JOINT EXTERNAL EVALUATION OF IHR CORE CAPACITIES of the REPUBLIC OF SERBIA

Mission report:

8–12 October 2018

World Health Organization

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ABBREVIATIONS

AMR	antimicrobial resistance
CAESAR	Central Asian and Eastern European Surveillance of Antimicrobial Resistance
CME	continuing medical education
EBS	event-based surveillance
ECDC	European Centre for Disease Prevention and Control
ELISA	enzyme-linked immunosorbent assay
EQA	External quality assurance
EU	European Union
HCAI	health care-associated infection
IATA	International Air Transport Association
IBS	indicator-based surveillance
IMS	information management system
INFOSAN	International Food Safety Authorities Network
IPC	infection prevention and control
IPHS	Institute of Public Health of Serbia "Dr Milan Jovanović Batut"
ISO	International Standardization Organization
KAP	Knowledge, Attitudes and Practices (survey)
MAFWM	Ministry of Agriculture, Forestry and Water Management
MCM	medical countermeasures
MMDAS	Medicines and Medical Devices Agency of Serbia
MoH	Ministry of Health
MoI	Ministry of Interior
MoU	Memorandum of Understanding
NFP	national IHR focal point
NGO	nongovernmental organization
NMP	National Monitoring Plan
NRL	national reference laboratory
OIE	World Organisation for Animal Health
PCR	polymerase chain reaction
PHEIC	public health emergency of international concern
RASFF	Rapid Alert System for Food and Feed (of the European Union)
Rulebook	Official document in the country that guides implementation of specific laws
SOP	standard operating procedure
WHO	World Health Organization

EXECUTIVE SUMMARY

The Republic of Serbia has a long history in health: its first medical laboratory was established in 1900 to control and prevent the spread of infectious diseases; and later the country was among the first to eradicate smallpox. Underpinning those efforts is a strong framework of laws and legislation, meticulously documented by the national experts who completed the Joint External Evaluation (JEE) assessment. This JEE was triggered by the Health Minister's request to WHO to conduct the peer-to-peer evaluation of Serbia's capacities in 19 technical areas to fulfil its obligations under IHR (2005).

During the week the country provided a number of examples where it is working at developed and even demonstrated capacity. For example, Serbia's emergency response for natural disasters is exceptional. Of particular note is the response to the extensive floods that occurred in 2014; response to that disaster, led by the Emergency Management Sector within the Ministry of Interior, was well-coordinated, swift and saved lives – as assessed by a WHO evaluation. In addition, simultaneously with the JEE, Serbia hosted a NATO disaster simulation including a chemical event. This showcased many capabilities in such technical areas as preparedness, linking security forces and chemical events.

Another positive example is the Government's capacity to manufacture multiple vaccines and a strong immunization programme. In addition, indicator-based surveillance in Serbia is well structured and robust; the One-Health intersectoral approach the country has reached so far (and continues to improve) is quite advanced, with examples of good practice of zoonotic multisectoral surveillance. Also noteworthy was the point of entry Nikola Tesla Belgrade International Airport: During the field visits of the JEE the external team found that the airport excels in preparedness and response with respect to ill travellers (thanks again to the robust legal framework in place). Best practices at the airport include a continuously operated health post (staffed with doctors) and referral of ill travellers who cannot be treated by the health staff there.

During the week a number of thematic gaps also emerged. Despite the robust existent legislation in the country, there are a number of technical areas in which the relevant minister or Parliament has not formally approved national plans or enacted legislation (e.g. the National Health Emergency and Preparedness plan) underpinning technical areas (e.g. Preparedness and Response). The lack of such approval has negatively affected the scores in some areas; fortunately, once such plans are officially endorsed the scores will quickly rise.

In several technical areas standard operating procedures (SOPs) were not necessarily contained in the nation's rulebooks, but lay with one or two people managing an area, who use their prior experience and previous precedents and lessons learned to inform decisions. This means that the procedures in place (e.g. for radiation emergencies) may not be adequately conducted if the main technical colleague is not available – raising a clear issue of sustainability and of a critical gap should the acting officer be unavailable. For example, a multisectoral national emergency contingency plan, which explicitly states each of the practical steps to take during an emergency for radiation emergencies and available to all stakeholders, would address this issue.

The sustainability of Serbia's health workforce also loomed over the discussions during the week. During several presentations national colleagues mentioned shortages of staff, while others mentioned the hiring freeze in the public sector imposed by the International Monetary Fund. Still others noted the ageing health workforce – a large proportion of health staff will be retiring in the next 10–15 and it sounded as if there were insufficient numbers of trained staff to replace them.

Quality of care should not just be considered within public health training, but also in the health sector overall. While Serbia was early to establish laboratories in the 20th century, it is lagging behind in adopting technological advances of the 21st century, such as centralized databases and electronic reporting of surveillance and laboratory results.

The multisectoral and multidisciplinary excellence seen during emergencies was often notably absent when a health situation remained below the level of an emergency. In such situations, challenges were seen in intersectoral coordination, collaboration and communications (e.g. in the technical area of surveillance with West Nile virus cases, where the country recognizes and is working to address the currently informal and ad hoc coordination).

One theme that recurred frequently was the need for a framework to manage information, budget and activity across each technical area and between interconnected areas. (The need for an active body to coordinate all IHR activity usually becomes apparent during national action planning. However Serbia is well advanced in IHR implementation so a need of this type is already being identified.)

Overarching recommendations

- Approve the National Health Emergency and Preparedness plan for the health sector and a national multisectoral emergency preparedness and response plan (including budget lines for their implementation, and specific details of activities at subnational levels).
- Clarify mechanisms for whole-of-government activities to do in the period before an emergency is declared. For example, a mechanism to conduct an assessment of needs and risks from which to procure medical supplies before an emergency or outbreak is declared. The process should be changed so that medical supplies can be procured as needed.
- As part of the One-Health approach, Serbia should consider updating its systems of data collection and reporting, from paper-based to electronic, including centralized databases, particularly across sectors. For example, an electronic surveillance system exists in the veterinary sector, but not yet for the public health sector. Creation/enhancement of this system and its interoperability with the veterinary sector would allow Serbia to more quickly detect and respond to any emerging zoonoses, among other threats to the population.
- Review the current national workforce strategy (e.g. through a training needs assessment) and realign it considering target competencies, and leveraging non-traditional training technologies and alternative staffing mechanisms like public-private partnerships or privatization. In this process the country might also consider amending legislation related to the need to have a medical doctor conduct all medical-related functions in Serbia, which places great demands on doctors. A change in the law could mean delegating certain activities (such as vaccination) to other trained health staff; this would ease the pressure on doctors and could be done in such a way as to maintain high quality of care.
- The country should write and make available plans and SOPs for the technical areas in which rulebooks do not specify strategies and practical procedures. This would ensure that anyone appointed and acting in that role would have the written plans and procedures in place to manage her/his responsibilities during an emergency situation. Further, this opportunity could be used to align the country's action plans and guidelines (by whatever name they are referred to in the country) with internationally accepted – and published – WHO guidelines.
- Harmonize country's mechanisms with existing regional and international mechanisms, such as the EU Civil Protection Mechanism (with which it is already involved) to comply with IHR.
- Once the international airport has been designated a PoE with WHO, a quarantine facility should be established there as part of the IHR (2005) requirements for designated PoE.

Given Serbia's demonstrated strengths in many technical areas, its extensive legal framework and its commitment to continue to improve, Serbia could be a positive example to other countries in the region with respect to meeting IHR (2005) requirements. In taking the step of assessing its core IHR capacities and addressing its gaps, Serbia can set an example in the region. This then would mean that the region as a whole would be better prepared for whatever future emergencies may bring.

SCORES AND PRIORITY ACTIONS

Technical areas	Indicator no.	Indicator	Score	Priority Actions
PREVENT				
National legislation, policy and financing	P.1.1	The State has assessed, adjusted and aligned its domestic legislation, policies and administrative arrangements in all relevant sectors to enable compliance with the IHR	2	Perform an extended comprehensive assessment and identify needed adjustments to finalize the development of the legal framework for IHR implementation. Allocate a dedicated budget for IHR or define the comprehensive components of the budget, identifying existing allocations as well as unallocated shortfalls. Define a uniform multisectoral national plan for IHR as part of the Serbian official document structure. Create the legal mandate that defines a single centre for coordination, planning, monitoring and implementation of IHR.
	P.1.2	Financing is available for the implementation of IHR capacities	3	
	P.1.3	A financing mechanism and funds are available for timely response to public health emergencies	4	
IHR coordination, communication and advocacy	P.2.1	A functional mechanism established for the coordination and integration of relevant sectors in the implementation of IHR	3	Streamline and formalize the structure and formulate the main tasks of a multisectoral committee for implementation of IHR (2005). Develop standard operating procedures (SOPs) that incorporate an "all-hazard approach" for the multisectoral working group established to address public health threats Conduct regular meetings with all partners of the multisectoral committee for exchange of knowledge and progress with respect to IHR implementation as well organization of tabletop and simulation drills to test the SOPs.
Antimicrobial resistance	P.3.1	Effective multisectoral coordination on AMR	3	Adopt and implement the National Program and Action Plan for the Control of Antimicrobial Resistance in all disciplines and ensure continued funding and human resources. Improve the surveillance of AMR in the veterinary field for food of animal origin; designate NRLs and improve the capacity of the laboratories to conduct AMR testing. Establish a comprehensive method of registering resistant human infection agents at health care institutions. Continue the development of specific guidelines for prudent antibiotic use for specific, diseases of national importance in the veterinary field.
	P.3.2	Surveillance of AMR	2	
	P.3.3	Infection prevention and control	3	
	P.3.4	Optimize use of antimicrobial medicines in human and animal health and agriculture	3	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Zoonotic diseases	P.4.1	Coordinated surveillance systems in place in the animal health and public health sectors for zoonotic diseases/ pathogens identified as joint priorities	3	Prioritize the approval of the operational agreement between the main institutions/actors in charge of human and animal health, in order to formalize and strengthen data and/or information exchange on, and coordinated response to, zoonotic diseases. Design and perform a joint assessment of the multisectoral surveillance and response systems to document their timeliness and effectiveness across administrative levels for the response to vector-borne zoonotic diseases. Strengthen multisectoral timely exchange of data on zoonotic events and zoonotic agents by supporting the digitization of the human health surveillance system, and designing an integrated/ interoperable approach with the existing animal health sector electronic surveillance system, in order to enable timely integrated analysis for early detection, joint risk assessments and continuous monitoring of risk management. Develop a national plan for vector control in order to harmonize and increase the timeliness of vector control in Serbia.
	P.4.2	Mechanisms for responding to infectious and potential zoonotic diseases established and functional	3	
Food safety	P.5.1	Surveillance systems in place for the detection and monitoring of foodborne diseases and food contamination	3	Implement the surveillance of food for presence of microbiological and chemical hazards at the retail level. Develop SOPs for foodborne disease outbreaks with special emphasis on the roles, tasks and communication lines of the multisectoral players. Adopt the National Food Safety Emergency Plan.
	P.5.2	Mechanisms are established and functioning for the response and management of food safety emergencies	2	
Biosafety and biosecurity	P.6.1	Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities)	2	The Government should create a strong foundation for all future training plans by performing and documenting or publishing a new, expanded, detailed and comprehensive revised training needs assessment for biosafety and biosecurity. The relevant ministries should use the appropriate legal instruments to establish common enforceable safety and security requirements or licensing conditions for all laboratories. The Government should develop and maintain an inventory of dangerous pathogens and toxins, a record of the facilities that conserve or treat them, and a programme of active monitoring. The appropriate bodies should define specific policies for using diagnostic tests to eliminate or reduce the need for the cultivation of dangerous pathogens.
	P.6.2	Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture)	2	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Immunization	P.7.1	Vaccine coverage (measles) as part of national programme	3	Provide national vaccine reserves to ensure continuous, timely and complete immunization in the event of epidemics, shortages, delayed procurement, manufacturing problems; this includes considering the expansion of the production capacity and product variety of the domestic vaccine manufacturer. Establish and introduce an electronic immunization register for the entire country. Intensify efforts to improve the implementation of the immunization programme in all segments with public campaigns and well-trained personnel (e.g. increase uptake of vaccines by health care workers, children, the elderly).
	P.7.2	National vaccine access and delivery	4	
DETECT				
National laboratory system	D.1.1	Laboratory testing for detection of priority diseases	4	Appoint a national authority for the coordination of national reference laboratories which should have, among others, the responsibility of implementing an external quality management system for all national reference laboratories. Establish an electronic system for timely dissemination of laboratory results and reporting of notifiable diseases, which should be integrated into an electronic surveillance system (see recommendation in the "Surveillance" technical area). Enhance the usage of advanced molecular diagnostics through investment in training and laboratory equipment.
	D.1.2	Specimen referral and transport system	3	
	D.1.3	Effective national diagnostic network	3	
	D.1.4	Laboratory quality system	2	
Surveillance	D.2.1	Surveillance systems	2	Set up an electronic data management system for human health IBS surveillance data, which is able to integrate data from clinical case reporting with data from microbiological laboratories and, where appropriate, integrated/interoperable with the animal health sector electronic surveillance tool. Train relevant professionals on the following identified areas that need strengthening: EBS, risk assessment methodologies and advanced statistical analysis of surveillance data, possibly through a multisectoral approach. Perform a feasibility study for the implementation of active EBS in Serbia in order to guide the implementation strategy for this part of surveillance. Perform an evaluation of the human health sector IBS in order to assess the key issues to address to improve adherence to case definitions, timeliness and completeness.
	D.2.2	Use of electronic tools	2	
	D.2.3	Analysis of surveillance data	4	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Reporting	D.3.1	System for efficient reporting to FAO, OIE and WHO	4	Supplement established mechanisms for reporting process and procedures for coordination in response to PHEICs with a formal mechanism for interaction between the sectors on a regular manner (i.e. protocol on coordination between ministries, with terms of references, roles and responsibilities). Harmonize reporting matrices used by different sectors (particularly Public health and Veterinary Public Health) at all levels (e.g. ministerial level, national and regional level) and introduce among all stakeholders. Develop standard operating procedures (SOPs) for assessment, verification and reporting to WHO and OIE through national focal points about a potential public health emergency.
	D.3.2	Reporting network and protocols in country	4	
Human resources (animal and human health sectors)	D.4.1	An up-to-date multi-sectoral workforce strategy is in place	2	To prepare a full list of knowledge/skills needed for IHR-related activities and according to such a list to prepare a list of specialists (public health, communicable diseases, urgent medicine/ reanimation, toxicology, radiation medicine, clinical microbiology, laboratory, pharmacy, surveillance, food safety, veterinary medicine, else) who could be picked up for strengthening public health care when it required (happened public health hazards). According to such a list to prepare road map for SME/refreshing courses (or targeted training) in IHR related topics. To support National focal point for IHR of the Ministry of Health in their overall activities for becoming the WHO Collaborating Centre in CME for IHR-involved staff.
	D.4.2	Human resources are available to effectively implement IHR	3	
	D.4.3	In-service trainings are available	3	
	D.4.4	FETP or other applied epidemiology training programme in place	3	
RESPOND				
Emergency preparedness	R.1.1	Strategic emergency risk assessments conducted and emergency resources identified and mapped	3	Finalize and adopt the National Emergency Plan and the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations. Initiate resource mapping at the subnational level in public health, veterinary and other sectors. Test the various plans through simulation exercises and develop a mechanism to adjust plans according to the findings of these simulation exercises.
	R.1.2	National multi-sectoral multi-hazard emergency preparedness measures, including emergency response plans, are developed, implemented and tested	1	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Emergency response operations	R.2.1	Emergency response coordination	4	Establish operational health emergency centres based on the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations, including a joint information centre for all-hazard risk communication and in line with the WHO Framework for a Public Health Emergency Operations Centre. Evaluate response to emergencies that have triggered the activation of the national EOC and develop a mechanism to adjust plans according to the findings of these evaluations.
	R.2.2	Emergency operations centre (EOC) capacities, procedures and plans	3	
	R.2.3	Emergency Exercise Management Programme	3	
Linking public health and security authorities	R.3.1	Public health and security authorities (e.g. law enforcement, border control, customs) linked during a suspect or confirmed biological, chemical or radiological event	3	Expand existing standard operating procedures (SOPs) (including for a joint/shared risk assessment) and communication protocols, including roles and responsibilities; and reinforce existing mechanisms to improve exchange of reports and information for all hazards on a regular basis between authorities and bodies at national, subnational and local level through convening of a multisectoral working group. Formalize a MoU or other agreements/protocols and align them within existing systems and structures to facilitate preparedness and response to all hazards. Develop a joint training programme between public health and security authorities to familiarize, exercise, and update procedures/protocols for improved coordination and information sharing between authorities to prepare for and respond to all hazards at national, subnational and local level.
Medical countermeasures and personnel deployment	R.4.1	System in place for activating and coordinating medical countermeasures during a public health emergency	2	Harmonize all necessary measures with existing WHO recommendations/documents (such as the WHO Interagency Emergency Health Kit, 2011 & 2017, the Classification and minimum standards for foreign medical teams in sudden-onset disasters, 2013, etc.).
	R.4.2	System in place for activating and coordinating health personnel during a public health emergency	2	
	R.4.3	Case management procedures implemented for IHR relevant hazards	2	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Risk communication	R.5.1	Risk communication systems for unusual/ unexpected events and emergencies	2	Develop an all-hazards emergency risk communication plan, test it with a tabletop or simulation exercise, and adopt it within existing plans and mechanisms for emergency preparedness and response in line with IHR (2005) requirements. Strengthen coordination mechanisms, including communication SOPs and clearance protocols within and between ministries and stakeholders by establishing a joint agency communication working group to update roles and responsibilities, including testing, sharing of resources and development of joint action plans. Strengthen cooperation between NGOs and scientific and research institutions to develop, implement, monitor and evaluate social science-based methods and interventions to reinforce community engagement mechanisms at local, regional and national levels. Utilize and reinforce two-way communication mechanisms (KAP surveys, intercept interviews, focus groups, etc.) to strengthen engagement with target audiences, assess risk perception, and develop and test message templates for anticipated and high-risk public health threats. Conduct an audience and media analysis, including for social media, to improve understanding of how target audiences receive and use health information.
	R.5.2	Internal and partner coordination for emergency risk communication	3	
	R.5.3	Public communication for emergencies	4	
	R.5.4	Communication engagement with affected communities	2	
	R.5.5	Addressing perceptions, risky behaviours and misinformation	4	
IHR-RELATED HAZARDS AND POINTS OF ENTRY				
Points of entry	PoE.1	Routine capacities established at points of entry	3	The airport Nikola Tesla Belgrade is a possible entry point to be designated under the IHR. The existing public health emergency plan and the generic emergency preparedness and response plan at the airport should be integrated into the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations. Staff at the airport have to be trained in handling public health emergencies, with a special focus on the use of personal protective equipment and the safe transport of patients with suspected life-threatening and contagious diseases. Premises for potential medical assessment and/or screening at the airport should be identified.
	PoE.2	Effective public health response at points of entry	2	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Chemical events	CE.1	Mechanisms established and functioning for detecting and responding to chemical events or emergencies	3	Update the national chemical profile of defined priority chemical agents. Finalize and exercise the national multisectoral chemical response plan. Incorporate chemical management and response specialists into the national health sector workforce strategy. Establish the mandated Joint Entity for Integrated Chemicals Management organization and a centralized information-exchange mechanism to share information about chemical events among this multisectoral organization.
	CE.2	Enabling environment in place for management of chemical events	2	
Radiation emergencies	RE.1	Mechanisms established and functioning for detecting and responding to radiological and nuclear emergencies	2	Develop a multisectoral radiation emergency contingency plan, along with associated sector-specific standard operating procedures. Train and exercise both health care workers and response personnel in other sectors on radiation response operations. Designate and adequately equip reference health care facilities for treatment of patients exposed to radiation.
	RE.2	Enabling environment in place for management of radiological and nuclear emergencies	2	

Scores: 1=No capacity; 2=Limited capacity; 3=Developed capacity; 4=Demonstrated capacity; 5=Sustainable capacity.

PREVENT

NATIONAL LEGISLATION, POLICY AND FINANCING

INTRODUCTION

The International Health Regulations (IHR) (2005) provide obligations and rights for States Parties. In some States Parties, implementation of the IHR (2005) may require new or modified legislation. Even if new or revised legislation may not be specifically required, States may still choose to revise some regulations or other instruments in order to facilitate IHR implementation and maintenance. Implementing legislation could serve to institutionalize and strengthen the role of IHR (2005) and operations within the State Party. It can also facilitate coordination among the different entities involved in their implementation. See detailed guidance on IHR (2005) implementation in national legislation at http://www.who.int/ihr/legal_issues/legislation/en/index.html. In addition, policies that identify national structures and responsibilities as well as the allocation of adequate financial resources are also important.

Target

Adequate legal framework for States Parties to support and enable the implementation of all their obligations and rights made by the IHR. Development of new or modified legislation in some States Parties for the implementation of the Regulations. Where new or revised legislation may not be specifically required under a State Party's legal system, the State may revise some legislation, regulations or other instruments in order to facilitate their implementation in a more efficient, effective or beneficial manner. States Parties ensure provision of adequate funding for IHR implementation through the national budget or other mechanisms. Country has access to financial resources for the implementation of IHR capacities. Financing that can be accessed on time and distributed in response to public health emergencies, is available.

LEVEL OF CAPABILITIES

Serbia has a layered system of legal authority including law, regulation, rulebooks and guidelines that strongly tie operations into detailed law, allowing formal codification to occur at many levels. That mature legal framework reflects its rich history and positions the country to strongly support the IHR (2005). This is both a strength and a weakness: the existing regulations allow the implementation of most of the requirements related to IHR (2005), but IHR-related regulation is not found in a single place. Key legal elements include the Law on Emergency Situations and the rulebook on conditions and measures of quarantine. The former is a legal best practice, empowering rapid action. Pursuant to the Law on Emergency Situations, appropriate multisectoral emergency staff are activated to engage all resources without the obligation to follow standard time-consuming procedures.

The country is far along in the process of joining the European Union (EU). Within that process, laws have been harmonized with the EU legislation, and accordingly, the IHR. This does not provide the same assurances as a systematic assessment of IHR requirements, but it does create a fresh awareness of the IHR legal foundation.

The Government's executive activities are highly functional. While the national IHR focal point (NFP) has been designated – the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" within the Ministry of Health – no specific regulations for IHR implementation have been adopted. However,

relevant government entities implement IHR functions within their regular activities, and the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS) serves as the focal point. The twenty-four Serbian districts have local Institutes which mirror the IPHS. In addition to the Ministry of Health (MoH), the Ministry of Interior plays a key role in responding to emergencies; the Ministry of Finance allocates the budget; The Ministry of Agriculture, Forestry and Water Management (MAFWM) oversees animal health; and the Ministry of Justice assists with new regulations.

Although a formal structured assessment of relevant (IHR) legislation has not been carried out, EU harmonization activities are relevant. Due to the broader EU framework, additional work is needed to identify all areas for adjustment in order to demonstrate the use of relevant legislation in all sectors of the IHR.

Activities related to compliance with IHR requirements is fully financed by the Government. Much of this funding falls under the responsibility of the MoH: "Organization of preparedness for crisis and emergencies: epidemics, extreme climate events and other events and disasters". Funds are provided based on the Law on the Budgetary System, Ministry of Health Program 1802, specifically: "Supporting the work of Institute of Public Health of Serbia "Dr Milan Jovanović Batut"" (RSD 7 194 924.00) and "Supporting the work of Institutes of public health" (RSD 39 518 223.00. Of this, RSD 2 213 932.00 was earmarked for IHR implementation). Overall, 5.3% of the national health budget has been allocated for IHR activities. There are budget lines within all relevant ministries involved in IHR implementation, but a single formal IHR budget line does not exist.

Once allocated, funds are distributed on a regular basis. All budget lines in all sectors are largely insufficient to cover IHR implementation. For example, there is a significant shortage of human resources, and existing allocations do not allow the recruitment of new employees in the public sector. Emergency funding mechanisms exist, and funds are available to respond in a timely manner, as was tested during the floods in 2014 and 2016. Each relevant ministry has its own budget line for emergencies (the MoH manages the budget line for public health emergencies). However, if resources are exceeded, there is no public body authorized to raise additional resources.

In summary, Serbia has a mature and robust legal and finance system, is actively involved in improvement as it positions itself to join the EU, and is poised to move to Demonstrated Capacity in all three indicators with a few focused priority actions.

Indicators and scores

P.1.1 The State has assessed, adjusted and aligned its domestic legislation, policies and administrative arrangements in all relevant sectors to enable compliance with the IHR – Score 2

Strengths and best practices

- There is a strong body of law that supports most of the requirements of the IHR (2005) even though it is not written in a single IHR section.
- The process of preparing to join the European Union (EU) has created an opportunity to strengthen the legislation and policy that underlies the IHR.
- The system of law, regulation, rulebook and guideline allows for considerable operational detail to be incorporated into the legal framework.

Areas that need strengthening and challenges

- Although much work has been done in the assessment of the entire IHR legal foundation, it is not yet sufficiently detailed to fully identify the adjustments needed to ensure that all legislative gaps have been addressed.

P.1.2 Financing is available for the implementation of IHR capacities – Score 3

Strengths and best practices

- Financial planning is vested in the MoH and is well developed.
- Funding is specifically allocated to the Program Activity "Support to the work of the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" and that Institute proposes the allocation of those funds.

Areas that need strengthening and challenges

- Budget funds allocated to all budget lines in all sectors are limited, and as such are largely insufficient to cover all needs in this area (IHR implementation).
- There is a significant shortage of human resources, and existing budgetary allocations and constraints do not allow the recruitment of new employees.
- There is no clear needs analysis that details specific funding shortfalls and the consequences of those shortfalls.

P.1.3 A financing mechanism and funds are available for the timely response to public health emergencies – Score 4

Strengths and best practices

- In accordance with the Budget of the Republic of Serbia, the Law on Emergency Situations and the rulebook on conditions and measures of quarantine, there are mechanisms for distributing all available financial resources when needed for IHR emergency response.
- Within each sector/ministry there are special budget lines for all aspects of emergency management, as well as funds for rapid response during public health emergencies.
- In the event of an emergency at any level, appropriate multisectoral emergency staffs are activated with the mandate to engage all the resources necessary in a rapid and short-term implementation of an emergency public procurement procedure.

Areas that need strengthening and challenges

- There is no public body authorized to raise resources in the event of a public health emergency that exceeds available resources.
- Each ministry has a budget line established for activities related to any emergency, so the availability and timeliness have not been fully defined for the specific cases of public health emergencies.

Recommendations for priority actions

- Perform an extended comprehensive assessment and identify needed adjustments to finalize the development of the legal framework for IHR implementation.
- Allocate a dedicated budget for IHR or define the comprehensive components of the budget, identifying existing allocations as well as unallocated shortfalls.
- Define a uniform multisectoral national plan for IHR as part of the Serbian official document structure.
- Create the legal mandate that defines a single centre for coordination, planning, monitoring and implementation of IHR.

IHR COORDINATION, COMMUNICATION AND ADVOCACY

INTRODUCTION

The effective implementation of the IHR requires multisectoral/multidisciplinary approaches through national partnerships for efficient alert and response systems. Coordination of nationwide resources, including the designation of a national IHR focal point (NFP), and adequate resources for IHR implementation and communication, is a key requisite for a functioning IHR mechanism at country level.

Target

Multisectoral/multidisciplinary approaches through national partnerships that allow efficient, alert and response systems for effective implementation of the IHR. Coordinate nationwide resources, including sustainable functioning of a National IHR Focal Point – a national centre for IHR communications which is a key obligation of the IHR – that is accessible at all times. States Parties provide WHO with contact details of National IHR Focal Points, continuously update and annually confirm them.

LEVEL OF CAPABILITIES

The Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS) is the NFP appointed by the Ministry of Health of Serbia and registered by the World Health Organization (WHO). The NFP is capable of reporting on incidents/public health emergencies related to IHR (2005) and is continuously available. Mechanisms for coordination have been established through the implementation of legislation.

These mechanisms ensure timely and systematic information exchange between the NFP and the World Organisation for Animal Health (OIE) national focal points in case of the occurrence of a zoonotic disease pursuant to the Regulations on the Method of Monitoring Zoonosis and Zoonotic Agents (Official Gazette of RS, No. 76/2017). The latest event that tested the country's systems for identification and reporting of a potential public health emergency of international concern (PHEIC) was 5 July 2018 when the IPHS notified WHO of cases of West Nile fever.

As a result, the responsibility of planning and implementing preventive measures, preparedness, response to emergencies, and elimination of consequences thereof was transferred to the joint activity of the competent state administration bodies, autonomous provinces and local self-government units. The responsibilities of each of the listed entities are defined by the Law on Emergency Situations (Articles 9–15).

For other health emergencies, responsible ministries, according to the regulations of Serbia, are obliged to establish mechanisms of cooperation, especially in the field of determining health risks. Numerous multisectoral working groups and expert commissions have been appointed by different ministries and represent functional mechanisms of multisectoral response in relation to different topics. Depending on the priority of the identified risk, individual multisectoral working groups are appointed by the Government of Serbia.

Indicators and scores

P.2.1 A functional mechanism established for the coordination and integration of relevant sectors in the implementation of IHR – Score 3

Strengths and best practices

- A national IHR focal point (IHR NFP) has been established.
- An OIE Delegate has been appointed.
- A regulatory framework for coordination, communication and reporting is in place.
- Coordination, communication and reporting mechanisms have been tested recently, i.e. through coordination and communication during the floods in 2014 and 2016.
- There is an established health surveillance system for the migrant population since 2015 (reporting is pursuant to Article 7 of IHR – cases of imported disease – Plasmodium vivax malaria).
- West Nile fever and dengue fever events in Serbia have been reported to WHO in a timely manner.

Areas that need strengthening and challenges

- The multisectoral committee for implementation of the IHR is functioning on an ad hoc basis.
- A capacity building plan with continuous education and training activities to strengthen national capacities has not been developed.
- Multisectoral coordination and information sharing mechanisms related to IHR with sectors outside public health and animal health lack a formal structure.
- Human and financial resources are insufficient for effective capacity building for implementation of IHR (2005).

Recommendations for priority actions

- Streamline and formalize the structure and formulate the main tasks of a multisectoral committee for implementation of IHR (2005).
- Develop standard operating procedures (SOPs) that incorporate an "all-hazard approach" for the multisectoral working group established to address public health threats
- Conduct regular meetings with all partners of the multisectoral committee for exchange of knowledge and progress with respect to IHR implementation as well organization of tabletop and simulation drills to test the SOPs.

ANTIMICROBIAL RESISTANCE

INTRODUCTION

Bacteria and other microbes evolve in response to their environment and inevitably develop mechanisms to resist being killed by antimicrobial agents. For many decades, the problem was manageable as the growth of resistance was slow and the pharmaceutical industry continued to create new antibiotics.

Over the past decade, however, this problem has become a crisis. Antimicrobial resistance is evolving at an alarming rate and is outpacing the development of new countermeasures capable of thwarting infections in humans. This situation threatens patient care, economic growth, public health, agriculture, economic security and national security.

Target

A functional system in place for the national response to combat antimicrobial resistance (AMR) with a One-Health approach, including:

a) Multisectoral work spanning human, animal, crops, food safety and environmental aspects. This comprises developing and implementing a national action plan to combat AMR, consistent with the Global Action Plan (GAP) on AMR.

b) Surveillance capacity for AMR and antimicrobial use at the national level, following and using internationally agreed systems such as the WHO Global Antimicrobial Resistance Surveillance System (GLASS) and the OIE global database on use of antimicrobial agents in animals.

c) Prevention of AMR in health care facilities, food production and the community, through infection prevention and control measures.

d) Ensuring appropriate use of antimicrobials, including assuring quality of available medicines, conservation of existing treatments and access to appropriate antimicrobials when needed, while reducing inappropriate use.

LEVEL OF CAPABILITIES

Antibiotics are widely used in Serbia in both animal and human health sectors, as is the case is other European countries; AMR is also high in the country. In response, the Minister of Health recently initiated a working group, which meets regularly, of a multidisciplinary team of experts to develop a national programme for the control of AMR, which includes an action plan, monitoring of the implementation, and participation in education and media campaigns about the topic. The action plan has been drafted and shall be adopted in the near future. The testing of food for AMR, however, is not included in the national programme. This gap is being addressed within the European Union (EU) Twinning Project[1], which is "improving the system of the Republic of Serbia in the field of zoonoses, foodborne diseases and AMR".

Surveillance of hospital infections at the national level was initiated in 2001 and national prevalence studies have been conducted. A system for notification and surveillance of AMR in human isolates is in place and includes a national reference laboratory (NRL) and a national network of 22 clinical laboratories that monitors the susceptibility of invasive isolates of bacteria from blood and liquor. However, the data suggest disproportionate sampling of nosocomial infections in more severely ill and pretreated patients and an underrepresentation of community-acquired infections. Serbia is also a member of the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network and AMR data have been included in CAESAR annual reports since 2014.

1 http://www.parlament-twinning.eu

The veterinary system in Serbia has a network of 12 laboratories located within various veterinary specialist and scientific institutes. While AMR surveillance is done in the network as part of daily activities and scientific research, its methodology is not accredited.

Antibiotics are available by prescription only in public health and animal sectors. The Medicines and Medical Devices Agency of Serbia (MMDAS) collects and analyses data on distribution of medicines for antibiotics for human and veterinary use. MMDAS ensures that medicine for human and veterinary use meets the prescribed quality, efficiency and safety requirements.

Hand hygiene guidelines have been developed and implemented. However, hand hygiene compliance is only measured at health care facilities according to local plans. Monitoring of the implementation of hand hygiene guidelines at the national level is foreseen for 2019.

Guidelines for good farming practices and biosafety have been developed and their implementation evaluated. Some national guidelines on prudent antibiotic use for several infections have been published in the pubic health sector. In the veterinary field guidelines on prudent use have been published as well; guidelines for specific diseases are in development.

Indicators and scores

P.3.1 Effective multi-sector coordination on AMR – Score 3

Strengths and best practices

- A special working group for rational use of antibiotics (multidisciplinary team of experts) has developed a draft of the National Program and Action Plan for the Control of Antimicrobial Resistance.
- Within the EU Twinning Project – enhancing the capacities of the Serbian authorities in zoonoses and foodborne disease control – a protocol on cooperation between veterinary and public health authorities has been developed, which will institutionalize the cooperation between the authorities in these sectors related to zoonoses and foodborne diseases.

Areas that need strengthening and challenges

- Sustainable funding and human resources for the National Program and Action Plan for the Control of Antimicrobial Resistance is lacking.
- A single software solution is lacking for monitoring the resistance of bacteria isolated from human, animal and food samples – development and integration of such a system is needed.

P.3.2 Surveillance of AMR – Score 2

Strengths and best practices

- The NRL and a network of microbiological laboratories manage the AMR surveillance system in the public health sector; data on the susceptibility of invasive bacterial isolates to particular antibiotics in accordance with the European Centre for Disease Prevention and Control (ECDC) recommendations and the international CAESAR network are collected.
- The laboratories within various veterinary specialist and scientific institutes perform AMR testing daily and for scientific research, but without accredited methods.
- MMDAS collects and analyses data on distribution of veterinary and human medicines.

Areas that need strengthening and challenges

- The capacity of laboratories for AMR testing of animal isolates and isolates from food is a challenge (e.g. additional equipment, tests, staff training).
- The lack of unique and comprehensive methods of registering resistant agents of infections at health care institutions prevents their further detailed analysis at this point.

P.3.3 Infection prevention and control – Score 3

Strengths and best practices

- National programmes for prevention, detection, notification, control and eradication of infections exist in the public health and veterinary sectors.
- Guidelines for good farming practices and biosafety have been developed and distributed; their implementation is evaluated by veterinarians.
- Each health care institution has an infection prevention and control (IPC) plan which is monitored.
- Hand hygiene guidelines are developed at the national level and based on WHO guidelines.

Areas that need strengthening and challenges

- Hand hygiene compliance at national level is informally and occasionally measured at health care facilities, according to local plans – compliance is not (yet) nationally monitored.
- Sustainable financing of the measures concerning animal health care programmes is lacking.

P.3.4 Optimize use of antimicrobial medicines in human and animal health and agriculture – Score 3

Strengths and best practices

- MMDAS ensures that medicines for both human and veterinary use on the market meet prescribed quality, efficiency and safety requirements.
- National guidelines on the appropriate use of antibiotics in public health are developed for several diseases.
- Guidelines for the use of antibiotics in animals are developed and distributed.
- The use of antibiotics as a growth promoter in animal feed is prohibited.

Areas that need strengthening and challenges

- Professional knowledge in the field of AMR and effective management of antibiotic use need to be strengthened.
- Guidelines for the use of antibiotics in animals for specific diseases are not yet fully adopted (they are currently being developed).

Recommendations for priority actions

- Adopt and implement the National Program and Action Plan for the Control of Antimicrobial Resistance in all disciplines and ensure continued funding and human resources.
- Improve the surveillance of AMR in the veterinary field for food of animal origin; designate NRLs and improve the capacity of the laboratories to conduct AMR testing.
- Establish a comprehensive method of registering resistant human infection agents at health care institutions.
- Continue the development of specific guidelines for prudent antibiotic use for specific, diseases of national importance in the veterinary field.

ZOONOTIC DISEASES

INTRODUCTION

Zoonotic diseases are communicable diseases that can spread between animals and humans. These diseases are caused by viruses, bacteria, parasites and fungi carried by animals, insects or inanimate vectors that aid in its transmission. Approximately 75% of recently emerging infectious diseases affecting humans are of animal origin; and approximately 60% of all human pathogens are zoonotic.

Target

Functional multi-sectoral, multidisciplinary mechanisms, policies, systems and practices are in place to minimize the transmission of zoonotic diseases from animals to human populations.

LEVEL OF CAPABILITIES

There is a legal document supporting intersectoral collaboration for zoonotic disease surveillance, in the framework of the One-Health approach in Serbia (rulebook on monitoring zoonoses and zoonotic agents – Official Gazette of RS No. 76/2017). Further, the human and animal health sectors have jointly identified the following priority zoonotic diseases in cooperation with the European Union (EU), World Health Organization (WHO), World Organisation for Animal Health (OIE) and countries in the region: brucellosis, echinococcosis, rabies, Q fever, tularaemia, avian influenza, West Nile virus, haemorrhagic fever with renal syndrome. Except for the latter, all are under surveillance by both the animal and the human health sectors.

Notwithstanding, the human and animal health sectors have issued separate surveillance plans/procedures and run mostly parallel systems. Exchange of information and collaboration occurs regularly but largely at an informal level. This collaboration mechanism is strengthened, and has been proven effective, during emergency situations. An inter-institutional agreement on data exchange between the main institutions in charge of human and animal health surveillance is in the process of being approved. This should favour a more formalized interaction between the two sectors in the field of zoonotic disease surveillance.

Examples of good practice of zoonotic multisectoral surveillance in Serbia include the ongoing surveillance of avian influenza, rabies and West Nile virus. Surveillance of the first two diseases are older, formalized systems. Surveillance of avian influenza led to the organization of annual human-animal health meetings since 2004 and to the production of a joint animal and human health pandemic plan in 2005 that was tested successfully during the 2009 influenza pandemic across administrative levels and sectors. Active rabies surveillance on animals/wildlife combined with successful implementation of rabies vaccination measures have led to the elimination of rabies in domestic animals and to a drastic reduction of the number of cases of rabies in wild animals.

West Nile virus surveillance was first established in 2012 and its multisectoral connotation has progressively been formalized. As part of this process, a previously established multisectoral working group on West Nile virus has been formalized this year becoming a multisectoral working group for vector-borne diseases. This working group includes, but is not limited to, nominated representatives of the animal health, medical entomology, human health, environment and wildlife protection, microbiology and blood safety sectors.

The multisectoral working group for vector-borne diseases met before the beginning of the 2018 transmission season of West Nile virus to update the surveillance guidelines using a multisectoral approach and to agree on vector-control activities to implement when the first mosquitoes carrying

the virus would be detected. Enhanced surveillance for the disease began on 1 June 2018 for both the human and animal health sectors. During the entire surveillance period, the working group received weekly epidemiological updates from human, entomological and animal/wildlife (birds and horses) surveillance activities (including data on all suspected/probable/confirmed cases/mosquito pools). This information reportedly triggered actions on blood safety measures and activated, through the district and municipal authorities, vector-control measures at local level. The working group met again due to the unexpectedly high number of human cases and deaths reported this year, conducting qualitative risk assessments and defining and implementing extraordinary vector-control measures that were financed through national budget reserves.

To date, no joint assessments of those zoonotic disease surveillance and control systems have been performed to document the timeliness and efficiency of existing multisectoral operational mechanisms, including systematic information exchange between animal/wildlife surveillance units, human health surveillance units and other relevant sectors.

Indicators and scores

P.4.1 Coordinated surveillance systems in place in the animal health and public health sectors for zoonotic diseases/pathogens identified as joint priorities – Score 3

Strengths and best practices

- Harmonized legislation/case definitions exist between the human and animal health sectors.
- A consolidated network of public health and veterinary institutes exists.
- There is a formalized multisectoral working group for vector-borne disease surveillance.
- Zoonotic disease surveillance systems are in place for avian influenza, rabies and West Nile virus.

Areas that need strengthening and challenges

- The information and data exchange mechanisms in the context of surveillance and response to priority zoonotic diseases across sectors need to be formalized and strengthened.
- Timeliness and efficiency of existing multisectoral operational mechanisms to respond to zoonotic diseases need to be assessed.
- Human resources are inadequate.
- There is insufficient coordination between MoH and MoA surveillance programmes, specifically when an event is not declared an emergency.
- The human health sector lacks an electronic data management system for surveillance – where appropriate, such a system (when developed) should be integrated/interoperable with the existing animal health sector electronic surveillance tool.

P.4.2 Mechanisms for responding to infectious and potential zoonotic diseases established and functional – Score 3

Strengths and best practices

- A strong legal framework and mandate are available and harmonized across the human and animal health sectors towards responding to zoonotic diseases.
- Multisectoral response systems are in place for several priority zoonotic diseases.

Areas that need strengthening and challenges

- Multisectoral response mechanisms to priority zoonotic diseases need to be formally defined and strengthened.
- The lack of a national programme for vector-control leads to fragmented, ad hoc actions done with delay.

Recommendations for priority actions

- Prioritize the approval of the operational agreement between the main institutions/actors in charge of human and animal health, in order to formalize and strengthen data and/or information exchange on, and coordinated response to, zoonotic diseases.
- Design and perform a joint assessment of the multisectoral surveillance and response systems to document their timeliness and effectiveness across administrative levels for the response to vector-borne zoonotic diseases.
- Strengthen multisectoral timely exchange of data on zoonotic events and zoonotic agents by supporting the digitization of the human health surveillance system, and designing an integrated/interoperable approach with the existing animal health sector electronic surveillance system, in order to enable timely integrated analysis for early detection, joint risk assessments and continuous monitoring of risk management.
- Develop a national plan for vector control in order to harmonize and increase the timeliness of vector control in Serbia.

FOOD SAFETY

INTRODUCTION

Food- and water-borne diarrhoeal diseases are leading causes of illness and death, particularly in less developed countries. The rapid globalization of food production and trade has increased the potential likelihood of international incidents involving contaminated food. The identification of the source of an outbreak and its containment is critical for control. Risk management capacity with regard to control throughout the food chain continuum must be developed. If epidemiological analysis identifies food as the source of an event, based on a risk assessment, suitable risk management options that ensure the prevention of human cases (or further cases) need to be put in place.

Target

A functional system is in place for surveillance and response capacity of States Parties for foodborne disease and food contamination risks or events with effective communication and collaboration among the sectors responsible for food safety.

LEVEL OF CAPABILITIES

The competent authorities for food safety are the Ministry of Agriculture, Forestry and Water Management (MAFWM), which is in charge of all food of animal and non-animal origin, and the Ministry of Health (MoH), which is responsible for the safety of drinking water and certain foods (vitamin supplements, food for infants and children). The measures related to food safety are defined in an appropriate legislative framework with several laws, by-laws and rulebooks.

The MAFWM is responsible for the prevention, early detection, notification and eradication of zoonoses in animals and animal diseases, including diseases transmitted by food of animal origin. A National Monitoring Plan (NMP) is adopted each year for the monitoring of residues of veterinary medicinal products, hormones, chemical hazards and prohibited substances in food and feed. However, the annual NMP does not test food for the presence of microbiological hazards and chemicals in final products at the retail level. The European Union (EU) Twinning Project is addressing this gap by "improving the system of the Republic of Serbia in the field of zoonoses, foodborne diseases and AMR".

The veterinary system has a network of 12 laboratories within various veterinary specialist and scientific institutes.

The MoH has the legislative framework for the surveillance of foodborne diseases in humans. It includes a surveillance system that includes foodborne diseases, which is implemented by 25 public health institutes. Foodborne diseases are notifiable and reported to the public health institutes. Genotyping methods are used to compare human and food samples. In the event of outbreak or epidemics of foodborne disease, a team of representatives from the relevant services of the human and veterinary health sectors responds.

Detailed instructions are described in rulebooks for the response and management of food safety emergencies, which existing multisectoral working groups can access. However, no multisectoral standard operating procedures (SOPs) exist and the cooperation between sectors is not institutionalized or defined by a formal document. The EU Twinning Project, in which Serbia is involved, does offer a "protocol on cooperation between veterinary and public health authorities". This protocol is meant to institutionalize the cooperation between the authorities of the two sectors in areas of mutual interest, however it has not yet been adopted in the country. Additionally, a food safety emergency plan has been developed, but not adopted.

There is an active International Food Safety Authorities Network (INFOSAN) emergency contact point within the MoH. That contact point communicates with the national focal point for rapid notification and alert for food and feed located in the MAFWM, which communicates with the European Union's Rapid Alert System For Food And Feed (RASFF); the process of communication is guided by SOPs.

A council for risk assessment in food was established in 2017 and includes members from the public health and veterinary health sectors. The council is responsible for ad hoc problems and risk assessments. Thus far, risk assessments have been mainly qualitative, but members are trained in quantitative risk assessment as well, and will use it more in future.

Indicators and scores

P.5.1 Surveillance systems in place for the detection and monitoring of foodborne diseases and food contamination – Score 3

Strengths and best practices

- The competent authorities have defined food safety responsibilities, which are established in legal and institutional frameworks.
- There is an established system of surveillance and monitoring of priority foodborne diseases and hazards.
- Laboratories are capable of performing the necessary tests during epidemics or contamination.
- There is an efficient mechanism (formal and informal) for rapid information exchange in the event of suspicion of outbreaks or research of events between all stakeholders/relevant sectors.

Areas that need strengthening and challenges

- Testing of food is not covered in the annual monitoring for zoonoses (the NMP); this is covered by the EU Twinning Project under the title "Improving the system of the Republic of Serbia in the field of zoonoses, foodborne diseases and AMR".
- SOPs and instructions for formalized multisectoral cooperation and communication have not been developed.

P.5.2 Mechanisms are established and functioning for the response and management of food safety emergencies – Score 2

Strengths and best practices

- The National Food Safety Emergency Plan will be part of the National Emergency Response Plan of the health system and is in the process of adoption.
- A National Strategy for Emergency Response and Rescue exists.
- Contact points related to food safety (i.e. the national IHR focal point, INFOSAN emergency contact point and RASFF national contact point) and SOPs exist in the country.
- A council for risk assessment in the field of food safety has been established.

Areas that need strengthening and challenges

- All procedures are defined by laws and division of jurisdiction, but there is no clear formalized division of tasks and procedure of information exchange for multisectoral cooperation
- The National Food Safety Emergency Plan in the field of food safety has not been adopted.
- No simulation exercises for emergencies in the field of food safety have been conducted.

Recommendations for priority actions

- Implement the surveillance of food for presence of microbiological and chemical hazards at the retail level.
- Develop SOPs for foodborne disease outbreaks with special emphasis on the roles, tasks and communication lines of the multisectoral players.
- Adopt the National Food Safety Emergency Plan.

BIOSAFETY AND BIOSECURITY

INTRODUCTION

It is vital to work with pathogens in the laboratory to ensure that the global community possesses a robust set of tools – such as drugs, diagnostics, and vaccines – to counter the ever-evolving threat of infectious diseases.

Research with infectious agents is critical for the development and availability of public health and medical tools that are needed to detect, diagnose, recognize and respond to outbreaks of infectious diseases of both natural and deliberate origin. At the same time, the expansion of infrastructure and resources dedicated to work with infectious agents have raised concerns regarding the need to ensure proper biosafety and biosecurity to protect researchers and the community. Biosecurity is important in order to secure infectious agents against those who would deliberately misuse them to harm people, animals, plants or the environment.

Target

A whole-of-government multisectoral national biosafety and biosecurity system with dangerous pathogens identified, held, secured and monitored in a minimal number of facilities according to best practices; biological risk management training and educational outreach conducted to promote a shared culture of responsibility, reduce dual-use risks, mitigate biological proliferation and deliberate use threats, and ensure safe transfer of biological agents; and country-specific biosafety and biosecurity legislation, laboratory licensing and pathogen control measures in place as appropriate.

LEVEL OF CAPABILITIES

Serbia has laws and regulations on biosafety and biosecurity in place, such as the Rulebook on Preventive Measures for Safe and Healthy Work during Exposure to Biological Hazards. It also has a developed laboratory system with many biosafety and biosecurity practices in place in individual laboratories. However, national direction and national oversight has not been emphasized, leading to significant questions about the degree to which these practices have been implemented and are sufficient. Some of the elements of a biosafety and biosecurity system that are in place include: a list of dangerous pathogens, a relatively comprehensive national regulatory framework for biosafety and biosecurity scattered across various rulebooks, and a tendency for pathogen collections to be stored primarily in certain reference laboratories. A laboratory licensing procedure exists but only for technical (equipment), infrastructure and personnel conditions; the procedure does not specifically refer to the level of biosafety and biosecurity. Systematic measures of laboratory licensing and pathogen control are therefore not applied, and those procedures that are in place at national level are not uniformly implemented by all laboratories.

Bearing that in mind, many institutions are certified according to International Organization for Standardization (ISO) 9001 (Quality Management Systems) and ISO 17025 (General Requirements for the Competence of Testing and Calibration Laboratories) within the framework of accreditation of laboratory testing procedures. This means the country is obliged to adopt and follow the procedures for securing laboratories as well as other standard operational procedures, such as those defined according to WHO documents. In the human health sector, 30 laboratories were certified, and 9 of the 97 laboratories that participated in a laboratory-strengthening project were accredited. The Law on Veterinary Medicine and the associated rulebooks define many biosafety requirements in the veterinary sector, such as equipment, conditions for safety of personnel and protection against the possible spread of pathogens

outside the laboratory. In addition, all veterinary laboratories have been accredited according to ISO 17025. This also promotes the education of personnel at the institutional level. The commission formed by the Veterinary Directorate oversees many aspects of veterinary laboratory compliance.

There are no national training programmes in Serbia and national records are not kept. All certified and accredited laboratories individually train personnel on all issues including biosecurity and biosafety measures, but such training is institutionally determined and not necessarily applicable to uncertified laboratories. A general training needs assessment was recently conducted, which included questions related to biosafety and biosecurity[2], but it was not sufficiently detailed to support the development of a robust national training programme. On the positive side, interest is increasing as the Ministry of Defence is actively working to raise the awareness of the scientific and professional public and decision-makers regarding the recognition of the importance of microorganisms in terms of biosafety and the risks in terms of bioterrorism, major epidemics and pandemics, and emerging diseases.

Indicators and scores

P.6.1 Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities) – Score 2

Strengths and best practices

- There is a comprehensive body of legal regulations and rulebooks on biosafety and biosecurity addressing such areas as safety at work, waste management, dangerous goods transport, dual-use goods and dangerous pathogens.
- Many laboratories are certified according to ISO 9001 or accredited according to ISO 17025 or ISO 15189 (Medical Laboratories -- Requirements for Quality and Competence), with standard operating procedures for handling dangerous materials in biosafety cabinets, processes for risk assessment, response plans for accidents and procedures for securing the laboratories.
- Commissions organized by the ministries ensure compliance by laboratories in terms of equipment, personnel and working conditions, including issues of biosafety and biosecurity.

Areas that need strengthening and challenges

- There are no common safety and security requirements or licensing conditions for all laboratories.
- There is no centralized inventory of dangerous pathogens and toxins, monitoring of facilities that contain them or policy for the consolidation of sites.
- There is no defined policy or specific recommendations for promoting diagnostic tests that eliminate the need for the cultivation of dangerous pathogens.
- National resources (budget and human resources) are currently insufficient to support a comprehensive national biosafety and biosecurity system, i.e. for proper and timely maintenance of facilities and equipment, organization of training and supervision of the implementation of regulations.

P.6.2 Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture) – Score 2

Strengths and best practices

- Staff in many facilities, including those who maintain or work with dangerous pathogens and toxins, are provided with information and training on biosafety and biosecurity.
- There is a mechanism for ensuring staff competencies and controlling training standards in all laboratories, although not specifically in terms of biosafety and biosecurity.

2 Project SR 13 IPA HE 01 17 TWL: Improving microbiology diagnostic system quality in the function of surveillance on communicable diseases in the Republic of Serbia.

Areas that need strengthening and challenges

- Serbia has not performed a sufficiently comprehensive assessment of training needs for biosafety and biosecurity.
- There is no national record of staff training or testing of biosecurity/biosafety procedures.
- There is no comprehensive and sustainable academic training in institutions, including those where employees maintain or work with dangerous pathogens and toxins.
- Insufficient resources, personnel and facilities are available to maintain training and supervision of staff competencies on biosafety and biosecurity.

Recommendations for priority actions

- The Government should create a strong foundation for all future training plans by performing and documenting or publishing a new, expanded, detailed and comprehensive revised training needs assessment for biosafety and biosecurity.
- The relevant ministries should use the appropriate legal instruments to establish common enforceable safety and security requirements or licensing conditions for all laboratories.
- The Government should develop and maintain an inventory of dangerous pathogens and toxins, a record of the facilities that conserve or treat them, and a programme of active monitoring.
- The appropriate bodies should define specific policies for using diagnostic tests to eliminate or reduce the need for the cultivation of dangerous pathogens.

IMMUNIZATION

INTRODUCTION

Immunizations are estimated to prevent more than two million deaths a year globally. Immunization is one of the most successful global health interventions and cost-effective ways to save lives and prevent disease. Measles immunization is emphasized because it is widely recognized as a proxy indicator for overall immunization against vaccine preventable diseases. Countries will also identify and target immunization to populations at risk of other epidemic-prone vaccine preventable diseases of national importance (e.g. cholera, Japanese encephalitis, meningococcal disease, typhoid and yellow fever). Diseases that are transferable from cattle to humans, such as anthrax and rabies, are also included.

Target

A national vaccine delivery system – with nationwide reach, effective distributions, access for marginalized populations, adequate cold chain and ongoing quality control – that is able to respond to new disease threats.

LEVEL OF CAPABILITIES

Serbia's Immunization programme has a clear legal foundation. The country has a vaccination calendar in place for children up to the age of 18 (including measles). The measles vaccine coverage rate for children aged 12 months is greater than 90% (single dose).

Vaccination is mandatory and free of charge for children and pregnant women. The vaccine programme is financed and provided by the Government (Republic Health Insurance Fund – either via tender from a supplier or from the Institute of Virology, Vaccines and Sera "Torlak"). The Institute produces, stockpiles and delivers vaccines in the cold chain to all districts and all vaccination sites. Both the delivered vaccines and administered vaccinations are documented, which is currently done by hand. An electronic register would allow for a better understanding of the current vaccination rates and the needs in the coming years. The district public health service follows up with families who fail to have their children vaccinated.

Every vaccination point (outpatient clinic) can order what it needs for the mandatory vaccination each year. If there is an unexpected demand (e.g. an epidemic) or the need for supplemental vaccination, districts can order limited additional quantities (i.e. additional supply can be constrained by domestic production capacity, through delays from international manufacturers or limits in the budget). For that reason there should be some mechanism to ensure that there is enough vaccine to supply all districts at all times.

During plenary it was also noted that many health care workers are under-vaccinated against measles, which became clear during the 2017–2018 measles outbreak. For sufficient vaccination of children and outreach for special target groups there is a need for more specialized medical doctors and health care staff to increase the opportunities to be vaccinated.

While there is no widespread cohesive anti-vaccination campaign in Serbia, there are groups of younger people/parents who reject vaccination (particularly against measles), because of fear of unexpected side-effects or other irrational thoughts.

Indicators and scores

P.7.1 Vaccine coverage (measles) as part of national programme – Score 3

Strengths and best practices

- The vaccination programme is mandatory, includes a central procurement mechanism and a quality-controlled delivery system.
- Immunization is free of charge to all children and pregnant women (a very good practice to ensure a high rate of vaccination).
- Immunization can be conducted through well-distributed outpatient clinics and a network of health institutions, including public health services.
- A system to capture unexpected side-effects (adverse events following immunization) is established.
- Every vaccination is documented with the name of the child and the serial number of vaccine.

Areas that need strengthening and challenges

- Given the ageing health workforce, it is anticipated that relatively soon there may be insufficient numbers of paediatricians and other personnel in outpatient clinics to meet the needs of the national vaccination programme for all target groups – including health care personnel. (The vaccination of children at schools may be a way to handle the lack of clinicians and improve vaccination rates.)
- There is no electronic documentation system to support precise and timely planning for vaccine procurement and, when vaccination rates dip, document points of action for (supplemental) vaccination campaigns.

P.7.2 National vaccine access and delivery – Score 4

Strengths and best practices

- The national vaccine manufacturer – the Institute of Virology, Vaccines and Sera "Torlak" – partly provides vaccines based on the calendar of immunization. For the rest, it procures/distributes the necessary vaccines from other suppliers.
- The vaccine distribution system functions well (the cold chain is maintained at every stage of distribution) and is documented.

Areas that need strengthening and challenges

- The availability of all mandatory vaccines or needed vaccines in epidemic situations should be improved (i.e. no stock outs should occur). (The extension of production and stockpiling of a certain amount of vaccines may be an option.)

Recommendations for priority actions

- Provide national vaccine reserves to ensure continuous, timely and complete immunization in the event of epidemics, shortages, delayed procurement, manufacturing problems; this includes considering the expansion of the production capacity and product variety of the domestic vaccine manufacturer.
- Establish and introduce an electronic immunization register for the entire country.
- Intensify efforts to improve the implementation of the immunization programme in all segments with public campaigns and well-trained personnel (e.g. increase uptake of vaccines by health care workers, children, the elderly).

DETECT

NATIONAL LABORATORY SYSTEM

INTRODUCTION

Public health laboratories provide essential services including disease and outbreak detection, emergency response, environmental monitoring and disease surveillance. State and local public health laboratories can serve as a focal point for a national system, through their core functions for human, veterinary and food safety including disease prevention, control and surveillance; integrated data management; reference and specialized testing; laboratory oversight; emergency response; public health research; training and education; and partnerships and communication.

Target

Surveillance with a national laboratory system, including all relevant sectors, particularly human and animal health, and effective modern point-of-care and laboratory-based diagnostics.

LEVEL OF CAPABILITIES

The national laboratory system in Serbia in human health sector consists of 25 national reference laboratories and additionally, as part of the public health institutes, 25 laboratories which are capable of analysing human specimens and approximately 50 more laboratories in secondary and tertiary hospital care facilities. (In the private sector there are approximately 40 laboratories for the analysis of human specimens.) Within the Ministry for Agriculture, Forestry and Water Management there are 12 laboratories for the analysis of veterinary specimens, and four laboratories for analysis of genetically-modified organisms. Serbia has laboratories for pathogens that require either biosafety level 1 (BSL-1) or BSL-2. Currently, no facilities exist in the country that can handle pathogens requiring a BSL-3 or higher.

There are 49 diseases in Serbia that are notifiable according to law. The country has the diagnostic capacity to diagnose those notifiable diseases in accordance with current European Union (EU) case definitions, except for viral haemorrhagic fevers, plague, smallpox and yellow fever. For the diagnosis of these four diseases, agreements with international partners are in place provide the diagnostic methods if needed.

Core diagnostic tests for the analysis of human specimens in Serbia are defined according to EU recommendations. Among others, the following core tests are conducted: isolation and serotyping of Salmonella ssp. (including S. Typhi); isolation, direct examination and molecular identification of Mycobacterium tuberculosis; detection of West Nile virus by enzyme-linked immunosorbent assay (ELISA) and polymerase chain reaction (PCR); PCR for influenza virus; culture for poliovirus; serology for HIV, rapid diagnostic test and direct examination of peripheral blood for Plasmodium spp., PCR for Morbillivirus, PCR for rubella virus, and PCR for pertussis. For the majority of these tests, national reference laboratories (NRLs) exist and regular external quality assurance (EQA) is carried out.

The notification of the results from laboratory tests to the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" can be done in several ways: electronically by sending a scanned report by email, on paper via the postal service, or in case of urgent or unusual events, immediately by phone.

In terms of quality assurance there are big differences between diagnostic laboratories in the country. In particular, accreditation, quality management, the use of standardized methods and the implementation of biosafety and biosecurity measures differ greatly between laboratories. In human health sector use of an electronic data management system in NRLs and other laboratories is only partially implemented, and laboratory networks between NRLs and other laboratories including laboratories from peripheral levels are not very strong. Systematic quality control measures are not carried out, mainly due to the lack of a responsible entity for coordination and quality assurance of diagnostics at the national level.

A comprehensive assessment of diagnostic capacities for human specimens has been conducted recently.[3]

Indicators and scores

D.1.1 Laboratory testing for detection of priority diseases – Score 4

Strengths and best practices

- Nine laboratories of the human public health sector have been accredited according to International Standardization Organization (ISO) 17025 and ISO 15189. All 12 laboratories of the animal health sector have been accredited according to ISO 9001 and ISO 17025.
- Four national laboratories are part of WHO laboratory networks, namely the NRL for influenza and other respiratory viruses, the NRL for poliomyelitis and enteroviruses and the NRL for measles and rubella of the Institute of Virology, Vaccines and Sera "Torlak", and the laboratory for influenza at the Institute of Public health of Vojvodina in Novi Sad.

Areas that need strengthening and challenges

- Currently lacking is a quality assurance programme for all microbiology laboratories, with emphasis on a national EQA system for all laboratories that carry out diagnostic tests for human specimens.
- While molecular testing is conducted for several diseases (e.g. influenza, tuberculosis, pertussis, tick-borne encephalitis virus, West Nile virus, measles, rubella and toxoplasmosis) the use of advanced diagnostic methods should be expanded to other pathogens, and additional molecular methods such as sequencing should be considered.
- Whereas for the veterinary sector standardization of testing is given in all 12 laboratories, the respective standardization of diagnostic methods is not implemented fully for the analysis of human specimens.

D.1.2 Specimen referral and transport system – Score 3

Strengths and best practices

- A system is in place to transport specimens to a national laboratory from intermediate levels or districts.

Areas that need strengthening and challenges

- National guidelines and standard operating procedures (SOPs) should be developed for all international standards adopted through Serbia's legal system regarding the collection, packing and transport of specimens – in particular of high-priority specimens in emergency situations.
- Transportation of samples should be carried out according to national guidelines/SOPs, once they are finalized.
- Ensure sustainable funding for the transportation of samples.

3 GAP assessment report 2018. The Twinning Light (TWL) project "Improving microbiology diagnostic system quality in the function of surveillance on communicable diseases in the Republic of Serbia".

D.1.3 Effective national diagnostic network – Score 3

Strengths and best practices

- Confirmatory diagnostics can be performed in 25 reference laboratories within the human sector and three reference laboratories within the veterinary sector.

Areas that need strengthening and challenges

- Effective modern point-of-care and laboratory-based diagnostics are not widely distributed; their use should be expanded.
- Laboratory links between central laboratories, NRLs and peripheral laboratories should be reinforced.

D.1.4 Laboratory quality system – Score 2

With regard to the laboratory quality system it is important to note that there are major differences in capabilities between the human and the veterinary sectors. In Serbia, all laboratories belonging to the Ministry of Agriculture, Forestry and Water Management have accreditation and conduct standardized testing of specimens, whereas this is only the case for a small number of the laboratories within the human sector.

Strengths and best practices

- All veterinary laboratories are accredited according to ISO 17025 and ISO 9001 and do have standardized diagnostic tests.
- National programme for EQA is in place in the veterinary sector, including veterinary laboratories and laboratories for food and water testing.

Areas that need strengthening and challenges

- Assurance of quality management should be expanded to all laboratories providing diagnostic testing, in particular those analysing human specimens.

Recommendations for priority actions

- Appoint a national authority for the coordination of national reference laboratories which should have, among others, the responsibility of implementing an external quality management system for all national reference laboratories.
- Establish an electronic system for timely dissemination of laboratory results and reporting of notifiable diseases, which should be integrated into an electronic surveillance system (see recommendation in the "Surveillance" technical area).
- Enhance the usage of advanced molecular diagnostics through investment in training and laboratory equipment.

SURVEILLANCE

INTRODUCTION

The purpose of real-time surveillance is to advance the safety, security and resilience of the nation by leading an integrated surveillance effort that facilitates early warning and situational awareness of all IHR hazard-related events.

Target

(1) Strengthened foundational indicator- and event-based surveillance that are able to detect events of significance for public health and health security; (2) improved communication and collaboration across sectors and between sub-national (local and intermediate), national and international levels of authority regarding surveillance of events of public health significance; and (3) improved national and intermediate level regional capacity to analyse and link data from and between, strengthened, early-warning surveillance, including interoperable, interconnected electronic tools. This would include epidemiologic, clinical, laboratory, environmental testing, product safety and quality and bioinformatics data; and advancement in fulfilling the core capacity requirements for surveillance in accordance with the IHR and OIE guidelines.

LEVEL OF CAPABILITIES

A well-structured and articulated legal framework regulates the operation of indicator-based surveillance (IBS) and event-based surveillance (EBS) in both the veterinary and human health sectors. In the human health sector, recent legal revisions of the laws and rulebooks have aligned reporting requirements to those of the European Union (EU): including 49 infectious diseases and health care issues, fully adopting EU and World Health Organization (WHO) case definitions. Syndromic surveillance is activated for defined events and emergency situations; it is currently in place to monitor migrant health in refugee centres.

The health sector has identified 18 priority diseases/health care issues and the human and animal sectors have identified eight priority zoonotic diseases in cooperation with the EU, WHO, World Organisation for Animal Health (OIE) and countries in the region.

There is a legal document supporting intersectoral collaboration for zoonotic disease surveillance, in the framework of One-Health, and concordance on the selected priority diseases to monitor. However, the two sectors have separate plans/procedures and run essentially parallel surveillance systems. Exchange of information and collaboration occurs at a largely informal level. This collaboration mechanism is strengthened, and has been proven effective, during emergency situations. An inter-institutional agreement on data exchange between the main institutions in charge of human and animal health surveillance is in the process of being approved. This should favour a more formalized interaction between the two sectors in the field of zoonotic disease surveillance.

Indicator-based surveillance systems in both the human and animal health sectors are consolidated and operational with regular collection, analysis and reporting of data. Both sectors rely on strong networks of respectively 24 and 12 intermediate level institutions for the collection, verification and transmission of data to the national level.

The animal health sector operates through a secure electronic surveillance tool that allows for timely notification and production of predefined reports. This system is not in place in the health sector, which largely relies on a paper-based notification system (for both laboratory results and disease notifications). Intermediate level institutions collate case-based data in un-standardized local databases and transmit

only limited aggregated data periodically to the national level. Timeliness and completeness of surveillance data are therefore reported as a challenge in the human sector (but not in the animal health sector).

Data are reportedly analysed daily in both the human and animal health sectors at national level, with the production of regular reports (daily reporting in the case of outbreaks or unusual diseases). Central electronic surveillance databases of the human and animal health sectors are not connected. Reporting of zoonotic disease surveillance for each sector is mostly independent. An exception is West Nile virus for which, since 2018, bi-weekly integrated reports are published online on the website of the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS).

Qualitative risk assessments of data/events are reportedly conducted within 48 hours in case of suspicious disease occurrences using the International Health Regulations (IHR) Annex 2 algorithm. These assessments can be conducted within one sector or jointly by both the human and animal health sectors if appropriate, using both formal and informal channels. Events meeting the criteria for IHR notification are then shared with WHO as required.

Some event-based surveillance elements are in place including media monitoring and activities to favour community-based rumour-detection. Intermediate level institutes of public health are required by law to investigate, validate and report with the highest available detail to the national level unusual events. Upon receiving such notification legally-defined information flows and response actions are in place. However, such events are received passively by the national level and no active EBS surveillance system with clear objectives, procedures and outputs is in place.

Indicators and scores

D.2.1 Surveillance systems – Score 2

Note: Serbia exceeds this score in indicator-based surveillance performance in both human and animal health sectors.

Strengths and best practices

- Surveillance has a strong legal basis, harmonized with EU regulations.
- IBS is centralized and comprehensive, with strong surveillance networks connected across sectors for conditions like West Nile fever, influenza, acute flaccid paralysis, tuberculosis and HIV/AIDS.
- There is robust laboratory diagnostic capacity in both the human and animal health sectors.
- Active community engagement and sensitization exists, to discover and report unusual health events.
- Syndromic surveillance can be activated in case of unusual or emergency situations (the ALERT system for early detection of outbreaks of infectious diseases in Serbia).
- Country participates in numerous joint surveillance activities and projects both through bilateral agreements and international networks.

Areas that need strengthening and challenges

- The strict application of the revised EU case definitions in notification needs to be verified.
- The connection of national reference laboratories with the surveillance system needs to be strengthened.
- Further training of clinicians and other health professionals is needed to reduce under-notification.
- Existing standard operating procedures/guidelines for event-based surveillance need to be tested.
- A feasibility study to define the most suited country-specific strategy to implement an EBS system, as defined by WHO, has not been conducted.
- Completeness and timeliness of human health IBS data can be improved.

D.2.2 Use of electronic tools – Score 2

Note: Serbia exceeds this score in the animal health sector.

Strengths and best practices

- The basic IT infrastructure in the health care system is in place, and this makes the context favourable for projects aimed at the development of digital surveillance data flows.
- Integrated information system in the veterinary sector (veterinary medicine) is functional.
- The syndromic ALERT system was implemented and multisectoral and multidisciplinary mechanisms for coordination and communication were successfully tested in Serbia during the 2014 floods.
- The veterinary information system has tailor-made integrated IT tools for data processing and analysis (Oracle Business Intelligence).

Areas that need strengthening and challenges

- There is a need for standardization and IT linkage of the institutes of public health countrywide with IPHS for faster flow of relevant data from the district to the national level.
- Integration of microbiological diagnostics and reporting systems at all levels is needed, in order to ensure completeness and timeliness of reporting, analysis and, consequently, detection of unusual/unexpected diseases events in the human population.
- There is a need for a secure integrated electronic surveillance tool at all levels, which is aligned with current legal requirements for sensitive data protection.

D.2.3 Analysis of surveillance data – Score 4

Strengths and best practices

- Developed capacity exists (human resources such as epidemiologists and epizootiologists are available).
- IBS data are regularly analysed, and reports produced, at national level.

Areas that need strengthening and challenges

- Capacity in analytical statistical approaches to outbreak investigation, time-series analysis and forecasting needs to be further developed.
- Capacity in the execution of quantitative risk assessments needs to be strengthened in order to reinforce existing risk assessment activities.
- There is a lack of focused training courses related to the two points above.

Recommendations for priority actions

- Set up an electronic data management system for human health IBS surveillance data, which is able to integrate data from clinical case reporting with data from microbiological laboratories and, where appropriate, integrated/interoperable with the animal health sector electronic surveillance tool.
- Train relevant professionals on the following identified areas that need strengthening: EBS, risk assessment methodologies and advanced statistical analysis of surveillance data, possibly through a multisectoral approach.
- Perform a feasibility study for the implementation of active EBS in Serbia in order to guide the implementation strategy for this part of surveillance.
- Perform an evaluation of the human health sector IBS in order to assess the key issues to address to improve adherence to case definitions, timeliness and completeness.

REPORTING

INTRODUCTION

Health threats at the human–animal–ecosystem interface have increased over the past decades, as pathogens continue to evolve and adapt to new hosts and environments, imposing a burden on human and animal health systems. Collaborative multidisciplinary reporting on the health of humans, animals and ecosystems reduces the risk of diseases at the interfaces between them. The national IHR focal points, the OIE delegate, and WAHIS national focal point should have access to a toolkit of best practices, model procedures, reporting templates, and training materials to facilitate rapid (within 24 hours) notification of events that may constitute a public health emergency of international concern (PHEIC) to WHO and listed diseases to OIE, and will be able to rapidly (within 24/48 hours) respond to communications from these organizations.

Target

Timely and accurate disease reporting according to WHO requirements and consistent reporting to/information of FAO and OIE.

LEVEL OF CAPABILITIES

The Institute of Public Health of Serbia "Dr Milan Jovanović Batut" acts as the national International Health Regulations (IHR) focal point (NFP) of Serbia. The Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management and contact points for seven territorial areas together with other services, represent the national body for cooperation with the World Organisation for Animal Health (OIE).

At the national level there are several protocols and rulebooks[4] that regulate the notification and reporting system within the sectors. The country is a signatory of IHR (2005), and thus has adopted policies for emergency public health events. Specifically, the Law on Population Protection Against Infectious Diseases and Law on Veterinary Medicine integrate policies related to emergency events. In the field of environmental protection several laws stipulate procedures for notifying the ministry responsible for public health in the event of occurrence of pollutants in concentrations that are dangerous to human health as well as changes that may pose a threat to human life and health.

The NFP and national body for cooperation with the OIE are operational and have capabilities of reporting internationally in a timely manner. Mechanisms that ensure the exchange of information between the National IHR Focal Point and the National OIE Focal Points in case of the occurrence of a zoonotic disease are based on the rulebook on the Method of Surveillance of Zoonoses and Zoonotic Agents. Urgent reporting is done by telephone, in electronic form or other manner suitable for urgent notification. The Institute of Public Health of Serbia has a direct information exchange with the Veterinary Directorate, however there are no formal mechanisms for information exchange and interaction with other sectors.

The National IHR Focal Point uses bilateral information exchange mechanisms with other National IHR Focal Points via IHR channels as well as through mechanisms established by the European Centre for Disease Prevention and Control. Reporting is done according to standardized international professional doctrine, which is in line with World Health Organization (WHO) recommendations. In the context of veterinary medicine, Serbia has established formal relations with neighbouring countries and trade partners (trade in animals and foods of animal origin), mostly through signed interstate agreements, the

4 Rulebooks are official documents in the country that guide implementation of specific laws.

so-called Veterinary Agreements. These agreements define the mutual recognition of services, establish cooperation and communication rules, and include individual international veterinary certificates for all relevant products. They also provide a mechanism for reporting on the occurrence of infectious diseases or detailing the measures in force in the event of an outbreak, and implementation of specific preventive measures for certain diseases, including zoonoses.

All events reported internationally have been done in accordance with IHR, Annex 2, Article 6, and through the application of several international regulations on veterinary medicine.

Indicators and scores

D.3.1 System for efficient reporting to FAO, OIE and WHO – Score 4

Strengths and best practices

- The notification and reporting mechanisms within the sectors are in place and have been adopted in national legislation.
- The NFP and OIE Focal Points have been appointed and are available continuously.
- A network of institutes for public health and a network of veterinary institutes are in place.
- Exchange of information between the public health and animal health sectors occurs.
- There are established systems of reporting internationally to WHO and OIE.
- Best practices have been shown for reporting and exchange of information through workshops, real events (e.g. identification of West Nile virus) and bilateral collaboration (e.g. through investigation of contact tracing persons exposed to a diseased person).

Areas that need strengthening and challenges

- A formal system for exchange of information between sectors that are involved in response in case of a public health event is lacking.
- There are no formal relations with neighbouring countries regarding health care.
- There is no document that defines a multisectoral procedure for evaluating and assessing potential reporting events.
- There is no document defining roles (competencies, authorities and obligations) of institutions from different sectors.

D.3.2 Reporting network and protocols in country – Score 4

Strengths and best practices

- There is timely exchange of information and coordinated reporting procedures between the public health and animal health sectors from the local to the national and international level.
- Reporting systems in place are tested in exercises and real events.
- Rapid risk assessments as part of "One-Health Surveillance" has been established, which includes weekly reporting of results of West Nile virus surveillance obtained from the veterinary and entomology sectors.

Areas that need strengthening and challenges

- Formed and trained multisectoral teams need to be strengthened for timely reporting on potential emergency public health event.
- Country does not have standard operating procedures in place for approving and reporting a potential public health emergency to WHO.

Recommendations for priority actions

- Supplement established mechanisms for reporting process and procedures for coordination in response to PHEICs with a formal mechanism for interaction between the sectors on a regular manner (i.e. protocol on coordination between ministries, with terms of references, roles and responsibilities).
- Harmonize reporting matrices used by different sectors (particularly Public health and Veterinary Public Health) at all levels (e.g. ministerial level, national and regional level) and introduce among all stakeholders.
- Develop standard operating procedures (SOPs) for assessment, verification and reporting to WHO and OIE through national focal points about a potential public health emergency.

HUMAN RESOURCES

INTRODUCTION

Human resources are important in order to develop a sustainable public health system over time by developing and maintaining a highly qualified public health workforce with appropriate technical training, scientific skills and subject matter expertise. Human resources includes nurses and midwives, physicians, public health and environmental specialists, social scientists, communication, occupational health, laboratory scientists/technicians, biostatisticians, IT specialists and biomedical technicians and a corresponding workforce in the animal sector: veterinarians, animal health professionals, para-veterinarians, epidemiologists, IT specialists etc.

The recommended density of doctors, nurses and midwives per 1,000 population for operational routine services is 4.45 plus 30% surge capacity. The optimal target for surveillance is one trained (field) epidemiologist (or equivalent) per 200,000 populations who can systematically cooperate to meet relevant IHR and PVS core competencies. One trained epidemiologist is needed per rapid response team.

Target

States Parties with skilled and competent health personnel for sustainable and functional public health surveillance and response at all levels of the health system and the effective implementation of the IHR (2005).

LEVEL OF CAPABILITIES

In Serbia, there is a network of institutes of public health; the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS) acts at the national level and 24 institutes of public health act at regional level.

At the end of 2017, there were 162 epidemiology specialists practising in Serbia, while 15 other medical doctors were attending specialization in epidemiology. In addition, there are 12 epidemiologists employed in the military health sector, 6 of whom are active in this field, and there are 9 epidemiologists at work at the Faculty of Medicine in Belgrade. Of the total number of epidemiologists, 125 work at the Institutes of Public Health.

The latest figure of medical doctors comes from 2016; the total number of medical doctors employed in health care institutions from the Network Plan (health care institutions in the public sector) that year was 21 502; there were 3.05 medical doctors per 1000 inhabitants.

However, the overall view of the public health sector in general looks less optimistic. As an example, investigation conducted by several Serbian authors[5] showed that "shortage and poor distribution of public health specialists underline the urgent need for workforce recruitment and retention in public health institutes in order to ensure the coordination, management, surveillance and provision of essential public health services over the next decade". That conclusion defined the necessary direction for strengthening Serbian public health workforce capacity. Understanding of this problem has forced the Ministry of Health to look for possible solutions.

5 Santric Milicevic M, Vasic M, Edwards M, Sanchez C, Fellows J. Strengthening the public health workforce: an estimation of the long-term requirements for public health specialists in Serbia. Health Policy. 2018; 122(6):674–680 (https://www.sciencedirect.com/science/article/pii/S0168851018300666, accessed 24 October 2018).

The Law on Health Care and Law on Public Health define the tasks and roles of the IPHS as an institution to be responsible for, among others, determining the necessary health measures in emergencies and disasters and to implement them, and carrying out the development of professional training of human resources, as well as education of personnel in the area of public health. Bearing in mind existing capacity of the IPHS, the Ministry of Health (MoH) has nominated the IPHS as the national International Health Regulations (IHR) focal point (NFP), and as the competent authority to represent Serbia in the EU HEALTHY GATEWAYS Joint Action project (HP-JA-04-2017 – Preparedness and action at points of entry (ports, airports, ground crossings).

The European Commission's Strengthened International Health Regulations and Preparedness in the EU is a Joint Action project as well (SHARP-JA). The current project is going to start as of 1 January 2019. During the preparatory phase, as the result of numerous meetings, Serbia (the IPHS in particular) was designated to take the lead in one of 10 Work Packages in this Project, i.e. WP8: "Training and local exercises, exchange of working practices".

One of the first steps in Serbia's current activities related to human resources is preparation of the Global Training Plan to assess country needs in various areas of IHR, basing on existing experience and relevant World Health Organization (WHO) documents. To that end, the IPHS has already started with the assessment of needs for education in the areas of IHR at the European level (the Balkans region in particular), preparation of a training curricula and provision of training and education courses.

These activities and their results are expected to reach a very ambitious goal – to become in the near future the WHO Collaborating Centre in Continuing Medical Education (CME) in IHR-related topics.

Indicators and scores

D.4.1 An up-to-date multi-sectoral workforce strategy is in place – Score 2

Strengths and best practices

- There are annual operational personnel plans made individually for each health care institution from the Health Care Institutions Network Plan (public sector).

Areas that need strengthening and challenges

- There is a lack of a long-term national strategy for development of workforce/human resources for IHR-related activities (including laboratory, biosafety, veterinary, toxicology, primary health care, etc.), which includes a road map with concrete steps and goals that need to be achieved.
- There is no long-term strategy document for development of workforce and human resources.

D.4.2 Human resources are available to effectively implement IHR – Score 3

Strengths and best practices

- Serbia has demonstrated appropriate capacity of existing health care institutions and staff (according to Health Statistical Yearbook Of Republic Of Serbia, 2016)[6].
- In 2017, there was a sufficient number of epidemiologists working in the country: 2.8 epidemiologists per 100 000 inhabitants, or 1 epidemiologist per 36 000 inhabitants.
- Multidisciplinary task forces have been formed according to needs and at different levels (from national to local). They consist of representatives of various relevant institutions that communicate through joint meetings and other forms of communication.

Areas that need strengthening and challenges

- Applicable regulations and employment conditions in the public health sector define the need for a medical degree, but do not sufficiently include other disciplines or sectors.
- There are almost no veterinarians in the public health workforce (e.g. zoonoses, food safety, etc.).

6 Health Statistical Yearbook Of Republic Of Serbia, 2016. Belgrade: Institute of Public Health of Serbia; 2017 (http://www.batut.org.rs/download/publikacije/pub201620180419.pdf, accessed 7 November 2018).

D.4.3. In-service trainings are available – Score 3

Strengths and best practices

- Training plans have been developed and professional bodies or relevant institutions/units conduct regular trainings in order to establish standards of skills and competencies for workforce at the national level.

Areas that need strengthening and challenges

- Development and introduction of different kinds of CME are needed: training-of-trainers courses, e-learning, short-term refresher courses to strengthen the human resources capacity including the sharing of experiences among specialists.
- The activities mentioned in the bullet point above need to be harmonized with existing WHO standards and recommendations and other Balkan medical education standards.

D.4.4 FETP or other applied epidemiology training programme in place – Score 3

Strengths and best practices

- All epidemiologists get specialized training on outbreak preparedness and response on a regular basis.
- The Emergency Management Sector within the Ministry of Interior has a National Training Center for Emergency Situations.

Areas that need strengthening and challenges

- The interaction between the military and civil sectors (including potentially of the Ministry of Interior) in the field of IHR-related activities (capacity building in particular) needs to be strengthened.
- There is no special training programs related to contingency planning, management of emergency situations of this type in the health care system.

Recommendations for priority actions

- To prepare a full list of knowledge/skills needed for IHR-related activities and according to such a list to prepare a list of specialists (public health, communicable diseases, urgent medicine/reanimation, toxicology, radiation medicine, clinical microbiology, laboratory, pharmacy, surveillance, food safety, veterinary medicine, else) who could be picked up for strengthening public health care when it required (happened public health hazards). According to such a list to prepare road map for SME/refreshing courses (or targeted training) in IHR related topics.
- To support National focal point for IHR of the Ministry of Health in their overall activities for becoming the WHO Collaborating Centre in CME for IHR-involved staff.

RESPOND

EMERGENCY PREPAREDNESS

INTRODUCTION

Emergency preparedness is defined as "the knowledge and capacities and organizational systems developed by governments, response and recovery organizations, communities and individuals to effectively anticipate, respond to, and recover from the impacts of likely, imminent, emerging or current emergencies." A state of preparedness is the combination of planning, allocation of resources, training, exercising, and organizing to build, sustain, and improve operational capabilities at national, intermediate and local or primary response level based on strategic risk assessments. A strategic risk assessment identifies, analyses and evaluates the range of risks in a country and enables risks to be assigned a level of priority. Strategic risk assessments include analyses of potential hazards, exposures and vulnerabilities, identification and mapping of available resources, and analyses of capacities (routine and surge) at the national, intermediate and local or primary levels to manage the risks of outbreaks and other emergencies. Emergency preparedness applies to any hazard that may cause an emergency, including relevant biological, chemical, radiological and nuclear hazards, natural hazards, other technological hazards and societal hazards.

Target

(1) Existence of national strategic multi-hazard emergency risk assessments, risk profiles, and resource mapping (2) Existence of multi-hazard emergency response plans, (3) Evidence, from after action and other reviews, of effective and efficient multisectoral emergency response operations for outbreaks and other public health emergencies.

LEVEL OF CAPABILITIES

Serbia has a strong and comprehensive legal framework relating to emergency preparedness that explains roles and responsibilities of the stakeholders. A multi-hazard risk assessment has been developed in 2017, involving all relevant sectors. As a result, 11 risk groups were identified and resources were mapped for all sectors. A web-based application is available at national level to monitor resources in terms of staff and equipment. Stockpiles are in place and a mechanism for their mobilization exists under the coordination of the "Republic Directorate for Commodity Reserves". These mechanisms have proven their effectiveness in the management of the major floods that Serbia faced in 2014.

The multi-hazard, multisectoral National Emergency Plan and the "National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations" have been developed but not yet approved. However, the national Institute of Public health of Serbia "Dr Milan Jovanović Batut" has developed its plan for emergency operation, which has been approved.

Indicators and scores

R.1.1 Strategic emergency risk assessments conducted and emergency resources identified and mapped – Score 3

Strengths and best practices

- Cross-sectorial multi-hazard risk assessment developed.
- Resources mapped in all sectors, updated in real-time and available electronically.

Areas that need strengthening and challenges

- There is a lack of available resources (human and financial) for the maintenance of the risk assessment and mapping of resources.

R.1.2 National multisectoral multi-hazard emergency preparedness measures, including emergency response plans, are developed, implemented and tested – Score 1

Strengths and best practices

- Operational mechanism for response is in place and has been tested in 2014 during the floods.

Areas that need strengthening and challenges

- The national multisectoral response plan needs to be finalized and formalized.
- There is a need for training and exercises at national and subnational level exercising the national multisectoral response plan.

Recommendations for priority actions

- Finalize and adopt the National Emergency Plan and the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations.
- Initiate resource mapping at the subnational level in public health, veterinary and other sectors.
- Test the various plans through simulation exercises and develop a mechanism to adjust plans according to the findings of these simulation exercises.

EMERGENCY RESPONSE OPERATIONS

INTRODUCTION

A public health emergency operations centre is a central location for coordinating operational information and resources for strategic management of public health emergencies and emergency exercises. Emergency operations centres provide communication and information tools and services, and a management system during a response to an emergency or emergency exercise. They also provide other essential functions to support decision-making and implementation, coordination and collaboration.

Target

Countries will have a coordination mechanism, incident management systems, exercise management programmes and public health emergency operation centre (EOC) functioning according to minimum common standards; maintaining trained, functioning, multisectoral rapid response teams, and trained EOC staff capable of activating a coordinated emergency response within 120 minutes of the identification of an emergency.

LEVEL OF CAPABILITIES

Serbia has demonstrated its ability to coordinate response to emergency situations in the past through the successful handling of large disasters, such as the floods in 2014. A "Protection and Rescue System", which is part of the National Security System, is activated when an emergency is declared. All administrative levels down to the municipal level are involved, through a structure of headquarters for coordination at each level. Members of the national-level headquarters include ministers in the field of public administration and local government, defence, health, agriculture, water management and forestry, labour and social policy and environmental protection, foreign affairs, telecommunications, construction, mining, energy, information, finance, trade and services. In addition, national agencies in meteorology, seismology or hydrology are involved, along with public enterprises and private companies of relevance for rescue operations.

In the public health sector, a coordination operation and communication centre has been established operating continuously, and which includes response teams that are similarly continuously available. Similarly, a national crisis centre is established in the Veterinary Directorate, which is continuously available during emergencies.

Several tabletop and command-post simulation exercises have been conducted in recent years in Serbia. An international field exercise involving NATO is taking place in Serbia at the time of the JEE mission. However, these exercises and drills are not part of an integrated programme that would cover all sectors needing to be involved.

The existing comprehensive mechanism for coordinating response to emergencies has not yet been formalized through the adoption of a national multi-hazard and multisectoral emergency preparedness and response plan.

Indicators and scores

R.2.1 Emergency response coordination – Score 4

Strengths and best practices

- An emergency management headquarters is in place to monitor response operations, mobilize resources, coordinate risk communication and assesses vulnerability.
- The national headquarters is supported by one provincial headquarters, 24 district headquarters, 25 city headquarters and 119 municipal headquarters.
- In the public health sector, a coordination & operation centre is in place, with teams available continuously.

Areas that need strengthening and challenges

- Coordination has been tested at national but not subnational levels.

R.2.2 Emergency operations centre capacities, procedures and plans – Score 3

Strengths and best practices

- National EOC structures are established on an ad-hoc level in response to emergencies.

Areas that need strengthening and challenges

- The absence of an adopted emergency preparedness and response plan in the health service prevents the national EOC from being fully activated within two hours of receiving an alert that requires such activation.

R.2.3 Emergency exercise management programme – Score 3

Strengths and best practices

- Several exercises have been conducted in recent years.

Areas that need strengthening and challenges

- Simulation exercises are not conducted regularly at all levels.
- Exercises are not planned as part of a structured programme to test national capabilities with involvement of subnational levels.

Recommendations for priority actions

- Establish operational health emergency centres based on the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations, including a joint information centre for all-hazard risk communication and in line with the WHO Framework for a Public Health Emergency Operations Centre[7].
- Evaluate response to emergencies that have triggered the activation of the national EOC and develop a mechanism to adjust plans according to the findings of these evaluations.

7 http://www.who.int/ihr/publications/9789241565134_eng/en/

LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

INTRODUCTION

Public health emergencies pose special challenges for law enforcement, whether the threat is manmade or naturally occurring. In a public health emergency, law enforcement will need to quickly coordinate its response with public health and medical officials.

Target

Country conducts a rapid, multisectoral response for any event of suspected or confirmed deliberate origin, including the capacity to link public health and law enforcement, and to provide timely international assistance.

LEVEL OF CAPABILITIES

In Serbia state administration and local government authorities act in accordance with the law and sub-legal acts, which define the basis for their actions, mutual cooperation and information exchange, including the field of emergency situations. The Law on Emergency Situations defines the organization and cross-sectoral cooperation in response to emergencies. It establishes the Republic Emergency Headquarters at national level, as well as provincial or municipal headquarters operating at those respective levels. The Emergency Headquarters also creates, if necessary, auxiliary expert-operational teams for specific response and rescue tasks.

The Ministry of Interior (MoI) is responsible for the implementation of the Law on Emergency Situations, and in its scope, among other things, it has the following responsibilities: 1) coordinates all entities of the system of response and rescue in matters of organization, planning, preparation and implementation of measures and activities to prevent and reduce risk – this includes protection and rescue telecommunication and information systems for management and coordination of response and rescue, and data and information transmission and information and protection thereof; 2) organizes a system of observation, informing, early warning and alerting on the territory of Serbia; 3) keeps records of human and material resources for the needs of response and rescue; and 4) orders the partial mobilization of necessary human and material resources.

There is no specific Memorandum of Understanding (MoU) or other agreement between public health and security authorities at national level. However, ministries, other entities and special organizations in Serbia, within their scope of work, act in accordance with the needs in a professional, organizational and operational sense.

The National Emergency Notification Center within the MoI receives information on a potential biological, chemical and radiological event that may be deliberately provoked. They have a procedure for further notification of competent institutions, whose jurisdiction is defined by law, but also by special agreements or contracts. There is a national poisoning centre located within the Military Medical Academy, which is a reference institution for determining the presence of poisons and for assessing the risk of poisoning.

The Project of the Radiation Safety and Security Measures is an integral part of technical documentation for facilities where sources of ionizing radiation have been or are used, and the implementation of which ensures that such facilities meet the required level of protection from ionizing radiation for occupationally-exposed persons, the general population and the environment.

There is a developed action plan within the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS) for dealing with elementary and major disasters and emergencies; this defines the procedures for action in the case of various types of emergencies, including coordination and communication with other sectors. Examples of procedures for the functioning of the medical and emergency services in emergency situations include preparedness and response to H1N1 in 2009, floods in 2014 and Ebola virus disease in 2014.

Training courses at the national level have been organized for representatives of different sectors. In 2015, with the support of the World Health Organization (WHO), training on emergency procedures that have public health implications were conducted in 121 units of government (which included 1211 participants). Participants were representatives of various sectors, institutions, entities and civil society organizations at the local level. Serbia also participated in a simulation exercise that was organized by the International Atomic Energy Agency (IAEA) that included a nuclear accident at a nuclear power plant in Hungary in 2017.

Indicators and scores

R.3.1 Public health and security authorities (e.g. law enforcement, border control, customs) linked during a suspect or confirmed biological, chemical or radiological event – Score 3

Strengths and best practices

- Legislation that prescribes and provides basic frameworks for cooperation between different sectors, including public health and security authorities, in response to emergency and crisis situations is in place.
- There are plans defining the framework for information exchange and emergency response between different sectors, including public health and security authorities.
- Examples of procedures for the functioning of the medical and emergency services in emergency situations include preparedness and response to H1N1 in 2009, floods in 2014 and Ebola virus disease in 2014.

Areas that need strengthening and challenges

- There is a need to develop and/or update protocols and communication procedures for specific emergency situations that take a multisectoral approach through convening a multisectoral working group, including public health and security authorities at national, subnational and local levels.
- Multisectoral simulation exercises and training opportunities for improved preparedness and response to all hazards are lacking.
- There is a need to update procedures for regular, more formalized communication and exchange of information within and between sectors.

Recommendations for priority actions

- Expand existing standard operating procedures (SOPs) (including for a joint/shared risk assessment) and communication protocols, including roles and responsibilities; and reinforce existing mechanisms to improve exchange of reports and information for all hazards on a regular basis between authorities and bodies at national, subnational and local level through convening of a multisectoral working group.
- Formalize a MoU or other agreements/protocols and align them within existing systems and structures to facilitate preparedness and response to all hazards.
- Develop a joint training programme between public health and security authorities to familiarize, exercise, and update procedures/protocols for improved coordination and information sharing between authorities to prepare for and respond to all hazards at national, subnational and local level.

MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

INTRODUCTION

Medical countermeasures are vital to national security and protect nations from potentially catastrophic infectious disease threats. Investments in medical countermeasures create opportunities to improve overall public health. In addition, it is important to have trained personnel who can be deployed in case of a public health emergency for response. Regional (international) collaboration will assist countries in overcoming the legal, logistical and regulatory challenges to deployment of public health and medical personnel from one country to another. Case management procedures should be available to all staff, and implemented across the system during health emergencies due to IHR-related hazards.

Target

National framework for transferring (sending and receiving) medical countermeasures, and public health and medical personnel from international partners during public health emergencies and procedures for case management of events due to IHR related hazards.

LEVEL OF CAPABILITIES

There are sustainable reserves of MCM in Serbia: vaccines, medicines, personal protective equipment for medical and veterinary response measures. The Republic Directorate for Commodity Reserves manages these reserves, and performs state administration affairs and professional tasks related to organization of the commodity reserve system. Additional tasks managed by the Directorate include the collection, accommodation, preservation and restoration of republic commodity reserves; determining the scope, structure and quality of commodity reserves; managing quantity flows in order to maintain reserves at the necessary minimum; construction of storage capacity for the needs of the commodity reserves; material and financial operations and keeping records on commodity reserves, as well as other activities in this field.

Serbia has the necessary capacity to produce antibiotics, vaccines, laboratory equipment and supplies; however, there is no unique strategic national stockpile of defined medical countermeasures and there is no dedicated budget for it. One part of the stock exists within the Republic Directorate for Commodity Reserves. Appropriate funds are provided from the national emergency budget reserve.

One the main actors in this field is the Ministry of Interior (Emergency Management Sector). It proposes and implements necessary policies in matters of emergency assistance, protection and rescue, initiates and executes ratification of international agreements, and conducts other general acts for successful execution of international cooperation in personnel deployment. The Emergency Management Sector organizes training and control of operational readiness of departments and emergency services; organizes and equips the specialized units for the territory of Serbia and the administrative districts; and organizes and acquires services, maintains and stores equipment for protection and rescue purposes. The Emergency Management Sector is also responsible for drafting and proposing regulations and recommendations that meet the European Union's emergency response and protection requirements with a view to fully regulating such activities and the establishment of institutional, organizational conditions and human resources for the implementation of protection and rescue in emergency situations.

At the same time there is a lack of a legislative basis and standard treatment guidelines (including unified diagnostic measures for different health threats) for international cooperation in the field of the International Health Regulations (IHR).

At the beginning of the 2016 the World Health Organization (WHO) started coordinated activity with the Ministry of Health of Serbia in the development of the National Health Emergency Preparedness And Response Plan. The plan is fully developed and in place, but needs final official endorsement. The current plan includes chapters specifically dedicated to medical countermeasures and personnel deployment.

Indicators and scores

R.4.1 System in place for activating and coordinating medical countermeasures during a public health emergency – Score 2

Strengths and best practices

- A preparedness plan exists for pandemic influenza-related illnesses and has been adapted for the needs of other infectious diseases epidemics.
- Crisis plans of the Veterinary Directorate exist.
- There is a National Poison Control Center located within the Military Medical Academy assuring capacities for providing medical services for prevention and therapy of chemical substances, as well as services for detection of chemical substances in biological materials, water, land and air.
- A mobile toxicological and chemical team exists, which can respond to threats due radiological agents (it is activated in case of large-scale accidents threatening human health).
- The military health care system has plans, studies, procedures and instructions related to the sending and receiving of medical countermeasures within the military health system and the territory of Serbia (which defines logistical and security issues).
- Serbia has the necessary capacity to produce antibiotics, vaccines, laboratory equipment and supplies.
- The supplies of certain medicines and vaccines are planned annually/bi-annually or every three years, depending on the type of medical countermeasure in accordance with the country's laws and regulations. The stock level is planned in accordance with internationally accepted recommendations (i.e. outlined by WHO), most often for a period of 3–6 months.

Areas that need strengthening and challenges

- There is no defined plan for sending and receiving medical countermeasures during public health emergencies.
- There is a simplified procurement procedure that allows for urgent purchases from abroad – but only under request of the Ministry of Health/Ministry of Interior. At the same time the content of current stock is not coordinated with existing WHO recommendations such as the Interagency Emergency Health Kit (2011; 2017), the WHO Essential Medicines list 20th edition (2017) and the WHO Essential Medicines list for Children 6th edition (2017).

R.4.2 System in place for activating and coordinating health personnel during a public health emergency – Score 2

Strengths and best practices

- The country has appropriate experience in international cooperation at the European level and globally when it comes to engaging health personnel.
- There are developed short-terms plans for strengthening capacities in the field of epidemiology, infectivity, microbiology, hygiene, epizootiology and other professional areas related to other etiologic threats.
- The country has appropriate experience in providing education and meetings outside the country on strengthening skills in the field of IHR implementation.
- The Plan for Preparedness for a Pandemic Influenza Emergency Situation Center within the Ministry of Interior and the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (IPHS) exists.

Areas that need strengthening and challenges

- There is a need to develop a detailed plan of actions for getting/sending personnel and medical countermeasures from/to outside the country's borders to implement emergency response measures, including a legal basis, mutual cooperation on visas and fulfilling other requirements for rapid entry into the country and arrival at the scene with appropriate budget allocations.
- There is a need to improve mutual procedures for managing cases of threats of importance to the IHR (for the Balkan region in particular).

R.4.3 Case management procedures implemented for IHR relevant hazards – Score 2

Strengths and best practices

- There are guidelines for managing cases for priority illnesses that tend to develop into an epidemic (Ebola virus disease, tuberculosis, malaria, pandemic influenza, vaccine-preventable diseases).
- MCM are referenced within a chapter of the National Health Emergency Preparedness and Response Plan of the Ministry of Health: "Medical countermeasures, personnel deployment and reception and utilization of international medical personnel in emergencies".
- Legal regulations and by-laws exist in the area of health protection of the population and animals against infectious diseases.
- There are necessary SOPs in place for referral and transport of patients to health facilities (ambulances, hospitals).
- There are appropriate personnel trained to handle cases in emergency situations of importance to the IHR (2005).

Areas that need strengthening and challenges

- There is a need to assemble a command team and engage it in operational exercises to test the National Health Emergency Preparedness and Response Plan of the Ministry of Health (MCM, personnel deployment and reception and utilization of international medical personnel in emergencies) and the capacity for coordinated activities (in the Balkan region in particular).

Recommendations for priority actions

- Harmonize all necessary measures with existing WHO recommendations/documents (WHO Interagency Emergency Health Kit, 2011 & 2017[8]; Classification and minimum standards for foreign medical teams in sudden-onset disasters, 2013[9], etc.).

8 http://www.who.int/emergencies/kits/iehk/en/ – The 2017 kit is found in an MS Excel file at the bottom of the page.

9 http://www.who.int/hac/global_health_cluster/fmt_guidelines_september2013.pdf

RISK COMMUNICATION

INTRODUCTION

Risk communications should be a multilevel and multifaceted process which aims at helping stakeholders define risks, identify hazards, assess vulnerabilities and promote community resilience, thereby promoting the capacity to cope with an unfolding public health emergency. An essential part of risk communication is the dissemination of information to the public about health risks and events, such as disease outbreaks. For any communication about risk caused by a specific event to be effective, the social, religious, cultural, political and economic aspects associated with the event should be taken into account, including the voice of the affected population.

Target

State Parties use multilevel and multifaceted risk communication capacity. Real-time exchange of information, advice and opinions between experts and officials or people who face a threat or hazard (health or economic or social wellbeing) to their survival, so that informed decisions can be made to mitigate the effects of the threat or hazard and protective and preventive action can be taken. This includes a mix of communication and engagement strategies, such as media and social media communications, mass awareness campaigns, health promotion, social mobilization, stakeholder engagement and community engagement.

LEVEL OF CAPABILITIES

Serbia has formal government risk communication arrangements for emergency response within an Incident Management System (IMS) through its Ministry of Health (MoH) and Ministry of Interior (MoI) - Emergency Management Sector. Public relations/media personnel are available from the MoH (from the Institute of Public Health of Serbia "Dr Milan Jovanović Batut", IPHS) and the MoI (Emergency Management Department) and are well-versed in risk communication principles and practice.

Communications is included in the Law on Emergency Situations, and a National Strategy for Protection and Rescue in Emergencies defines obligations and procedures of various entities in the system of early warning and response to public health threats. During designation of a national emergency, public communications are regulated through the Emergency Management Sector as well as the Department of Media and Communications at the Cabinet of the MoI. The health sector has action and response plans that include communications to respond to disease outbreaks and natural and other health emergencies, for the territory under its jurisdiction.

Despite having formal government arrangements and clear strengths, Serbia can strengthen cross-cutting risk communication capabilities. There is a dedicated team that is responsible for this area but resources, including surge staff, are not sufficient to respond to large-scale emergencies. Existing national response plans and mechanisms include risk communication but should be expanded to include a national all-hazard, multisectoral emergency risk communication plan in line with the International Health Regulations (IHR) (2005) to systematize timely and transparent release of information, communication coordination, effective two-way communication and community engagement, and use of effective channels and key influencers.

Formal and informal communication and coordination mechanisms exist but with limited partner and stakeholder engagement (such as health care workers, civil society organizations, private sector and other non-state actors), which particularly impacts subnational emergency response efforts to disease outbreaks, including West Nile virus. A communication capacity mapping of all relevant stakeholders

should be considered and a working group convened to update roles and responsibilities, joint action plans, share resources and test standard operating procedures (SOPs) for risk communication preparedness, readiness and response.

There is planned and systematic public communication through a mix of platforms (newspapers, radio, television and Internet) in relevant languages and with comprehensive geographical coverage. Although communication is intended to be proactive with all audiences, qualitative or formative research methods are not systematically used. Risk perception is passively gathered through a media clipping service but there is limited use of other mechanisms to detect, verify or respond to rumours or misinformation. Social media is not systematically used. A detailed audience and media analysis, including social media, could be used to improve understanding of how target audiences receive and use health information through a variety of channels.

The Center for Health Promotion located within the IPHS carries out activities of social mobilization, health promotion and community engagement of local communities. Activities of the IPHS are carried out in cooperation with a network of 24 public health institutes in Serbia. Community engagement, social mobilization and behaviour change communication based on social science methods and interventions exist but could be strengthened to prepare for and respond to outbreaks or other health emergencies.

A stronger evidence-based approach should be considered to scale-up operational capacity through contextualized social science methods and interventions, including use of Knowledge, Attitudes and Practices (KAP) surveys, intercept interviews, focus groups, etc. These methods systematically enhance community consultation mechanisms with target audiences and serve as a foundation for monitoring and evaluation processes. Building on existing initiatives and utilizing comparative advantages of international agencies, partners and nongovernmental organizations (NGOs), such as the World Health Organization (WHO), United Nations agencies and the Red Cross of Serbia could provide stronger links to community engagement opportunities, assess risk perception through formative research, and develop and test public health messages in target audiences. In addition, a multisectoral mapping of existing processes, programmes, partners and stakeholders could help to identify needs and gaps and strengthen coordination and cooperation within and between sectors, including with NGOs and scientific and research institutions.

Indicators and scores

R.5.1 Risk communication systems for unusual/unexpected events and emergencies – Score 2

Strengths and best practices

- Government laws, regulations and procedures exist that define obligations and procedures of various entities in the system of early warning and response to public health threats.
- Risk communication is included in existing national and health sector preparedness and response plans and mechanisms.
- Ministries and agencies have public relations officers and spokespersons that are well versed in risk communication principles and practice.
- Best practices from pandemic influenza preparedness activities, response to the influx of migrants/refugees, and flooding have been applied to other public health threats.

Areas that need strengthening and challenges

- There is need to develop a national all-hazard, multisectoral emergency risk communication plan and SOPs and incorporate them into existing national and health sector response plans and mechanisms.
- Timely adoption of the National Health Emergency Preparedness and Response Plan, to include an all-hazard risk communication plan as an annex.

- There is a need to increase risk communication capacity at local, regional and national levels through joint training and testing with multisectoral agencies and stakeholders, including tabletop and simulation exercises.
- There is a need to prioritize and advocate for a sustained budget and contingency budget for communications surge staff, materials and activities.

R.5.2 Internal and partner coordination for emergency risk communication – Score 3

Strengths and best practices

- There are demonstrated examples of multisectoral coordination mechanisms in previous outbreaks and health emergencies, such as with the influx of migrants/refugees and floods.
- Established network and coordination mechanisms and procedures exist between ministries and authorities at local, regional and national levels.

Areas that need strengthening and challenges

- There is need of expanding the network to include relevant partners and stakeholders, map capacities, and to improve multisectoral coordination and information-sharing mechanisms and procedures.
- Strengthened coordination mechanisms including communication SOPs and clearance protocols within and between ministries and stakeholders are needed, e.g. by establishing a joint agency communication working group to update roles and responsibilities, including testing, sharing of resources and joint action plans.

R.5.3 Public communication for emergencies – Score 4

Strengths and best practices

- Public communications is regulated through the Emergency Management Sector as well as in the Department of Media and Communications at the Cabinet of the MoI and with relevant ministries and agencies in declared national emergencies.
- The MoH and IPHS provide planned and systematic public communication through a mix of platforms (newspapers, radio, television and internet) in relevant languages and with comprehensive geographical coverage.
- Standard news and other communication materials are regularly updated and provided on the internet for a variety of audiences.

Areas that need strengthening and challenges

- There is a need to conduct an audience and media analysis (including for social media) to improve understanding of how target audiences receive and use health information.
- The MoH and IPHS do not currently utilize social media platforms as part of their communication strategy to prevent, detect and respond to all hazards.
- Risk communication best practices need to be strengthened, including managing uncertainty and risk perception, in media outreach (including social media) to improve uptake of public health advice and address concerns, rumours and misinformation.
- Regular media and spokesperson training courses for authorities and bodies at national, subnational and local levels are not organized.

R.5.4 Communication engagement with affected communities – Score 2

Strengths and best practices

- The Center for Health Promotion located in IPHS carries out activities of social mobilization, health promotion and community engagement with local communities.
- Multisectoral coordination and planning has been demonstrated for the implementation of activities for social mobilization and health promotion to respond to outbreaks and health emergencies.

- Established two-way communication and feedback mechanisms between affected populations exist, as evidenced through health promotion and social mobilization activities during the floods in 2014 and 2016.

Areas that need strengthening and challenges

- Cooperation and coordination with NGOs and scientific and research institutions need to be strengthened to develop, implement, monitor and evaluate social science-based methods and interventions to reinforce community engagement mechanisms at local, regional and national levels.
- There is a need to implement social science-based methods and interventions and reinforce two-way communication mechanisms (e.g. KAP surveys, intercept interviews, focus groups, etc.) to strengthen engagement with target audiences, assess risk perception, and develop message templates and test messages for anticipated and high-risk public health threats.
- There is a need to provide regular briefing, training and engagement to community-engagement teams to scale-up local, regional and national capacity.

R.5.5 Addressing perceptions, risky behaviours and misinformation – Score 4

Strengths and best practices

- A media clipping service provides monitoring of the media to detect and guide response to misinformation, rumours and risky behaviours.

Areas that need strengthening and challenges

- There is a need to allocate additional resources to strengthen two-way communication channels to detect and respond to rumours and misinformation, including for social media.
- Additional two-way communication mechanisms and feedback loops are needed to gather, analyse and provide feedback to target audiences.
- There is a need to identify and equip trusted influencers (health care workers, NGOs, civil society organizations, private sector and other non-state actors) to improve response through effective channels.

Recommendations for priority actions

- Develop an all-hazards emergency risk communication plan, test it with a tabletop or simulation exercise, and adopt it within existing plans and mechanisms for emergency preparedness and response in line with IHR (2005) requirements.
- Strengthen coordination mechanisms, including communication SOPs and clearance protocols within and between ministries and stakeholders by establishing a joint agency communication working group to update roles and responsibilities, including testing, sharing of resources and development of joint action plans.
- Strengthen cooperation between NGOs and scientific and research institutions to develop, implement, monitor and evaluate social science-based methods and interventions to reinforce community engagement mechanisms at local, regional and national levels.
- Utilize and reinforce two-way communication mechanisms (KAP surveys, intercept interviews, focus groups, etc.) to strengthen engagement with target audiences, assess risk perception, and develop and test message templates for anticipated and high-risk public health threats.
- Conduct an audience and media analysis, including for social media, to improve understanding of how target audiences receive and use health information.

IHR-RELATED HAZARDS AND POINTS OF ENTRY

POINTS OF ENTRY

INTRODUCTION

All core capacities and potential hazards apply to "points of entry" and thus enable the effective application of health measures to prevent international spread of diseases. States Parties are required to maintain core capacities at designated international airports and ports (and where justified for public health reasons, a State Party may designate ground crossings), which will implement specific public health measures required to manage a variety of public health risks.

Target

States Parties designate and maintain core capacities at international airports and ports (and where justified for public health reasons, a State Party may designate ground crossings) that implement specific public health measures required to manage a variety of public health risks.

LEVEL OF CAPABILITIES

There are no designated points of entry (PoE) in Serbia and no national emergency plan available. So the effectiveness of public health response at PoE can only be theoretically evaluated. However, Airport Nikola Tesla Belgrade has many capabilities to mitigate and respond to public health threats. During the Joint External Evaluation assessment these capabilities were evaluated as if the international airport were already officially designated as a point of entry to the World Health Organization (WHO).

Airport Nikola Tesla Belgrade has in place standard operating procedures (SOPs) for the handling of potentially infected passengers and arrangements for their transportation and treatment through agreements with the competent state authorities. These SOPs are part of the generic plan for all emergencies at the airport. Facilities at the airport exist, including health staff such as doctors who are available continuously. Ill or suspected ill travellers can be referred to the Clinic for infectious and tropical diseases in the Clinical Center of Serbia in Belgrade when needed. Airport Nikola Tesla Belgrade has measures in place for entry screening of passengers, to detect a public health threat of international concern, but needs to develop such measures also for exit screening. The decision on measures for entry/exit of passengers through the Belgrade Airport in case of public health threat (in order to prevent the closure of borders) is not under the jurisdiction of an airport operator.

The country should consider designating at least one point of entry under the International Health Regulations (IHR). Doing this for Airport Nikola Tesla Belgrade, for example, will give Serbia the opportunity to harmonize the airport with current IHR requirements and bring it in line with other European Union (EU) regulations.

Indicators and scores

PoE.1 Routine capacities established at points of entry – Score 3

Strengths and best practices

- The Belgrade airport has an onsite medical emergency service, with a physician and other health staff continuously available.
- The service is able to treat patients irrespective of whether they have passed through the country's border or not, and to transport the patients to the designated health facility (Clinic for infectious and tropical diseases in the Clinical Center of Serbia in Belgrade) in case of emergency.
- There is a well-equipped emergency centre at the airport, which is activated in case of an emergency (e.g. public health threat).
- All relevant institutions are part of the management structure of the emergency centre: border control, airport security, rescue service, fire department and sanitary inspection.
- The sanitary inspection unit at the airport, which works with the municipal public health administration, is informed about all ongoing public health outbreaks worldwide and can react in the event passengers arrive from countries or areas where such outbreaks are taking place.

Areas that need strengthening and challenges

- The Ministry of Health should evaluate the core capacities named in Annex 1B of the IHR (2005) at the airport or other points of entry.
- SOPs need to be put in place for the care of infected passengers and protection of public health and airport personnel.

PoE.2 Effective public health response at points of entry – Score 2

Strengths and best practices

- Rules are in place for transportation and treatment of persons suspected of having a (highly) infectious disease.
- The sanitary inspection unit and physicians are continuously on call and aware of potential cases of infectious diseases.
- The veterinary service is also present at the airport, whenever needed, and there are rules for treatment and potential quarantine of animals.
- There is a routine programme for vector control in airplanes.
- The emergency plan of the airport is generic and includes all relevant sectors.

Areas that need strengthening and challenges

- The generic response plan for public health events in both human and animal sectors at the airport is not integrated into the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations.
- Airport Nikola Tesla Belgrade has not been officially designated a PoE.
- Regular training and simulation exercises related to public health threats for the staff at the airport are not conducted.

Recommendations for priority actions

- The airport Nikola Tesla Belgrade is a possible entry point to be designated under the IHR. The existing public health emergency plan and the generic emergency preparedness and response plan at the airport should be integrated into the National Plan of Preparedness and Response of the Health System in Crisis and Emergency Situations.
- Staff at the airport have to be trained in handling public health emergencies, with a special focus on the use of personal protective equipment and the safe transport of patients with suspected life-threatening and contagious diseases.
- Premises for potential medical assessment and/or screening at the airport should be identified.

CHEMICAL EVENTS

INTRODUCTION

Timely detection and effective response of potential chemical risks and/or events requires collaboration with other sectors responsible for chemical safety, industries, transportation and safe disposal. This would entail that State Parties need to have surveillance and response capacity to manage chemical risk or events and effective communication and collaboration among the sectors responsible for chemical safety.

Target

States Parties with surveillance and response capacity for chemical risks or events. This requires effective communication and collaboration among the sectors responsible for chemical safety, industries, transportation and safe disposal, animal health and the environment.

LEVEL OF CAPABILITIES

Serbia is a signatory to a number of international treaties related to chemical safety, and has a robust set of laws that provide a legal framework for environmental protection and safe management of chemicals based on the precautionary principle endorsed by the European Union. Guidelines exist for the surveillance, assessment and management of chemical events, but timely mechanisms for information exchange regarding chemical events from chemical surveillance, environmental monitoring and chemical incident reporting do not exist. Event-based surveillance is capable of detecting chemical events.

Individual chemical facilities maintain local response plans per regulatory requirements, but there is currently no national chemical event response plan (although the drafting of one has been initiated). In case of a chemical event, both the Ministry of Interior and the Ministry of Environmental Protection have responsibilities for response, but the number of trained staff available to respond to chemical events is considered inadequate. Other stakeholders in chemical events include the Ministry of Health, the Ministry of Agriculture, Forestry and Water Management, the Ministry of Labor, Employment, Veteran and Social Policy, the Institute of Public Health of Serbia "Dr Milan Jovanović Batut" (with its network of public health laboratories), the Serbian Institute of Occupational Medicine "Dr Dragomir Karajovic", and the Military Medical Academy – National Poison Control Center. The latter two both serve as reference health care facilities for the diagnosis and treatment of chemical poisoning cases.

Indicators and scores

CE.1 Mechanisms established and functioning for detecting[10] and responding to chemical events or emergencies – Score 3

Strengths and best practices

- Chemical facility operators conduct continuous surveillance and assessment of any releases of chemicals, promptly notify all competent chemical services agencies and the public, and implement emergency measures.
- Military Medical Academy – National Poison Control Center maintains case management guidelines for poisoning cases and makes available consultations as needed to the civilian sector.

10 Detection capacity also includes not only surveillance but also the laboratory capacity required for the verification of any events.

- Priority chemicals have been identified through inventories of facilities that meet the European Union Seveso III Directive, through the national registry of pollutants and through the national chemicals registry.
- The 24 regional public health institutes have laboratory capacity to test clinical samples for common analytes; European Union laboratories provide additional analytical capacity beyond that present domestically.
- Chemical management staff have completed training in the risk assessment of physical-chemical, ecotoxicological and toxicological properties of chemicals.

Areas that need strengthening and challenges

No mechanisms exist to facilitate rapid exchange of information about chemical events among chemical units, surveillance units and other relevant sectors.

CE.2 Enabling environment in place for management of chemical events – Score 2

Strengths and best practices

- Response plans exist for individual chemical facilities.
- A national response plan has been drafted to address two major scenarios for large-scale chemical release.

Areas that need strengthening and challenges

- Although national pollutant and chemical registries exist, a chemical profile of the country has not been updated since 2008.
- The draft national chemical response plan has not yet been promulgated and exercised.
- No multisectoral coordination mechanism to manage chemical events exists; although Article 7 of the Law on Chemicals provides for the establishment of a Joint Entity for Integrated Chemicals Management, this entity has not yet been established.
- No evaluation mechanism exists to assess the effectiveness of chemical response activities.

Recommendations for priority actions

- Update the national chemical profile of defined priority chemical agents.
- Finalize and exercise the national multisectoral chemical response plan.
- Incorporate chemical management and response specialists into the national health sector workforce strategy.
- Establish the mandated Joint Entity for Integrated Chemicals Management organization and a centralized information-exchange mechanism to share information about chemical events among this multisectoral organization.

RADIATION EMERGENCIES

INTRODUCTION

To counter radiological and nuclear emergencies, timely detection and an effective response towards potential radiological and nuclear hazards/events/emergencies are required in collaboration with sectors responsible for radiation emergency management.

Target

States Parties should have surveillance and response capacity for radiological emergencies and nuclear accidents. This requires effective coordination among all sectors involved in radiation emergencies preparedness and response.

LEVEL OF CAPABILITIES

Serbia is a signatory to the Early Notification and Assistance in Case of Nuclear Emergency (1986) conventions. Recent nuclear accidents in Chernobyl in 1986 and Fukushima in 2011 have caused the country to raise its level of preparedness to respond in the event of a radiation emergency. Although Serbia has conducted security assessments for the purpose of adopting a regulation on the establishment of accident action plans, it has not conducted a baseline public health assessment with regard to radiation safety in the past five years.

The Agency for Protection Against Ionizing Radiation and Nuclear Safety of Serbia is the primary radiation monitoring and regulatory authority. This agency operates a national network of environmental monitoring stations, and licenses laboratories in the health and other sectors to conduct analyses for radiation contamination of air, water and consumer goods. Consumer products' monitoring is conducted as needed when necessitated by a radiation event or as a result of suspected contamination. Customs officials also routinely monitor products at border crossings, with either portal monitors and/or gamma spectrometers.

The 2018 Decree on the Establishment of an Action Plan in the Event of an Accident addresses detection of, response to, and recovery from radiation emergencies, but no national contingency plan currently exists. The national coordinating body for the management of radiation emergencies is the Republic Emergency Staff; the Agency for Protection Against Ionizing Radiation and Nuclear Safety of Serbia provides technical advisory services during emergencies. This new law also calls for national implementation of associated training and exercises, the keeping of records and the updating of plans, but so far these provisions have not yet been implemented. It should be noted, however, that the country has participated in international exercises in which it tested its capacities related to radiation responses.

The Ministry of Health is responsible for identifying health care facilities that have capacities to respond to a nuclear or radiological emergency, but no list of such institutions has been approved to date, and no systematic training of appropriate health care workers has occurred. The Military Medical Academy maintains case management guidelines, and can provide technical consultations as needed. No decorporation agents or potassium iodide are available within national medical countermeasures stocks.

Indicators and scores

RE.1 Mechanisms established and functioning for detecting and responding to radiological and nuclear emergencies – Score 2

Strengths and best practices

- National laws and rulebooks addressing detection, assessment and response to radiation emergencies exist; the specifications of the roles and responsibilities of various authorities, the competencies of workers in the radiation sector and the exposure guidelines related to medical treatment with radioisotopes are particularly noteworthy.
- A network of nine gamma-monitoring stations provides environmental monitoring data every ten minutes to the Agency for Protection Against Ionizing Radiation and Nuclear Safety of Serbia; data are routinely shared with the European Union (EU).
- Serbia has competent human capacities and accredited laboratories for conducting measurements of radioactivity and levels of contamination, as well as for estimating population exposures in case of nuclear or radiological accidents.
- Case management guidelines for treatment of patients with radiation exposures exist.

Areas that need strengthening and challenges

- Standard operating procedures (sops) for implementation of risk assessment, reporting, event confirmation and notification, and investigation actions need to be developed.
- Reference health care facilities have not been designated for the treatment of patients exposed to radiation; health care staff have not been adequately trained in detection, decontamination and treatment of exposed patients.
- Stocks of decorporating and prophylactic medical countermeasures for radiation emergencies are not available.
- A routine multisectoral exercise programme that is integrated into a broader national public health emergency management framework does not exist.

RE.2 Enabling environment in place for management of radiation emergencies – Score 2

Strengths and best practices

- Competent authorities are designated in multiple sectors for addressing various aspects of nuclear and radiation events.
- The Ministry of Interior is capable of establishing emergency management headquarters to coordinate intersectoral response operations.

Areas that need strengthening and challenges

- Requirements for development of plans in response to nuclear or radiological events exist, but a national multisectoral contingency plan has not yet been prepared.
- The Ministry of Interior facilitates the coordination and communication between sectors when an emergency is declared, but in situations below the level of an emergency mechanisms to foster that exchange are lacking.

Recommendations for priority actions

- Develop a multisectoral radiation emergency contingency plan, along with associated sector-specific standard operating procedures.
- Train and exercise both health care workers and response personnel in other sectors on radiation response operations.
- Designate and adequately equip reference health care facilities for treatment of patients exposed to radiation.

APPENDIX 1: JEE BACKGROUND

Mission place and dates

Belgrade, Serbia, 8 to 12 October 2018

Mission team members:

- Dr Cory Couillard, the United States, WHO Regional Office for Europe
- Dr Denis Coulombier, France, European Centre for Disease Prevention and Control
- Dr Daniel Joseph Duvall, the United States, Centers for Disease Control and Prevention (Nigeria)
- Dr Dagmar Heim, Switzerland, Swiss Federal Food and Veterinary Office
- Dr Indra Linina, Latvia, State Emergency Medical Service (team co-lead)
- Dr Flavia Riccardo, Italy, Italian National Institute of Health
- Dr Peter Rzeszotarski, the United States, Centers for Disease Control and Prevention (team lead)
- Dr Kathrin Schuldt, Germany, Robert Koch Institute
- Dr Vladimir Shukhov, Russian Federation, Moscow State University of Medicine & Dentistry
- Dr Angela Wirtz, Germany, Ministry of Health State of Hessia

Objective

To assess (host country's) capacities and capabilities relevant to the 19 technical areas of the JEE tool for providing baseline data to support (host country's) efforts to reform and improve their public health security.

The JEE process

The JEE process is a peer-to-peer review. The entire external evaluation, including discussions around the priority actions, the strengths, the areas that need strengthening, best practices, challenges and the scores are collaborative, with JEE team members and host country experts seeking full agreement on all aspects of the final report findings and recommendations.

Should there be significant and irreconcilable disagreement between the external team members and the host country experts, or among the external experts, or among the host country experts, the JEE team lead will decide the outcome; this will be noted in the final report along with the justification for each party's position.

Limitations and assumptions

- The evaluation was limited to one week, which limited the amount and depth of information that could be managed.
- It is assumed that the results of this evaluation will be publically available.
- The evaluation is not just an audit. Information provided by <host country> will not be independently verified but will be discussed and the evaluation rating mutually agreed to by the host country and the evaluation team. This is a peer-to-peer review.

Key host country participants and institutions

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- Dr Mirjana Bogunovic, Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"
- Dr Tamara Boskovic, Ministry of Agriculture, Forestry and Water Management
- Mr Milenko Bozovic, Border Police
- Dr Vladimir Cakarevic, Ministry of Health
- Prof. Dr Radovan Cekanac, Military Medical Academy of the University of Defence
- Mr Uros Cukanovic, Institut of Virology, Vaccines and Sera "Torlak"
- Dr Dragana Dimitrijevic, Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"
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- Dr Dragana Vujicic, Ministry of Health, Sector for Drugs, Medical Supplies

Supporting documentation provided by host country

NATIONAL LEGISLATION, POLICY AND FINANCING

- Law on the Protection of Population against Infectious Diseases (Official Gazette of RS, No. 15/2016)
- Regulation on protection of population against infectious diseases (Official Gazette of RS, No. 22/2016)
- Law on Public Health (Official Gazette of RS, No. 15/2016)
- Law on Health Care 15 (Official Gazette of RS, No. 113/2017)
- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
- National emergency protection and rescue plan (Official Gazette of RS, No. 86/2011)
- Law on Transport of Dangerous Goods (Official Gazette of RS, No. 88/2010 and 104/2016 – other law)
- National Plan of Public Health Emergency Preparedness and Response in Crisis and Emergencies (has been finalized and is awaiting adoption)
- Rulebook on conditions and measures of quarantine and requirements for quarantine facilities (Official Gazette of RS, No. 90/2016)
- Action plan for natural and other major disasters and emergencies, pursuant to Article 26 of the Statute of the Institute of Public Health of Serbia "Dr Milan Jovanović Batut"
- Rules of procedure of the National Assembly IX Procedures for Adoption of Acts and Other Procedures (Official Gazette of RS, No. 13/2009)
- Regulations for the list of especially dangerous contagious animal diseases and the list of animal diseases which must be reported, as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 49/2006)
- Regulations on the program measures for health protection of animals for year 2018 (Official Gazette of RS, No. 11/2018)
- Guidelines for surveillance, prevention and control of West Nile virus, 2015. Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate
- Guidelines for surveillance, prevention and control of West Nile virus, 2017. Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate
- Plan for surveillance, prevention and control of West Nile virus, 2018. Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate
- Law on Veterinary Medicine (Official Gazette of RS, No. 91/2005, 30/2010 and 93/2012), with accompanying regulations (http://www.vet.minpolj.gov.rs/srb/dokumenti/pravilnici, accessed 7 November 2018)
- Law on Animal Welfare (Official Gazette of RS, No. 41/2009)
- Rulebook on development of a crisis management plan (Official Gazette of RS, No. 90/2015)
- Program of control, prevention, suppression and eradication of avian influenza in the Republic of Serbia (http://www.vet.minpolj.gov.rs/legislativa/krizni_planovi/Program_za_kontrolu_prevenciju_suzbijanje_i_iskorenjivanje_avijarne_influence_u_Srbiji.pdf, accessed 7 November 2018)
- Rulebook on monitoring of zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)
- Law on Transport of Dangerous Goods (Official Gazette of RS, No. 88/2010 and 104/2016 – other law)
- Law on Radiation Protection and on Nuclear Safety (Official Gazette of RS, No. 36/2009 and 93/2012)

- Law on Environmental Protection (Official Gazette of RS, No. 135/2004, 36/2009, 36/2009 – other law, 72/2009 – other law, 43/2011 – Decision of CC and 14/2016)
- Law on Water (Official Gazette of RS, No. 30/2010, 93/2012 and 101/2016)
- Law on Food Safety (Official Gazette of RS, No. 41/2009)
- Public health strategy in the Republic of Serbia for the period 2018–2026 (Official Gazette of RS, No. 61/2018). This strategy was adopted pursuant to the Article 45 par. 1 of the Law on Government and published on 8 August 2018
- Draft law on the confirmation of loan agreement (loan for development policies in the area of natural disasters risk management with option for postponed withdrawal of funds) between the Republic of Serbia and the International Bank for Reconstruction and Development
- Action plan for implementation of the national program for managing the risk of natural disasters, 2017–2020
- Law on the Confirmation of the Memorandum of Understanding on Institutional Framework of the Disaster Preparedness and Prevention Initiative for South Eastern Europe (2013) (Official Gazette of RS, No. 3/2015 – International agreements)
- Law on Maximum Number of Employees in the Administration (Official Gazette of RS, No. 68/2015 and 81/2016)
- Consent on new employment and additional hiring by beneficiaries of public fund (Official Gazette of RS, No. 113/2013, 21/2014, 66/2014, 118/2014, 22/2015 and 59/2015)
- Law on the Budgetary System of the Republic of Serbia for 2018 (Official Gazette of RS, No. 113/2017)
- Law on the Budgetary System of the Republic of Serbia for 2017 (Official Gazette of RS, No. 99/2016 and 113/2017)
- Law on the Budgetary System of the Republic of Serbia for 2016 (Official Gazette of RS, No. 103/2015)
- Law on the Budgetary System of the Republic of Serbia for 2015 (Official Gazette of RS, No. 142/2014 and 94/2015)

IHR COORDINATION, COMMUNICATION AND ADVOCACY

- OIE PVS Pathway reports
- Reports to WHO governing bodies on IHR implementation (such as the Executive Board and World Health Assembly)
- Legislation, protocols or other policies related to reporting to WHO
- Any plans that have been drafted or other evidence that covers response to possible biological, chemical and radiological events
- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
- National strategy for emergency response and rescue (Official Gazette of RS, No. 86/2011)
- Law on Veterinary Medicine – Rulebook on development of crisis management plan (Official Gazette of RS, No. 90/2015)
- Action plan for natural and other major disasters and emergencies. Institute of Public Health of Serbia "Dr Milan Jovanović Batut", adopted 15 May 2014
- General Interest Program. Ministry of Health of the Republic of Serbia
- Annex 2 of the International Health Regulations (2005)
- Law on the Protection of Population Against Infectious Diseases (Official Gazette of RS, No. 15/2016)

- Rulebook on notifying infectious diseases and special health issues (Official Gazette of RS, No. 44/2017 and 58/2018)
- Expert and methodological instructions for the intensified epidemiological surveillance of infectious diseases during and after floods
- Guidelines on the manner and procedure for keeping records and reporting on health surveillance of the migrant population – refugees, asylum seekers and asylees
- Expert-methodological instruction for controlling West Nile virus
- Expert-methodological instruction for flu control
- Rulebook on the list of particularly dangerous infectious animal diseases and the list of notifiable animal diseases as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 49/2006)

ANTIMICROBIAL RESISTANCE

- Law on Public Health (Official Gazette of RS, No. 15/2016)
- Regulation on protection of population against infectious diseases (Official Gazette of RS, No. 22/2016)
- Public health strategy in the Republic of Serbia (Official Gazette of RS, No. 55/2005, and correction 101/2007 and 65/2008)
- Law on Veterinary Medicine (Official Gazette of RS, No. 91/2005, 30/2010 and 93/2012)
- Regulations for the list of especially dangerous contagious animal diseases and the list of animal diseases which must be reported, as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 42/2006)
- Rulebook on type and manner of epidemiological surveillance of infectious diseases and special health issues (Official Gazette of RS, No. 3/2017)
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- Council recommendation of 15 November 2001 (2002/77/EC) on the prudent use of antimicrobial agents in human medicine
- Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)
- Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health
- Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
- European Parliament resolution of 27 October 2011 on the public health threat of antimicrobial resistance
- Law on Medicines and Medical Devices (Official Gazette of RS, No. 20/2010, 107/2012, 105/2017 – other law and 113/2017 – other law)
- Rulebook on the form and contents of receipts for veterinary medicines, as well as the manner of issuing and prescribing veterinary medicines (Official Gazette of RS, No. 48/2017)

- Rulebook on the development of the program of animal health protection for 2018 (Official Gazette of RS, No. 11/2018)
- Rulebook on the classification and treatment of by-products of animal origin, veterinary and sanitary conditions for the construction of facilities for the collection, processing and destruction of by-products of animal origin, the manner of carrying out official control and self-control, as well as the conditions for livestock graveyards and pits (Official Gazette of RS, No. 31/2011)
- Rulebook on recording data on laboratory testing, deadlines and reporting on obtained results (Official Gazette of RS, No. 73/2017)
- Rulebook on prevention, early detection and eradication of hospital infections (Official Gazette of RS, No. 77/2015)
- Rulebook on health care quality indicators (Official Gazette of RS, No. 49/2010)
- Rulebook on specializations and narrower specialties of health workers and healthcare associates (Official Gazette of RS, No. 10/2013 and 91/2013)
- Rulebook on development of a crisis management plan (Official Gazette of RS, No. 90/2015)
- Rulebook on monitoring of zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)

ZOONOTIC DISEASES

- Law on Veterinary Medicine (Official Gazette of RS, No. 91/2005, 30/2010 and 93/2012)
- Law on Food Safety (Official Gazette of RS, No. 41/2009)
- Regulations for the list of especially dangerous contagious animal diseases and the list of animal diseases which must be reported, as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 49/2006)
- Rulebook on development of crisis management plan (Contingency Plan) (Official Gazette of RS, No. 90/2015)
- Rulebook on the development of the program of animal health protection for 2018 (Official Gazette of RS, No. 11/2018)
- Law on the Protection of Population Against Infectious Diseases (Official Gazette of RS, No. 15/2016)
- Rulebook on notifying infectious diseases and special health issues (Official Gazette of RS, No. 44/2017)
- Rulebook on manner of monitoring zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)
- Regulation on the protection of population against infectious diseases (Official Gazette of RS, No. 22/2016)
- International Health Regulations (2005)
- Rulebook on monitoring of zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)
- Expert and methodological instructions for implementation of surveillance of the West Nile Virus (WNV) in humans on the territory of the Republic of Serbia in the season summer/autumn 2018
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- Guidelines for surveillance, prevention and control of West Nile virus, 2017. Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate
- Plan for surveillance, prevention and control of West Nile Virus, 2018. Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate

FOOD SAFETY

- Law on Food Safety (Official Gazette of RS, No. 41/2009)
- Law on Veterinary Medicine (Official Gazette of RS, No. 91/2005, 30/2010 and 93/2012)
- Law on Inspection Control (Official Gazette of RS, No. 36/2015)
- Law on Sanitary Control (Official Gazette of RS, No. 125/2004)
- National strategy for emergency response and rescue (Official Gazette of RS, No. 86/2011)
- Rulebook on manner of monitoring zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)
- Rulebook on notifying infectious diseases and special health issues (Official Gazette of RS, No. 44/2017 and 58/2018)
- Case definitions of infectious diseases (http://www.batut.org.rs/download/publikacije/20170807SrbijaDefinicijeSlucajevaZarazneBolesti.pdf, accessed 7 November 2018)
- Rulebook on keeping medical records, entering data and reporting (Official Gazette of RS, No. 40/1981 and 30/2013)
- Rulebook on the health safety of dietary products (Official Gazette of RS, No. 45/2010, 27/2011, 50/2012, 21/2015, 75/2015 and 7/2017)
- Rulebook on food additives (Official Gazette of RS, No. 53/2018)
- Rulebook on food enzymes (Official Gazette of RS, No. 51/2018)
- Rulebook on aromas (Official Gazette of RS, No. 52/2018)
- Rulebook on hygiene of drinking water (Official Gazette of SRY, No. 42/1998 and 44/1999)
- Rulebook on quality and other requirements for natural mineral water, natural spring water and bottled drinking water (Official Gazette of SMNE, No. 53/2005 and Official Gazette of RS, No. 43/2013)
- Rulebook on quality and other requirements for salt in human consumption and food industry (Official Gazette of SMNE, No. 31/2005)
- Rulebook on quality and other requirements for additional ingredients in the production of food products and foodstuffs (Official Gazette of SRY, No. 62/2002 and Official Gazette of SMNE, No. 56/2003 and 4/2004)
- Rulebook on mandatory health examinations of certain categories of employees in sanitary facilities, mandatory and recommended medical examinations for categories of population (Official Gazette of RS, No. 3/2017)
- Rulebook on type and manner of epidemiological surveillance of infectious diseases and special health issues (Official Gazette of RS, No. 3/2017)
- Rulebook on the training program for acquiring basic knowledge of personal hygiene and measures for protection against infectious diseases, its implementation, costs, commission fees and other issues (Official Gazette of RS, No. 15/2017)
- Rulebook on recording data on laboratory testing, deadlines and reporting on obtained results (Official Gazette of RS, No. 73/2017)
- Rulebook on manner of monitoring zoonoses and zoonotic agents with accompanying forms (Official Gazette of RS, No. 76/2017)
- Rulebook on general and special conditions of food hygiene at any stage of production, processing and distribution of food (Official Gazette of RS, No. 72/2010)
- Rulebook on development of the program for monitoring the safety of food of animal origin for 2018 (Official Gazette of RS, No. 20/2018)

- Rulebook on development of the program for monitoring the safety of animal feed for 2018 (Official Gazette of RS, No. 19/2018)
- Rulebook on development of programs for systematic monitoring of residues of pharmacological, hormonal and other harmful substances in animals, products and food of animal origin and animal feed (Official Gazette of RS, No. 91/2009)
- Rulebook on development of measures for the early detection and diagnosis of infectious diseases of transmissible spongiform encephalopathies, their implementation, as well as measures to prevent the spread, suppress and eradicate this disease (Official Gazette of RS, No. 96/2010)
- Rulebook on special conditions for hygiene of small fruits in fresh and frozen state at any stage of production, processing and distribution (Official Gazette of RS, No. 48/2016)
- Rulebook on post-registration control of plant protection products for 2018 (Official Gazette of RS, No. 40/2018)
- Rulebook on development of the program for monitoring the safety of food of plant and mixed origin for 2018 (Official Gazette of RS, No. 65/2018)
- Rulebook on developing and organizing rapid alert system for food and feed (Official Gazette of RS, No. 62/2013)
- Rulebook on the manner and procedure for conducting official control of food of animal origin and the official control of animals before and after their slaughter (Official Gazette of RS, No. 99/2010)
- Regulation on the structure and method of work of emergency departments (Official Gazette of RS, No. 98/2010)
- A guide to microbiological criteria for food, June 2011
- Good practice guide in the field of sanitary control, 2005
- Health-statistical yearbook of the Republic of Serbia 2016 (http://www.batut.org.rs/download/publikacije/pub201620180419.pdf, accessed 7 November 2018)
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- Emergency and crisis response protocol, department of agriculture inspection. Ministry of Agriculture, Forestry and Water Management
- Instruction on the manner and rules of official sampling for monitoring of certain substances and residues in live animals and products of animal origin (No. 323-07-01577/2010-05 of 6.04.2010)
- Operational plan for agricultural inspection for crisis management in the field of safety of food of plant origin, 2018
- List of laboratories and types of tests by food groups of plant and mixed origin (Attachment 1)
- EU summary report on zoonoses, zoonotic agents and food-borne outbreaks 2016. EFSA Journal. 2017;15(12):5077
- Negotiating team for negotiating the accession of the Republic of Serbia to the European Union. Chapter 12: Food safety, veterinary and phytosanitary issues (http://www.eu-pregovori.rs/srl/pregovaracka-poglavlja/poglavlje-12-bezbednost-hrane-veterinarska-i-fitosanitarna-pitanja, accessed 7 November 2018)
- Serbia Floods 2014. United Nations Serbia/European Commission/World Bank Group (http://www.sepa.gov.rs/download/SerbiaRNAreport_2014.pdf, accessed 7 November 2018)
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- Program analysis of the capacities of state and private sector institutions for the implementation of national monitoring of foodstuffs and products of general use, 2018/2019. Institute of Public Health of Serbia "Dr Milan Jovanović Batut", Ministry of Health

- Post-registration control of plant protection products for 2018 (according to the Rulebook – Official Gazette of RS, No. 40/2018). Ministry of Agriculture, Forestry and Water Management
- Program for monitoring food safety of plant and mixed origin for 2018 (according to the Rulebook, Official Gazette of RS, No. 65/2018). Ministry of Agriculture, Forestry and Water Management
- Program for monitoring the safety of food of animal origin for 2018 (according to the Rulebook, Official Gazette of RS, No. 20/2018). Ministry of Agriculture, Forestry and Water Management
- Program for monitoring the safety of feed for 2018 (according to the Rulebook, Official Gazette of RS, No. 19/2018). Ministry of Agriculture, Forestry and Water Management
- Program of systematic monitoring of residues of pharmacological, hormonal and other harmful substances in animals, products of animal origin, food of animal origin and animal feed (according to the Rulebook, Official Gazette of RS, No. 91/2009). Ministry of Agriculture, Forestry and Water Management
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- Law on Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Official Gazette of RS, No. 87/2011)
- Law on Export and Import of Dual-Use Goods (Official Gazette of RS, No. 95/2013)
- Law on the Transport of Dangerous Goods (Official Gazette of RS, No. 88/2010 and 104/2016) (https://www.paragraf.rs/propisi/zakon_o_zdravstvenoj_zastiti.html, accessed 7 November 2018)
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  - Decision on the determination of goods for whose import, export or transit is prescribed the acquisition of certain documents (Official Gazette of RS, No. 92/2017 and 29/2018)
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  - Rulebook on the quality assurance of professional work of health institutions, private practices, health workers and healthcare associates (Official Gazette of RS, No. 35/2011)
- Law on Health Care
- Law on Genetically Modified Organisms (Official Gazette of RS, No. 41/2009)

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- Regulation on the Program for the Protection of Health of the Population against Infectious Diseases (Official Gazette of RS, No. 22/2016)
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- Rulebook on the Program of Mandatory and Recommended Immunization of the Population Against Certain Infectious Diseases (Official Gazette of RS, No. 112/2017, 11/2018 and 58/2018)
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- Law on Health Insurance (Official Gazette of RS, No. 109/2005, 126/2014 and 10/2016)
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- Rulebook on the establishment of the Program of Animal Health Protection Measures for 2018 (Official Gazette of RS, No. 11/2018)
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- Rulebook on the list of particularly dangerous infectious animal diseases and the list of notifiable animal diseases as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 49/2006)
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- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
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- Rulebook on specializations and subspecializations of health workers and health associates (Official Gazette of RS, No. 10/2013, 91/2013, 113/2013, 109/2014, 53/2018) (http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/reg/viewAct/f66380db-9cfe-4351-95e3-54b8c24b5c8c, accessed 7 November 2018)
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- Law on Fire Protection (Official Gazette of RS, No. 111/2009 and 20/2015)
- Law on Commodity Reserves (Official Gazette No.104/2013)
- Law on Protection of Population from Infectious Diseases (Official Gazette of RS, No. 15/2016)
- Veterinary Law – Rulebook on the establishment of a crisis management plan (Official Gazette of RS, No. 90/2015)
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- Decree on the content and method of drafting response and rescue plans in emergency situations

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- Action plan for dealing with elementary and other major disasters and emergencies, adopted on 15 May 2014 (soft copy). Institute of Public Health of Serbia "Dr Milan Jovanović Batut"
- Report on the work of the Republic Directorate for Commodity Reserves for 2017
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  - "Workshop on emergency management and community resilience: a goal for Serbia", CEI-PENTA/Institute of Public Health of Serbia "Dr Milan Jovanović Batut", 2–5 June 2015, Belgrade, Serbia
  - Civil-Military Emergency Preparedness (CMEP) TTX command and simulation practice– Role and functioning of the Republic Staff for Emergencies, 13-15.09.2016, Belgrade, Serbia
  - ConvEx–3 Belgrade, June 2017 – organized by the Agency for Protection against Ionizing Radiation and Nuclear Safety of Serbia in cooperation with the International Atomic Energy Agency (IAEA)

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- Law on Public Health (Official Gazette of RS, No. 15/2016)
- Law on Veterinary Medicine (Official Gazette of RS, No. 91/2005, 30/2010 and 93/2012)
- Rulebook on the establishment of a crisis management plan (Official Gazette of RS, No. 90/2015)
- Rulebook on the list of particularly dangerous infectious animal diseases and the list of notifiable animal diseases as well as the manner of reporting of their outbreak and cessation (Official Gazette of RS, No. 49/2006)
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- Rulebook on the manner and organization of the use of specialized units of CP (Official Gazette of RS, No. 26/2011)

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- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
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- Law on Environmental Protection (Official Gazette of RS, No. 135/2004, 36/2009, 36/2009 – other law, 72/2009 – other law, 43/2011 – Decision of CC and 14/2016)
- Law on Protection Against Ionizing Radiation and on Nuclear Safety (Official Gazette of RS, No. 36/2009 and 93/2012)
- Decree on the establishment of an Emergency Action Plan (Official Gazette of RS, No. 30/2018)
- Conclusion on the establishment of the operational headquarters for the response and rescue of pandemics, epidemics and infectious diseases (in the process of being adopted)
- Rulebook on the method of monitoring zoonoses and zoonotic agents (Official Gazette of RS, No. 76/2017)
- Program for control, prevention, suppression and eradication of avian influenza in the Republic of Serbia. Ministry of Agriculture, Forestry and Water Management
- Action plan for dealing with elementary and other major disasters and emergencies. Institute of Public Health of Serbia "Dr Milan Jovanović Batut", issued on 15 May 2014
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- Agreement on business-technical cooperation, No. 401-00-60/2016-06, 21 June 2016, between the Environmental Protection Agency and the Institute for Public Health of Serbia "Dr Milan Jovanović Batut"

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- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
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- Law on Protection of Population from Infectious Diseases (Official Gazette of RS, No. 15/2016)
- Decree on the planning and type of goods and services for which centralized public procurements are being conducted (Official Gazette of RS, No. 29/2013, 49/2013, 51/2013 – corr., 86/2013, 119/2014, 86/2015, 95/2016, 111/2017 and 56/2018)
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- Law on Animal Welfare (Official Gazette of RS, No. 41/2009)
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- National guidelines for safe waste management. 2008 (http://www.kbs.co.rs/pdf/vodic_medicinski_otpad,.pdf, accessed 7 November 2018)
- Law on Sanitary Control (Official Gazette of RS, No. 125/2004)
- Organizational structure of health institutions in the Republic of Serbia in 2017, available at: http://www.batut.org.rs/download/izvestaji/organizaciona_struktura_2017_12_31.pdf
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- National Strategy for Emergency Response and Rescue (Official Gazette of RS, No. 86/2011)
- Law on the Budget System (Official Gazette of RS, No. 54/2009, 73/2010 and 101/2010)
- Decree on the content and method of drafting response and rescue plans in emergency situations (Official Gazette of RS, No. 8/2011)
- Decree on the composition and method of work of emergency staffs (Official Gazette of RS, No. 98/2010)
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- DPPI SEE- Disaster preparedness and prevention initiative for South Eastern Europe – The Initiative for Disaster Management and Response in Disasters of Southeast European Countries
- Law on Health Care (Official Gazette of RS, No. 107/2005, 72/2009 – other law, 88/2010 and 99/2010)
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- Subprogram 4 of the Program of General Interest of the Ministry of Health
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- Action plan for natural and other major disasters and emergencies. Institute of Public Health of Serbia "Dr Milan Jovanović Batut"
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- Points of entry self evaluation report of Serbia
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- International Health Regulations (2005)
- Decision on the establishment of the coordinating entity for border crossings in the Republic of Serbia
- Integrated Border Management Strategy in the Republic of Serbia 2017–2020 (Official Gazette of RS, No. 55/2005, 71/2005 – correction, 101/2007, 65/2008, 16/2011, 68/2012 – CC, 72/2012, 7/2014 – CC, and 44/2014)
- Action plan for the implementation of an Integrated Border Management Strategy in the Republic of Serbia 2017–2020 (Official Gazette of RS, No. 55/2005, 71/2005 – correction, 101/2007, 65/2008, 16/2011, 68/2012 – CC, 72/2012, 7/2014 – CC, and 44/2014)

CHEMICAL EVENTS

- A list of surfactants for which an authorization has been issued or an act authorizing the use of surfactants in a detergent in the EU and a list of surfactants for which authorization is required and surfactants prohibited in the EU (Official Gazette of RS, No. 94/2010)
- Annual inspection plan – Department for Accidents and Chemicals, Sector for Environmental Monitoring and Precaution, MEP
- Environmental report (http://www.sepa.gov.rs/, accessed 7 November 2018)
- Guidelines on the establishment of preventive measures for the safe storage, warehousing and use of particularly hazardous chemicals (Official Gazette of RS, No. 06/2017)

- Information desk for chemicals and biocidal products. Available at: http://www.ekologija.gov.rs/organizacija/sektori/sektor-za-upravljanje-zivotnom-sredinom/odeljenje-za-hemikalije/informativni-pult-za-hemikalije-i-biocidne-proizvode, accessed 7 November 2018
- Informing consumers about hazardous chemicals (http://www.ipohem.gov.rs/, accessed 7 November 2018)
- Instruction on methodology for making assessment of vulnerability from natural disasters and other accidents and plans for response and rescue in emergency situations (2017/2018)
- Integrated Seveso Registry – Law on Environmental Protection (Official Gazette of RS, No. 135/2004), Article 60
- Law on Agricultural Land (Official Gazette of RS, No. 62/2006, 65/2008 – other law, 41/2009, 112/2015 and 80/2017)
- Law on Chemicals (Official Gazette of RS, No. 36/2009, 88/2010, 23/2011, 92/2011, 93/2012 and 25/2015)
- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
- Law on Environmental Protection (Official Gazette of RS, No. 135/2004, 36/2009, 72/2009, 43/2011 and 14/2016)
- Law on Food Safety (Official Gazette of RS, No. 41/2009)
- Law on Ground Protection (Official Gazette of RS, No. 112/2015)
- Law on Inspection Supervision (Official Gazette of RS, No. 36/2015)
- Law on Ministries (Official Gazette of RS, No. 44/2014, 14/2015, 54/2015, 96/2015 and 62/2017)
- Law on Occupational Safety and Health (Official Gazette of RS, No. 101/2005 and 91/2015)
- Law on the Health Safety of the Items of General Use (Official Gazette of RS, No. 92/2011)
- Law on the Confirmation of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Official Gazette of the FRY, No. 2/1999 – International Treaties)
- Law on the Confirmation of the Convention on the Transboundary Effects of Industrial Accidents (Official Gazette of RS, No. 42/2009 – International Agreements)
- Law on the Confirmation of the Rotterdam Convention on the Proceeding of Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade (Official Gazette of RS, No. 38/2009 – International Agreements)
- Law on the Confirmation of the Stockholm Convention on Persistent Organic Pollutants (Official Gazette of RS, No. 42/2009 – International Agreements)
- Law on the Health Suitability of General Use Objects (Official Gazette of RS, No. 92/2011)
- Law on Transport of Hazardous Goods (Official Gazette of RS, No. 88/2010 and 104/2016)
- Law on Waste Management (Official Gazette of RS, No. 36/2009, 88/2010 and 14/2016)
- Law on Water (Official Gazette of RS, No. 30/2010 and 93/2012)
- List of candidate substances for the List of Substances of Concern (Official Gazette of RS, No. 58/2016 and 22/2018)
- List of surfactants for which an authorization has been issued or an act authorizing the use of surfactants in a detergent in the EU and the List of surfactants for which approval is refused and surfactants prohibited in the EU (Official Gazette of RS, No. 94/2010)
- National Profile for Chemicals Management, 2006 (updated in 2008)
- Plan for accident protection and taking measures to prevent accidents and limit the impact of the accident on human life and health, material goods and the environment (Official Gazette of RS, No. 48/2016)

- Progress and achievement reports of defined goals of the Strategic Approach to International Chemicals Management (SAICM)
- Rulebook on classification, packaging, marking and advertising of chemicals and certain products in accordance with the Globally Harmonized System for Classification and Marking of the United Nations, (Official Gazette of RS, No. 105/2013 and 52/2017)
- Rulebooks on detergents (Official Gazette of RS, No. 25/2015)
- Report on the work of the sector for precaution and environmental surveillance and statements
- Report on the work of the sector for surveillance and precaution in the environment and statements available through the MEP (http://www.ekologija.gov.rs/dokumenti/, accessed 7 November 2018)
- Rulebook on closer conditions for keeping dangerous chemicals in the sales area and the manner of marking them (Official Gazette of RS, No. 31/2011 and 16/2012)
- Rulebook on criteria for substance identification as PBT or vPvB (Official Gazette of RS, No. 23/2010)
- Rulebook on detailed conditions for keeping dangerous chemicals in the sales area and the manner of marking it (Official Gazette of RS, no.31 /2011 and 16/2012)
- Rulebook on import and export of certain hazardous chemicals (Official Gazette of RS, No. 89/2010, 15/2013 and 114/2014)
- Rulebook on licenses for performing traffic activity, or permits for the use of particularly hazardous chemicals (Official Gazette of RS, No. 06/2017)
- Rulebook on methods for testing hazardous properties of chemicals (Official Gazette of RS, No. 117/2013)
- Rulebook on restrictions and prohibitions on the production, placing on the market and use of chemicals (Official Gazette of RS, No. 90/2013, 25/2015, 02/2016 44/2017 and 36/2018)
- Rulebook on the chemical adviser and the conditions that must be fulfilled by a legal entity or entrepreneur that carries out the training and control of the knowledge of chemical advisors (Official Gazette RS, No. 13/2011, 28/2011 and 47/2012)
- Rulebook on the content of the accident prevention policy and its content and methodology for the development of the safety report and the accident safety plan (Official Gazette RS, No. 41/2010)
- Rulebook on the contents of the notice on the new Seveso facility or the termination of the operation of the Seveso plant i.e. complex (Official Gazette of RS, No. 41/2010)
- Rulebook on the contents of the safety data sheet (Official Gazette of RS, No. 100/2011)
- Rulebook on the List of Hazardous Goods and their quantities and criteria for determining the type of documents produced by the operator of the Seveso plant or complex. (Official Gazette of RS, No. 41/2010) and 51/2015)
- Rulebook on the manner in which the chemical safety assessment is carried out and the content of the chemical safety report (Official Gazette of RS, No. 37/2011)
- Rulebook on the manner of keeping records on chemicals (Official Gazette of RS, No. 31/2011)
- Rulebook on the manner of preparation and content of the accident plan (Official Gazette of RS, No. 82/2012)
- Rulebook on the Register of Chemicals (Official Gazette of RS, No. 16/2016, 06/2017, 117/2017)
- Rulebook on types and quantities of hazardous substances, facilities and other criteria on the basis of which the accident protection plan is drawn up and measures are taken for preventing accidents and limiting the impact of the accident on human life and health, material goods and the environment (Official Gazette of RS, No. 48/2016)

- The list of substances causing concern (Official Gazette of RS, No. 94/2013,101/2016 and 22/2018)
- Rulebook on the list of classified substances (Official Gazette of RS, No. 50/2017)
- Tool for Seveso plant operators – the safety data sheet for each chemical contains the necessary information

RADIATION EMERGENCIES

- Agreement between the Government of Hungary and the Government of the Republic of Serbia on the timely exchange of information in the event of a radiation emergency (Official Gazette of the Republic of Serbia, No. 19/2015 – International Agreements)
- Law on Protection Against Ionizing Radiation and on Nuclear Safety (Official Gazette of RS, No. 36/2009 and 93/2012), Article 10
- Rules on the conditions for obtaining the authority for performing of the protection activities against ionizing radiation (Official Gazette of RS, No. 101/2016), Articles 3, 4, 6, and 14
- Civil-Military Emergency Preparedness (CMEP) TTX Command simulation exercise – role and functioning of the Republic staff for emergencies, 13–15 September 2016, Belgrade, Serbia
- Convention on Assistance in the Case of Nuclear Accidents or Radiological Hazards (Official Gazette of the SFRY, No. 4/1991 – International Treaties)
- ConvEx–3 Belgrade, June 2017 – organized by the Agency for Protection against Ionizing Radiation and Nuclear Safety of Serbia in cooperation with the International Atomic Energy Agency (IAEA)
- Decree on the establishment of an action plan in the event of an accident (Official Gazette of RS, No. 30/2018)
- Law on Emergency Situations (Official Gazette of RS, No. 111/2009, 92/2011 and 93/2012)
- Law on Protection Against Ionizing Radiation and on Nuclear Safety (Official Gazette of RS, No. 36/2009 and 93/2012)
- Law on Ratification of the Convention on Assistance in the Case of Nuclear Accidents or Radiological Hazards (Official Gazette of the SFRY, No. 4/1991 – International Treaties)
- Law on the Transport of Hazardous Goods (Official Gazette of RS, No. 104/2016)
- Regular annual reports on the level of exposure of the population to ionizing radiation from the environment, available on the Agency's website: http://www.srbatom.gov.rs/srbatom/monitoring-radioaktivnosti.htm, accessed 7 November 2018
- Regulation on Ratification of the Convention on Early Notification of Nuclear Accidents (Official Gazette of SFRY, No. 15/1989 – International Agreements)
- Regulations in the field of radiation and nuclear safety and security, available at: http://www.srbatom.gov.rs/srbatom/zakonska-regulativa.htm, accessed 7 November 2018
- Rulebook on control of the radioactivity of goods on import, export and transit (Official Gazette of RS, No. 44/2011)

World Health Organization

JOINT EXTERNAL EVALUATION OF IHR CORE CAPACITIES of the REPUBLIC OF SERBIA

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