lists that includes types of activities and if the project activity is found to be included in these lists, then an ESIA is undertaken.

The ESIA study will follow the World Bank Group Environmental and Social Standards (ESSs) of ESF.

2.1.1 Screening

Screening is the process of deciding on whether an EIA is required. This may be determined by size (e.g., production capacity, greater than a predetermined surface area of irrigated land that would be affected, more than a certain percentage or flow to be diverted or more than a certain capital expenditure). Alternatively, it may be based on site-specific information. Guidelines for whether an EIA is required will be country specific depending on the laws or regulations (i.e., can be named as "Legislation") in force. Legislation often specifies the criteria for screening and full EIA.

Screening step of the Project has been finalized and the environmental and social risks of the construction and operation of the Torlak Institute BSL-3 Subproject were rated as "Substantial", in accordance with the WB ESF. Therefore, it is a requirement for comprehensive ESIA as per WB requirements.

2.1.2 Scoping

Scoping is a crucial step in an ESIA process that identifies the key issues to be addressed in the ESIA study. Scoping allows defining which issues should be addressed in the assessment and which issues are of little or no relevance to the project. Scoping is the stage at which initial consultations with stakeholders start which is an important part of a sound ESIA process. This report presents the findings of the scoping exercise.

Following the scoping step, baseline studies will be conducted, available information on the current environmental and social baseline conditions will be gathered including up-to-date and secondary data, social surveys, ecological surveys, baseline field surveys (air, noise, water, groundwater, soil etc.).

After preparation of Scoping Report, Public Participation Meeting for the disclosure of Scoping Report before ESIA preparation process will be conducted. The engagement and consultations with stakeholders will not be limited by the disclosure and consultations on this Scoping Report but will also be held by MoH throughout the entire stages of the Project.

All studies to be conducted will be in line with WB Environmental and Social Standards requirements, GIIP, relevant international standards and guidelines and Serbian legal requirements. EIA Report will not be prepared according to Serbian regulation. For the financing of the Project, ESIA report is being prepared in line with WB ESSs.

2.1.3 Baseline Study and Data Collection

For the key issues identified in the scoping phase, available information on the current environmental and social baseline conditions will be gathered that include available reports prepared to date and secondary data (e.g., existing published materials and documents, maps, reports, etc.). Ecological walkover surveys will be conducted within the scope of the ESIA study. Baseline environmental and social field surveys (social surveys, traffic, air, noise, water, groundwater baseline measurements) will be conducted within the scope of the ESIA Study. Soil quality sampling during excavation works will be conducted in the construction phase of the Project in case any contamination identified. If any additional baseline data collection need is identified during the scoping phase, relevant data will be collected to be incorporated into the assessment study and these will be discussed with MoH and agreed prior to undertaking the studies.

2.1.4 Impact Assessment

Assessment of environmental and social impacts will be undertaken by predicting the magnitude of impacts and evaluating the significance of impacts, followed by proposing mitigation measures for key significant impacts and assessing whether any residual impact remains after the implementation of the mitigation measures. Assessment of impacts will be based on the results of the scoping study. The assessment will evaluate environmental and social changes from the baseline as a result of the Project. The assessment will review all possible impacts and determine which impacts are likely to be significant.

Environmental and Social Impact Assessment (ESIA) will be prepared to identify and assess the severity of potential environmental and social impacts on receptors and identified resources; develop and describe mitigation measures that will be taken to prevent or minimize any potential negative effects and maximize the potential benefits for the construction and operation phases of the Project.

2.1.5 Identification of Mitigation Measures

In order to avoid, minimize or remedy the significant impacts, mitigation measures will be identified based on the Serbian regulatory requirements, Good International Industry Practices, WB ESSs, the World Bank Group (WBG) Environmental, Health, and Safety Guideline (EHS), WB EHS Guideline for Health Care Facilities, the WHO Laboratory Bio-Safety Manual (LBM) (fourth edition, 2020) and the WHO Biorisk Management: Laboratory Biosecurity Guidance (2006, WHO/CDS/EPR/2006.6). Measures will aim to avoid creating environmental or social impacts from the outset of development activities, and where this is not possible, to implement additional measures that would minimize, mitigate, and as a last resort, offset and/or compensate any potential residual adverse impacts. Mitigation measures can also include measures to provide environmental and social benefits for project affected people/stakeholders (see Table 8-1 for identified PAP's).

2.1.6 Environmental and Social Management Plan (ESMP)

ESMP will include the mitigation measures for each impact during construction, commissioning, operation and decommissioning phases of the Project, responsibilities for the implementation of the mitigation measures, the timing and monitoring and audit requirements. The ESMP will focus on the avoidance of impacts, and where this is not possible, will present technically and financially feasible and cost-effective mitigation measures to minimize or reduce possible impacts to acceptable levels.

2.1.7 Stakeholder Engagement

The ESIA study will include consultation activities at the early stages (starting with scoping phase) to consider the views/concerns raised by Internal Stakeholders (Contractors and workers, Health Care Workers and supportive staff, Institute management, Citizens who will benefit from laboratory services), citizens living in Belgrade, Government / Authorities, Technical stakeholders, NGOs, Local Communities (surrounding settlements, Local Businesses, Schools and Faculty of Pharmacy, Healthcare Institutions) during the assessment of impacts and for identifying mitigation measures.

A Stakeholder Engagement Plan (SEP) has been developed for the SECRP detailing how the project will engage with stakeholders. Adhering to this Plan, a customized SEP has been prepared for the subproject. Project specific SEP and Final Draft ESIA Report will also be made publicly available.

2.1.7.1 Previous Stakeholder Engagement

The Ministry of Health (MoH) disclosed the draft ESMF and SECRP SEP documents on their website on 3 February 2021 and announced invitation for public consultations for the public, bodies and organizations interested in the subject documents prepared for SECRP.

On 24 February 2021, at 11:00 AM (local time), public consultations and presentation of the draft ESMF and SECRP SEP documents were organized at the premises of the Project Coordination Unit (PCU), Pasterova 1, III floor, Belgrade.

For the subproject, on 31.10.2022, face-to-face introductory meetings were held between officials from 2U1K and Enacta Environmental and Social departments and officials from the Ministry of Health and Torlak Institute. The meeting before noon was between the Ministry of Health, 2U1K, Enacta, while the second meeting took place in the afternoon at the Torlak Institute with the participation of the Institute officials. The purpose of the meetings was to introduce the Scoping, ESIA and SEP documents to be prepared by 2U1K and this business process and to request technical information from the authorities that they will need in this process.

2.1.7.2 Future Stakeholder Engagement

Public Participation Meetings

For subproject, it is envisaged that one consultation with affected groups and other relevant andinterested stakeholders will be held, the first after the completion of the Scoping report and the second after the completion of the ESIA report.

The Project Owner will be responsible for engagement with government stakeholders and citizens as an on-going process throughout the life of the Project. Internal and external stakeholders will be able to share their opinions and grievances via a range of options such as Project owner's web-site, letters, and face to face meetings..

2.2 Scoping Approach

As stated in sections above, the ESIA will be developed to comply with the requirements of the relevant WB ESSs as listed below:

Relevant World Bank Environmental and Social Standards (ESS)

ESS 1: *Assessment and Management of Environmental and Social Risks and Impacts*

ESS 2: *Labour and Working Conditions*

ESS 3: *Source Efficiency and Prevention and Management of Pollution*

ESS 4: *Public Health and Safety*

ESS 5: *Land Acquisition, Land Use Restriction, and Involuntary Resettlement*

ESS 6: *Conservation of Biodiversity and Sustainable Management of Living Natural Resources*

ESS 8: *Cultural Heritage*

ESS 10: *Stakeholder Engagement and Disclosure of Information**D***

ESS 5 is not relevant since no land acquisition is expected within the scope of the Project. In addition, ESS 7 is not triggered for this Project as there is no indigenous community identified by WB guidelines in impact area.

The ESIA will also take into account the World Bank Group (WBG) Environmental, Health, and Safety (EHS) Guideline W(EHS), WB EHS Guideline for Health Care Facilities, the WHO Laboratory Bio-Safety Manual (LBM) (fourth edition, 2020) an the WHO Biorisk Management: Laboratory Biosecurity Guidance (2006, WHO/CDS/EPR/2006.6).

In accordance with WB ESS1, during scoping stage:

- Impacts were assessed for all key stages of the Project including construction and operation, and for accidents and emergencies;
- All components of the Project (including facilities, infrastructure and associated facilities) were considered;
- Project alternatives were analysed;
- Cumulative environmental and social risks and impacts were considered;
- Relevant legislation, national and international standards were identified;
- Impacts on physical, natural, social, cultural and economic environment were considered together with the health and safety of the community and the workers.

The assessment will address adverse impacts together with measures, as well as positive or beneficial impacts to enhance them.

2.3 Project Categorization

World Bank Group classifies the projects into four categories, depending on the type, location, sensitivity, and scale of the project and the nature and magnitude of its potential environmental impacts. The Bank takes into account (i) the nature and magnitude of environmental and social risks and impacts of subprojects; (ii) sectoral and geographical context; and (iii) type of financing.

According to World Bank Group, the risk category of the proposed project is classified as Substantial. It is possible to reduce and control the majority of the project's impacts by proper environmental and social management, together with the monitoring that will be outlined in the ESMP and management plans to be prepared during ESIA process, according to scoping results. The Subproject's risk category will be reconsidered based on the results of the ESIA study, as needed.

2.4 Data Collection

This ESIA Scoping Report has largely been produced on the basis of desk study. Moreover, field survey observations and the project information made available by the Subcontractor were useful as well as the ESIA team's experience in various projects.

2.5 Limitations

This Scoping Report is prepared based on design information available at the time of its preparation. Where necessary assumptions have been made and discussed in the relevant chapters. Any further changes or optimization in the Project design and plan during the stages of ESIA process will also be assessed and included in the ESIA Report.

2.6 Impact Assessment Methodology

2.6.1 Introduction

The key objectives of the ESIA are to assess the potential environmental and social impacts associated with the construction, operation and decommissioning of the Project, and to identify measures that can be adopted to avoid, minimise or offset adverse impacts and enhance beneficial impacts. Figure 2-1 below shows the flow chart of the standard ESIA process.

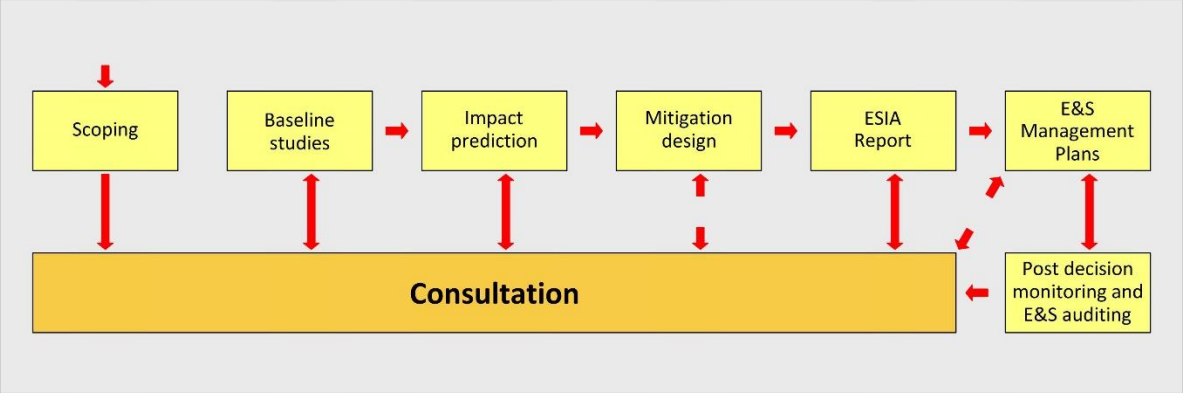

Figure 2-1. ESIA Process

2.6.2 Baseline Data Collection

Primary and secondary E&S baseline information will be collected through:

- Technical reports prepared by the Project Company and its consultants, including ESIA consultants;
- Secondary data sources (published materials and documents, maps by government agencies, research organizations and other relevant organizations);
- Review of aerial photographs of the Project Area and its surroundings;

- Interviews with specialists, field surveys and consultation with experts and community consultation.

Baseline data collection will start during the scoping phase and continue to support the assessment process. Baseline studies and findings will be described in the relevant chapters of the ESIA Report.

2.6.3 Assessment of Impacts

The impact assessment process predicts and describes impacts that are expected to occur for different phases of the Project. Where possible, impacts are quantified to the extent practicable, which may include size of land affected; increase in noise or air pollution levels above acceptable standards; volume of waste or water discharged; number of households affected, etc. For each impact, its significance is evaluated by defining and evaluating two key aspects:

- The magnitude of the impact; and
- The sensitivity of the feature or receptor that will be impacted.

Impact magnitude is a function of the following impact characteristics:

I. Geographical Extent (G);
II. Duration (D);
III. Intensity (I);
IV. Frequency or Likelihood (F or L);
V. Reversibility (R).

Impact Magnitude = (G+D+I+F (or L)) x R

The magnitude can also be defined as the severity of the potential impact. It indicates whether such an impact is irreversible or reversible. If the adverse effect of a project can not be mitigated, then the magnitude of the impact is considered as very high.

Sensitivity/vulnerability/importance of the impacted resource/receptor to the type of activity proposed (e.g., habitat clearance, topsoil removal, etc.) or the impact of a Project activity (e.g., dust, noise, water pollution, or induced population influx). This requires a range of physical, biological, cultural or human factors to be taken into account and may also need to include other factors such as legal protection, government policy, stakeholder views and economic value.

As in the case of magnitude, the sensitivity/vulnerability/importance designations themselves are universally consistent, but the definitions for these designations will vary on a resource/receptor basis. The universal sensitivity/vulnerability/importance designations are:

- Low;
- Medium; and
- High.

Receptor sensitivity definitions considered for the impact assessment Process are given in Table 2-1**Error! Reference source not found.**.

The Impact significance is calculated by multiplying the Impact magnitude by the Sensitivity Score:

Impact Significance = Impact magnitude x S

Description of the Impact Significance Provided in Table 2-2.

Table 2-1. Receptor Sensitivity

Receptor Sensitivity (S)[1] describes the ability of the receptor to withstand adverse impacts. It takes into consideration not only activity-impact-receptor pathways, but also social and	**1**	**Low:** Local community and/or environment is fully equipped/has the tools to manage changes of life quality: • Species and/or population has high capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), and is potentially unaffected or marginally affected; • People being least vulnerable to change or disturbance (i.e. ambient conditions such as air quality are well below applicable legislation and international guidance); • Individuals who are able to quickly adapt to temporary disruption in their living conditions, livelihood status or a change in the status of public infrastructure.

[1] Receptors may be people, ecological and physical components of the environment. Receptor sensitivity considers how a particular receptor may be more or less susceptible to a given impact. More sensitive receptors may experience a greater degree of change, or have less ability to deal with the change, compared with less sensitive receptors that may be more resilient or adaptable.

environmental characteristics of the receptor that might make it more or less resilient to change.	**3**	**Medium:** Local community and/or environment is partially equipped/has the tools to manage changes of life quality. For example: • Internationally threatened species /protected area within the area impacted by project activities outside of period of high sensitivity or during routine or reliably predictable peak presence; • Species and/or population which has moderate capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), leading to potential temporary but sustainable effect which does not substantially alter character or result in significant loss of ecological functionality; • People being vulnerable to change or disturbance (i.e. ambient conditions such as air quality are below adopted standards; • Negative change in livelihood status, household assets/income or living conditions. Temporary disruption to businesses resulting in a small drop in business revenue; • Increased risk to public health that can be controlled using detailed mitigation measures; and • Disruption to public infrastructure that results in an inconvenience to other users.
	5	**High:** Sensitive local community and/or environment not equipped or prepared to cope with social and environmental impacts such as changes of life quality. For example: • Internationally threatened species / protected area within the area impacted by project activities during period of high sensitivity (e.g. during breeding, spawning or nesting) and during routine or reliably predictable peak presence; • Species and/or population which has little or no capacity to absorb or adapt to change (i.e. little or no capacity to move away from or adapt to the project impact), leading to potential for substantial change of character and/or loss of ecological functionality; • Most vulnerable groups (i.e. groups that will be more affected by ambient conditions such as air quality, dust, noise, traffic, etc.); • People /citizens who may misinterpret the Lab3 operation work; • Individuals with a marginal livelihood, low socio-economic income or poor quality living conditions; • Individuals who are vulnerable due to their age, disability or other reason and who may require special assistance during engagement activities; and • Businesses with a marginal economic existence which are not able to easily adapt to change.

Table 2-2. Description of the Impact Significance

Score of the Impacts		
Value	**Score**	**Definition**
4-25	**Negligible**	An impact of "**Negligible"** significance is one where a resource/receptor (including people) will essentially not be affected in any way by a particular activity or the predicted effect is deemed to be 'imperceptible' or is indistinguishable from natural background variations.
26 - 75	**Low**	An impact of "**Low"** significance is one where a resource/receptor will experience a noticeable effect, but the impact magnitude is sufficiently small (with or without mitigation) and/or the resource/receptor is of low sensitivity/ vulnerability/ importance. In either case, the magnitude should be well within

Score of the Impacts		
Value	**Score**	**Definition**
		applicable standards.
76 - 150	**Medium**	An impact of "**Medium"** significance has an impact magnitude that is within applicable standards but falls somewhere in the range from a threshold below which the impact is minor, up to a level that might be just short of breaching a legal limit. Clearly, to design an activity so that its effects only just avoid breaking a law and/or cause a major impact is not best practice. The emphasis for moderate impacts is therefore on demonstrating that the impact has been reduced to a level that is as low as reasonably practicable (ALARP). This does not necessarily mean that impacts of moderate significance have to be reduced to minor, but that moderate impacts are being managed effectively and efficiently.
151 - 250	**High**	An impact of "**High"** significance is one where an accepted limit or standard may be exceeded, or large magnitude impacts occur to highly valued/sensitive resource/receptors. An aim of impact assessment is to get to a position where the Project does not have any major residual impacts, certainly not ones that would endure into the long term or extend over a large area. However, for some aspects there may be major residual impacts after all practicable mitigation options have been exhausted (i.e. ALARP has been applied). An example might be the visual impact of a facility. It is then the function of regulators and stakeholders to weigh such negative factors against the positive ones, such as employment, in coming to a decision on the Project.
251 - 500	**Very High**	An impact of "**Very High"** significance after all feasible mitigation measures have been identified and assessed warrants the highest level of attention and concern. As with residual impacts of major significance, the regulators and stakeholders will need to closely evaluate whether the positive impacts of the project outweigh residual negative impacts of very high significance. In many cases residual critical impacts can be considered as a potential fatal flaw of the project.

Once mitigation measures are applied, the residual impact significance (i.e. impact significance after the implementation of the mitigation measures) is evaluated, with the same methodology mentioned above.

2.6.4 Development of Mitigation Measures

One of the aims of an ESIA consists of determining mitigation measures in order to limit any potential negative impacts affecting all physical, biological and socioeconomic resources and receptors due to Project activities. Mitigation measures will be defined against each significant adverse impact by making use of avoidance, minimization, restoration and remediation as appropriate. Mitigation measures to be provided in each impact assessment table will be also grouped under each project phase such as design, pre-construction, post construction and operation. In general, mitigations suggested for operation phase will be directly related to the Project design, in this respect these mitigations will be also grouped under design phase.

A hierarchy of mitigation options is considered, with avoidance at the source of the impact as a priority and compensatory measures or offsets to reduce the impact significance as a last resort. The mitigation hierarchy that is utilised in identification of mitigation measures are presented in Table 2-3 below.

Table 2-3. Hierarchy of Options for Mitigation

Options	Explanation
Avoid at Source; Reduce at Source	Avoiding or reducing at source is designing the project so that a feature causing an impact is designed out (e.g., avoiding constraint areas during site selection) or altered (e.g., reduced waste volume).
Abate on Site	This involves adding something to the design to abate the impact (e.g., pollution controls).
Abate at Receptor	If an impact cannot be avoided, reduced or abated on-site then measures can be implemented off-site (e.g., noise screening at properties).
Repair or Remedy	Some impacts involve unavoidable damage to a resource. Repair essentially involves restoration and reinstatement type measures.

2.7 Identification of Mitigation Measures

According to the Environmental and Social Standard 1 (ESS1) on “Assessment and Management of Environmental and Social Risks and Impacts” that is part of the WB’s Environmental and Social Framework (ESF) (2018) delineating the objectives of the ESIA requirements that are also applicable to the projects funded through an FI, environmental and social assessment is required “to identify, evaluate and manage the environmental and social risks and impacts of the project in a manner consistent with the ESSs.” Furthermore, ESS1 necessitates the ESIA to be undertaken “to adopt a mitigation hierarchy approach to: (a) anticipate and avoid risks and impacts; (b) where avoidance is not possible, minimize or reduce risks and impacts to acceptable levels;(c) Once risks and impacts have been minimized or reduced, mitigate; and (d) where significant residual impacts remain, compensate for or offset them, where technically and financially feasible.”

Therefore, as part of the ESIA process, after the assessment of identified impacts, mitigation measures for each adverse impact are defined in order to avoid, minimize or remedy the significant adverse impacts. Mitigation measures also include measures to provide environmental and social benefits. The residual impacts that are likely to remain after the implementation of mitigation measures as well as the cumulative impacts are also assessed in ESIA.

Mitigation can be carried out by changes in the design, engineering modifications, and the adoption of measures to address the specific impacts. During the ESIA, mitigation measures will be identified based on the Serbian regulatory requirements, WB’s ESF requirements, as well as international best practices. The mitigation measures will be developed in order to manage impacts and minimize the residual adverse impacts regarding the environment,

socio-economic, health and safety issues by taking the national and international standards and threshold values into consideration with the most stringent criteria taken as the benchmark to define the necessary measures.

The identified measures will be discussed with the Borrower and WB and, the final decisions will be integrated into the Environmental and Social Management Plan. Implementation of the measures identified in the ESMP (Environmental and Social Management Plan) will be monitored during the construction and operation phases of the Project to ensure the effective enforcement of these measures.

3 LEGAL FRAMEWORK: NATIONAL AND INTERNATIONAL REQUIREMENTS

The Chapter outlines the regulatory framework and applicable standards that should be met/followed from the construction to the Project's lifetime. In this context, in case of differences between national regulation and international standards, the most stringent requirement will be taken into account.

3.1 National Legislation

National laws and regulations are evaluated within two sub-headings: "General Laws and Regulations" refer to all laws, regulations, acts etc. that the Project is affiliated from a wider perspective. "Specific Laws and Regulations" heading gives more specific regulations and acts which are about laboratory safety and biosafety issues.

General Laws and Regulations

a) Constitution of Serbia (''Official Gazette of RoS'', No. 98/06),
b) The Law on Public Health ("Official Gazette of RoS", No. 15/2016),
c) Law of Health Care (''Official Gazette of RoS'' No. 25/19),
d) Labor Law (''Official Gazette of RoS'' No. 24/05, 61/05, 54/09, 32/13, 75/14, 13/17, 113/17 and 95/18)
e) Law on Civil Servants (''Official Gazette of RoS'', No. 79/05, 81/05, 83/05, 64/07, 67/07, 116/08, 104/09, 99/14, 94/17, 95/18 and 157/20),
f) Law on Medicines and Medical Devices (''Official Gazette of RoS'', No.30/10, 107/12, 113/17 – other law and 105/17 – other law),
g) Rulebook on medical waste management ("Official Gazette of RS", No. 48/19),
h) Law on Environmental Protection ("Official Gazette of RoS" No. 135/04, 36/09, 72/09, 43/11, 14/16 and 95/18),
i) Law on Environmental Impact Assessment ("Official Gazette of RoS" No. 135/04, 36/09),
j) The Law on Waste Management ("Official Gazette of RoS" No. 36/09, 88/10, 14/16 and 95/18),
k) The Law on Occupational Safety and Health ("Official Gazette of RoS" No. 101/05, 91/15 and 113/17),
l) Law on Planning and Construction ("Official Gazette of RoS" No. 72/09, 81/09, 64/10, 24/11, 121/12, 42/13, 50/13, 98/13, 132/14, 145/14, 83/18, 31/19, 37/19, 9/20 and 52/21),
m) Law on Nature Protection, ("Official Gazette of RoS" No. 36/09, 88/10, 91/10, 14/16 and 95/18),
n) Law on Strike ("Official Gazette of RoS" No. 29/96),

o) Law on Prevention of Harassment at the Workplace ("Official Gazette of RoS" No.36/10),
Law on Professional Rehabilitation and Employment of Persons with Disabilities ("Official Gazette of RoS" No. 36/09 and 32/13),
p) Law on Employment and Unemployment Insurance ("Official Gazette of RoS" No. 36/09, 88/10, 38/15, 113/17 other law – 113/17 and 49/21),
q) Law on Retirement and Disability Insurance ("Official Gazette of RoS" No. 34/03, 64/04, 84/04 – other law 85/05, 101/05, 63/06, 05/09, 107/09, 101/10, 93/12, 62/13, 108/13, 75/14, 142/14, 73/18, 46/19, 86/19 and 62/21)
r) Law on Health Insurance ("Official Gazette of RoS" No. 25/19)
s) Law on Peaceful Settlement of Labor Disputes ("Official Gazette of RoS" No. 125/04, 104/09 and 50/18),
t) Law on Gender Equality ("Official Gazette of RoS" No. 104/09),
u) Law on Employment of Foreign Citizens ("Official Gazette of RoS" No. 128/14, 113/17, 50/18 and 31/19)
v) Law on the Prohibition of Discrimination ("Official Gazette of RoS" No. 22/09 and 52/21)
w) Law on Protection of Whistle Blowers ("Official Gazette of RoS" No. 128/14)
x) Act on Public Information, 2003 ("Official Gazette of RoS" No. 43/03, 61/05, 71/09 and 89/10),
y) Aarhus Convention entered into force on 30 October 2001, Serbia's accession is on 31 July 2009.

Project Specific Laws, Regulations and Standards

The Project specific Serbian legislation and standards are also considered during the E&S studies:

- Decree on establishing the List of Projects for which the Impact Assessment is mandatory and the List of projects for which the EIA can be requested ("Official Gazette of RoS" No.114/08)
- Rulebook on the contents of requests for the necessity of Impact Assessment and on the contents of requests for specification of scope and contents of the EIA ("Official Gazette of RoS" No. 69/05)
- Rulebook on the contents of the EIA ("Official Gazette of RoS" No. 69/05)
- Rulebook on the procedure of public inspection, presentation and public consultation about the EIA ("Official Gazette of RoS" No. 69/05)
- Rulebook on the work of the Technical Committee for the EIA ("Official Gazette of RoS" No. 69/05)
- Law on confirmation of convention on information disclosure, public involvement in process of decision making and legal protection in the environmental area ("Official Gazette of RoS", 38/09)

- Rulebook on preventive measures for safe and healthy work related to exposure to biological hazards (“Official Gazette of RoS” No. 96/10)
- Rulebook on Conduct of Employers and Employees in Relation to Prevention and Protection from Harassment at Work (“Official Gazette of RoS” No. 62/10)
- The Law on Disaster Risk Reduction and Emergency Management (Offical Gazette of the RS No. 87/2018)
- The Law on Free Access to information on Public Importance (Official Gazette of the RS No 120/2004, 54/2007, 104/2009,36/2010,and 105/2021

Serbia has mostly adopted the European Union regulatory requirements on Environmental Impact Assessment (EIA) into national legislation, including the EIA Directive (Directive 92/11/EC). The national EIA procedure comprises the phases of screening, scoping, impact assessment and public consultation, furthermore, an EIA is required during the Preliminary design phase of a project. The requirement for an EIA is initiated by a formal screening study to identify the categorization of the proposed project. The fulfilment of EIA requirements is a requirement to receive construction permit for the proposed project. The Project is out of scope of the national EIA regulation.

The preparation of plans and technical documentation for the Project is regulated by various regulations under the Republic of Serbia, the list below presents the main classifications of these regulations in that matter, respectively;

1. Regulations on the development of planning and technical documentation: the key law for the preparation of planning and technical documentation is the Planning and Construction Law (Official Gazette No: 145 / last amendment on 2014) that regulates both the scope and the content of spatial, urban plans and technical documentation. Strategic Environmental Impact Assessment is an integral part of the spatial plan of the special purpose area.
2. Regulation in the field of environmental protection. The preparation of environmental impact assessment of spatial and urban plans is regulated by the Law on Strategic Impact Assessment (Official Gazette No.:80 / last amended on 2010) and the preparing technical documentation by the Law on Environmental Impact Assessment (Official Gazette No: 36/ last amended on 2009).

General requirements for the competence of testing laboratories are contained in the standard ISO / IEC 17025. The structure of this standard is such that it contains a group of requirements related to management and a group of technical requirements, and by meeting these requirements, the laboratory applies a quality system / 9002 and / or ISO / IEC 17025. ISO / IEC 17025, General requirements for the competence of testing and calibration laboratories, corresponds to the national standard ISO IEC 17025, 2006 edition entitled General requirements for the competence of testing laboratories and laboratories for calibration.

Serbia ratified the Aarhus Convention in 2009. Provisions of the Aarhus Convention were incorporated into the environmental regulation, including the Law on Environmental Impact Assessment and the Law on Strategic Environmental Impact Assessment.

The Law on Environment Protection is the framework national environmental law. The law regulates the integral system of environmental protection ensuring the human right to live and develop in a healthy environment as well as developing a balanced economy and protection of the environment in Serbia.

The Law on Strategic Impact Assessment regulates the conditions, manner, and procedure for assessing the impact of certain plans and programs, on the environment.

The Law on the Environmental Impact Assessment regulates the following:

- Process of Environmental Impact Assessment,
- Content of the Environmental Impact Assessment Study,
- Participation of interested authorities and organizations and the public (Within seven days from the date of receipt of the application for the EIA Study approval, the competent authority shall inform the project developer, the authorities, organisations and the public concerned about the time and venue for public consultation, presentation and debate on the EIA Study. Public debate may not be held sooner than 20 days from the date when the public was informed. The project developer shall participate in the public presentation and debate on the EIA Study. The Minister shall prescribe more precisely the procedure for public consultation, presentation and debate),
- Cross-border notification for projects that can have significant impacts on the environment of another state, and;
- Monitoring.

A gap analysis between the relevant Serbian legislation and applicable WB ESSs and details how these gaps are fulfilled within the ESIA study will be provided in the ESIA report. Among the additional measures and actions required in the scope of ESIA studies in order to fulfill the requirements of the applicable WB ESSs on top of the national legislation requirements are; the development of SEP, Grievance Mechanism and ESMP.

3.2 International Standards

3.2.1 Requirements by World Bank Group

The ESIA will be prepared in accordance with the requirements of WBG. These include WB's ESF as detailed below:

WB's Environmental and Social Framework

The WB adopted a new set of environment and social policies called the ESF in 2016 after the review of the Safeguard Policies with the objective of creating better long-term development outcomes. As of 2018, the ESF began to be applied to all new WB investment project financing. Thus, the Environmental and Social Standards (ESSs) of the WB ESF will be taken into consideration in the ESIA studies and development of the relevant mitigation measures and monitoring plan. ESSs given in ESF have a more comprehensive approach to environmental and social risk, particularly on social issues. The list of the WB's ESSs relevant to the Project are given in Table 3-1..

Table 3-1. WB E&S Standards

Standard
ESS1: Assessment and Management of Environmental and Social Risks and Impacts
ESS2: Labour and Working Conditions
ESS3: Resource Efficiency and Pollution Prevention and Management
ESS4: Community Health and Safety
ESS6: Biodiversity Conservation and Sustainable Management of Living Natural Resources
ESS8: Cultural Heritage
ESS10: Stakeholder Engagement and Information Disclosure

As mentioned above the Project and the social and environmental elements in the AoI of the Project do not include elements or activities that are related to the scope of ESS5 (Land Acquisition, Restrictions on Land Use and Involuntary Resettlement), ESS7 (Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities) and ESS9 (Financial Intermediaries). Although there is no critical/natural habitat or any protected areas within the AoI, environmental impact assessment studies will be carried out considering ESS 6 (Biodiversity Conservation and Sustainable Management of Living Natural Resources) and Chance Find Procedure will be prepared in line with ESS 8 (Cultural Heritage).

ESIA will also consider the World Bank Group (WBG) Environmental, Health, and Safety (EHS) Guideline and WHO Guidelines related to health care facilities are usually considered as benchmark International Good Practice Standards, including IFC EHS guideline for Health care Facilities, and where applicable Sectoral Guidelines. More specifically, the WHO Laboratory Bio-Safety Manual (LBM) (fourth edition, 2020) is directly applicable as international best practice requirements to the proposed BSL-3 laboratory project. For the impact assessment and development of mitigation measures the performance levels and measures that are given in the EHS Guidelines will be taken into consideration in addition to the national legislative requirements. Furthermore, as required by WB's ESF and ESS1 when the national regulations differ from the levels and measures presented in the EHS Guidelines, the more stringent threshold or standard will apply to the Project. WB's Pollution

Prevention and Abatement Handbook will also be taken into consideration for the development of mitigation measures.

These are applicable documents of World Bank Group and Good International Industry Practice (GIIP):

- World Bank Environmental and Social Framework (ESF) and Guidance Notes for Loan Beneficiaries;
- World Bank Group (WBG) Environmental, Health and Safety Guidelines (EHS);
- World Bank Group EHS Guidelines for Health Care Facilities;
- World Bank Group EHS Guidelines applicable to Water and Sanitation;
- World Bank Group EHS Guidelines applicable to Electric Power Transmission and Distribution;
- World Bank Group EHS Guidelines applicable to Gas Distribution Systems;
- World Bank Group EHS Guidelines applicable to Pharmaceuticals and Biotechnology Manufacturing;
- World Bank Group Gender-Based Harassment and Abuse Guidelines
- WHO Laboratory Bio-Safety Manual (LBM), fourth edition, 2020;
- WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6;
- UN Model Regulations for the Transport of Dangerous Goods;

3.2.2 Key Legislation in European Union and International Reference Documents

Serbia officially applied for European Union for membership on 22 December 2009. Accession negotiations are currently ongoing. Therefore, key Legislation in European Union and International Reference Documents that are relevant to the Project are presented below:

General Provisions/Programmes

- Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment

  (Official Journal/Date: L124/16.4.2014; Entry into force: 25.01.2014);

- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

  (Official Journal/Date: L334/17.12.2010; Entry into force: 06.01.2011);

- Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

(Official Journal: L41, 14.02.2003; Entry into force: 14.02.2003);

- Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088

  (Official Journal/Date: L198/22.06.2020; Entry into force: 13.07.2020);

- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods

  (Official Journal/Date: L260/30.09.2008; last amended on 01.07.2022);

Biosafety

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

  (Official Journal/Date: L311/28.11.2001; last amended on 01.01.2022);

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

  (Official Journal/Date: L033/08.02.2003; last amended on 07.08.2009);

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

  (Official Journal/Date: L102/07.04.2004; last amended on 07.08.2009);

- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use

  (Official Journal/Date: L262/14.10.2003; Entry into force: 24.10.2003);

- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products

  (Official Journal/Date: L91/09.04.2005; Entry into force: 29.04.2005);

Safety At Work

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work

  (Official Journal/Date: L183/29.06.1989; last amended on 11.12.2008);

- Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (Text with EEA relevance)

  (Official Journal/Date: L134/01.06.2010; Entry into force 21.06.2010);

- Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

  (Official Journal/Date: L13/17.01.2014; Entry into force 17.01.2014);

- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC).

  (Official Journal/Date: L 262, 17.10.2000, p.21)

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

  (Official Journal/Date: OJ L 183, 29.6.1989, p. 1)

Water Protection and Management

- Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

  (Official Journal/Date: L327/22.12.2000; Entry into force: 22.12.2000; last amended on 20.11.2014);

- Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment

  (Official Journal/Date: L135/30.05.1991; Entry into force: 19.06.1991; last amended on 01.01.2014);

- Directive 2006/118/EC of the European Parliament and of the Council of 12 December of 2006 on the protection of groundwater against pollution and deterioration

(Official Journal/Date: L372/19 27.12.2006; last amended on 11.07.2014).

Monitoring of Atmospheric Pollution

- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe

  (Official Journal/Date: L152/11.06.2008; Entry into force: 11.06.2008; last amended on 18.09.2015);

- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel, and polycyclic aromatic hydrocarbons in ambient air

  (Official Journal/Date: L23/26.01.2005; Entry into force: 15.02.2005; last amended on 18.09.2015).

Prevention of Noise Pollution

- Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise

  (Official Journal/Date: L189/18.07.2002; Entry into force: 18.07.2002; last amended on 26.07.2019).

Conservation of Wild Fauna and Flora

- Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora

  (Official Journal/Date: L206/22.7.1992; Entry into force: 10.6.1992; last amended on 01.07.2013);

- Council Directive 2009/147/EC of 30 November 2009 on the conservation of wild birds

  (Official Journal/Date: L20/26.1.2010; Entry into force: 26.1.2010; last amended on 26/06/2019).

Waste Management

- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

  (Official Journal/Date: L312/22.11.2008; Entry into force: 12.12.2008; last amended on 05.07.2018).

Air Quality

- United Nations Economic Commission for Europe Convention on Long-range Transboundary Air Pollution (CLRTAP) (Geneva, 1979) (Ratification date: 18 April 1983);
- United Nations Framework Convention on Climate Change (1992) (Ratification date: 24 May 2004);
- Kyoto Protocol to United Nations Framework Convention on Climate Change (1997) (Ratification date: 26 August 2009);
- Convention for the Protection of the Ozone Layer (Vienna, 1985) (Ratification date: 20 September 1991);
- Montreal Protocol on Substances that Deplete the Ozone Layer (1987) (Ratification date: 19 December 1991).

Biological Diversity

- Convention on Biological Diversity (Rio, 1992) (Ratification date: 27 December 1996);
- Convention on the Conservation of European Wildlife and Natural Habitats (Bern, 1979) (Ratification date: 20 February 1984);
- International Convention for the Protection of Birds (Paris, 1950) (Ratification date: 14 June 1967).

Cultural Heritage

- European Convention on the Protection of the Archaeological Heritage (Valletta Agreement, 1992) (Ratification date: 05 August 1999);
- Convention concerning the Protection of the World Cultural and Natural Heritage (Paris, 1972) (Ratification date: 14 February 1983).

Other International Requirements

Several international standards are available and can be applied for the project in addition to national and international regulations and laws:

- ISO 35001: 2009 Bio-risk Management for Laboratories
- CEN/CWA 15793 Laboratory Bio Risk Management Standard
- DIN 1946 Ventilation and Air Conditioning (for the healthcare sector)
- DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance or ANSI/ASHRAE/ASHE Standard 170-2017, Ventilation of Health Care Facilities

- EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and Refrigeration products)
- TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments
- FAO, 2018. Biosafety Primer 2018. Bangkok. 120 pp.
- WHO Good Manufacturing Practices for Biological Products, Annex 2
- WHO White Paper-Establishing Manufacturing Capabilities for Human Vaccines, 2017
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, 2020
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), 2016
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006
- ANSI Z9.14: Testing and performance verification methodologies for ventilation systems for Biological Safety Level 3 (BSL-3) and animal Biological Safety Level 3 (ABSL-3) facilities
- Industry Standards and Best Practices
- US GMP requirements for the manufacturer of Biological Product 21 CFR Part 600
- FDA Vaccine and Related Biological Product Guidances
- FDA CMC and GMP Guidances (ex.: Process Validation: General Principles and Practices, Guidance for Industry)
- US cGMP Guide Biologics 21 CFR 610 - General Biological Products Standards
- US 21 CFR Part 200 & 210 Current Good Manufacturing Practice
- Transport of Biological Materials, OIE Terrestrial Manual Chapter 1.1.3., 2018
- ICAO-Technical Instructions for The Safe Transport of Dangerous Goods by Air (Annex 18) IATA-Dangerous Goods (63rd 2022)
- Biological Weapon Convention, 1975
- General requirements for the competence of testing laboratories are contained in the standard ISO / IEC 17025.

4 PROJECT DESCRIPTION

The Torlak Institute of Virology, Vaccines and Sera is a national manufacturer of high-quality, safe, and effective vaccines, sera and other immunobiological products.

The Institute is one of the oldest institutions of this kind in the world, with 95 years of experience and tradition. The Institute was founded by the Serbian Government.

The Institute monitors, studies, examines, identifies, introduces, and implements professional and scientific methods of prevention and diagnosis of infectious diseases, performs scientific research and educational activities with the aim of developing new technologies and improving vaccines production. As a national vaccine producer, the Institute supplies healthcare institutions performing public health activities in the Republic of Serbia with vaccines from the compulsory immunization program, as well as with other vaccines needed. In addition to vaccines, the Institute produces sera and other immunobiological and diagnostic products, medical devices, and food supplements. The Torlak Institute performs trade, i.e., the import and export of medicines, medical devices, food supplements and raw materials to produce medicines and other devices.

A new diagnostic laboratory building with BSL-3 within the existing Torlak Institute as the Project in accordance with the requirements of WHO Laboratory Biosafety Manual, 4th edition, 2020. The Project is under the Serbia Emergency COVID-19 Response Project (SECRP) and the ESIA report will be prepared for the construction and operation of the BSL-3 laboratory in the new diagnostic laboratory building.

In order to provide laboratory support to the system of epidemiological surveillance, warning and rapid response to possible threats to public health at the national and global level, it is necessary to develop capacities for detection through the isolation of the above-mentioned microorganisms and the implementation of in-house (internal) diagnostic tests.

The establishment of a BSL3 laboratory opens the possibility of developing in-house tests and their use, both for diagnostic purposes and for scientific research, as well as the introduction of new diagnostic procedures that could not be carried out in the existing space of BSL2 laboratory.

Unlike commercial tests, the development and use of in-house (internal) diagnostic tests allows the laboratory to be independent in diagnosing pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the appearance of a new "threatening" infectious agent. This is especially important given that in times of high global demand, there can be enormous difficulties in obtaining commercial diagnostic kits.

The prerequisite for the development of in-house (internal) diagnostic tests, for the analysis of the virus genome and the determination of the sensitivity of the virus to antiviral drugs, is the isolation of the virus from patient samples. To begin with, isolation of viruses such as West Nile virus, dengue virus, SARS-CoV-2, hantaviruses and others which are from the Risk Group 3 of pathogenic microorganisms is planned. Cultivation of Risk Group 3 bacterial infectious agents and determination of sensitivity to drugs are also planned. All these analyzes contribute to the improvement of the quality of the health system's response to the threat of infectious diseases because they enable more efficient prevention of the spread of the epidemic and better treatment of the consequences of infectious diseases. Also, the safety of healthcare workers is significantly improved.

The BSL-3 laboratory will be available not only to the "Torlak" Institute, whose primary activity is in the field of virology, but also to other diagnostic and scientific research institutions in Serbia. It will support Serbia's infrastructure and human resources with BSL3 training in order to address the challenges and threats to the country's public health.

The Project will be located on the state-owned land already within Torlak Institute and consist of 4 floors (basement, ground floor and 3 upper floors), with a total area of approximately 4,500 m^2 in which one BSL-3 laboratory will be established in a total area of approximately 150 m^2. Other premises within the new building will be biosafety level 2 or lower. The general layout and land use map of the Project are given in Figure 4-1 and Figure 4- respectively.

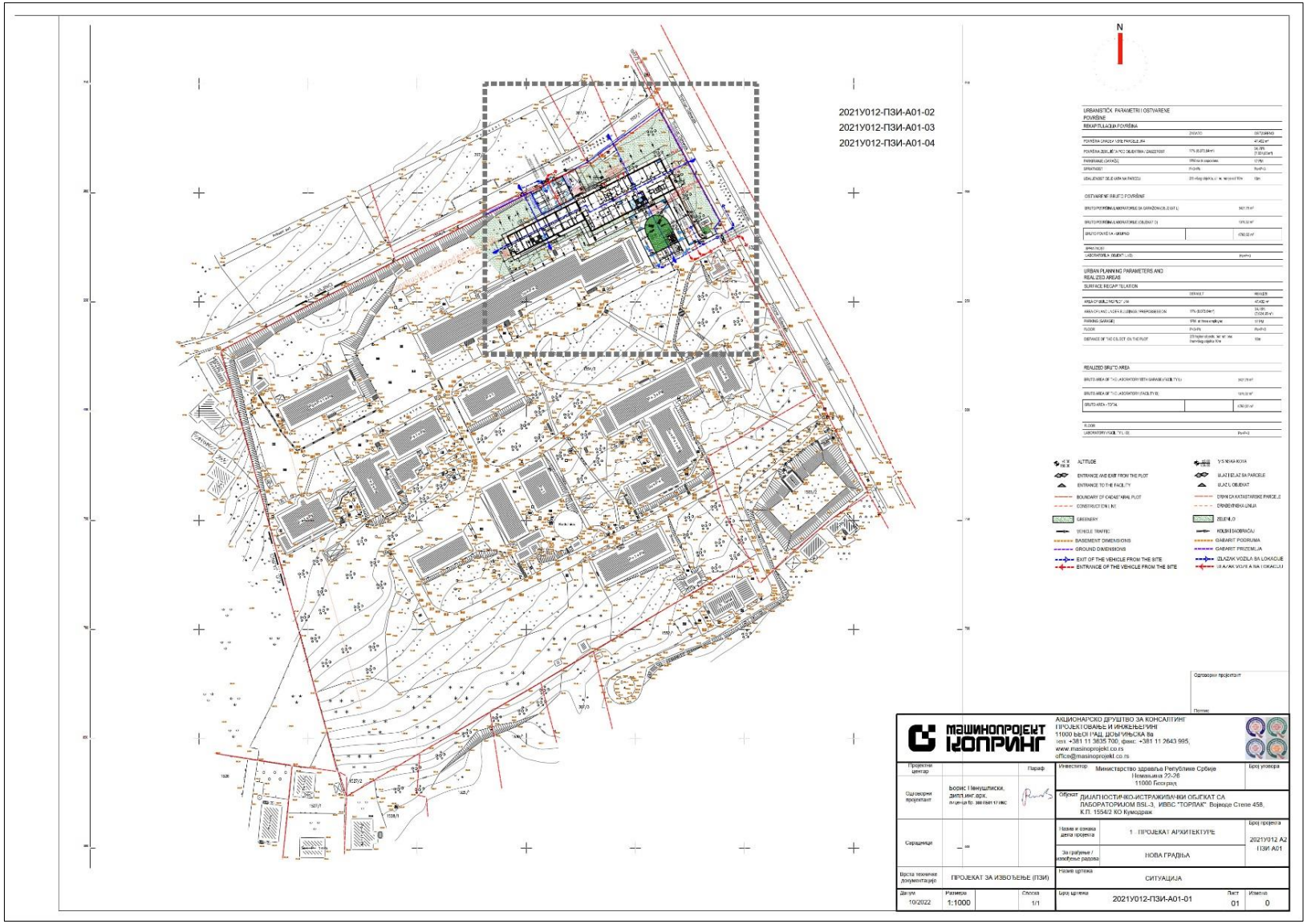

Figure 4-1. General Layout of the Project

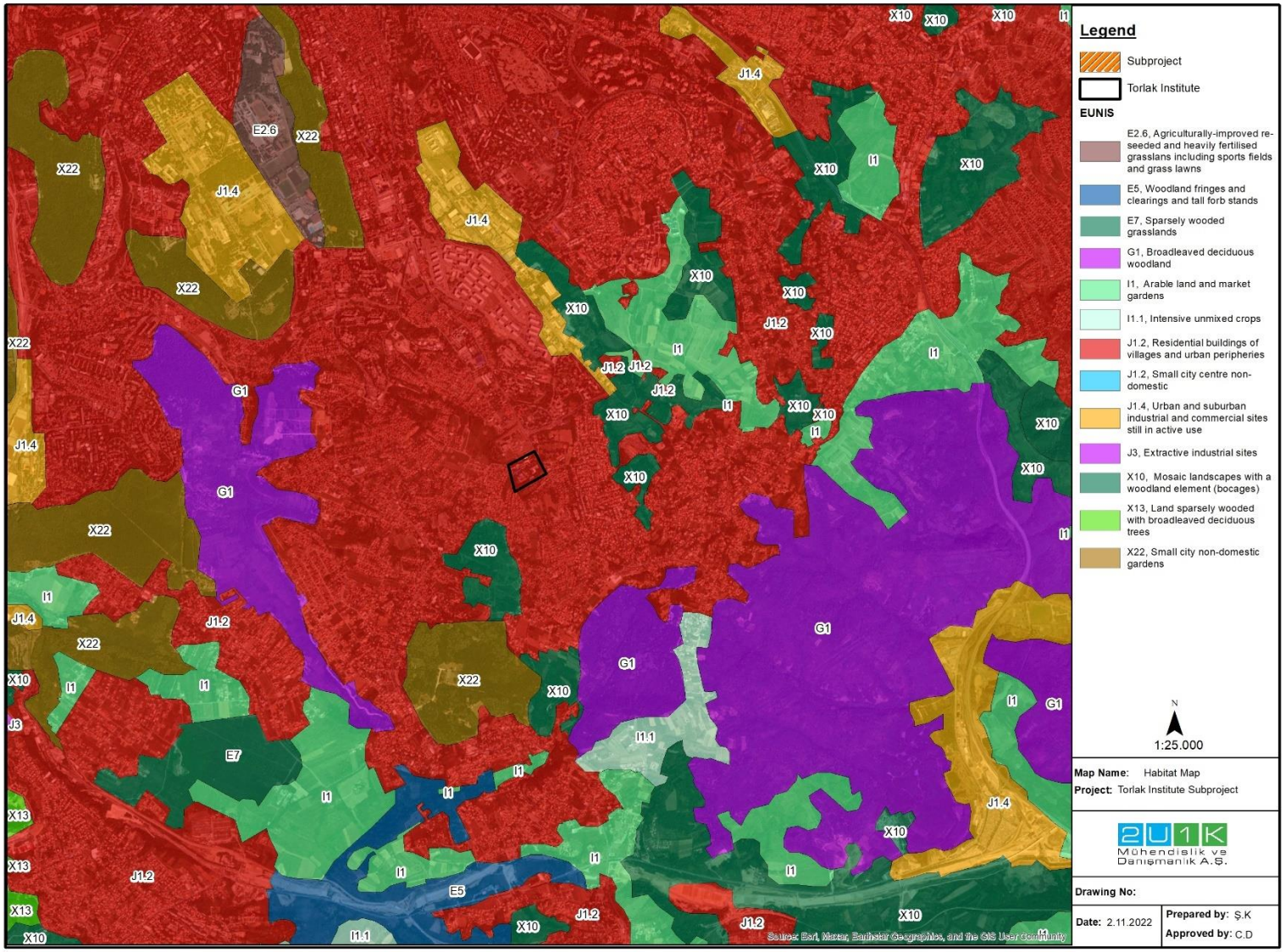

Figure 4-2. Land Use Map of the Project

4.1 Project Components

The Project has been designed as a diagnostic laboratory building with biosafety level 3 (BSL-3.)

Biosafety levels for laboratories are designated based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from various risk groups.[2]

The BSL-3 laboratory within the scope of the Project will fulfil the requirements for handling pathogenic agents that require such a level of biosafety, like SARS-CoV-1, yellow fever virus, West Nile virus, eastern equine encephalitis virus, and MERS-CoV but also various bacterial, fungal and rickettsia pathogens.

The classification of infective microorganisms by risk group is given Table 4-1.

Table 4-1. The Classification of Infective Microorganisms by Risk Group[3]

Risk Group 1 (no or low individual and community risk)	A microorganism that is unlikely to cause human or animal disease.
Risk Group 2 (moderate individual risk, low community risk)	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3 (high individual risk, low community risk)	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4 (high individual and community risk)	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

[2] WHO Biosafety Manual (3rd edition, 2004)

[3] WHO Biosafety Manual (3rd edition, 2004)

Biosafety Level–1 (basic)

Biosafety level 1 applies to laboratory settings in which personnel work with low-risk agents that pose little to no threat of disease in healthy adults. An example of a microbe that is typically worked with at a BSL-1 is a non-pathogenic strain of E. coli.

A BSL-1laboratory typically consists of work taking place on benches without the requirement of use of special contaminant equipment or facility design. A BSL-1 laboratory requires standard microbial practices. It does not require special practices or to be isolated from surrounding facilities

Biosafety Level – 2 (basic)

BSL-2 covers laboratories that work with agents associated with human diseases (i.e., pathogenic or infections organisms) that pose a moderate health hazard to personnel and the environment. Examples of agents typically worked with in a BSL-2 include equine encephalitis viruses and HIV, as well as Staphylococcus aureus (staph infections).

BSL-2 laboratories maintain the same standard microbiological practices as BSL-1 laboratories, but also includes enhanced measures to prevent injuries such as cuts and other breaches of the skin, specifically to prevent ingestion and mucous membrane exposures.

Biosafety Level – 3 (containment)

A BSL-3 laboratory typically includes work on either indigenous or exotic agents that be transmitted through air and can cause serious or potentially lethal infections. Examples of microbes worked with in a BSL-3 includes yellow fever, West Nile virus, the bacteria that causes tuberculosis, eastern equine encephalitis virus, and MERS-CoV, but also various bacterial, fungal and rickettsia pathogens.

The work is often strictly controlled and registered with the appropriate government agencies. Access is restricted for all times and all work is performed in a biosafety cabinet or other primary containment devices. Laboratory personnel are also under medical surveillance and could receive immunizations for pathogenic agents they work with.

Laboratory protective clothing must be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes. Laboratory protective clothing must not be worn outside the laboratory, and it must be decontaminated before it is laundered. Respiratory protective equipment may be necessary for some laboratory procedures.

BSL-3 laboratories are designed to be easily decontaminated. As an additional safety measure, these laboratories must use controlled or “directional” air flow to ensure that air flow from non-laboratory areas (such as the hallway) into laboratory areas. Other engineered safety features include a requirement for entry through two self-closing, interlocked doors, sealed windows, floors, and walls, and filtered ventilation systems.

BSL-3 laboratories have the following containment requirements detailed below.

1. The laboratory must be separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors must be lockable. All windows must be closed and sealed.
2. Each laboratory room must contain a hands-free controlled sink for handwashing located near the room exit door as well as an eye-wash station. .
3. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled as well as the laboratory furniture are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, benchtops and floors should be smooth, impermeable to liquids, and resistant to the chemicals and disinfectants normally used in the laboratory.
4. BSL-3 laboratories must be equipped for decontamination of laboratory waste using an incinerator, an autoclave, and/or another method of decontamination, depending on the biological risk assessment. If infectious waste is transported out of the laboratory, it should be transported in unbreakable and leakproof containers according to national or international regulations, as appropriate.
5. Biological safety cabinets should be located away from doors, from room supply louvers, and from heavily travelled laboratory areas.
6. A ducted exhaust air ventilation system is provided. This system creates directional airflow, which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failures.
7. HEPA-filtered exhaust air from a Class II biological safety cabinet (BSC) can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from Class II BSCs is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III BSCs are used, they should be directly connected to the exhaust system. If Class III BSCs are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets

8. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. The period for the replacement of HEPA filters will be determined according to specific decontamination tests. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
9. Vacuum lines should be protected with liquid disinfectant traps and HEPA filters, or their equivalent. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).
10. The Biosafety Level-3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.
11. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

Biosafety Level – 4 (maximum containment)

As the highest level of biological safety, a BSL-4 laboratory requires maximum containment features and consists of work with highly dangerous and exotic biological agents that pose a high risk of life-threatening disease that may be transmitted via the aerosol route and for which there is no available vaccine or therapy. Two examples of such microbes include Ebola and Marburg viruses.

In addition to BSL-3 considerations,in BSL-4 laboratories personnel work in a Class III BSC or in a Class II BSC with a full body, air-supplied, positive pressure suit. The BSL-4 facility is often a separate building or completely isolated zone with complex, specialized ventilation requirements and waste management systems, for both solid and liquid waste, to prevent the release of hazardous biological agents into the surrounding community and the environment.

The relation of risk groups to BSLs, practices and equipment are presented in Table 4-2.

Table 4-2. Relation of Risk Groups to Biosafety Levels, Practices and Equipment

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – BSL 1	Basic teaching, research	Good Microbiological Technique (GMT)	None; open bench work
2	Basic – BSL 2	Primary health services; diagnostic services,	GMT plus protective clothing, biohazard sign	Open bench plus biological safety cabinets

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
		research		(BSC) for potential aerosols
3	**Containment – BSL-3**	**Special diagnostic services, research**	**As level 2 plus special clothing, controlled access, directional airflow**	**BSC and/or other primary devices for all activities**
4	Maximum Containment – BSL 4	Dangerous pathogen units	As level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double ended autoclave (through the wall), filtered air

According to the Biosafety level; description, sample organisms, pathogen type and autoclave requirements are given Table 4-3.

Table 4-3. The Difference Between BSLs and Their Corresponding Safety Requirements

Biosafety Level	BSL-1	BSL-2	BSL-3	BSL-4
Description	No Containment Defined organisms Unlikely to cause disease	Containment Moderate Risk Disease of varying severity	**High Containment** **Aerosol Transmission** **Serious/Potentially lethal disease**	Max Containment “Exotic”, “High-Risk Agents Life-threatening disease
Sample Organisms	E.coli	Influenza, HIV, Lyme Disease	**Tuberculosis**	Ebola Virus
Pathogen Type	Agents that present minimal potential hazard to personnel & the environment	Agents associated with human disease & pose moderate hazards to personnel & the environment.	**Indigenous or exotic agents, agents that present a potential for aerosol transmission, & agents causing serious or potentially lethal disease.**	Dangerous & exotic agents that pose a high risk of aerosol-transmitted laboratory infections & life-threatening disease.
Autoclave Requirements	None	None	**Pass-thru autoclave with Bioseal required in laboratory room.**	Pass-thru autoclave with Bioseal required in laboratory room.

Source: Laboratory Biosafety Manual (LBM), WHO (fourth edition 2020; and third edition 2004)

Table 4-4 summarizes the facility requirements at four biosafety levels.

Table 4-4. Summary of Biosafety Level Requirements

Isolation of laboratory	BSL-1	BSL-2	BSL-3	BSL-4
Isolation[a] of laboratory	No	No	**Yes**	Yes
Room sealable fordecontamination	No	No	**Yes**	Yes
Ventilation: inward air flow controlled ventilationsystem HEPA-filtered air exhaust	 No No No	 Desirable Desirable No	 **Yes** **Yes** **Yes/No[b]**	 Yes Yes Yes
Double-door entry	No	No	**Yes**	Yes
Airlock	No	No	**No**	Yes
Airlock with shower	No	No	**No**	Yes
Anteroom	No	No	**Yes**	-
Anteroom with shower	No	No	**Yes/No[c]**	No
Effluent treatment	No	No	**Yes/No[c]**	Yes
Autoclave: on site in laboratory room double- ended	 No No No	 Desirable No No	 **Yes** **Desirable** **Desirable**	 Yes Yes Yes
Biological safety cabinets	No	Desirable	**Yes**	Yes
Personnel safety monitoring capability[d]	No	No	**Desirable**	Yes

a Environmental and functional isolation from general traffic.
b Dependent on location of exhaust.
c Dependent on agent(s) used in the laboratory.
d For example, window, closed-circuit television, two-way communication.

4.2 Main Phases of the Project

4.2.1 Construction of the Project

In the scope of the project, a laboratory building of 4 floors with a total area of 4,500 m^2 will be constructed within the existing Torlak Institute. Within the scope of the Project's electricity works, a transformer station next to the existing building of Torlak Institute is planned to be built (see Figure 4-3). Electricity, water, wastewater, natural gas and transportation infrastructure for the Project already exists within the Torlak Institute, therefore construction of any associated facility is not foreseen. Capacity of the transformer station to be built will be 1000 kVa. Two underground connection lines for the transformer station (10kV, type XHE 49-A 3x (1x150) mm^2) will have approximately 200 m length.

Steps for the construction of a building is given below:

Site preparation, levelling works, excavation

The construction site must be cleaned before the execution of works. The site preparation includes the removal of roots of trees, and debris, and levelling ground area.

Rough Construction Works

The rough construction works starts after finishing of the excavation works and include foundation, construction of the walls above the ground, slabs, reinforced concrete floors and load bearing walls, columns, beams, brickwork, stairs, staircase landings, chimneys, shafts, lift shafts, etc. and roofing.

Mechanical and Electrical Installations

Mechanical and electrical installation works will be completed. Mechanical systems may include elements of infrastructure, plant and machinery, tools, components, heating and ventilation etc. Electrical systems might include, power supply and distribution, telecommunications, computing instrumentation, control systems etc.

General requirements for construction of BSL-3 Laboratories are given below.

- A hands-free sink and eyewash are available near the exit.
- The laboratory has self-closing doors
- Exhaust air cannot recirculate; laboratory must have sustained directional airflow and air must flow into the
- Laboratory from clean areas towards potentially contaminated areas.

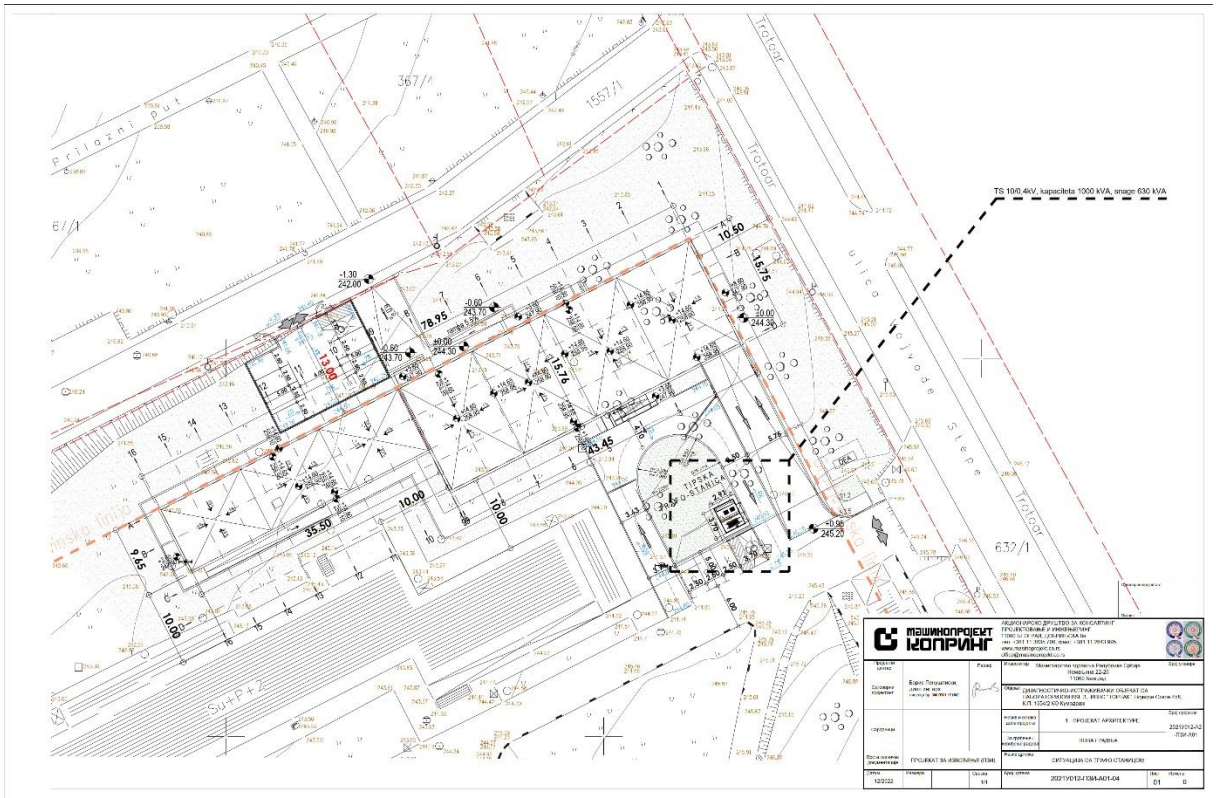

Figure 4-3. Map Showing the Transformer Station to be built within the Scope of the Project

Technical control services will be performed prior, during and after the development of design documentation in order to make the verification process more efficient. It will include, but not be limited, to:

- Verification of design documentation for construction permits;
- Assessment of the adequate conditions for building foundations;
- Verification of correctness and accuracy of applied technical and technological solutions and construction means and methods;
- Stability and safety;
- Rationality of recommended materials;
- Compatibility with the national law and other international regulations, technical norms, standards and quality norms.

Technical control services will be performed simultaneously with the development of design documentation in order to make the verification process more efficient.

The scope of the technical control services for the subject location described above shall include, but will not be limited to:

Verification of design documentation for construction permits, including the following:

- Design documentation compliance with elaborates and studies which will be part of design documentation i.e. firefighting elaborate, energy efficiency elaborate, any other elaborate that may be required by the law;
- Design documentation compliance with all designing inputs (Terms of Reference, geotechnical researches, geodetic layouts etc.);
- Design documentation compliance with local and international norms and standards pertaining to laboratory facilities i.e. but not limited to Good Laboratory Practice (GLP); WHO Laboratory Bio-Safety Manual (LBM), fourth edition, 2020; WHO Bio risk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6, ISO 35001: 2009 Bio-risk Management for Laboratories.
- Internal compliance of the designs within technical documentation;
- Compliance of technical documentation for the construction permit with recommended measures contained in the Studies, Elaborates or Projects (i.e. Environmental and Social Impact Assessment (ESIA) and its Environmental and Social Management Plan (ESMP), required by the relevant laws pertaining to construction of laboratory facilities.

Verification of emergency preparedness

Verification of the bill of quantities and technical specifications:

- Verification of the compliance between the design for construction permit and the bill of quantities;
- Verification of the compliance between the design for construction permit and technical specifications;
- Verification of the compliance between technical specifications and applicable laws, norms and standards;
- Verification of technical specifications and the bill of quantities' comprehensiveness, quality and sufficient level of details.
- Verification of materials planned to be used which should be up-to-date, hi-tech, and durable; choice of materials should be done in accordance with specific working environments in the new building laboratories including these in BSL-3 level: irradiation, toxic, caustic and chemically aggressive substances;

Since the construction site is close to the Belgrade city centre, the construction of a worker accommodation camp is not expected.

Key environmental and social impacts during construction phase are expected to be;

- Community health and safety and security risks and nuisance due to increased traffic load and dust and noise generation
- Waste management (excavated soil, construction wastes including hazardous waste)
- Wastewater management
- Occupational health and safety risks for construction workers

- Potential cumulative risks and impacts due to construction activites (increased traffic load, increased stress on infrastructure, waste generation etc.)

4.2.2 Certification of the Project as BSL3 Laboratory

Laboratory certification is the systematic examination of all safety features and processes within the laboratory (engineering controls, personal protective equipment, and administrative controls). Biosafety practices and procedures are also examined. Laboratory certification is an on-going quality and safety assurance activity that should take place on a regular basis. Therefore, laboratory certification differs from laboratory commissioning activities in several important ways.

Laboratory certification helps to ensure that:

1. Proper engineering controls are being used and are functioning adequately as designed,
2. Appropriate site and protocol specific administrative controls are in place,
3. Personal protective equipment is appropriate for the tasks being performed,
4. Decontamination of waste and materials has been adequately considered and proper waste management procedures are in place,
5. Proper procedures for general laboratory safety, including physical, electrical, and chemical safety are in place.

Adequately trained safety and health or biosafety professionals may conduct laboratory certification activities. Institutions may employ personnel having the appropriate skill-set required for conducting audits, surveys or inspections (these terms are used interchangeably) associated with the certification process. However, institutions may consider engaging or be required to engage a third party to provide these services.

Biomedical research and clinical laboratory facilities may develop audit, survey or inspection tools to help ensure consistency in the certification process. Care must be taken to ensure that these tools are used only by appropriately trained personnel, and that they are not used as a substitute for a sound professional biosafety assessment. Examples of such tools are provided in Tables 5–7 of the WHO Biosafety Manual (3rd edition, 2004)

The BSL laboratories within the scope of the Project will be commissioned and certified by an independent third-party in line with the WHO requirements as specified in the WHO Laboratory Bio-Safety Manual (3rd edition, 2004) . A separate procurement procedure will be conducted by the PCU, and Certification Consultant/Team will be engaged. The Certification Team will include the requirements below:

- PhD in Microbiology and/or biotechnology related fields
- Completed at least3 BSL3 labs certification process

- Minimum 5 years of experience as a bosafety and/or biosecurity consultant
- Minimum 10 years of experience as a BSL3 facility certification specialist
- Regular participation in biosafety and/or biosecurity conferences
- Experience in biorisk assessment
- Experience in review and approval for BSL3 facility designs
- Experience in supervising constructions for BSL3 facilities
- Commissioning experience in BSL3 facilities
- Training experience in biosafety and/or biosecurity

The certification process of the Project will be conduct using the tools provided in Tables 5–7 (Laboratory Safety Surveys) of the WHO Biosafety Manual (3rd edition, 2004). Findings of the audit, survey or inspection should be discussed with laboratory personnel and management. Within the laboratory, an individual should be identified and made responsible for ensuring that corrective actions are taken for all deficiencies identified during the audit process. Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed. Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed.

Annual recertification will be also scheduled and organized.

With respect to the commissioning and certification of BSL laboratories, the Project will refer to the international standards, guidelines and regulations including but not limited to:

- WHO Laboratory Bio-Safety Manual (LBM), 3rd edition, 2004 and 4th edition, 2020,
- CWA 15793:2008 Laboratory Biorisk Management Standard,
- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020,
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019,
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006, and
- ANSI/ASSP Z9.14:2020 Testing and Performance-Verification Methodologies For Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems

The following items will be completed prior to operation;

- Certification and Recertification of the BSL3 laboratory at Torlak Institute,
- Establishment Technical Unit including HVAC system,
- Establishment Decontamination System,
- Establishment of Biorisk Programme,
- Establishment of Training Program 45of Laboratory for on-site/off-site Personnel,

- Establishment of Occupational Health & Safety Program at the Institute,
- Establishment of collection/handling & storage of sample & waste at the Institute,
- Establishment of transport of sample & waste in and off-site of the Institute,
- Emergency Hazards Systems (Fire, Electric, etc.),
- Emergency Preparedness and Response Program (ex. Abnormal events and accidents for facility operation.

In this context, detailed information on commissioning and certification of the Project will be provided in the ESIA of the Project.

4.2.3 Operation of the Project

The new BSL-3 laboratory will be constructed within the Torlak Institute and diagnostics, research, R&D activities are planned to be conducted.

The laboratory will also work as a public health laboratory and reception of biological material delivered from health institutions and biological material sampled on site from patients will be accepted.

The new BSL-3 laboratory will fulfil requirements for handling pathogens such as SARS-Cov2, enable widening the research related to detection of viral presence in air, wastewater, soil and elsewhere and also enable handling of many other pathogens that require such a level of biosafety, like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also different bacterial, fungal and rickettsia pathogens, thus greatly strengthening Serbia's national laboratory system.

General requirements for the operation of BSL-3 Laboratories are presented below:

Laboratory practices

- Access to the laboratory is restricted when work is underway.
- An Occupational Health Program exists for medical surveillance of laboratory staff. Laboratory staff are under medical surveillance and may be offered immunizations against infectious agents or toxins they work with, if available.
- Access to the laboratory is restricted and controlled at all times.

Safety equipment

- Appropriate PPE is worn, including lab coats and gloves, eye protection and face shields.
- All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).
- Autoclaving or alternative method of decontamination is available.
- Appropriate PPE must be worn, and respirators might be required.

- All work with infectious agents or toxins must be performed within appropriate biosafety cabinet.

4.3 Project Location

The Project is planned to be constructed in the Serbian capital Belgrade, within the existing complex of the Torlak Institute of Virology, Vaccines and Sera. The Project is an entirely new laboratory building to be constructed within the Torlak Institute. No renovation works of the existing facility buildings will be conducted within the scope of the Project. It was stated that the land is in public ownership and no land acquisition process, of private land/assets or restriction to assets and resources is expected within the scope of the Project.

The Torlak Institute of Virology, Vaccines and Sera is a national institution for prevention, treatment, and monitoring of infectious diseases. Today, “Torlak” has four reference national laboratories:

- National laboratory for influenza and other respiratory viruses
- National laboratory for poliomyelitis and enteroviruses
- National laboratory for rubella, morbilli, varicella and other rashes
- National laboratory for viral hemorrhagic fevers and ARBO viruses

The National laboratories of the Institute “Torlak” are a part of the European laboratory network of the World Health Organization (WHO) and have full membership status as the WHO accredited laboratories. The labs have achieved inter-laboratory cooperation with microbiological labs in the Republic of Serbia and the related labs in Europe. In particular, the national labs have achieved cooperation with their superior regional WHO reference labs.

The Torlak Institute is a national institution for the prevention, treatment, and monitoring of infectious diseases. The founder of the Institute is the Government of the Republic of Serbia. It is one of the oldest institutions of this type in the world, with a tradition and experience of more than 80 years. The Project’s location is urban and is located on the southern edge of the Belgrade, in settlement Jajinci (see Figure 4-4).

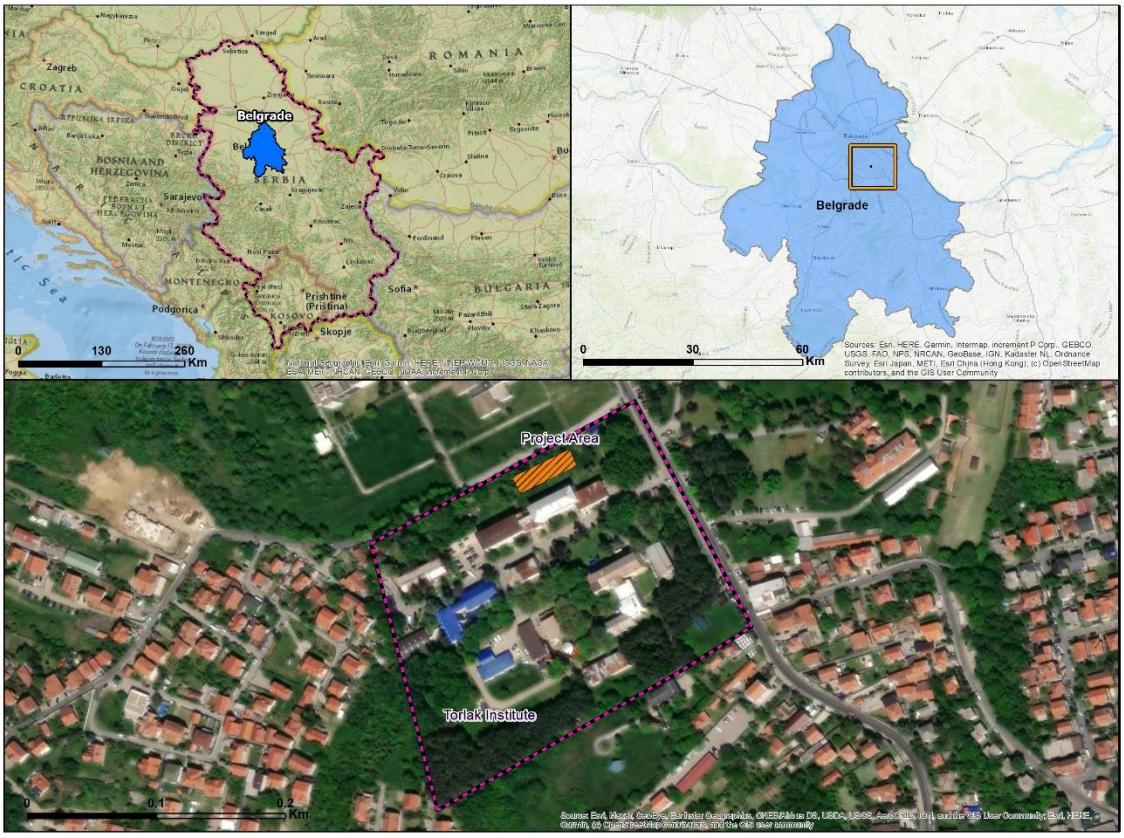

Figure 4-4. Project Location on the Regional Map

There is built infrastructure on the location. The Torlak complex where new diagnostic laboratory building with BSL-3 will be built is fenced, has an administrative building and four national reference laboratories for diagnostics at the same location, three of which are certified by the WHO.

Residential facilities are not located in the immediate vicinity of the Project Area, but the Torlak complex is mostly surrounded by business and industrial facilities, the Faculty of Pharmacy is on the north. Closest residential area is at 150 m distance from the new diagnostic laboratory building with BSL-3 at the Torlak Institute (Figure 4-5). Torlak Institute is located within a residential area and surrounded by settlements. The roads at the north and west of the Torlak Institute are also used by the Faculty of Pharmacy and the residential buildings as well as businesses for access. These sensitive receptors might be impacted by the construction activities (e.g., noise and dust due to earthworks and assembling as well as traffic load) and the operational activities might trigger social unrest. In this respect, the environmental and social risks and impacts of the Project on the surroundings along with proposed mitigation measures will be discussed in the ESIA report.

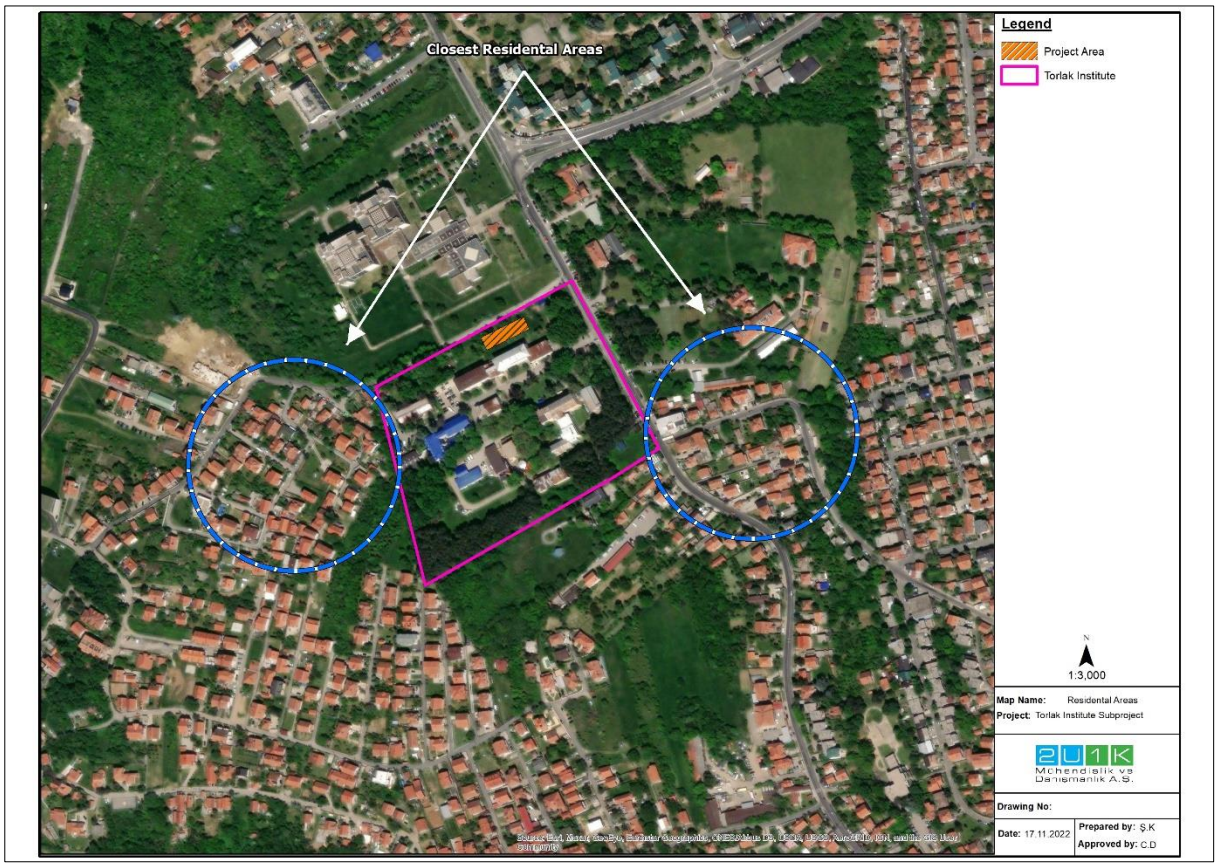

Figure 4-5. Closest Residential Areas around the Project Area

4.3.1 Existing Use of Project Area

Important findings identified during the site visit, which should be included in the planning phase before starting the Project's construction works are as follows; in addition to having sparse woodland, the Project Area also includes buried old stone and concrete structures with vent-holes and chimneys that are the existing infrastructures of Torlak Institute. Also, the existence of underground gas pipeline in a part of the Project Area has been verified by the Project representative. Moreover, it was observed that waste temporary storage areas in the region between the Project Area and the road were not well organized. During the site visit, no legacy environmental issues that potentially require additional analysis and/or remediation have been identified. Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Project in case any contamination is identified. If soil contamination is detected during construction phase within the Project area, soil sampling and analysis will be conducted in line with the requirements of below legislation;

•Regulation on systematic monitoring of the condition and quality of soil. 2020-06-18 Official Gazette of RS", number 88 of June 22, 2020

•Regulation on limit values of polluting, harmful and dangerous substances in soil. 2019-09-06 "Official Gazette of RS", no. 30 of April 20, 2018, 64 of September 6, 2019.

4.4 Project Area of Influence

According to the WB ESS 1 Guidance Note, the "Project area of influence" should be defined. The definition of the "Project area of influence" according to WB is:

> *"The area likely to be affected by the project, including all its ancillary aspects, such as power transmission corridors, pipelines, canals, tunnels, relocation and access roads, borrow and disposal areas, and construction camps, as well as unplanned developments induced by the project (e.g., spontaneous settlement, logging, or shifting agriculture along access roads)."*

This influence is highly impact dependent, such as an emission source's area of influence might be found with a dispersion model, while a wastewater discharge's area of influence will be related to the characteristics of the discharged wastewater. Thus, in the ESIA, the Project's area of influence will be defined according to the impact type and magnitude and impact assessment will be done. Potentially Affected Parties particularly for the settlements in the close vicinity of the Project area that might be of the primary receptors of the impacts such as odor, noise and dust will be identified based on the detailed impact assessment results. The closest residential receptor that is identified within the AoI of the Project Area is 150 m distance (see Figure 4-5). Torlak Institute is located within a residential area and surrounded by settlements.

ESIA of the Project will be prepared in line with the requirements of national and international regulations and WBG's guideline documents to present potential risks, impacts, required mitigation measures, residual impacts after mitigation, and potential cumulative impacts in the overlapping AoI of other (current and/or future) developments occurring at the Project Area or within the Project's wider AoI and downstream risks and impacts triggered over time.

The impact area of the Project has been determined regarding the environmental components, social aspects and impact factors that may be affected separately. In addition to this, WBG Policies require identification and definitions of the project AoI including the associated facilities[4] as well during scoping phase of the Project. Environmental components and impact factors considered within the scope of the Project constitute emissions, noise, terrestrial ecosystem, and residential areas, etc. Impacts have been studied in terms of construction and operation. Within the scope of the Project, there has been no identified potential associated facility as per WBG Policies and this will be confirmed as part of the ESIA studies.

[4] Facilities or activities that are not funded as part of the project and, in the judgment of the Bank, are: (a) directly and significantly related to the project; and (b) carried out, or planned to be carried out, contemporaneously with the project; and (c) necessary for the project to be viable and would not have been constructed, expanded or conducted if the project did not exist. For facilities or activities to be Associated Facilities, they must meet all three criteria.

Environmental and social risks for both construction and operation phases of the Project will be considered during the ESIA study. Potential environmental and social aspects such as waste management, biosafety and security, community health and safety, occupational health and safety and public fear and protest due to inadequate and insufficient information sharing during construction and operation phase will be managed through mitigation measures to be determined in ESIA Report and management plans. On the other hand, environmental impacts such as noise, emission, etc. and social aspects such as nuisance to surrounding settlements such as dust and noise, traffic load, community health, safety and security which will be caused by the works to be carried out during the preparation of the land, and during the construction phase of the Project, are temporary and these impacts will be over with the end of the construction activities.

5 IDENTIFICATION OF ALTERNATIVES

This section summarizes the alternatives to and in the Project and briefly explains why the current features are selected.

5.1 No-Project Alternative

This is the scenario where the Project will not be realized. The 'no project' alternative considers the scenario in which the existing Torlak Institute of Virology, Vaccines and Sera will continue its operation without any extensions and the current services of the concerned Institute will be kept as it is.

Torlak Institute Biosafety Level 3 Subproject is primarily under the Serbia Emergency COVID-19 Response Project (SECRP). Hence, since the existing Torlak Institute of Virology, Vaccines and Sera does not meet the requirements for the processing of pathogens such as SARS-Cov2 and there are also currently no facilities in Serbia that can handle pathogens requiring a BSL-3 or higher, in other words, in case of not establishing of a BSL-3 laboratory, the Serbia will continue to lack the potential of early detection and confirmation of in question cases besides missing the opportunity to strengthen its epidemiological capacity, national reference, and public health laboratories. Moreover, having not an appropriate laboratory would not allow for widening the research related to detection of viral presence in air, wastewater, soil and elsewhere. Most importantly, such a laboratory would enable handling of many other pathogens that require such a level of biosafety, like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also different bacterial, fungal and rickettsia pathogens, thus greatly strengthening Serbia's national laboratory system.

5.2 Technology Alternative

The planned Project's effects on the environment and public health will also depend on the general laboratory technology, tools, layout, and operational procedures to be used and installed during the operational stage. The environment and public health might be impacted directly or indirectly by the infectious sample handling, transfer, and storage facilities, infectious microbial containment technologies used in the proposed BSL 3 laboratory, the lab equipment and layouts, the operational procedures for the laboratory, as well as the waste management. Infectious microbiological organisms that jeopardize public health can escape due to failure of containment technologies installed, malfunctioning lab instruments, improper laboratory layouts, or due to errors during operational activities. In order to establish the design and technology selection criteria for the proposed BSL 3 Laboratory, a number of alternatives and standards were taken into account. The WHO Laboratory Bio-Safety Manual (LBM) (2020), OSHA Laboratory Safety Guidance and the World Bank Group EHS guidelines were taken into account for design, structure, and choice of suitable technologies for the planned BSL-3 laboratory.

As an alternative, a BSL-4 laboratory which use the maximum containment measures has not been preferred the Ministry of Health of Republic of Serbia for the proposed Project. As mentioned in the WHO Laboratory Biosafety Manual (4th edition, 2020) there are few such laboratories in the world as they are very expensive to build, operate and maintain, and are not required for most work. The assessment of technical necessities of BSL-3 and BSL-4 with regards to environmental and social impacts will be further provided in the ESIA report.

5.3 Project Area Alternatives

Within the complex of Torlak Institute of Virology, Vaccines and Sera, there are already several institutions for prevention, treatment and monitoring of infectious diseases that have been in operation for many years.

Due to the favourable conditions of the Torlak Institute creates for effective use of available land, skilled manpower, workflow, shared facilities, experience in risk management in events that may endanger public health and safety, being a place known by the public and in ensuring the biosafety and bio-security, the options of choosing other locations outside the Torlak Institute for the BSL-3 laboratory were merely rendered irrelevant.

Therefore, site selection process for the proposed new diagnostic laboratory building with BSL-3 Project was confined to the premises of the Torlak Institute.

6 ENVIRONMENTAL & SOCIAL BASELINE CONDITIONS

This is the section where the baseline condition of the Project Area and its vicinity is briefly described and base information about the measurements or studies to be carried-out within the scope of the ESIA studies. Also, the baseline conditions of the Project Area and its vicinity is detailed in this chapter under different sections according to its category. Each section will be detailed later for corresponding impact assessment within the Project's AoI in the Project ESIA report.

6.1 Land Use and Zoning

The Project is planned to be constructed in the Serbian capital Belgrade, within the existing complex of the Torlak Institute of Virology, Vaccines and Sera. The Project's location is urban and is located on the southern edge of the Belgrade, in settlement Jajinci.

The Project Area landcover is discontinuous urban fabric as can be seen from the Figure 6-1**Error! Reference source not found.**.

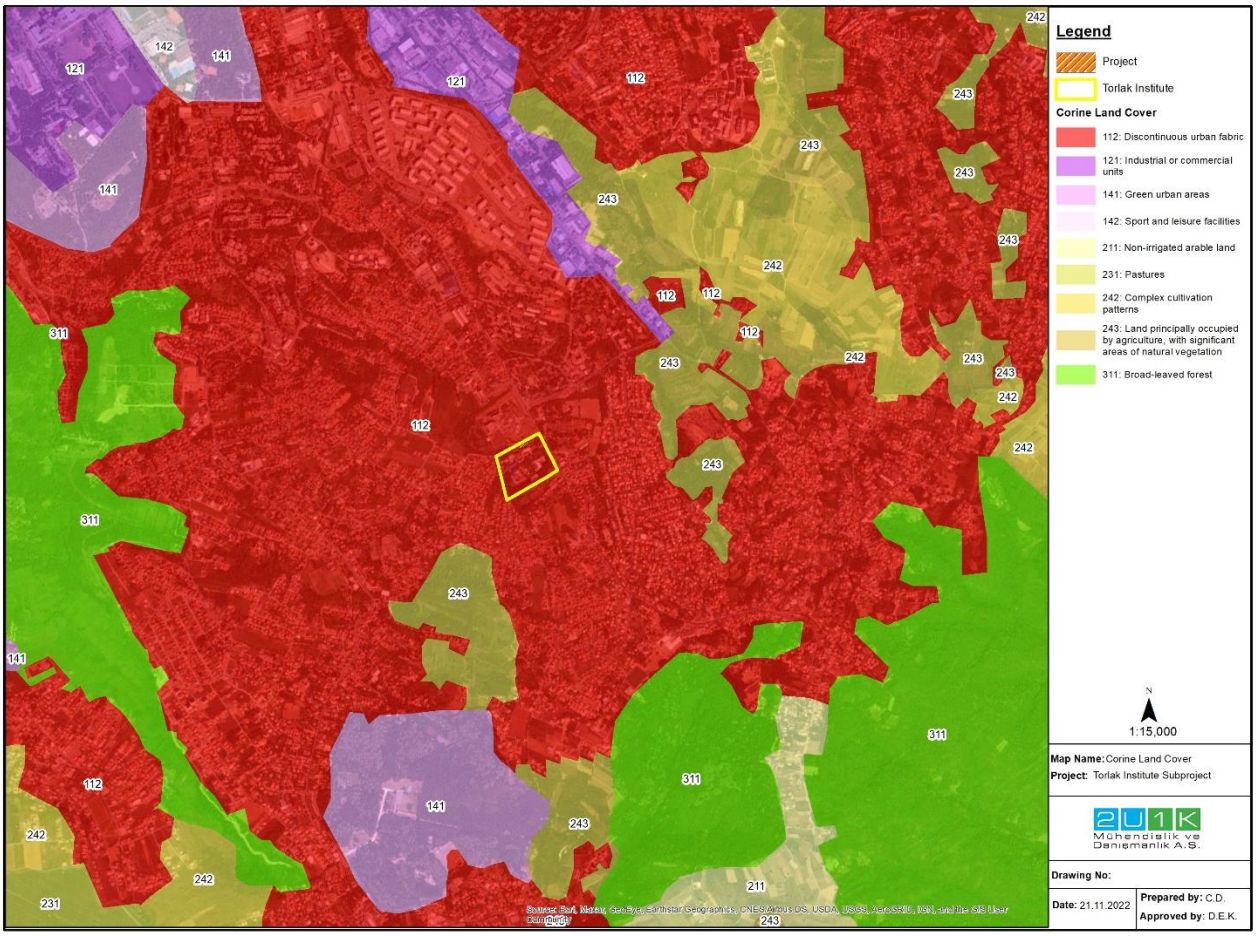

Figure 6-1. Corine Land Cover Map

Currently, the Project Area is not used by the municipality or stakeholders, and the parcel on which the Project is planned is not used by any formal or informal user. Within the Project Area there are buried old stone and concrete structures with vent-holes and chimneys that are the existing infrastructures of Torlak Institute. Also, the existence of underground gas pipeline in a part of the Project Area has been verified by the Project representative. Moreover, it was observed that waste temporary storage areas in the region between the Project Area and the road were not well organized. During the site visit, no legacy environmental issues that potentially require additional analysis and/or remediation have been identified. Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Project in case any contamination is identified. If contamination is detected during construction works, the ESIA will cover the necessary mitigation measures and the ESMP will include commitments for remediation and reclamation of the land.

6.2 Air

There is no site-specific air quality data publicly available for the Project Area nor any background air quality assessment has been conducted or provided by the Project Company within the scope of the Project. The detailed air quality assessment and modelling will be conducted during the ESIA stage of the Project. Coordinates and map of the air quality measurement points are presented in the Table 6-1 and Figure 6-2, respectively.

Table 6-1. Coordinates of the Air Quality Measurements

	X (WGS 1984 UTM Zone 34N)	Y (WGS 1984 UTM Zone 34N)
PM_{10} and $PM_{2.5}$-1	459935	4954819
PM_{10} and $PM_{2.5}$-2	460068	4954870

Figure 6-2. Measurement Points

Baseline air quality measurements will be conducted at two points for PM_{10} and $PM_{2.5}$ within the scope of the ESIA study and the results will be assessed in line with the WB General EHS Guidelines for Air Emissions and Ambient Quality.

Within the complex of the Institute, on the right side of Vojvode Stepe street, in a separate building, there is a boiler room. There are three boilers in the boiler room, two of which are in operation, namely boiler 3, which is connected by a flue channel to a metal emitter with insulation; and boiler 1, which is connected by a flue channel to the masonry broadcaster.

Heat energy from the burning of liquid fuel in boilers are used for the production of sanitary hot water, technological steam and for heating rooms in winter. Emission measurements at both boilers were performed with the request of Torlak Institute at 02.09.2022. Measurement results are presented in Table 6-2 and Table 6-3 respectively.

Table 6-2. Measurement Results of Boiler 3

Parameter	Unit	Measurement Results+ Error			Limit Value (SRPS EN ISO 16911-1 and RU.17)
		Measurement 1	Measurement 2	Measurement 1	
CO	mg/m^3	110.18±2.61	106.79±2.56	111.88±2.63	170

NO_X	mg/m^3	208.49±4.40	202.93±4.32	214.05±4.48	250
SO_2	mg/m^3	1066.54±19.33	1070.42±19.39	1078.18±19.53	1700

Table 6-3. Measurement Results of Boiler 1

Parameter	Unit	Measurement Results+ Error			Limit Value (SRPS EN ISO 16911-1 and RU.17)
		Measurement 1	Measurement 2	Measurement 1	
CO	mg/m^3	81.69±2.17	85.24±2.21	88.79±2.25	170
NO_X	mg/m^3	183.48±3.93	192.21±4.04	195.12±4.08	250
SO_2	mg/m^3	975.12±16.92	995.44±17.27	1003.56±17.40	1700

As can be seen from the measurements, limit values are met.

6.3 Noise

In order to assess the contribution of the proposed Project's effect on the sensitive receptors, background noise levels at the closest sensitive receptor have been measured as a first step and will be presented in the ESIA Report. For the baseline noise levels noise measurements will be taken at the Project Area and closest residential unit. Coordinates and map of the measurement points are presented in the Table 6-4 and Figure 6-3., respectively.

Table 6-4. Coordinates of the Noise Measurements

	X (WGS 1984 UTM Zone 34N)	Y (WGS 1984 UTM Zone 34N)
Noise-1	459935	4954819
Noise-2	460068	4954870

Figure 6-3. Measurement Points

Noise survey will be conducted per WB General EHS Guidelines for Noise. Daytime and night-time measurements will be taken over one-hour intervals at each location.

The WB General EHS Guideline suggests that any increase in background noise levels should be limited to a maximum of 3 dBA where background noise levels already exceed WB guideline values.

6.4 Water Resources and Water Quality

6.4.1 Water Resources

The Project Area is located within the boundaries of the Sava River Basin. The Sava River Basin (Figure 6-4) is a major drainage basin of South-eastern Europe with a total area of 97,713.20 km^2 and is one of the most significant sub-basins of the Danube River Basin, comprising 12 % of this basin.

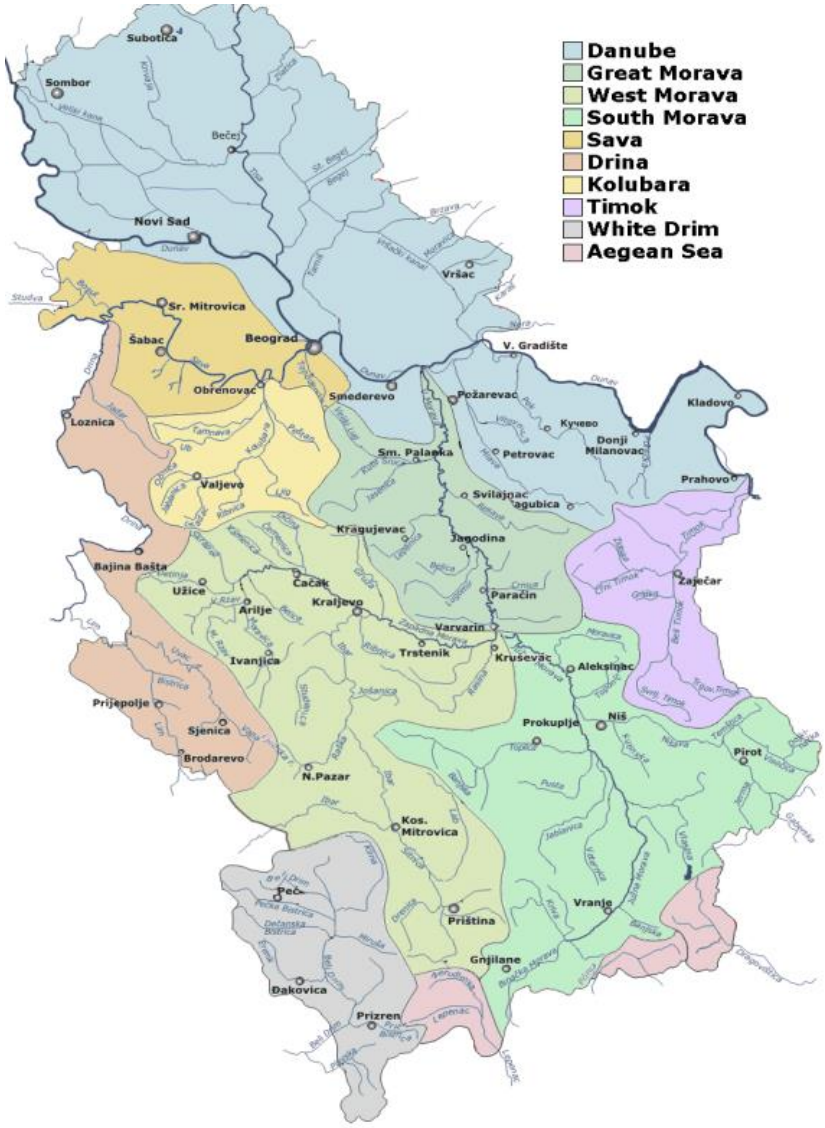

Figure 6-4. River Basins in Serbia **(Sava River Basin Management Report, 2014)**

As in 2005 the Serbia reported the following major water uses of Sava River:

- Thermal and nuclear power plants
- Public water supply
- Agricultural water use (Irrigation and Fish farms)
- Industry

Groundwater is the main source of drinking water in the Sava River Basin and an important water supply source for industry and agriculture (80-95 % of water is used for this purpose) (Sava River Basin Management Report, 2014).

6.4.2 Surface Water Quality

There are two main categorization of the surface water bodies in Serbia. The first categorization is defined as Water Quality Classes and the second categorization is the type of surface water bodies. The parameters which define the class, and the type of the water body is presented in Appendix-4 of the Decree.

According to the Decree on Water Classification (Official Gazette of RoS, 05/68), all surface waters are classified between I, II, IIa, IIb, III and IV river class. This Decree provides division of waters into 4 main classes (I-IV, with IIa and IIb subclasses), according to the degree of pollution and purpose. Class I rivers are the best quality (could be used for drinking in natural condition or after disinfection) surface waters while class IV surface waters are the worst (could be used after special treatment).

Decree on Water Classification (Official Gazette of RoS, 05/68) adopted specific water quality characteristics to define four classes of surface water quality, and these are provided in the table below.

Table 6-5. Classes of Surface Water Quality

Class	Description
I	Water bodies that are in their natural state or after disinfection can be used or exploited for supplying settlements with potable water, food industry and for breading of some certain species of fish (salmonids).
II	Water bodies that are suitable for swimming, recreation, water sports and for breeding some certain species of fish (cyprinids) and waters which are subject to normal methods of processing, and which, after processing, can be used to supply settlements with potable water and the food industry.
III	Water bodies that can be used for irrigation and industry, except the food industry.
IV	Water bodies that can be used or exploited for other purposes only after special treatment.

According to the Decree on Water Classification, water quality classes of the Sava River is given in Table 6-6.

Table 6-6. Classification of Surface Water Bodies According to the Decree on the Categorization of Watercourses

RIVER NAME	QUALITY CLASS (Official Gazette of the SFRY, No. 5/68)
The Sava Rive	II b

In addition to this classification stated above, water bodies are divided into six (6) types. According to the Regulation on Parameters of Ecological and Chemical Status of Surface Waters and Parameters of Chemical and Quantitative Status of Groundwater (Official Gazette of RoS, No. 74/11), thresholds for ecological status and class limits for ecological potential of surface water are prescribed for six (6) types of waters, which are even more

described through the Regulation on Determination of Surface and Groundwater Water Bodies (Official Gazette of RoS, No. 96/10). Types are valid only for Class I and Class II of surface watercourses due to the fact that excellent and good ecological status can only exist in these classes of watercourses.

The definitions of type classification are given below (The Republic of Serbia, 2015):

Table 6-7. Types of Surface Water Quality

Type	Description
1	Large lowland rivers dominated by fine sediments (the Danube River, the Sava River, the Great Morava River, the Tisza River, the Tamiš River, the Begej River and the Stari Begej River):
2	Large rivers dominated by medium sediments, excluding rivers in the Pannonian Plain
3	Small and medium watercourses up to 500 m.s.l. (mean sea level) dominated by coarse sediments
4	Small and medium watercourses above 500 m.s.l. dominated by coarse sediments
5	Watercourses in the Pannonian Plain (excluding type 1 watercourses)
6	Small watercourses outside of the Pannonian Plain not included in other types and watercourses not included in the rulebook that regulates this area

According to the Rulebook on Parameters of Ecological and Chemical Status of Surface Waters, and Quantitative and Chemical Status of Ground Waters ("Official Gazette RS" No. 74/11), types of water bodies is given in Table 6-8**Error! Reference source not found.**;

Table 6-8. Type Classification of Main Water Bodies in AoI of the Project

RIVER NAME	QUALITY CLASS (Official Gazette of RoS, No. 74/11)
The Sava River	Type 1

6.5 Wastewater

At present, urban wastewater from Belgrade is partially discharged into the Sava River and partially into the Danube River. It is apparent that a high proportion of urban wastewater in the Sava RB is discharged via the sewerage system into surface water without treatment.

The wastewater pollution load for the Sava River represents approximately 30-40% of the load generated from the central part of Belgrade. All discharge points on the Sava River are located near the confluence of the Sava and Danube (not more than 2 km or in the mixing zone) and therefore these discharges do not have a significant impact on the water quality of the upstream parts of the Sava River.

In the future, all urban wastewater from Belgrade will be treated at Veliko Selo WWTP and discharged into the Danube (Sava River Basin Management Report, 2014).

In this context, existing facility as Torlak institute's wastewater management will be detailed in ESIA of the Project. On the other hand, the Project as BSL-3 laboratory is intended to be constructed as dry-lab. Liquid waste per day is expected to be 5 litres and chemical decontamination of liquid waste is foreseen during the operation phase of the Project. Hence, there is no expected wastewater discharge to the receiving environment except for domestic wastewater. The ESIA report will include the disposal methods for the generated limited amount of liquid waste as well as the generated domestic wastewater.

6.6 Waste Management

Belgrade has a population of around 1.3 million of citizens in the inner-city area. According to preliminary 2011 census data, the population in the inner-city area has increased by about 10 %, which doesn't have significant influence on daily amount of generated waste per capita. Average daily amount of municipal solid waste generated in 2010 is 1,300 t/day, or 0.97 kg of waste generated daily per capita (based on quantities of generated waste.

The Public Utility Company "Gradska čistoća" is the only provider of municipal solid waste services, e.g., collection, transportation, and disposal. The waste collection service of the company is organized in ten functional units located on correspondent municipality (Popović, Filipović, & Božanić, 2012).

The existing facility as Torlak institute has an in-house developed "Waste Materials and Waste Management Policy" for the waste management in line with Serbian legislation. The concerned policy is defined including waste management plan for wastes with or without special treatment (waste material handling, storage and finally care), who is responsible for waste management and her/his duties. These wastes are as follows.

Wastes without special treatment

- Municipal waste: disposed of in garbage containers without any special treatment.
- Recycable waste: paper, glass, plastic, metals, electronic waste, etc.

Wastes with special treatment

- Chemical waste: chemicals that have expired or are not approved for use, oils and lubricants, substances that can be harmful to human health and the environment.
- Medical waste: used needles, syringes, cotton wool, gauze, microbiological substrates and the like. Medical waste also includes:
    - Biological waste: dead or sacrificed animals, body and tissue parts, tissue samples, secretions and excreta, blood products that cannot be used, etc.
    - Pharmaceutical waste: Pharmaceutical waste - live and inactivated vaccines, serums and expired medicines expired or otherwise unusable, etc.
- Technical waste: generated during the work of the service for technical and other similar tasks. It includes waste generated during construction or demolition too.

Detailed information on how and where wastes including medical, hazardous, and toxic wastes in the existing facility are disposed will be given in ESIA. On the other hand, the Project as BSL-3 laboratory is intended to be constructed as dry-lab. All the laboratory consumables are planned to be for single use. Solid waste per day is expected be 20 kg and decontamination of solid waste is planned to be on site by autoclaving during the operation phase of the Project. The final disposal method for the autoclaved wastes will be further discussed in the ESIA report.

6.7 Climate and Meteorology

Average monthly temperature data at Belgrade Meteorology Station are presented at Figure 6-5. The average maximum monthly temperature and the average minimum monthly temperature are approximately 30 and -2°C, respectively.

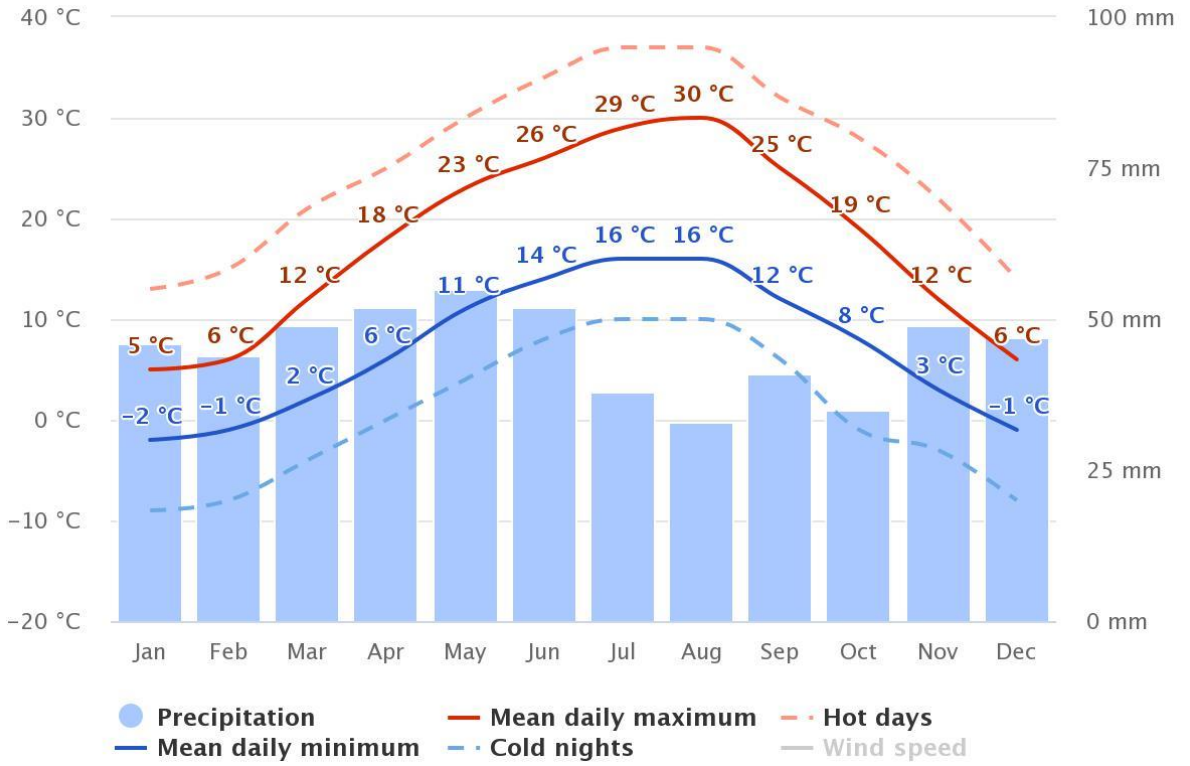

Figure 6-5. Average Daily Precipitation and Temperature

Depending on the atmospheric processes and relief characteristics of Serbia's territory, precipitation amount varies depending on the temperature and space. The general annual precipitation amount in the Country is 896 mm. The annual amount of precipitation increases with altitude. Annual precipitation over the Country ranges from 600 mm to 1,000 mm.

The majority part of Serbia has a higher amount of continental precipitation during warmer times of the year. Precipitation usually occurs in June and May. 12-13% of total annual

precipitation falls in June. The least amount of precipitation occurs in February and October with 5-6% of total annual precipitation. On the other hand, southwestern part of Serbia has Mediterranean precipitation regime based on relief, Mediterranean climate influence and mountain ranges' slopes and maximum precipitation occurs in November, December, and January while minimum precipitation occurs in August.

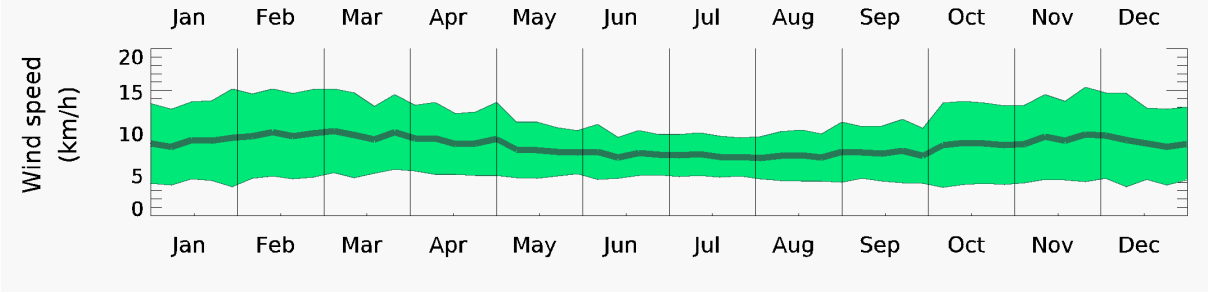

Figure 6-6. Average Wind Speed

6.8 Soil Quality

The Soil Map of Serbia (see Figure 6-7) consists of a large number of soil types and subclasses, each with a unique set of morphological, chemical and water-physical properties, each with different production characteristics (Licina, et al., 2011).

According to the census of agriculture (in 2012), 73.1% of the land in agricultural areas is cultivated. 20.7% of these areas consist of pastures and meadows. 4.8% of this area is used for fruit cultivation, 0.6% for vineyard and 0.7% for the garden (Pavlovic, Costic, Karadzic, & Mistrovi, 2017).

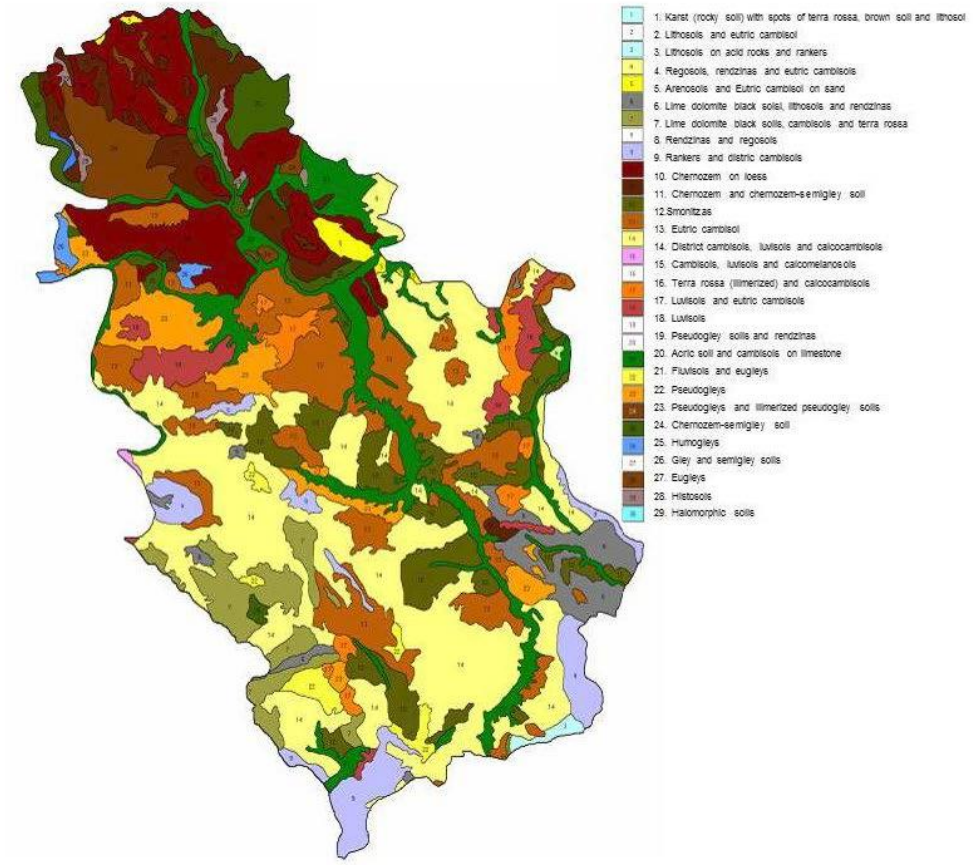

Figure 6-7. Soil Map of Serbia **(Serbian Environmental Protection Agency, 2015)**

The territory of Belgrade includes two regions. The first pedogeographical area, north of the Sava and the Danube, is the steppe and forest-steppe region of the Pannonian Plain. The second pedogeographical area extends south of the Sava and the Danube rivers. In the Pannonian Plain, the alluvial deposits on river terraces host fluvisols, gleysol, chernozems, and solonchaks (IUSS WORKING GROUP WRB, 2006). There are also loess plateaus with chernozems and salt marshes soils. South of the Sava and the Danube, Neogene sediments prevail. Overlying the sediments, eutric cambiosols developed, which dominate in the sequence: regosol–leptosol (rendzinas)–eutric cambisol– luvisol while the heavy sediments predominately contain clays (vertisol). In the areas of significant soil erosion there are many colluvial soils, and on the lower river terraces there are fluvisols, fluvic cambiosols and gleysols. Within Belgrade specifically in the urban area, technosols are common, especially in the area north of the Sava and the Danube rivers (Ilic, Rundić, & Calic, 2016).

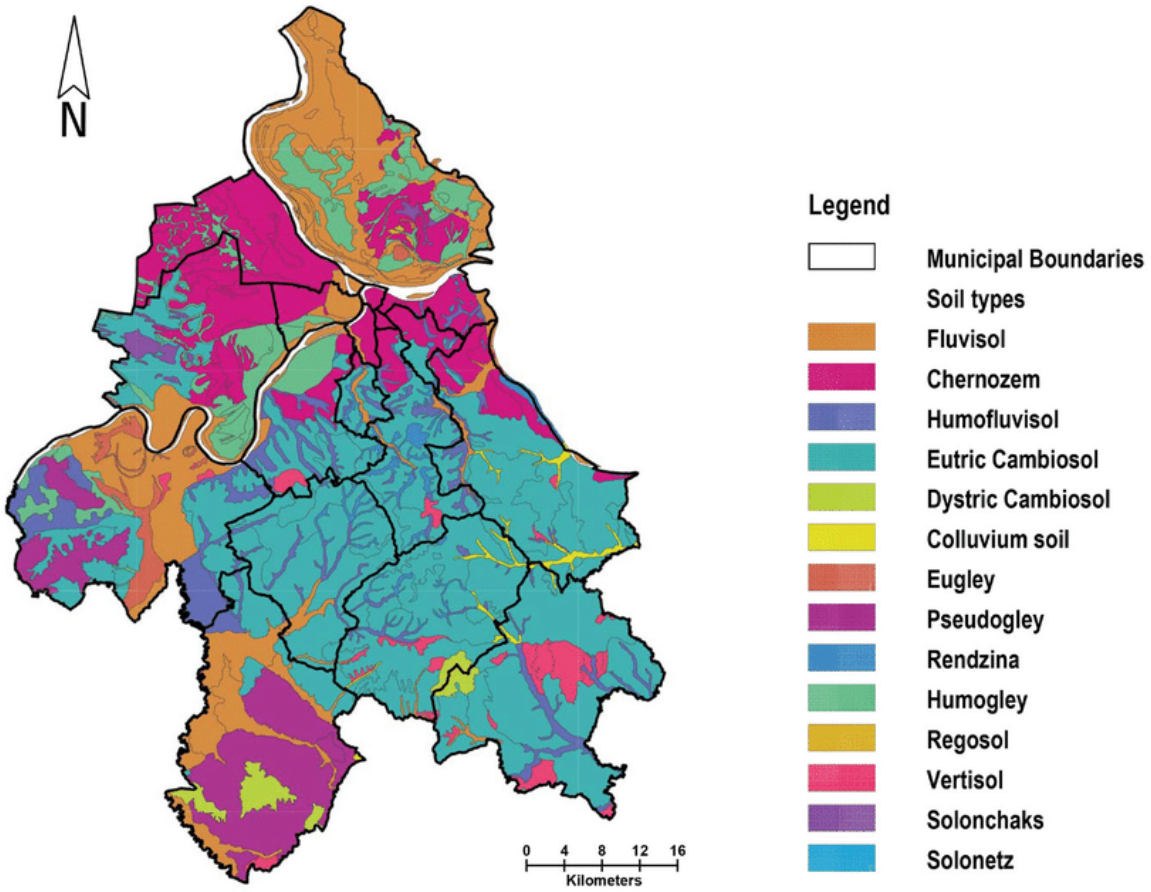

Figure 6-8. Soil Map of Belgrade

During the site visit, no legacy environmental issues that potentially require additional analysis and/or remediation have been identified. Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Project in case of any contamination is identified.

6.9 Geology

Serbia belongs to the Pannonian and particularly Peri-Pannonian regions in the scope of geological classification (Marovic, Djokovic, Pesic, Radovanovic, Toljic, & Gerzina, 2002). According to Horvath, et al. (2006), the Pannonian Basin is located in Eastern Europe. The Alpine, Carpathian and Dinaric Mountain belts environ the extensional basin of Neogene-Quaternary age. The basin is a wide zone of convergence between the Eurasian and African plates, the territory of Serbia can be defined in five geologic group that are a) Pannonian Basin b) Dinarides, c) Vardar Zone, d) Serbo-Macedonian Massif, e) Carpatho-Balkanides.

Belgrade, the capital of Serbia, is located in Southeast Europe, on the Balkan Peninsula, at the confluence of the Sava and the Danube Rivers. It covers an area of 3,227 km² of which almost 276.6 km² includes rivers and riparian land. Belgrade city area includes the southern margin of the Pannonian Basin, northern parts of the Vardar Zone and the Serbo-Macedonian Massif (MAROVIĆ et al., 2007).

Morphologically, two distinct units are clearly recognized: a) the southern part of the Pannonian Plain that represents vast plain and low land area located north of the Sava and Danube rivers, and b) a mountainous/hilly area (Mts. Šumadija, Avala and Kosmaj) located south of the Sava and Danube rivers. The primary morphological relief of the Belgrade area results from the tectonic movements that occurred during the Palaeogene and early Neogene. During the Oligocene Miocene, a few horsts (Mt. Avala, Mt. Kosmaj) and a large-scale tectonic basin (Pannonian Basin) were created, as well as small tectonic depressions south of the Pannonian Basin. The turbulent tectonic activity was accompanied by volcanism, which lasted until the end of the Miocene. Volcanic landforms created during this period are not preserved in the territory of Belgrade, instead igneous rocks from that period (Mt. Avala, Mt. Kosmaj) and pyroclastic material can be observed.

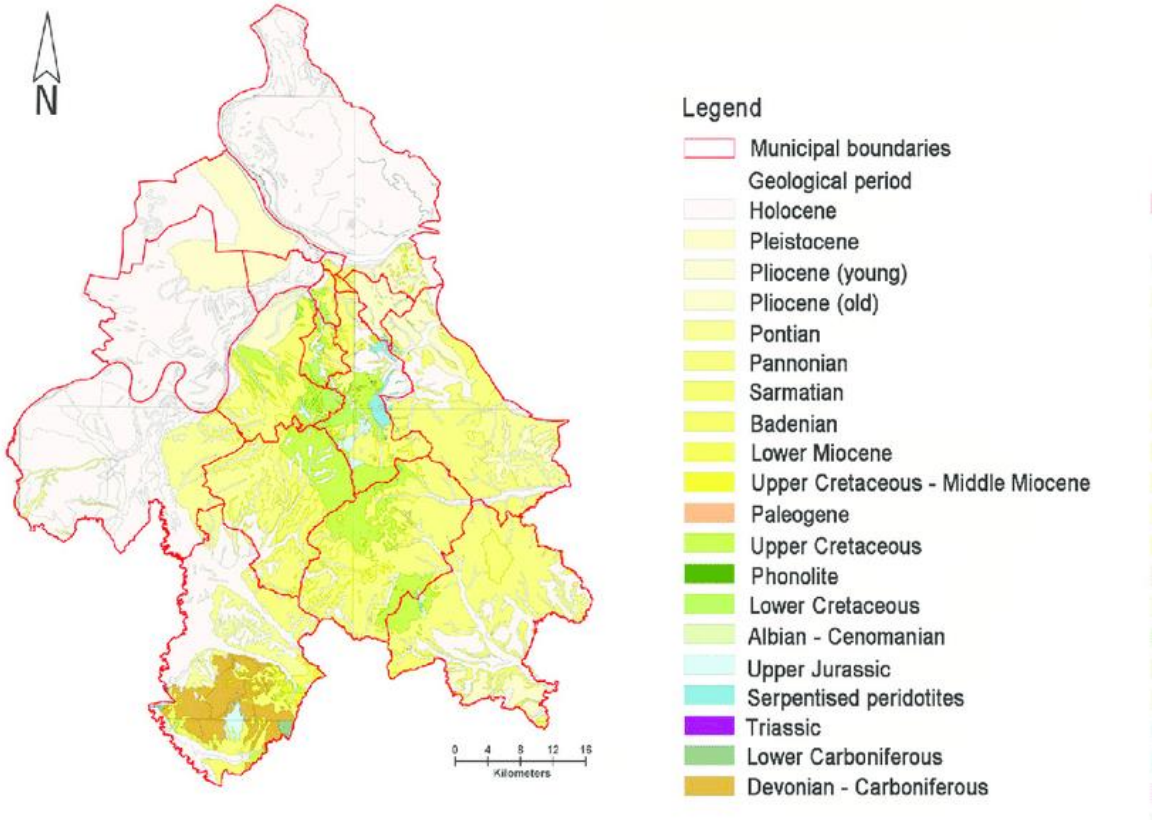

Figure 6-9. General Geological Map of Belgrade

Within the framework of the Project' ESIA, details about geological characteristics of the Project's AoI will also be given.

6.10 Ecological Features

Literature reviews was conducted to identify the ecological characteristics and habitats of the Project Area and AoI, to identify the species presents or likely to be presents in the Project Area and to identify Nationally Protected and Internationally Recognized Areas in the region where the project located.

Corine Land Cover (CLC) and European Nature Information System (EUNIS) data was used to assess the habitat structure of the area in the Geographic Information System (GIS).

According to EUNIS the project area located within the “J1.2 - Residential buildings of villages and urban peripheries”. No natural, modified, critical habitats are reflected in the existing habitat maps, which will be evaluated in detail as part of the ESIA. .

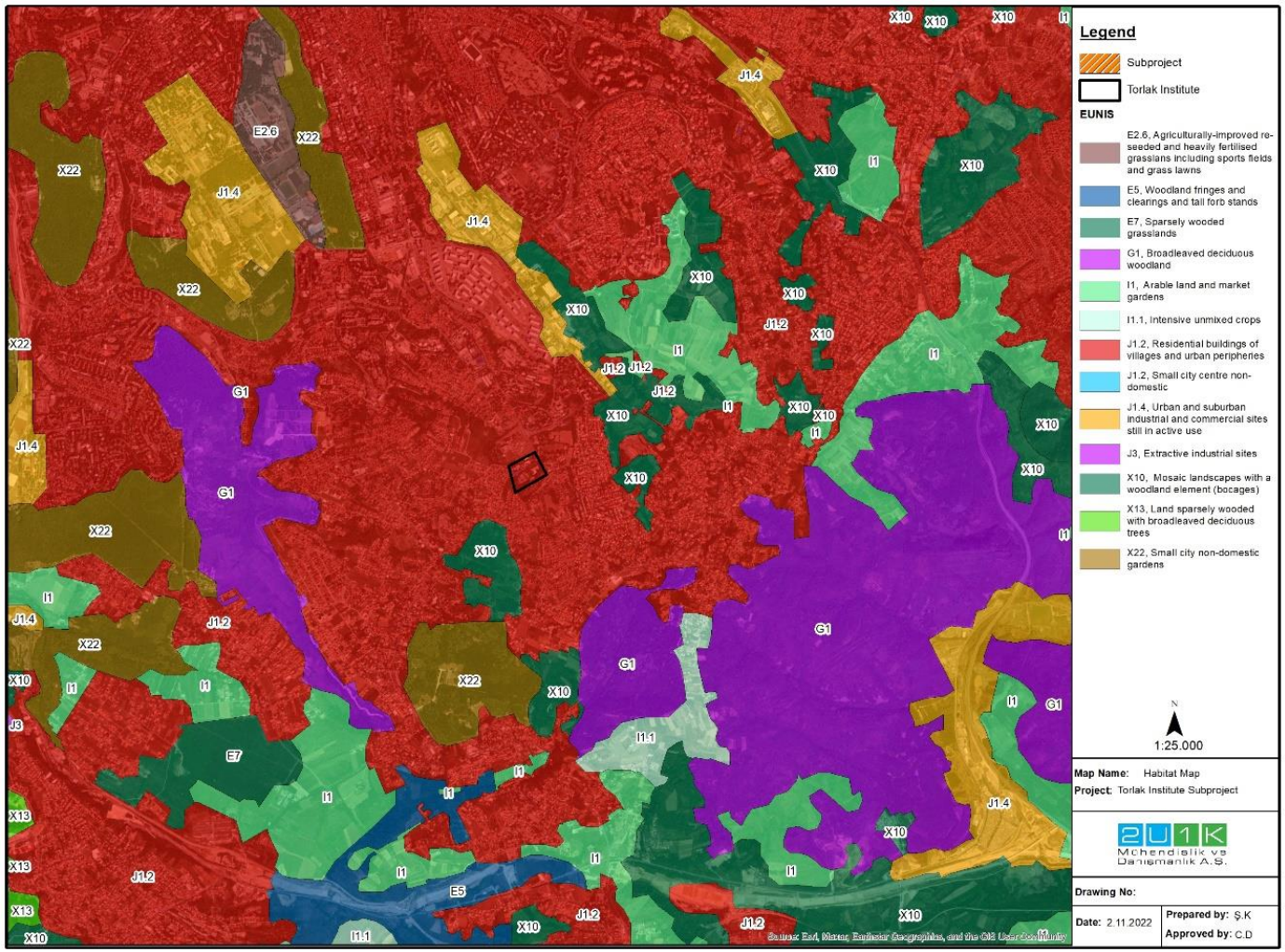

Figure 6-10. EUNIS Habitat Map

There are no Nationally Protected Areas within the Project Area and AoI. The closest protected area to the project area is the "Bajfordova Suma Natural Monument", which is approximately 2 km away by bird flight. The distances of protected areas to the Project Area are given in the Table 6-9 and Figure 6-11.

Table 6-9. Nationally Protected Areas

Nationally Protected Area	Distance
Bajfordova Suma Natural Monument	2 km
Miljakovacka Suma Natural Monument	2.5 km
Suma Kosutnjak Natural Monument	3.9 km
Avala Landscape of Outstanding Qualities	4.9 km

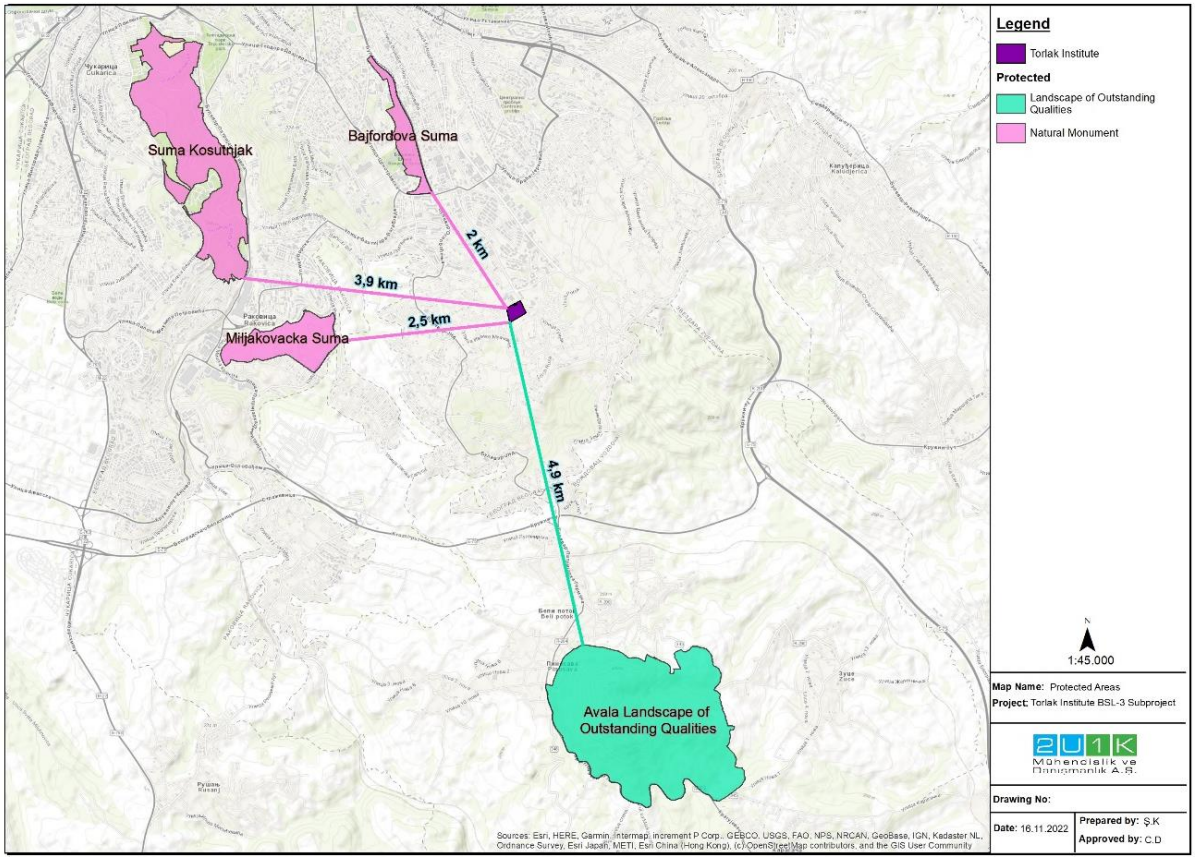

Figure 6-11. Nationally Protected Areas

Bajfordova Suma Natural Monument is 2.3 km long, up to 300 m wide. It covers an area of 39,61 hectares. Most common trees are pedunculate oak, red maple, silver maple and boxelder maple. The common birds are nightingale, blackcap, great_tit, magpie, woodpigeon and great spotted woodpecker. Mammals include hedgehog, moles, shrews, bats, the local brown subspecies of the red squirrel and least weasel.

Miljakovacka Suma is a protected natural monument since 2010. 105 plant species were recorded in the forest, such as rose, cherry, licorice, plane tree, ash, elm, linden, red and white hawthorn and cranberry. There are several insect species on the world list of endangered species found in this forest.

Suma Kosutnjak Natural Monument is declared protected due to significant spatial functions and bioecological values of the complex under forest vegetation and to preserve the habitat of diverse fauna of mammals, birds, insects, reptiles and amphibians, as well as signs of geological discovery.

Avala Landscape of Outstanding Qualities is extremely rich in vegetation and floristic elements. A large number of plant species, such as *Laburnum anagyroides* Medik., *Lilium martagon* L., *Prunus laurocerasus* L. and others are protected as natural rarities. Numerous bird species occur in oak, premontane and beech forests. The most important are *Falco tinnunculus, Strix aluco, Otus scops*, *Sitta europaea, Buteo buteo* and others. Of the total Avala flora, 15% are recognized and known medicinal plants.

There is an Internationally Recognized Area 8 km away from the project area named as *Usce* Save u Dunav Key Biodiversity Area (KBA) (Figure 6-12). Key Biodiversity Areas (KBAs) are the most significant areas considering their characteristics in terms of supporting biological components.

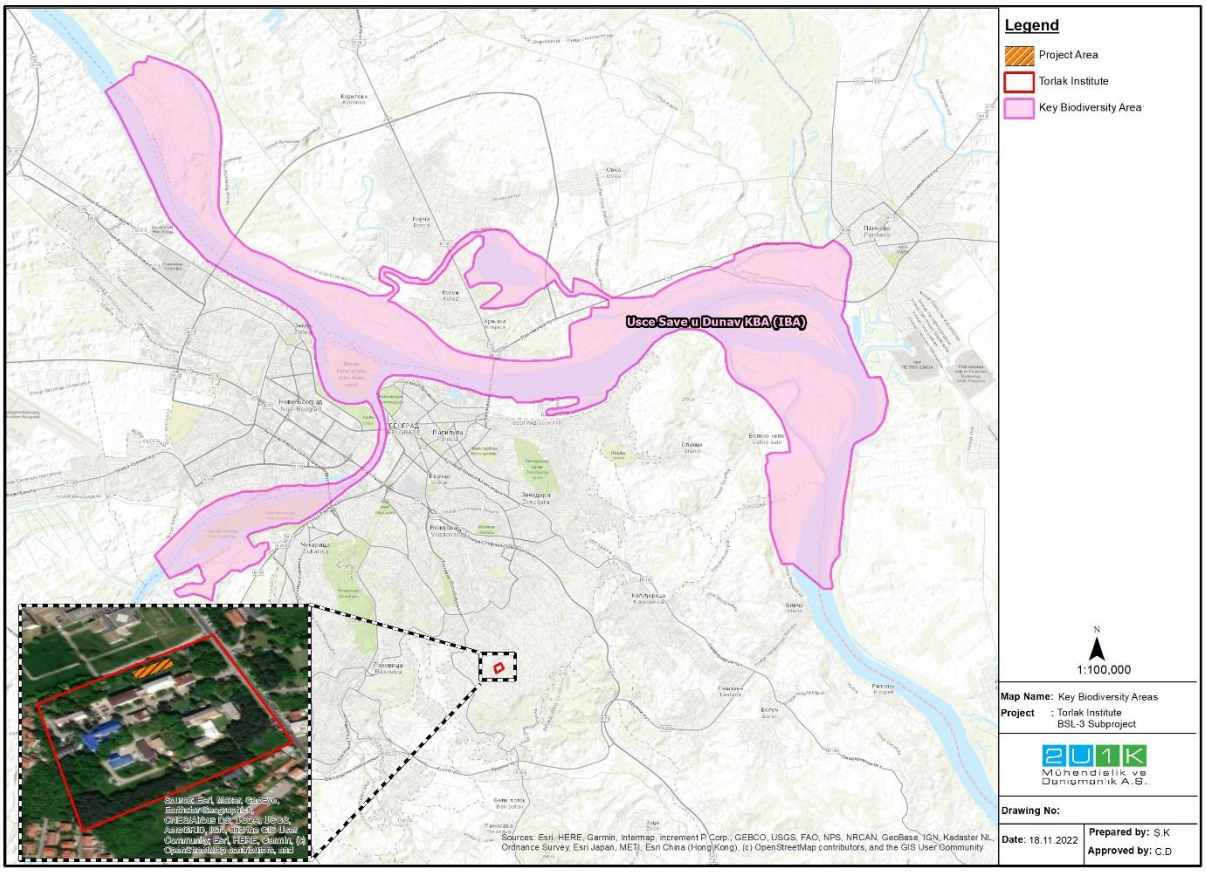

Figure 6-12. Internationally Recognized Area

Usce Save u Dunav KBA, comprises of 10 km of the Sava River and 39 km of the Danube within the cities of Belgrade and Pančevo. It connects several vast flood areas (Beljarica, Kožara, Veliko i Malo Ratno ostrvo) as well as river islands (Forkontumac, Čakljanac, Štefanac etc). An important part of the area is also the car fishpond "Mika Alas". The bordering forest are mainly comprised of industrial poplar species, with some patches of natural riparian forests.

In addition, the Project AoI does not include Internationally Recognized Areas of high biodiversity value, such as World Heritage Natural Sites, Biosphere Reserves, Ramsar Wetlands of International Importance, Important Bird Areas, and Alliance for Zero Extinction Sites. Neither of these areas is located in the vicinity of the Project Area.

After the biodiversity site surveys to be conducted, the species that are presents or are likely to be presents in the area will be determined, “Critical Habitat Assessment” will be carried out by examining the habitats in situ and appropriate mitigation measures will be presented in the ESIA.

6.11 Traffic

Vojvode Stepe Street is located in the north-east of the project area, which has two lanes, the nearest main road being round-trip. There is a single lane alleyway in the northwest of the project area. There are 3 intersections around the project area. There will be an entrance and exit to the project facility through a separate door. In order to determine the effects of the project on traffic, a special study, traffic counting will be carried out.

Table 6-10. Coordinates of the Traffic Study Locations

	X (WGS 1984 UTM Zone 34N)	Y (WGS 1984 UTM Zone 34N)
Traffic measurement location-1	460141	4954967
Traffic measurement location-2	460088	4955092

Figure 6-13. Measurement Points

6.12 Biosafety and Biosecurity

Torlak Institute has history working with and sera in research and production and has the capacity to build this level of facility with the help of external guide such as in consultancy,

engineering, commissioning. In Serbia, there is no established and certified BSL-3 laboratory for research and production purposes.

6.12.1 Biosafety

Serbia has national biosafety regulation in place that govern the implementation and enhancement of workplace safety and health for those involved in work processes, as well as persons encountered in the workplace. The legislation applies to all laboratories in the country.

According to the Joint External Evaluation (JEE) of International Health Regulations (IHR) core capacities of the Republic of Serbia, the Rulebook on Preventive Measures for Safe and Healthy Work during Exposure to Biological Hazards is one of the biosafety and biosecurity regulation in force. On biosafety and biosecurity, there is a substantial corpus of legal guidelines and rulebooks covering topics including safety at work, waste management, dangerous goods transport, dual-use goods, and dangerous pathogens.

The Directorate for Safety and Health at Work is responsible agency for the enforcement of biosafety legislation and regulations. Additionally, the Directorate is in charge for monitoring and evaluating the state of occupational health and safety and providing professional assistance in the field of employee health and safety.

The public health emergency response is part of the National Strategy for Emergency Protection and Rescue, and emergency response plan is publicly available, addressing plans for several contagious diseases of pandemic potential, this document is a framework for planning the response of all protective and rescue personnel in the event of a disaster or major accidents, including public health emergencies.

World Health Organization (WHO) provides international leadership on biosafety by addressing emerging issues, technologies and challenges, and providing guidance on best practice. WHO published the first edition of laboratory biosafety manual in 1983. It encouraged countries to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic biological agents in laboratories within their geographical borders. In the fourth edition of the WHO Laboratory biosafety manual, emphasis is placed on the importance of a “safety culture” that incorporates risk assessment, good microbiological practice and procedure (GMPP) and SOPs, appropriate introductory, refresher and mentoring training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions.

ESIA for the Project will be developed in compliance with WHO Laboratory Bio-Safety Manual (4th edition, 2020) in terms of biosafety along with the World Bank Group's applicable Environment, Health and Safety (EHS) guidelines, Biorisk Management:

Laboratory Biosecurity Guidance (2006) and other relevant international guidelines besides the national legislation requirements.

6.12.2 Biosecurity

There is no legislation and/or regulations related to biosecurity that address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed in place in Serbia.

According to Global Health Security Index, Country Score Justifications and References, 2021: Biosecurity requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed are not regulated by the Ordinance on Preventive Measures for Safety and Healthy Work with Biological Damages.

Currently, there is no regulations specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to background checks. However, the internal rules of the Dr Milan Jovanovic Batut Institute for Public Health, Institute for Public Health of Vojvodina, Clinic for Infectious and Tropical Diseases, and Directorate for National Reference Laboratories which might contain such data.

The information regarding on the safe and secure transport of infectious substances has publicly available information based on the Law on the Transport of Dangerous Goods to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential.

In conclusion, ESIA of the Project will particularly include WHO Biorisk Management: Laboratory Biosecurity Guidance (2006, WHO/CDS/EPR/2006.6), ISO 35001: 2009 Bio-risk Management for Laboratories and concerned GIIP’s to cover all biosecurity requirements.

6.13 Social Baseline Conditions

Social baseline conditions given in this section are based on desk-based studies. Interviews will be conducted with stakeholders including vulnerable groups who are expected to be affected during the ESIA. People and organizations that will be indirectly affected by the Project will also be interviewed to gather information on social baseline conditions.

Site specific data such as population, demographics, employment, education, services, land ownership etc. will be gathered through desktop studies and site surveys. In addition,

country-wide baseline information will be provided, and demographic characteristics of Serbia and Belgrade will be included in this section. Site surveys to obtain information on the social baseline conditions will include (community level surveys and interviews with stakeholders which have already been identified in SEP) and also with governmental agencies. Baseline data will be used in the ESIA to identify impacts and recommend communication practices with all stakeholders, including citizens.

6.13.1 Population and Demographics

The Republic of Serbia is located in South-Eastern Europe and covers the area of 88,361 km^2. Serbia shares a border with eight neighbouring countries as; Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Montenegro, Romania and the Northern Macedonia (United Nations Economic Commission for Europe, 2007).

According to Statistical Office of the Republic of Serbia, the estimated population is 6,982,604 (2018). The natural increase rate equals -5.4‰. The birth rate equals 9.2‰, and the death rate equals 14.6‰. The population average age is 43.2 years. In 2018 the life expectancy for males equals 73 years, and for females 79 years. The average age of mother at giving first live birth is 28.6. The leading death causes, both for male and female population, are bloodstream system diseases (Statistical Office of the Republic of Serbia, 2019).

The official language is Serbian written in Cyrillic, although Latin script is also widely used. In the areas inhabited by ethnic minorities, the languages and scripts of the minorities are in official use (United Nations Economic Commission for Europe, 2007).

6.13.2 Economy and Employment

Serbia is an upper middle-income country, according to the World Bank Group economy classification. The country relies on manufacturing and exports, directed largely by foreign investment. According to Fiscal Strategy, a document made by the Serbian Ministry of Finance, predicts that in 2019 GDP will grow around 3.5%, and 4% in 2020 and 2021. Top five sections in export were: Electrical machines and apparatus, road vehicles, iron and steel, rubber products and non-ferrous metals (as of 2018) (China - CEE Institute, 2019).

Serbia is one of the top 10 European countries that exports agricultural and food products (Public Policy Research Center, 2019). In 2018, the area of 754,048 ha was sown in the autumn sowing season, which in comparison to the final results of the autumn sowing season 2017 indicates a decrease by 7.3%. Observed by crop cultures, decreased values were noted for wheat (by 10.6%), barley (by 2.0%), ray (by 19.7%), oat (by 26.7%) and oilseed rape (by 17.2%). When related to the ten-year average of autumn sowing values

(2008 – 2017), the areas under wheat are larger by 0.5% (Statistical Office of the Republic of Serbia, 2019).

In 2018, the average gross salaries and wages amounted to RSD 68,629, while the average net salaries and wages (tax and contributions excluded) amounted to RSD 49,650. Related to 2017, the average gross salaries and wages increased by 6.0% in nominal terms, and by 3.9% in real terms, while the average net salaries and wages (tax and contributions excluded) increased by 6.5% in nominal terms, and by 4.4% in real terms. In 2018 the total number of registered employed amounted to 2,131,079, presenting increase of 3.3% if related to 2017. In comparison to the year 2017 the number of employed persons increased in all regions. The employment growth rate was most expressive in Region Vojvodine (4.1%), while the lowest growth rate was notable in Region Južne i Istočne Srbije (1.8%).

The largest share in individual consumption of households goes to expenditures for food and non-alcoholic beverages by 34.3% and housing, water, electricity, gas and other fuels by 16.7% (Statistical Office of the Republic of Serbia, 2019)

6.13.3 Health

The health care system in Serbia is based on a network of public health institutions funded by the National Health Insurance and from the state budget. Access to public health institutions is subject to health insurance. Preventive and curative services are provided at the local level in primary health care centres. Secondary medical care is offered in paediatric departments of local and regional general hospitals or outpatient clinics, and in specialized hospitals for children or adults. Tertiary medical care is provided by inpatient or outpatient subspecialty services in 5 major university children's clinics (Bogdanovic, Lozanovic, Milica, & Jovanovic, 2016).

The average life expectancy of Serbian people is 75.9 years, where for males it is 73 years and for females 79 years. The death rate is estimated to be 13.6 death per 1000 people and the birth rate is 8.6 births for every 1000 people. The fertility rate is pretty low being 1.44 children per woman and takes 208th place in the world rating (Central Intelligence Agency, 2018).

Health services provided to local people will be investigated during the ESIA phase.

6.13.4 Education

The educational system in Serbia includes preschool, primary, secondary, and higher education. The total duration of compulsory education in Serbia is 9 years. Children enter compulsory education at the age of 5½, when they start the pre-school preparatory programme, followed by 8 years of primary education (EURYDICE).In 2018 the total of 1,248,280 persons were covered by educational activity on certain level: preschool education

(17.5%); primary education (42.3%), upper-secondary education (20.2%), and higher education (20%). (Statistical Office of the Republic of Serbia, 2019)

However, Roma people have low enrolment and completion of education due to received discrimination. (EU's Country Report on Serbia , 2019) One-third of Roma do not complete compulsory education and only 11.5% of them graduate secondary school, only 0.7% of Roma people receive a university degree. (Bertelsmann Stiftung's Transformation Index, 2018).

6.13.5 Infrastructure Services

This section will contain the outputs of the fieldwork to be carried out at the community level. The sources of drinking, potable and agricultural water; public roads; transportation; wastewater and solid waste disposal methods, etc. will be investigated.

6.13.6 Cultural Heritage

There is no cultural property registration record that needs to be protected in the area where the Project will be built. However, as in any excavation work, it is possible to come across a cultural heritage item by chance. "Chance Find Procedure" will be added to the Project's ESIA, and project staff will receive training on this procedure.

6.13.7 Land Ownership

The Project Area belongs to the Project Owner and there are already institute buildings in the area according to Cadastral Plan. The Project Area is completely surrounded by fence. During the interviews with the representatives of the Project Owner, it was stated that the land is in public ownership. There are no informal or formal users on the land. No land acquisition will be required under the Project. Similarly, there will be no physical and/or economic displacement under the Project.

6.13.8 Vulnerable Groups

Vulnerable/disadvantaged individuals or groups refers to individuals and groups that are likely to be more vulnerable to Project-related impacts. Persons to which adverse project impacts may disproportionately fall on or those likely to be excluded/unable to access Project benefits. Such groups may often not have a voice to express their concerns or understand the impacts of a project. The vulnerability may stem from person's origin, gender, age, health condition, economic deficiency and financial insecurity, disadvantaged status in the community (e.g. minorities or fringe groups), dependence on other individuals or natural resources, etc. Engagement with the vulnerable groups and individuals often requires the application of specific measures and assistance aimed at the facilitation of their participation in the project-related decision-making so that their awareness of and input to the overall

process are commensurate to those of the other stakeholders. The vulnerable groups identified for the Project are as follows:

- **Front line health staff:** They may be exposed to direct exposure during the operation phase of the project. They are more likely to be affected by OHS risks than other employees.
- **Women staff:** They may be exposed to direct exposure during the operation phase of the project.
- **Staff with disabilities:** They may be exposed to direct exposure during the operation phase of the project.
- **Retired elderly and people with disabilities and chronical diseases in home lockdown and disabled people:** Their access to participation activities may be limited due to certain constraints. Their direct participation in decision-making propcess should be encouraged.
- **Households below poverty line that could not afford medicine, private doctors services, adequate nutrition:** They may be more affected by exposure to any impacts (dust, noise, traffic, unexpected accidents, etc.) during both the construction and operation period of the project / these impacts may take more time to be reversed.
- **Single parent headed households, male and female (with children up to 14 years; without some other relatives in the household):** Single parents are more likely to live in poverty when compared to cohabiting couples, and single mothers are much more likely to be poor when compared to single fathers. Special attention should be paid to the single parent in decision-making processes.
- **Homeless and** Roma population living in unhygienic settlements (enclaves) without water facilities, sewage, improvised houses**;** They are more sensitive to any potential negative impacts from the project.
- **Waste pickers:** It is important that they participate in consultation processes against diseases that can be transmitted from waste.

In the field work, vulnerable group screening will be carried out in community level surveys. The approach to vulnerable/disadvantaged individuals or groups in order to minimise any impacts arising from the Project is included in the Stakeholder Engagement Plan.

6.13.9 Information Disclosure

The project was disclosed to the public by the Serbian Ministry of Health through its website[5]. In the ESIA phase, a study will be conducted on the level of stakeholders' knowledge about the project and the ways in which they prefer to access information.

A public participation meeting (PPM) will be organised once the Scoping Report is finalised. At this meeting, a non-technical summary of the Project, consultation methods and the grievance mechanism will be introduced. In addition, suggestions, complaints and requests for information will be received from all interested persona and will be adequately and timiel addressed

The information provided from this meeting will contribute to the ESIA report. After the ESIA report is disclosed, a second PPM will be organised and the impacts discussed in the ESIA and the measures to be taken to address them will be shared with stakeholders. The consultation during ESIA will also enable the stakeholders to have awareness on the feedback mechanisms proposed by the project. The PIU social specialist prescribes the procedure for public consultations, and ensures that all important requests are fulfilled

All participants in the SEP will be invited to stakeholder engagement activities throughout the life of the project, including but not limited to: project staff, citizens, government agencies, NGOs, nearby communities, vulnerable groups/individuals.

[5] https://www.zdravlje.gov.rs/vest/372445/projekat-izgradnje-dijagnosticko-istrazivackog-objekta-sa-laboratorijom-treceg-nivoa-bioloske-bezbednosti-u-okviru-instituta-za-virusologiju-vakcine-i-serume-torlak.php

7 KEY ENVIRONMENTAL AND SOCIAL IMPACTS

In this Chapter, a scoping level assessment of the potential impacts from the Project is presented. The assessment at this stage is based on a general evaluation of the nature and extent of the Project activities and the current vulnerability of the potentially affected environmental and social elements in the likely AoI. Furthermore, WB's guidelines and ESF are taken into consideration.

The expected environmental and social issues for construction and operation phases listed in Table 7-1 in the impact matrix below are considered as warranting further attention in the relevant parts of the ESIA.

Table 7-1. Impact Matrix

Topic	Potential Impacts		Evaluation Criteria[6]
Air quality	**Construction Phase**	Fugitive dust and PM emissions due to: soil/earth movements, transport of excavated soils outside the Project Area, excavations, vehicle movements, stockpiles, unpaved surfaces. Exhaust emissions from the construction machinery and vehicles.	WB ESF/ESS1/ESS3 WB EHS Guidelines National Legislation Directive 2008/50/EC Directive 2004/107/EC
	Operation Phase	Emissions from heating system Emissions from lab ventilation	WB ESF/ESS1/ESS3 WB EHS Guidelines National Legislation Directive 2010/75/EU
Climate	**Construction Phase**	Greenhouse Gases (GHGs) Emissions from the construction machinery and vehicles.	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2008/50/EC c 2004/107/EC
	Operation Phase	Greenhouse Gases (GHGs) Emissions from the vehicles. GHGs emissions due to heating system	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2010/75/EU
Acoustics	**Construction**	Noise from the construction machinery and vehicles. No significant vibration	WB ESF/ESS1

[6] **Evaluation Criteria:** Impact assessment criteria includes national legislation, international standards, guidelines and regulations but not limited. Detailed assessment criteria will be given in ESIA Report.

Topic	Potential Impacts		Evaluation Criteria[6]
(Noise and vibration)	**Phase**	impact is expected from construction because there will not be any blasting operations involved.	WB EHS Guidelines National Legislation Directive 2002/49/EC
	Operation Phase	Potential noise generating equipment (depending on location of ventilation system, type of generator etc.)	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2002/49/EC
Geology, soil	**Construction Phase**	Excavation works during construction. Disturbance of topsoil during site clearance and potential degradation of topsoil quality due to improper management of topsoil. Potential accidental releases or leaks of fuel or chemicals from construction equipment, hazardous chemicals and waste storage areas.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
	Operation Phase	Potential accidental releases or leaks of chemicals, wastewater and due to project traffic.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
Water resources and quality	**Construction Phase**	Settled dust and sediment transport from construction site. Potential accidental releases or leaks. Water use for construction activities and at camps (if to be built) during construction phase.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
	Operation Phase	Potential accidental releases or leaks of chemicals, wastewater and due to project traffic.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management

Topic	Potential Impacts		Evaluation Criteria[6]
			Directive 2006/118/EC Directive 2008/98/EC
Wastewater	**Construction Phase**	Management of the additional wastewater generated from the construction workers.	WB ESF/ESS1/ESS3 WB EHS Guidelines Regulation on the removal and purification of atmospheric and wastewater on the territory of Belgrade
	Operation Phase	Bypass of untreated or insufficiently treated wastewater due to under design or equipment failure in the institute. Failure to meet the effluent discharge standards due to improper management of the healthcare unit. Failure to meet the effluent discharge standards due to risks of illegal discharges (regarding quality of wastewater discharged to sewer system particularly).	WB ESF/ESS1/ESS3 WB EHS Guidelines Regulation on the removal and purification of atmospheric and wastewater on the territory of Belgrade
Waste management	**Construction Phase**	Excavated soil and overburden. Solid wastes (including domestic and packaging wastes). Construction wastes (such as steel, cables, other types of construction materials). Hazardous wastes (including waste oil, oily rags, waste batteries and accumulators and similar). Packaging wastes	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2008/98/EC
	Operation Phase	Solid wastes (including domestic and packaging wastes). Hazardous wastes (including chemical residuals, waste oil, oily rags, waste batteries and accumulators and similar). Medical wastes (pathological, infectious, biological, blood, sharps, pharmaceutical etc.) Radioactive wastes Contaminated wastes Toxic waste	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Rulebook on medical waste management Directive 2008/98/EC
Material	**Construction**	Use of large quantities of construction materials.	WB ESF/ESS1/ESS3

Topic	Potential Impacts		Evaluation Criteria[6]
resources	**Phase**	Transportation of construction materials. Consumption of fuel by vehicles and machinery. Water and energy usage during construction.	WB EHS Guidelines
	Operation Phase	Additional electricity (and also water) requirement during the operation phase Supply of chemicals and laboratory equipment	WB ESF/ESS1/ESS3 WB EHS Guidelines UN Model Regulations for the Transport of Dangerous Goods Directive 2008/68/EC
Terrestrial and aquatic ecology	**Construction Phase**	Habitat loss Clear-cut of trees within Project Area	WB ESF/ESS6 WB EHS Guidelines Law on Nature Protection Council Directive 92/43/EEC Council Directive 2009/147/EC
	Operation Phase	No major impact is expected.	WB ESF/ESS6 WB EHS Guidelines Law on Nature Protection Council Directive 92/43/EEC Council Directive 2009/147/EC
Cultural heritage	**Construction Phase**	Possible damage or loss of artefacts if any	WB ESF/ESS8 WB EHS Guidelines European Convention on the Protection of the Archaeological Heritage Convention concerning the Protection of the World Cultural and Natural Heritage
	Operation Phase	No major impact is expected.	WB ESF/ESS8 WB EHS Guidelines European Convention on the Protection of the Archaeological Heritage Convention concerning the Protection of

Topic	Potential Impacts		Evaluation Criteria[6]
			the World Cultural and Natural Heritage
Traffic and transport	**Construction Phase**	Increased traffic load Impacts on roads due to transport of constructions materials.	WB ESF/ESS4 WB EHS Guidelines Law on Planning and Construction
	Operation Phase	No major impact is expected.	WB ESF/ESS4 WB EHS Guidelines Law on Planning and Construction
Visual impacts	**Construction Phase**	Visual impacts from the construction and excavation works and changes in the landscape. Nuisances due to potential, dust, wastes and temporary storage areas.	WB ESF/ESS1 WB EHS Guidelines
	Operation Phase	Change in the landscape and visual impacts from the institute.	WB ESF/ESS1 WB EHS Guidelines
Socio-economic impacts	**Construction Phase**	Increased employment. Nuisances to the nearby communities and nearby businesses due to potential odour, dust, and noise. Potential impacts on vulnerable/disadvantaged groups/individuals. Potential impacts on community, health, safety and security.	WB ESF/ESS1 WB ESF/ESS4 WB ESF/ESS 10 WB EHS Guidelines
	Operation Phase	Increased employment. Increase in diagnostics capacity. Increased production of vaccines. Potential impacts on vulnerable/disadvantaged groups/individuals (disrupted participation in consultation processes and greater vulnerability to potential adverse impacts). Potential impacts on nearby communities and citizens of Belgrade. Potential impacts on community, health, safety and security.	WB ESF/ESS1 WB EHS Guidelines WB Directive on disadvantaged and Vulnerable Groups
Labour and Working Conditions	**Construction Phase**	Non-compliance with national and international labour and working conditions OHS risks from construction works. Potential SEA/SH induced impacts.	WB ESF/ESS2 WB EHS Guidelines
	Operation	Non-compliance with national and international labour and working conditions	WB ESF/ESS2

Topic	Potential Impacts		Evaluation Criteria[6]
	Phase		WB EHS Guidelines
Occupational health and safety	**Construction Phase**	Activities with increased risks during the construction phase (working with machinery, noise, extreme weather conditions, etc.). Risks from insufficiently trained and/or inexperienced personnel to conduct these activities. Exposure to hazardous chemicals and wastes Life and fire safety during construction. Improper sub-contractor management. Insufficient construction camp conditions (if any)	WB ESF/ESS2 WB EHS Guidelines Law on Occupational Safety and Health Council Directive 89/391/EEC
	Operation Phase	Risks from insufficiently trained and/or inexperienced personnel to conduct the activities in the institute. Health risks to the workers and personnel, including infection during biologic tests in the institute. Exposure to hazardous chemicals and wastes Potential exposure to diseases during laboratory studies Health and safety risks due to potential in-situ accidents involving chemicals used for operation. Life and fire safety during operation.	WB ESF/ESS2 WB EHS Guidelines Rulebook on preventive measures for safe and healthy work related to exposure to biological hazards Council Directive 89/391/EEC Council Directive 2010/32/EU Council Directive 2013/59/Euratom Directive 2002/98/EC Directive 2004/23/EC Directive 2003/94/EC Directive 2005/28/EC
Community health, safety, and security	**Construction Phase**	Problems arising from the dust, noise, odour generation. Increased risks from the increased traffic by construction machinery and workers. Adequacy of Emergency Preparedness and Response Effective Communication and Community Notification	WB ESF/ESS4 WB EHS Guidelines Law on Public Health
	Operation Phase	Risks to the community from the operational failures of institute after the commissioning of the Project.	WB ESF/ESS4 WB EHS Guidelines

Topic	Potential Impacts		Evaluation Criteria[6]
		Life and fire safety during operation. Biosafety and biosecurity failure due to accidents, unexpected events (flood, sabotage, fire etc.) Impact of escaping of infectious agents from BSL-3 containment. Public reactions in case of non-transparent communication sharing. Adequacy of Emergency Preparedness and Response Effective Communication and Community Notification	Law on Public Health WHO Laboratory Bio-Safety Manual (LBM) WHO Biorisk Management: Laboratory Biosecurity Guidance Directive 2001/83/EC Directive 2002/98/EC Directive 2004/23/EC Directive 2003/94/EC Directive 2005/28/EC
Cumulative impacts/risks	**Construction Phase**	Added impacts from the construction phases (dust, noise, traffic, etc.) or operations of other projects around the Project Area and in the same district.	WB ESF/ESS4 WB EHS Guidelines
	Operation Phase	The potential cumulative impacts of the project-generated wastewater and waste on the AoI. Increased stress on waste collection network and final disposal facilities Community disease and safety risks from from patogens spill over during operation Diseases risks due to operation of the laboratory Increased traffic load	WB ESF/ESS4 WB EHS Guidelines

The WB ESSs will be taken into consideration in the ESIA studies and development of the relevant mitigation measures and monitoring plan. Details regarding these standards and the implications for the Project will be described in the ESIA Report by the references of the relevant EHS guidelines that give the necessary thresholds, criteria, and good management methodologies

8 STAKEHOLDER ENGAGEMENT AND INFORMATION DISCLOSURE

8.1 Stakeholder Identification

A stakeholder is defined as any individual, organization or group which is potentially affected by the Project, or which has an interest in the Project and its impacts. The objective of stakeholder identification is to establish which stakeholders may be directly or indirectly affected – either positively or negatively - ("affected parties") or have an interest in the Project ("other interested parties").

It is important that particular effort is made to identify any disadvantaged and vulnerable stakeholders who may be differentially or disproportionately affected by the Project or who may have difficulty participating in the engagement and development processes. Stakeholder identification is also an on-going process and will require regular review and update. The Stakeholder Engagement Plan has been prepared for this project to identify project stakeholders and establish engagement methods for the future of the Project.

For the purposes of effective engagement, stakeholders of the proposed project(s) can be divided into the following core categories:

- Affected Parties – persons, groups and other entities within the Project Area of Influence (AoI) that are directly influenced (actually or potentially) by the project and/or have been identified as most susceptible to change associated with the project, and who need to be closely engaged in identifying impacts and their significance, as well as in decision-making on mitigation and management measures;
- Other Interested Parties – individuals/groups/entities that may not experience direct impacts from the Project but who consider or perceive their interests as being affected by the project and/or who could affect the project and the process of its implementation in some way; and
- Vulnerable Groups – persons who may be disproportionately impacted or further disadvantaged by the project(s) as compared with any other groups due to their vulnerable status, and that may require special engagement efforts to ensure their equal representation in the consultation and decision-making process associated with the project.

Stakeholder identification has been an on-going process and different issues are likely to concern different stakeholders. Therefore, stakeholders have been grouped based on their connections to the Project. Understanding the connections of a stakeholder group to the Project helps identify the key objectives of engagement.

Identified stakeholder groups and their level of influence cross-referenced with their interest they may have in the project will determine the type and frequency of engagement activities necessary for each group. Using the color coding of interest and influence matrix below will help determine where to concentrate stakeholder engagement efforts and why.

The table below identifies the key stakeholder groups and categories, the nature of their interest in the project and their level of interest in and influence over the project and is based on the color code in the matrix below:

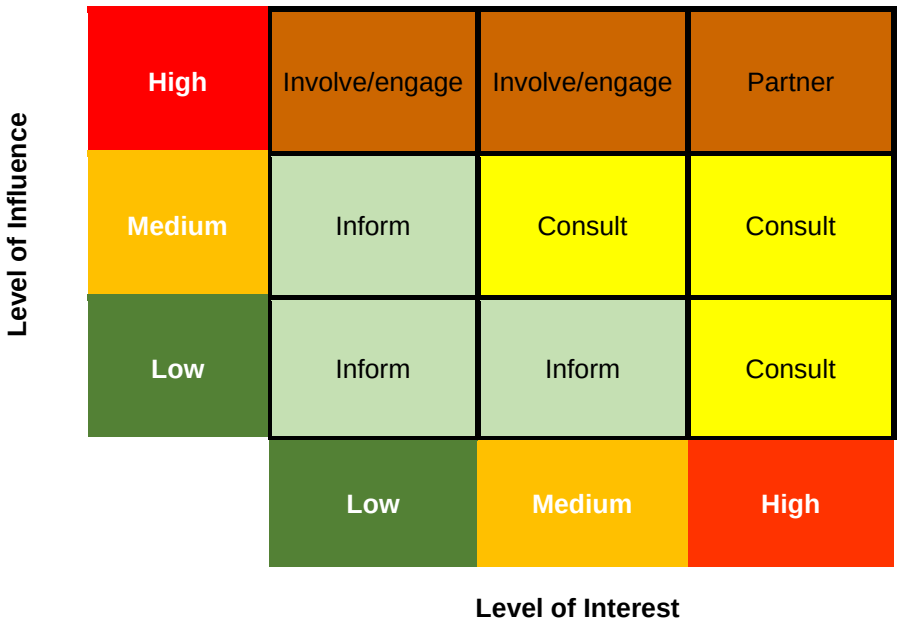

Table 8-1 presents the interested and affected stakeholders within the scope of the Project.

Table 8-1. Stakeholder Groups

Stakeholder groups		Level of interest	Level of influence	Level of engagement	Nature of Interest
Project Affected Parties	**Project Workers**				
	• Contractors and workers; • Health Care Workers and supportive staff; • Institute management.	High	High	Partner	Interest in OHS and management plans during construction and operation periods of the project.

Stakeholder groups	Level of interest	Level of influence	Level of engagement	Nature of Interest
Technical				
• Project designer; • ESIA Consultants.	High	Medium	Consult	Potential concerns over regarding environmental and social impacts and project designs
NGO's				
• NGOs especially ones dealing with social dialogue, community health and safety, ecology and vulnerable group.	High	Medium	Consult	Potential changes in potential environmental and social conditions
Local Communities				
• Local communities within the Project area	High	Medium	Consult	Concerns about health, safety, traffic, construction related impacts (noise, dust, damages, emissions, vibrations)
Nearby Businesses and Government Institutions				
• Local Businesses; • Schools and Faculty of Pharmacy; • Healthcare Institutions.	Medium	Low	Inform	Concerns about disruption of business and operation

Stakeholder groups		Level of interest	Level of influence	Level of engagement	Nature of Interest
					activities
Project Interested Parties	**Government / Authorities**				
	• Ministry of Health; • Ministry of Environmental Protection; • Ministry of Construction, Transport and Infrastructure; • Ministry of Labour and Social Policy; • Vozdovac Municipality; • Academic Institutes.	High	High	Partner	Institutional and legal arrangements, regulations
Vulnerable Groups	**Vulnerable Groups/Individuals (directly affected by the project)**				
	• Front line health staff; • Women staff; • Staff with disabilities; • Waste pickers.	High	Medium	Consult	Access to participation activities, greater exposure to potential adverse impacts
	Vulnerable Groups/Individuals (might be affected)				
	• Retired elderly and people with disabilities and chronical diseases in home lockdown; • Disabled; • Households below poverty line that could not afford medicine, private doctors services, adequate nutrition; • Homeless persons; • Single parent headed households, male and female (with children up to 14 years; without some other relatives in the household); • Roma population living in unhygienic settlements (enclaves) without water facilities, sewage, improvised houses.	Low	Low	Inform	Access to participation activities, greater exposure to potential adverse impacts

8.2 Grievance Mechanisms

The purpose of the Grievance Mechanism is foremost to give access to a problem-solving procedure to Project affected people including affected communities and project workers. Grievances can be an indication of growing stakeholder concerns and can escalate if not identified and resolved. Identifying and responding to grievances supports the development of positive relationships between Project workers, local communities, and other stakeholders.

The structured Grievance Mechanism will ensure that grievances associated with the Project are addressed through a transparent and impartial process. From the early stages of the Project lifecycle, the grievance procedure will be and will continue to be disclosed to the public through individual or group meetings, digital tools, printed materials, notice boards.

Currently, the Project Owner has established a grievance mechanism to address public grievances and views.

Within the scope of the project, different grievance mechanisms will be set up for the public and Project workers.

According to ESS 10, it is necessary to establish a systematic approach to stakeholder engagement that will help borrowers identify stakeholders and establish and maintain a constructive relationship with them. Project specific grievances will be obtained through:

- call on the provided phone number;
- website;
- e-mail;
- grievance boxes;
- in person by contacting the contact person.

In ESS 2, Worker Grievance Mechanism is defined as grievances from Project employees (including both direct and indirect employees). This mechanism is structured to make it an effective approach for early identification, assessment, and resolution of grievances throughout the life of the Project. The scope of the Worker Grievance Mechanism can be summarized as follows, but not limited to; occupational health and safety, labor conditions, wages, problems with the local community or co-workers, hygiene problems in common areas, insufficient food and/or worker safety, etc.

Project employees will be able to submit their complaints through complaint boxes. Complaint boxes will be placed in easily accessible areas in the project area. The grievance mechanism will be introduced to the workers in the onboarding and periodic trainings. Confidentiality is highly important for some workers; therefore, workers can raise grievances anonymously. Project workers wishing to lodge grievances anonymously should be allowed to do so.

8.3 Key Performance Indicators of SEP

The key performance indicators to be used during the implementation of SEP are set out below.

Table 8-2. Key Performance Indicators (KPI) and monitoring actions – Stakeholder Engagement

No	KPI
1	Number of public grievances received within 6 months and number of those resolved within the prescribed timeline
2	Number of Physical distancing communication messages targeting vulnerable populations
3	Number of specific health education/communication/awareness messages created for vulnerable populations.

9 ESIA TERMS OF REFERENCE

As a tentative structure, the following sections are planned for the ESIA study and its report.

- Executive Summary
  - A brief description of key findings including impact on communities and general public and recommended actions.
- Chapter 1-] Introduction
  not limited to but including:
  - Purpose of the ESIA
  - Structure of the ESIA
  - Objectives of the Project
- Chapter 2-] Project Description
  - The geographical, environmental, social and temporal context (e.g., project-specific pipelines, access roads, electricity supply, water supply, accommodation, raw material and product storage facilities), including the off-site investments that may be required by the proposed Project, and the main suppliers of the project are briefly described, design requirements and commissioning process
  - Capacity and experience of the implementation organization
  - Project description, through consideration of project details, indicates whether a plan is needed to meet the requirements of ESS 1 – 10
  - Project description presents a map with sufficient detail about the project area, area of influence and other areas that may be affected by the direct, indirect and cumulative impacts of the project.
  -
- Chapter 3-] Project Alternatives
  - Applicable alternatives to the proposed project regarding location, technology, design and operation, not only limited to including the no-project situation, are systematically compared but also discussing the pros and cons of potential locations in terms of their potential environmental and social impacts.
  - The applicability of environmental and social mitigation measures of alternatives, the capital and current expenditures of the alternative mitigation measures, their compliance with local conditions, as well as institutional, training and monitoring requirements for the alternative mitigation measures, are evaluated.

- For each alternative, environmental and social impacts are quantified and, where possible, assessed economically.
- Emergency preparedness and response during construction and operational phases.

Design Measures

The justification for the selection of a particular proposed project design is provided and the relevant EHS Guidelines are specified, or if the EHS Guidelines are found to be not applicable for the project, pollution prevention and reduction approaches are justified in line with recommended emission levels and good international industry practices.

- Chapter 4-] Institutional and Regulatory Framework
  - The legal and institutional framework, which is applicable to the project and taken as a basis in the realization of the environmental and social assessment including the issues referred to in paragraph 26 of ESS-1, is analyzed.
  - The current environmental and social framework of the Borrower is compared with WB ESF requirements and the gaps between them are identified.
  - The ESIA will assess the applicability of relevant national legislation, relevant guidelines and GIIP concerning the siting of the BSL-3 on its proposed location.
  - A detailed review of the proposed system for accreditation and oversight of the Belgrade BSL- 3 facility. Such review should address, inter alia: the standard(s) to which the lab will be certified (e.g., WHO, CDC); organizations accredited to carry out the certification process; additional elements or details of the certification process involve (e.g., duration of validity of the initial certification, requirements and process for annual renewal and interim audits).
- Chapter 5-] Scope and Methodology
  - This chapter will provide details on the scope and limitations of ESIA studies, and the methodology and criteria used for impact assessment.
- Chapter 6-] Environmental and Social Baseline

  This chapter will provide details on;
  - Baseline data relevant to the project location, design, operation or mitigation measures are presented in detail. They should contain information on project identification, planning and implementation dates, as well as a discussion about the accuracy, reliability and sources of these data.
  - Measures and quality of existing data, key data gaps and uncertainties related to projections are identified and predicted.

- Based on the available information, the scope of the subject area is evaluated and the relevant physical, biological, demographic and socioeconomic conditions are disclosed, including the changes envisaged to be made before the project begins.

And will include the subsections including;

- Land Use and Zoning
- Geology, Soils, Sediments, and Contaminated Land
  - This chapter will elaborate on the general conditions of the Project Area and surroundings
- Hydrology and Hydrogeology
  - This chapter will detail the hydrological conditions around the Project Area, and the current and additional impact on the groundwater resources.
- Material Resources and Waste Management
  - The Torlak Institute's and The Project's raw material, water use, electricity requirement (and how much it can generate itself), as well as solid and liquid waste management (including the wastewater) will be assessed separately for the construction and operation phases.
- Air Quality and Odour
  - This chapter will include construction related emissions and the emissions that might directly or indirectly result from operation of the Project. Dust and greenhouse gases with their respective dispersion models will be included as appendices, while their results will be discussed in the ESIA chapter itself.
- Noise
  - This chapter will mainly be related to the noise generated by the construction phase. The baseline studies that are being conducted and the proposed measurements and models will be included in this chapter.
- Traffic
  - This chapter will mainly be related to the construction phase additional traffic loads, how they are managed without causing stresses and accidents around the Project Area.
- Ecology
  - The chapter will discuss the ecology within and nearby Project Area by desktop study and site surveys and whether the Project will trigger any significant criteria

regarding biodiversity, and in case it does, separate management plans will be undertaken.

- Cultural Heritage
  - In case there is any impact of the Project over the (un)known cultural heritage/asset, or the absence of such an impact will be elaborated in this chapter.
- Socio-economy
  - The socio-economy of the region and its impact on the Project and vice versa will be detailed here, with potential amelioration of the community welfare.
- Community Health and Safety
  - The management systems and community health and safety including impacts on communities disadvantaged and vulnerable groups during the construction and operation phase of the Project will be elaborated. An external grievance mechanism and relevant national legislation will be closely followed.
- Labour and Working Conditions
  - The management systems and occupational health and safety during the construction and operation phase of the Project will be elaborated. An employee grievance mechanism and relevant national legislation, as well as Labour and Working Conditions will be closely followed.
- Chapter 7-] Environmental and Social Risks and Impacts and Mitigation measures
  - All relevant environmental and social risks and impacts of the project will be taken into account. Environmental and social risks and impacts specifically specified in ESS 1-10, except ESS 5 and ESS 7 which are not relevant to the Project as well as other environmental and social risks and impacts that may arise as a result of the specific feature and context of the project, are determined together with the risks and impacts specified in paragraph 28 of ESS-1.
  - E&S risks and impacts should be elaborated separately for construction and operational phase
  - Mitigation measures and significant negative residual impacts that cannot be mitigated are identified and the acceptability of these negative residual impacts is evaluated to the extent possible.
  - Differentiated measures are established so that adverse impacts do not disproportionately affect disadvantaged or vulnerable groups.

- The applicability of environmental and social mitigation measures, the capital and current expenditures of the proposed mitigation measures, their compliance with local conditions, as well as institutional, training and monitoring requirements for the proposed mitigation measures, are evaluated.
- Considerations that do not need further attention are determined and the justifications for this determination are presented.
- Mitigation measures for the operational phase should be proportionate to the risks of BSL-3 lab.

- Chapter 8-] Cumulative impact Assessment
- Chapter 9-] Stakeholder Engagement
  - Stakeholder Identification.
  - Stakeholder Engagement Approach.
  - Previous Stakeholder Engagement.
  - Future Stakeholder Engagement.
  - Grievance Mechanism.

Appendices

- List of the individuals or organizations that prepared or contributed to the environmental and social assessment.
- References—setting out the written materials both published and unpublished, that have been used.
- Record of meetings, consultations and surveys with stakeholders, including those with affected people and other interested parties. The record specifies the means of such stakeholder engagement that were used to obtain the views of affected people and other interested parties.
- Tables presenting the relevant data referred to or summarized in the main text.
- List of associated reports or plans.
- Official letters received from relevant ministries, provincial directorates and other public institutions.

Environmental and Social Management

An Environmental and Social Management Plan will be also prepared as a stand-alone document. It will include a monitoring plan to check the effectiveness of the measures developed in the ESIA. Implementation of the ESMP will be accomplished within the framework of a project-specific Environmental and Social Management System (ESMS) to be developed by the Project owner in accordance with the national and international standards (i.e., WB's ESF, WB's EHS guidelines). The ESMP can be supported by sub management plans which were outlined in Chapter 1 of this Scoping Report. The content of the ESMP includes the following:

Mitigation

The ESMP identifies measures and actions in accordance with the mitigation hierarchy that reduce potentially adverse environmental and social impacts to acceptable levels. The plan will include compensatory measures, if applicable. Specifically, ESMP;

- identifies and summarizes all anticipated adverse environmental and social impacts (including those involving but not limited to land use, involuntary resettlement worker and public health and safety, vulnerable groups and cultural heritage), or;
- summarizes—with technical details—each mitigation measure, including the type of impact to which it relates and the conditions under which it is required (e.g., continuously or in the event of contingencies), together with designs, equipment descriptions, and operating procedures, as appropriate;
- estimates any potential environmental and social impacts of these measures; and takes into account, and is consistent with, other mitigation plans required for the project (e.g., for involuntary resettlement, workforce, stakeholder engagement, or cultural heritage).

Monitoring

The ESMP identifies monitoring objectives and specifies the type of monitoring, with linkages to the impacts assessed in the environmental and social assessment and the mitigation measures described in the ESMP. Specifically, the monitoring section of the ESMP provides (a) a specific description, and technical details, of monitoring measures, including the parameters to be measured, methods to be used, sampling locations, frequency of measurements, detection limits (where appropriate), and definition of thresholds that will signal the need for corrective actions; and (b) monitoring and reporting procedures to (i) ensure early detection of conditions that necessitate particular mitigation measures, and (ii) furnish information on the progress and results of mitigation.

Capacity development and training

To support timely and effective implementation of environmental and social project components and mitigation measures, the ESMP draws on the environmental and social assessment of the existence, role, and capability of responsible parties on site or at the agency and ministry level.

Specifically, the ESMP provides a specific description of institutional arrangements, identifying which party is responsible for carrying out the mitigation and monitoring measures (e.g., for operation, supervision, enforcement, monitoring of implementation, remedial action, financing, reporting, and staff training).

To strengthen environmental and social management capability in the agencies responsible for implementation, the ESMP recommends the establishment or expansion of the parties responsible, the training of staff and any additional measures that may be necessary to support implementation of mitigation measures and any other recommendations of the environmental and social assessment.

Implementation schedule and cost estimates

For all three aspects (mitigation, monitoring, and capacity development), the ESMP provides (a) an implementation schedule for measures that must be carried out as part of the project, showing phasing and coordination with overall project implementation plans; and (b) the capital and recurrent cost estimates and sources of funds for implementing the ESMP. These figures are also integrated into the total project cost tables.

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SERBIA EMERGENCY COVID-19 RESPONSE PROJECT

REPORT ON PUBLIC CONSULTATIONS

for

CONSTRUCTION OF A NEW DIAGNOSTIC BUILDING WITH BSL-3 LABORATORY AT THE INSTITUTE OF VIROLOGY, VACCINES AND SERA "TORLAK", BELGRADE

Belgrade, June 2023

Table of Contents

1. BACKGROUND

The Republic of Serbia has received a loan from the World Bank Group in the amount of EUR 92 million equivalent for the implementation of SECRP. The objectives of the SECRP are: (a) to respond to the threat posed by COVID-19 and (b) to strengthen the national health system for public health preparedness in Serbia.

The Project will be financed under one of its subcomponents as the Subcomponent 1.1 of the Serbia Emergency COVID-19 Response Project (SECRP) financed by the World Bank Group. The objectives of the SECRP are: (a) to respond to the threat posed by COVID-19 and (b) to strengthen the national health system for public health preparedness in Serbia.

The Ministry of Health of Republic of Serbia intends to design and construct a new diagnostic laboratory building with Biosafety Level 3 (BSL-3) named Torlak Institute BSL-3 Subproject (hereinafter “Project”) within the existing Torlak Institute of Virology, Vaccines and Sera, Belgrade.

The joint venture (Contractor), which includes 2U1K Engineering and Consultancy Inc. Turkiye (leader), 2U1K International, UAE and Enacta doo Beograd-Vračar Serbia is engaged on development of Environmental and Social Impact Assessment (ESIA) and Environmental and Social Management Plan (ESMP) for the subject project and other associated documents, including Scoping Report (SR) and SEP (Stakeholder Engagement Plan).

The objectives of the organized public consultations for SR and SEP were the following:

- Presentation of SR and SEP prepared for the Project and approved by the Project Coordination Unit (PCU) and the World Bank (WB) to the Project stakeholders;
- Identify stakeholders' expectations and concerns;
- Provide stakeholders with the opportunity to raise their questions, incorporate their relevant comments into the Project, and;
- Inform all stakeholders involved in this Project, including Project Affected Persons, NGOs, potential Project staff, International Organisations, National and Regional Government Agencies about the Project and then finalize the Environmental and Social Impact Assessment (ESIA) with inputs/feedback from all stakeholders.

On April 4, 2023, the Contractor has received the WB “No objection” on SR and WB “No objection” for SEP on April 6, 2023, and therefore the public consultation was originally planned to be organized on May 5, 2023 at the premises of Dom Zdravlja (Primary Health Center) Savski Venac. Due mass shooting occurred in Serbia on May 3 and 4, 2023, the public consultation organization was stopped by the decision of the Ministry on May 5, 2023, therefore, the Contractor has received another date for public consultation (May 22, 2023) and approval to organise such meeting on online platform only.

During the online public discussion, organized on May 22, 2023, no comments or suggestions relevant to the SR and SEP were received.

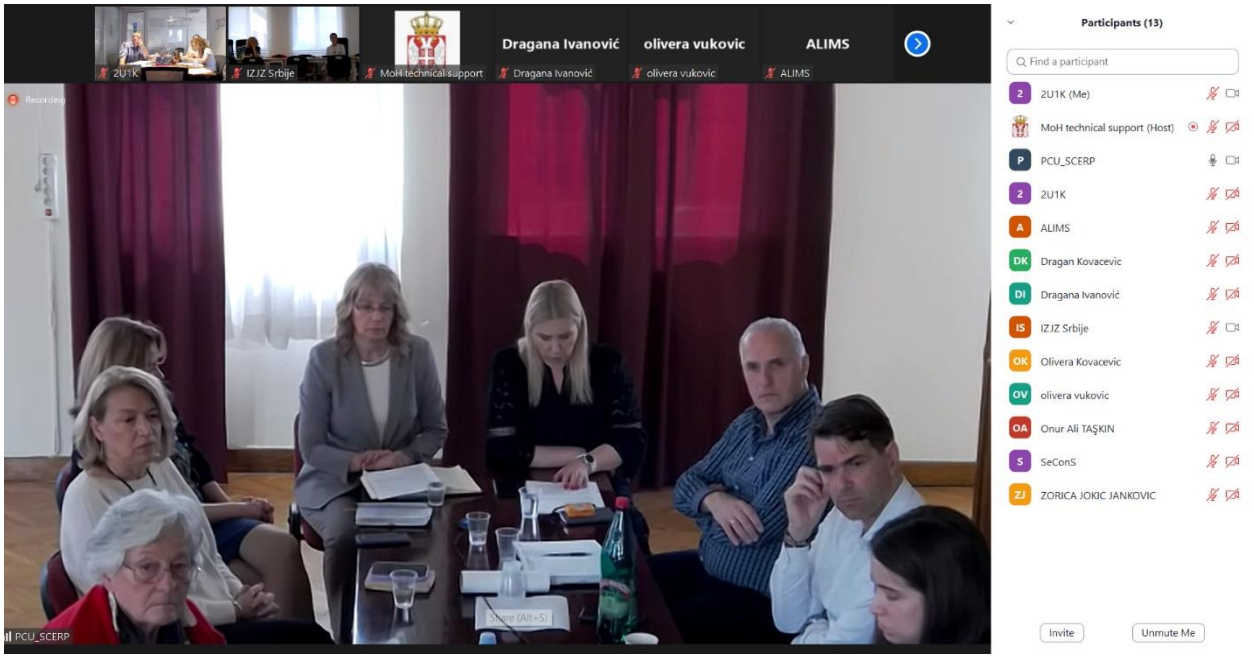
2. REPORT ON ON-LINE PUBLIC CONSULTATION, May 22, 2023

The SR and SEP are posted on the Ministry's website (Picture 6), together with an advertisement - an invitation to public consultations (Picture 5). Interested public is invited to participate during Public Consultations as well as to gain an insight into the SR and SEP document.

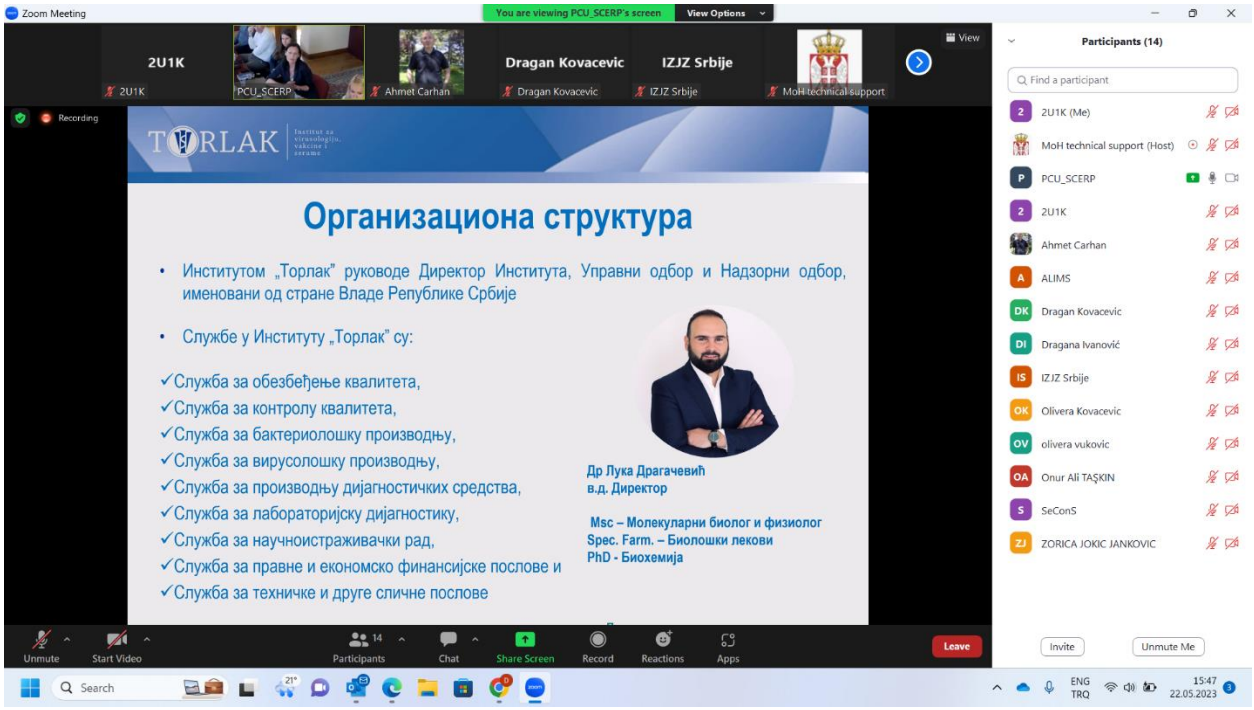
On-line consultations were attended by the following parties:

1. *PCU: 9 participants*
2. *Torlak: 2 participants*
3. *WB: 1 participant*
4. *BIRODI (Bureau for social research): 1 participant*
5. *Centar za edukaciju, inkluziju i razvoj zajednice USPON representative (Center for education, inclusion and community development USPON): 1 participant*

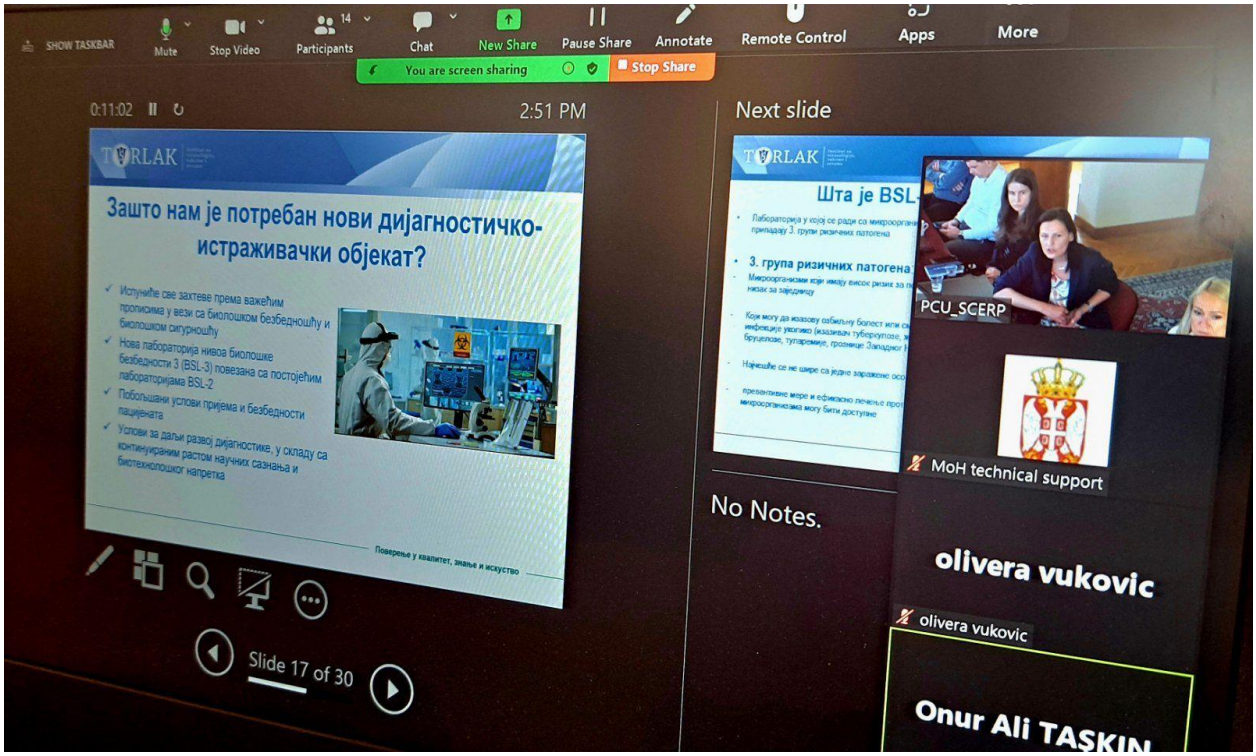
6. *ALIMS (Agency for Medicines and Medical Devices of Serbia): 4 participants*
7. *IJZS Batut (Institute for Public Health of Serbia, Dr. Milan Jovanović Batut) – 4 participants*
8. *Contractor representatives*



Picture 1: PPM online meeting



Picture 2: PPM online meeting



Picture 3: PPM online meeting

Picture 4: Power Point presentation for SR and SEP

The meeting started according to schedule at 14:30 PM. SR and SEP documents were presented to the interested attendees by the ENACTA representative – Mr. Dragan Kovacevic. During the public consultations, there were no comments, remarks or complaints related to issues presented in the SR and SEP, and no environmentally and socially related issues were raised.

Consultation started at 2:30 PM and ended at 3:30 PM, local time.

3. DOCUMENTATION

In compliance with the World Bank Environmental and Social Framework (ESF) and the Environmental and Social Standard 10 (ESS10)

Republic of Serbia
Ministry of Health

invites to

PUBLIC CONSULTATIONS
institutions, organizations, entities and the general public interested in the

ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT (ESIA) SCOPING REPORT
and
STAKEHOLDER ENGAGEMENT PLAN (SEP)

the prepared for

construction of a new diagnostic laboratory building with BSL-3 at the "Torlak" Institute of Virology, Vaccines and Sera, Belgrade subproject

in the framework of

"Serbia Emergency COVID-19 Response Project"

Interested parties can view ESIA Scoping Report and SEP at the following addresses:

- The premises of the Project Coordination Unit, Pasterova 1, Belgrade, during working days from 11:00 AM to 01:00 PM (local time), from the date of the announcement of this invitation until the public consultations
- At the Ministry of Health website: https://www.zdravlje.gov.rs/tekst/376352/izgradnja-dijagnosticko-istrazivackog-objekta-sa-bsl-3-laboratorijom-u-okviru-instituta-torlak.php

Comments and suggestions pertaining to the subject documents shall be submitted by mail to the Ministry of Health – Project Coordination Unit, Pasterova 1, Belgrade or by e-mail to covid_bsl3@zdravlje.gov.rs

On **May 22nd, 2023 at 2:30 PM**, public consultations and presentation of the subject documents will be held **online**, through a widely available internet platform. All interested parties are invited to confirm their presence and provide their e-mail addresses to: covid_bsl3@zdravlje.gov.rs by May 21st, 2023 at 1:00 PM.

For any additional information, please contact:

Ministry of Health
Project Coordination Unit
Pasterova 1, 3rd floor
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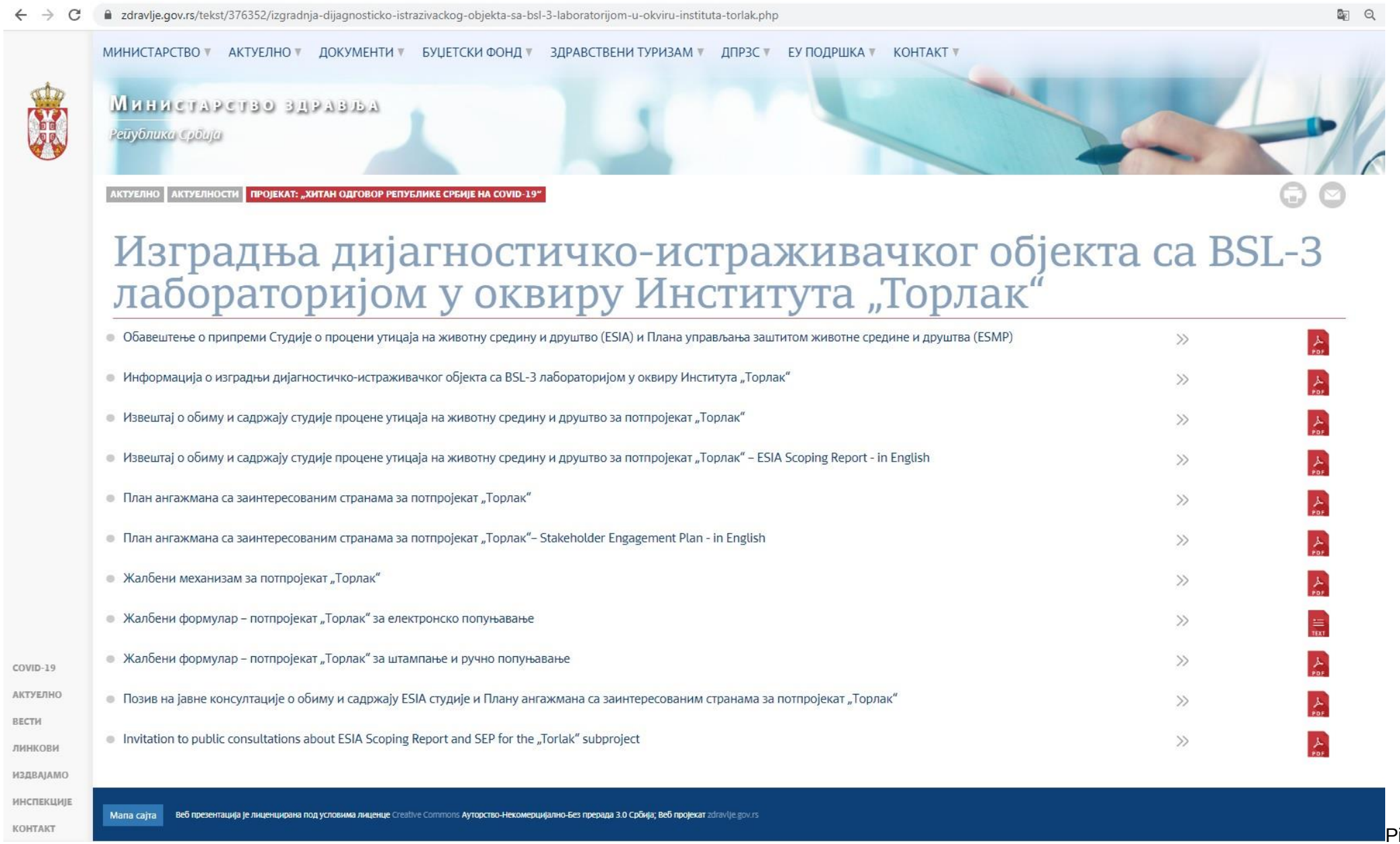
Picture 5: Announcement of public consultation Ministry web site



Pic

Picture 6: Public disclosure of SR and SEP documents, Ministry web site