### JOINT EXTERNAL EVALUATION OF IHR CORE CAPACITIES of MONTENEGRO

Mission report: 27–31 May 2019





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### **ABBREVIATIONS**

AMR	Antimicrobial Resistance
AST	Antimicrobial Sensitivity Testing
BfR	German Federal Institute for Risk Assessment
BSL	Biosafety Level
BTSF	Better Training for Safer Food
CAESAR	Central Asian and Eastern European Surveillance of Antimicrobial Resistance
CCMNE	Clinical Centre of Montenegro
CBRN	Chemical/Biological/Radiological/Nuclear
CDC	Centers for Disease Control and Prevention
DFSVPA	Directorate for Food Safety, Veterinary and Phytosanitary Affairs
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EOC	Emergency Operations Centre
EQA	External Quality Assessment
ERCC	European Response Coordination Centre
EU	European Union
EUCAST	European Committee for Antimicrobial Susceptibility
EVM	Effective Vaccine Management
FAO	Food and Agriculture Organization of the United Nations
FETP	Field Epidemiology Training Programme
GAP	Global Action Plan
HCAI	Healthcare-Associated Infections
IAEA	International Atomic Energy Agency
IEMS	Institute for Emergency Medical Assistance
IHR	International Health Regulations (2005)
INFOSAN	International Network of Food Safety Authorities
IPH	Institute for Public Health (Montenegro)
ISO	International Standards Organisation
JEE	Joint External Evaluation
MediPIET	Mediterranean Programme for Intervention Epidemiology Training
MNE	Montenegro

МоН	Ministry of Health
Mol	Ministry of Interior
ΝΑΤΟ	North Atlantic Treaty Organization
NFP	National IHR Focal Point
NIKRA	National Interdisciplinary Commission for Antibiotic Resistance Control
NRL	National Reference Laboratory
OIE	World Organisation for Animal Heath
PCR	Polymerase Chain Reaction
PHEIC	Public Health Emergency of International Concern
ΡοΕ	Points of Entry
PHI	Public Health Institute(Podgorica)
PVS	Performance of Veterinary Services
RAPEX	Rapid Exchange of Information System
SAICM	Strategic Approach to International Chemical Management
SEESIM	South Eastern Europe Simulation
SOP	Standard Operating Procedures
SVL	Specialist Veterinary Laboratory
UNECE	United Nations Economic Commission for Europe
VIS	Veterinary Information System
WAHIS	World Animal Health Information System
WHO	World Health Organization

### **EXECUTIVE SUMMARY**

This report is the product of a Joint External Evaluation (JEE) of Montenegro's capacity to prevent, detect and respond promptly and effectively to public health risks and public health emergencies of international concern. Montenegro undertook a self-assessment based on a JEE tool developed by the World Health Organization (WHO) to assess capacities related to the International Health Regulations (IHR) (2005). The self-assessment examined **19 technical areas** and was presented to a multi-sectoral external assessment team of experts from Member States, WHO, FAO (Food and Agriculture Organization of the United Nations) and OIE (World Organisation for Animal Health). It was discussed jointly with experts from Montenegro in a week-long meeting from May 27–31, 2019, in Podgorica, Montenegro and included visits to a number of sites in Podgorica, as well as in several other cities across the country.

Together with Montenegrin experts, the JEE team discussed the self-assessment to determine current strengths, areas for strengthening and to agree on scores for the 19 technical areas. Nearly 70 priority action recommendations were developed during the meeting.

Montenegro is a newly independent country, established in 2006. The external assessment team recognizes that a specific interest for Montenegro is the process of accession to the European Union (EU). It is the team's hope and intent that the results of this assessment will support Montenegro's preparations for this major milestone.

Montenegro should be commended for demonstrating major progress in a number of areas related to IHR, including the designation of a National IHR Focal Point (NFP) within the within the Institute for Public Health of Montenegro (IPH) and of a World Organisation for Animal Heath (OIE) Contact Point at the Directorate for Food Safety, Veterinary and Phytosanitary Affairs.

Montenegro has a strong legislative basis for work related to IHR with a set of robust laws, regulations and guidelines, for example in radiological emergencies, food safety, protection and rescue, and surveillance. A significant portion of its legislation is harmonized with the EU.

In addition, the country has put in place a number of plans and strategies that will facilitate IHR implementation, for example in the areas of antimicrobial resistance (AMR), disaster risk reduction, border management and human resources. In other areas, Montenegro could benefit from the development of strategies, guidelines and Standard Operating Procedures (SOPs).

Montenegro is a small country with a small population. As a result, many operating and communication procedures are informal and take place through personal contact. In an emergency, and in the absence of certain key staff, Montenegro would benefit from written guidelines or formal SOPs in a number of areas, for example for points of entry (PoE) or for risk assessment.

The country is endowed with strong institutions involved in implementing IHR including a range of ministries and departments, as well as specialized bodies to deal with specific issues. Although there are gaps, Montenegro should consider strengthening collaboration in several areas, for example by creating a national joint biosafety and biosecurity body.

Montenegro promotes a multi-sectoral approach in its work and has demonstrated its success in areas such as radiation and surveillance. Additional multi-sectoral training, for example in emergency response, would help engage all stakeholders.

Many health facilities of Montenagro are making important progress towards meeting IHR (2005) requirements, are up-to-date and fully functional: the national laboratory system is well established both for human and animal specimens, successful surveillance systems are in place in a number of sectors and the Emergency Operation Centre (EOC) 112 call number has been operational since 2015. Montenegro has a good immunization programme, although the measles, mumps and rubella (MMR) vaccine immunization rates should be strengthened; they have declined as a result of misinformation and scepticism on the part of anti-vaccine parents, which authorities are working to address.

Montenegro rightly recognizes the importance of accurate and timely communication, both in normal times and during potential or actual health emergencies. To this end, the country is reinforcing its communication and awareness-raising capabilities, especially risk communication in emergencies, to better use social media for information dissemination and messaging.

Several broad factors underpin the challenges faced by Montenegro in implementing the requirements of IHR (2005): the need for a One Health all-hazard approach, sustainable and discrete funding, and human resources in its broadest sense.

Consideration should be given to strengthening Montenegro's One Health approach and all-hazard approach and should include both human and animal health. This need is particularly reflected in the areas of AMR, zoonoses and food safety and will require strong communication and collaboration strategies, along with joint training.

However notable, many of the efforts undertaken by Montenegro's health system may be at risk without guaranteed and sustainable funding. While Montenegro's Law on Budget and Fiscal Responsibility allows funds from the permanent reserve to be used in a public health emergency, no sector has a formal budget line for IHR implementation and efforts to rectify this should be accelerated.

The lack of human resources in a number of fields is another area that needs building as this may undermine staff recruitment and retention and weaken the quality of services. Strengthening human resources at all levels while simultaneously providing continuing staff training and education could go a long way towards solidifying the health workforce and ensuring its efficacy, especially in emergency situations. Montenegro is ready to respond to radiological and nuclear threats.

In closing, efforts by Montenegro to involve a range of sectors and actors in its implementation of IHR demonstrates that this is not exclusively a health sector responsibility but that awareness, education and training are required across sectors if the IHR requirements are to be fulfilled and high levels of health security are to be maintained.

### Montenegro scores and priority actions

Table 1 is the summary of the final scores for each technical area (further details are shown in the respective report chapters), as agreed by the national and external JEE teams. The principles of the scoring system are described in the JEE tool, available from:

#### https://www.who.int/ihr/publications/WHO\_HSE\_GCR\_2016\_2/en/

Briefly, the scoring is a 5-step Likert Scale in which a score of 1 designates no capacity, and incremental obligatory criteria for each indicator must be fulfilled to reach the next level. A score of 5 designates that the country has the required capacity and is able to sustain it. Indicators are proxies and are chosen with the aim of representing a probable wider capability than the actual measured factor.

For ease of overview, a "traffic light" colouring system is used, whereby scores of 1 are shown as red; scores of 2 and 3 are yellow; and 4 and 5 are green.

### Note on scoring of technical areas of the JEE tool

The JEE process is a peer-to-peer review and a collaborative effort between host country experts and JEE team members. In completing the self-evaluation, the first step in the JEE process, and as part of preparing for an external evaluation, host countries are asked to focus on providing information on their capabilities based on the indicators and technical questions included in the JEE tool.

The host country may score their self-evaluation or propose a score during the onsite visit with the JEE team. The entire external evaluation, including the discussions around the score, strengths/best practices, the areas that need strengthening, challenges and the priority actions, is done in a collaborative manner, with the JEE team members and host country experts seeking agreement.

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

### SCORES AND PRIORITY ACTIONS

Technical areas	Indicator no.	Indicator	Score	Priority Actions
PREVENT				
National legisla- tion, policy and financing	P.1.1	The State has as- sessed, adjusted and aligned its domestic legislation, policies and administrative arrange- ments in all relevant sectors to enable com- pliance with the IHR	3	<ul> <li>Calculate the funding requirements of regular IHR activities for all relevant institutions and include them as separate budget lines used exclusively for IHR.</li> <li>Create the legal mandate that defines intersec- toral coordination and cooperation for imple- mentation of IHR.</li> <li>Strengthen communication and intersectoral</li> </ul>
	P.1.2	Financing is available for the implementation of IHR capacities	2	cooperation around IHR obligations between decision-makers and implementers.
	P.1.3	A financing mechanism and funds are available for timely response to public health emergen- cies	2	
IHR coor- dination, communi- cation and advocacy	P.2.1	A functional mecha- nism established for the coordination and integration of relevant sectors in the imple- mentation of IHR	2	<ul> <li>Develop SOPs for coordination between the National IHR Focal Point and relevant sectors.</li> <li>Strengthen the IHR implementation structure by appointing the chair of the national IHR team as National IHR Focal Point, appointing a vice-chair, regularly updating the list of members of the multi-sectoral working group for IHR implementation and organizing regular meetings of the national IHR team.</li> <li>Organize a yearly table-top or simulation exercise of a public health emergency of international concern (PHEIC) and use the outcomes to update SOPs.</li> </ul>
Antimi- crobial	P.3.1	Effective multi-sectoral coordination on AMR	2	<ul> <li>Establish a national committee to develop a list of recommended antibiotics and national</li> </ul>
resistance	P.3.2	Surveillance of AMR	2	guidelines for rational use of antibiotics in pub- lic health.
	P.3.3	Infection prevention and control	2	• Establish a national laboratory for AMR surveil- lance of animal and food isolates.
	P.3.4	Optimize use of antimi- crobial medicines in hu- man and animal health and agriculture	2	<ul> <li>Extend the National Action Plan for AMR to include agriculture and environmental protection.</li> <li>Develop a national strategy for the prevention and control of hospital infections.</li> </ul>

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Zoonotic disease	P.4.1	Coordinated surveil- lance systems in place in the animal health and public health sectors for zoonotic diseases/ pathogens identified as joint priorities	3	<ul> <li>Strengthen human resources for surveillance and control of zoonoses in human and veteri- nary sectors through training and simulations.</li> <li>Develop an IT interface between human and animal health surveillance and reporting on zoonotic diseases.</li> <li>Implement activities for surveillance of zoo-</li> </ul>
	P.4.2	Mechanisms for re- sponding to infectious and potential zoonotic diseases established and functional	3	noses in line with legislation, based on epide- miological factors in the risk assessment and develop SOPs and manuals.
Food safety	P.5.1	Surveillance systems in place for the detec- tion and monitoring of foodborne diseases and food contamination	3	<ul> <li>Finalize and implement a national food safety emergency plan.</li> <li>Appoint a designated Emergency Contact Point for the International Network of Food Safety Authorities (INFOSAN).</li> </ul>
	P.5.2	Mechanisms are estab- lished and functioning for the response and management of food safety emergencies	1	<ul> <li>Expand rapid risk assessment capacity by at- tracting specialists through adequate job facili- ties, continuing education and yearly simulation exercises.</li> <li>Improve SOPs, instructions, procedures and</li> </ul>
				guides required for management, information exchange and communication to an effective response to foodborne diseases.
Biosafety and bios- ecurity	P.6.1	Whole-of-government biosafety and biosecu- rity system in place for all sectors (including	2	<ul> <li>Develop a list of dangerous pathogens and toxins and a licensing procedure to regulate and control pathogens of concern in all relevant sectors.</li> </ul>
	P.6.2	human, animal and agriculture facilities) Biosafety and biosecu-	2	<ul> <li>Implement national biosafety and biosecurity licensing requirements for all laboratories work- ing with agents defined in the list.</li> </ul>
		rity training and prac- tices in all relevant sec- tors (including human,	-	<ul> <li>Provide systematic and effective education and training on biosafety and biosecurity manage- ment at a national level.</li> </ul>
		animal and agriculture)		<ul> <li>Establish a joint biosafety and biosecurity body at the national level, which would cover activi- ties in all sectors, both public and private.</li> </ul>
Immuni- zation	P.7.1	Vaccine coverage (measles) as part of national programme	1	<ul> <li>Increase coverage of all vaccines from the Im- munization Programme, with special emphasis on the measles, mumps and rubella (MMR)</li> </ul>
	P.7.2	National vaccine ac- cess and delivery	4	vaccine, by developing a communication strat- egy or social mobilization strategy focusing on vaccine promotion.
				• Implement an Effective Vaccine Management (EVM) study with related action plan for capac- ity building and improved practices for vaccines storage and distribution.
				<ul> <li>Introduce a remuneration system for providers who are effective in increasing immunization uptake and adherence to the immunization schedule.</li> </ul>

Technical areas	Indicator no.	Indicator	Score	Priority Actions			
DETECT	DETECT						
National laboratory system	D.1.1	Laboratory testing for detection of priority diseases	3	<ul> <li>Adopt a set of standard diagnostic methods and develop national diagnostic algorithms.</li> <li>Develop strategies for specific diagnostics,</li> </ul>			
oyotem	D.1.2	Specimen referral and transport system	2	especially for emerging infectious diseases, such as pathogens that require biosafety level			
	D.1.3	Effective national diag- nostic network	2	3 (BSL3). • Ensure the Ministry of Health undertakes a			
	D.1.4	Laboratory quality sys- tem	3	leading role in establishing the network of mi- crobiological laboratories, thereby improving the system's capacity.			
				<ul> <li>Create a national specimen referral network and transportation system.</li> </ul>			
				<ul> <li>Establish national EQA system and strengthen participation in international EQA programmes.</li> </ul>			
Real-time surveil-	D.2.1 D.2.2	Surveillance systems Use of electronic tools	4 3	<ul> <li>Integrate electronic data from clinical centres, specialized hospitals and private health facili- ties within the established surveillance system.</li> </ul>			
Iance     D.2.3     Analysis of surveillance data     4     Establis communifoodbor       Integratiagnosti     Integratiagnosti	<ul> <li>Establish an electronic notification system for communicable diseases in animals, including foodborne diseases.</li> </ul>						
			<ul> <li>Integrate electronic data from laboratory di- agnostics within the established surveillance system at local and national levels.</li> </ul>				
Reporting	D.3.1	System for efficient reporting to FAO, OIE and WHO.	3	<ul> <li>Raise public awareness on the implementation of the One Health approach and the all-hazard approach, including development of agreed</li> </ul>			
	D.3.2	Reporting network and protocols in country.	3	<ul> <li>protocols and SOPs.</li> <li>Improve communication between human and veterinary sectors by exchanging best practices, training and exercises with all partners involved in detecting and reporting relevant events.</li> </ul>			
				<ul> <li>Establish an electronic system to support the reporting of a potential PHEIC in the veterinary sector.</li> </ul>			
Workforce Develop- ment (ani-	D.4.1	An up-to-date multi- sectoral workforce strategy is in place.	2	<ul> <li>Ensure jobs are filled with high-quality person- nel in public health and animal health sectors through positive selection of personnel and pre-</li> </ul>			
mal and human	D.4.2	Human resources are available to effectively implement IHR.	3	<ul><li>vention of employee turnover.</li><li>Improve the quality of postgraduate education and continuing professional education.</li></ul>			
health sectors)	D.4.3	In-service trainings are available.	2	<ul> <li>Develop a multidisciplinary and multi-sectoral approach to support teamwork in the fields of</li> </ul>			
	D.4.4	FETP or other applied epidemiology training programme in place.	3	surveillance, prevention and control of infec- tious diseases.			

Technical areas	Indicator no.	Indicator	Score	Priority Actions			
RESPOND	RESPOND						
Emer- gency prepared- ness	R.1.1	Strategic emergency risk assessments con- ducted and emergency resources identified and mapped.	2	<ul> <li>Develop a national disaster risk assessment.</li> <li>Develop local disaster risk assessments.</li> <li>Develop national protection and rescue plans for different types of risks.</li> </ul>			
	R.1.2	National multi-sectoral multi-hazard emer- gency preparedness measures, including emergency response plans, are developed, implemented and tested.	2	<ul> <li>Develop a national plan of readiness and response in the health system.</li> <li>Map resources at the national level in public health, veterinary and other relevant sectors.</li> </ul>			
Emer- gency	R.2.1	Emergency response coordination.	4	Develop a comprehensive Emergency Pre- paredness and Response Plan for all partici-			
response opera-	R.2.2	Emergency operations centre (EOC) capacities, procedures and plans.	4	pants in protection and rescue for relevant risks at national and local levels. • Improve capacity of municipal protection and			
tions	R.2.3	Emergency Exercise Management Pro- gramme.	3	<ul> <li>rescue services by equipping and training them to respond to different types of risks, particularly in chemical, biological, radiological and nuclear protection (CBRN).</li> <li>Increase the number of employees in CBRN protection.</li> </ul>			
				<ul> <li>Develop a programme and plan of exercises at national and local levels in the protection and rescue system.</li> <li>Establish the National Training Centre for Pro- tection and Rescue.</li> </ul>			
Linking public health and security authori- ties	R.3.1	Public health and secu- rity authorities (e.g. law enforcement, border control, customs) linked during a suspect or confirmed biological, chemical or radiological event.	3	<ul> <li>Map out needs for human and material resources, and increase capacity accordingly.</li> <li>Organize simulation exercises at national and local levels with international assistance.</li> <li>Develop multi-sectoral SOPs or formal agreements for information sharing to respond to public health threats.</li> </ul>			
Medical counter- measures and per- sonnel deploy- ment	R.4.1	System in place for activating and coordi- nating medical counter- measures during a pub- lic health emergency.	4	<ul> <li>Identify health care facilities and equipment to ensure first response for mass casualty events.</li> <li>Develop a plan with defined procedures for the deployment of medical staff during a public health emergency.</li> </ul>			
	R.4.2	System in place for activating and coordi- nating health personnel during a public health emergency.	3	<ul> <li>Develop guidelines for case management of all IHR-related hazards.</li> </ul>			
	R.4.3	Case management procedures imple- mented for IHR relevant hazards.	2				

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Risk com- munica- tion	R.5.1	Risk communication systems for unusual/ unexpected events and emergencies.	2	<ul> <li>Formalize SOPs for the Intersectoral Team for Crisis Communication and improve internal communication.</li> <li>Use all communication channels, including</li> </ul>
	R.5.2	Internal and partner coordination for emer- gency risk communica- tion.	3	<ul> <li>social media, to disseminate information.</li> <li>Increase the number of staff available for risk communication as well as overall formal and informal education and promotion of spokes-</li> </ul>
	R.5.3	Public communication for emergencies.	4	persons skills in the emergency response ser- vices.
	R.5.4	Communication en- gagement with affected communities.	4	
	R.5.5	Addressing perceptions, risky behaviours and misinformation.	3	
IHR-RELA	TED HAZ	ARDS AND POINTS	OF EN	ſRY
Points of entry	PoE.1	Routine capacities es- tablished at points of	2	• Finalize the designation of one airport in line with IHR (2005) requirements.
	PoE.2	entry. Effective public health response at points of entry.	2	• Designate one port in line with IHR (2005) re- quirements and develop SOPs and guidelines to manage cross-border public health threats in the designated port.
				<ul> <li>Develop a plan for ongoing training in public health emergencies, and implement exercises at PoEs to improve multi-sectoral prepared- ness, communication and response.</li> </ul>
				• Continue establishing appropriate facilities aligned with the core capacity requirements under Annex 1B of the IHR (2005).
Chemical events	CE.1	Mechanisms estab- lished and functioning	2	• Establish a poison control centre according to WHO guidelines.
		for detecting and re- sponding to chemical events or emergencies.		• Strengthen administrative capacities to re- spond to different types of chemical event.
	CE.2	Enabling environment in place for management of chemical events.	2	<ul> <li>Ensure collection, evaluation and availability of information needed to assess chemical risks, including rapid risk assessment for all stakeholders involved in management of acute chemical events.</li> </ul>
				<ul> <li>Establish a mechanism for coordination and cooperation in managing chemical events, in- cluding participation in chemical or toxicologi- cal networks.</li> </ul>

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Technical areas	Indicator no.	Indicator	Score	Priority Actions
Radiation emergen- cies	RE.1	Mechanisms estab- lished and functioning for detecting and re- sponding to radiological and nuclear emergen- cies.	4	<ul> <li>Organize and promote simulation exercises to test responses to radiological emergencies at the national and local levels.</li> <li>Develop a joint programme with exercises to respond to different scenarios involving participants from relevant institutions at the national and local levels.</li> <li>Strengthen administrative and technical capacities and procedures including improving the mechanism for information collection and exchange.</li> <li>Identify healthcare facilities and personnel and equip them to respond to radiological emergency situations.</li> </ul>
	RE.2	Enabling environment in place for management of radiological and nuclear emergencies.	4	

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 State Parties. In some State 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 State 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 State 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. State 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.

### **MONTENEGRO LEVEL OF CAPABILITIES**

Montenegro is in the process of negotiating accession to the EU and is harmonizing its national legislation with EU legislation and with IHR. In the area of public health, two benchmarks have been reached, one in contagious diseases and the other in substances of human origin.

In addition, the Directorate for Food Safety, Veterinary and Phytosanitary Affairs (DFSVPA) has been working to fulfil the criteria to close negotiations for Chapter 12 (Food safety, veterinary and phytosanitary policy). While EU harmonization cannot substitute for the systematic assessment of IHR requirements, it provides a robust legal foundation for IHR.

Legislation is drafted with the participation of all institutions responsible for relevant areas of IHR, who nominate working groups to take part in the drafting process. Potential legislation is then opened for public discussion, which is followed by consultations with other relevant institutions. Laws are adopted by the Parliament of Montenegro, while secondary legal acts are adopted by the relevant ministers.

The Ministry of Health (MoH) has a leading role in implementing IHR, and prepares a management plan for crisis and emergency situations such as outbreaks, extreme climate conditions and other accidents and disasters. It also holds reserve funds for emergencies, climate and other disasters and events. The Directorate for Emergencies within the Ministry of Interior is responsible for the country's overall emergency response and for the coordination of responses by other government departments in an emergency.

In an emergency, the government can appoint a multi-sectoral coordination team composed of several ministries and led by the Prime Minister. The team makes decisions related to procurement and distribution of medical countermeasures and coordinates the role of participants in protection and rescue. In an emergency, public procurement processes may be accelerated.

Montenegro has no formal overall budget line for IHR implementation although relevant ministries do have budgets they are committed to using for IHR-related activities. The Law on Budget and Fiscal Responsibility allows funds from the permanent reserve to be used in the event of urgent and unexpected expenses. The law also provides for the rapid mobilization of these funds within 48 hours if needed.

In 2014, Montenegro signed an agreement with the EU on Civil Protection Mechanisms to strengthen cooperation between the EU and Member States, and facilitate coordination in civil protection. This is designed to enhance the efficiency of prevention, readiness and response to both natural and man-made disasters.

A loan agreement was signed in May 2017 between the International Bank for Reconstruction and Development and the governments of Montenegro and several other countries in the region. Disaster management is funded by annual contributions from these countries.

### **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 3

#### Strengths and best practices

- Legislation relevant to IHR (2005) exists.
- The EU Directive on serious cross-border threats 1082/2013 is implemented through national legislation.
- In an emergency, the government can establish a coordination team composed of several ministries and led by the Prime Minister.
- The MoH is a member of the Health Network for South Eastern Europe.

#### Areas that need strengthening and challenges

- Legislation is in place, but awareness on implementation and responsibility for IHR in all sectors needs strengthening.
- Adjustments to address legislative gaps related to IHR compliance should be identified.
- IHR-related communication and intersectoral cooperation should be strengthened between decision-makers and implementers.

#### P.1.2 Financing is available for the implementation of IHR capacities - Score 2

#### Strengths and best practices

• The MoH is responsible for financial planning of basic public health functions for health care, including the control of disease.

#### Areas that need strengthening and challenges

- Funds allocated for IHR implementation are limited and insufficient to cover all needs and activities.
- A detailed analysis is needed of funding deficits for IHR-specific activities and the consequences of those deficits.
- There is a lack of human resources and of funds for new staff recruitment in the areas of emergencies and IHR implementation.

### P.1.3 A financing mechanism and funds are available for the timely response to public health emergencies – Score 2

### Strengths and best practices

- A legal process exists to allocate funds rapidly when a public emergency arises.
- Extraordinary procurement of personal protection equipment, medicines and vaccines was undertaken with success during the 2009 influenza pandemic and Ebola preparedness in 2014.

### Areas that need strengthening and challenges

- There are insufficient funds for timely response to public health emergencies.
- Reallocation of funds between various sectors for timely response to public health emergencies should be improved.

- Calculate the funding requirements of regular IHR activities for all relevant institutions and include them as separate budget lines used exclusively for IHR.
- Create the legal mandate that defines intersectoral coordination and cooperation for implementation of IHR.
- Strengthen communication and intersectoral cooperation around IHR obligations between decision-makers and implementers.

# IHR COORDINATION, COMMUNICATION AND ADVOCACY

### **INTRODUCTION**

The effective implementation of the IHR requires multi-sectoral/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**

Multi-sectoral/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.

### MONTENEGRO LEVEL OF CAPABILITIES

Montenegro ratified the IHR (2005) on 5 February 2008 and committed to the smooth implementation of its obligations.

A National IHR Team has been appointed by the Ministry of Health. There is also a network of sectoral focal points from relevant institutions including representatives of the Ministry of Health, Ministry of Agriculture and Rural Development, Ministry of Transport, Maritime Affairs and Telecommunications, Ministry of Foreign Affairs and European Integration, Ministry of Physical Planning and Environmental Protection, Ministry of Defence, Ministry of Interior (Directorate for Emergencies and Integrated Border Management Department), Ministry of Economy, Ministry of Sustainable Development and Tourism, Customs Administration, Environmental Protection Agency, Agency for Medicines and Medical Devices, Ministry of Education and Sports, Public Health Institute (PHI) Podgorica Health Centre, Kotor Harbour Master Office, Bar Harbour Master Office, Maritime Safety Department and Administration for Inspection Affairs. The IPH acts as the National IHR Focal Point. It is recommended to appoint the chair of the national IHR Team as NFP to give this important position 'a face'.

The Operational Plan of Action in Emergency Situations was developed in 2014 and lists responsible persons and their contact details.

In addition, the creation of a specific budget line for IHR-related activities is recommended.

Diseases are trans-boundary. As Montenegro can expect the international community to fight disease outbreaks at their source, the same will be expected of Montenegro by the international community. To prevent, detect and respond to a public health emergency of international concern (PHEIC) is a global endeavour in which all countries need to be active partners. Montenegro is a small country with limited human resources whose professionals protect the public health of Montenegro and of the international community. They have demonstrated significant success but nonetheless function under difficult circumstances, with very limited resources and too few qualified and up-to-date staff. IHR investments are necessary to maintain a high level of health security. SOPs and annual table-top exercises are necessary to build confidence and to update procedures.

### **Indicators and scores**

### P.2.1 A functional mechanism established for the coordination and integration of relevant sectors in the implementation of IHR – Score 2

#### Strengths and best practices

- Relevant legislation is in place.
- The IPH is designated as the NFP.
- The OIE delegate is appointed for animal health events.
- A network of sectoral focal points is in place.
- There is a regular communication, coordination and reporting framework.
- Communication and coordination in emergency situations have proven effective, as during the 2009 influenza pandemic, the 2010 floods and Ebola in 2014.
- The IPH participates in the WHO IHR annual meetings.

#### Areas that need strengthening and challenges

- Educational and training activities are needed that stress the importance of IHR implementation.
- Simulation exercises should take place.
- SOPs for IHR should be developed.
- A dedicated budget line should be established for IHR.

- Develop SOPs for coordination between the National IHR Focal Point and relevant sectors.
- Strengthen the IHR implementation structure by appointing the chair of the national IHR team as National IHR Focal Point, appointing a vice-chair, regularly updating the list of members of the multi-sectoral working group for IHR implementation and organizing regular meetings of the national IHR team.
- Organize a yearly table-top or simulation exercise of a PHEIC and use the outcomes to update 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)* Multi-sectoral 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.

### MONTENEGRO LEVEL OF CAPABILITIES

In 2012, the Government of Montenegro enacted the National Strategy for the Control of Bacterial Resistance to Antibiotics, which defined monitoring of bacteria's resistance to antibiotics as a strategic assignment. A 2014 research protocol of monitoring and control of bacteria's resistance to antibiotics found that the established system remained weak.

In March 2019, Montenegro formally approved an action plan for AMR. The plan covers the main areas identified in the Global Action Plan on AMR, in particular awareness raising, education, surveillance, prevention of infection and optimizing the use of antimicrobials in both human and veterinary sectors. It does not, however, cover agriculture and environmental protection.

The plan was developed by the National Interdisciplinary Commission for Antibiotic Resistance Control (NIKRA). The commission meets four times a year and is chaired by the director of the Directorate of Health Care of the MoH. It includes doctors, veterinarians, epidemiologists and lawyers.

Montenegro has established a National Reference Laboratory (NRL) within the IPH to monitor bacteria's resistance to antibiotics. The laboratory monitors isolates of invasive bacteria (blood and spinal fluid) and their antibiotic susceptibility. There are 12 microbiological laboratories operating as state laboratories, and some perform antimicrobial sensitivity testing (AST) and have established external quality control. Some of the laboratories send strains to the NRL, but the country has no fully functional

referral system with bio banking of strains. Most of the laboratories use the standard method for AST that aligns with the European Committee for Antimicrobial Susceptibility (EUCAST) breakpoints and interpretative criteria.

Montenegro reports annually to the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR). Reported data might be disproportionately in favour of nosocomial infections from severely ill patients, while community acquired infections are underrepresented. In addition, lack of systematic collection of data from private laboratories might pose a challenge for AMR surveillance. There is no surveillance of AMR on animal and food samples.

Although there is no national programme for Infection and Prevention and Control (IPC), all healthcare facilities at secondary and tertiary level are obliged by law to adopt a programme to monitor, prevent and combat hospital infections. This is implemented through a Commission for the Prevention and Suppression of Hospital Infections, which submits semi-annual reports to the National Committee for Hospital Infections. All healthcare facilities have safe water supplies and water quality is monitored. Montenegro is a member of the OIE, and there are monthly meetings between the Specialist Veterinary Laboratory (SVL) and the MoH.

Hand hygiene guidelines for good clinical practice are developed and in use. Teams of trained personnel follow up compliance with the guidelines.

Antibiotics are available by prescription only. While there are national guidelines for treatment of infections and rational use of antibiotics in humans, no such guidelines exist in the animal sector. Montenegro does not have quality testing of antibiotics, but a multi-sectoral team for identification of non-standard, false and forged antimicrobials was established in 2017.

### Indicators and scores

### P.3.1 Effective multi-sector coordination on AMR – Score 2

### Strengths and best practices

- An interdisciplinary commission for AMR control, NIKRA, is in place, with quarterly meetings of experts on human, animal and food safety.
- A two-year (2019-2020) integrated national action plan for AMR is in place.
- A national strategy for antibiotic resistance control of bacteria is in place for 2017-2021 and includes such awareness-raising events as Antibiotics Awareness Week.

### Areas that need strengthening and challenges

- The AMR national action plan should be expanded to include agriculture and environmental protection.
- The AMR surveillance plan should be adopted by the veterinary sector and include standardized AST testing capacity and increased human resources.
- A national guide for the rational use of antibiotics should be developed to reduce consumption of antimicrobial medicines in both human and veterinary sectors.

### P.3.2 Surveillance of AMR – Score 2

Note: the human health sector has a centrally coordinated national AMR surveillance system at a score of 4. Due to the absence of an AMR surveillance system in the animal food production sectors, the integrated score is 2.

### Strengths and best practices

• The National Reference Laboratory and other microbiological laboratories manage AMR surveillance in the public sector, with data reported internationally through the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network.

• AST is done using breakpoints and interpretative criteria issued by the European Committee for Antimicrobial Susceptibility (EUCAST) or the American Clinical and Laboratory Standards (CLSI), with regular external quality control.

### Areas that need strengthening and challenges

- The SVL should implement AST testing of animal isolates and isolates from food.
- Information systems for integrated surveillance of bacteria resistance from animal samples and samples of foodstuff of animal origin should be developed.
- Surveillance data on AST should be strengthened by increasing the origin and number of samples and including results from private laboratories.

### P.3.3 Infection prevention and control – Score 2

### Strengths and best practices

- Healthcare institutions have programmes for prevention, detection, notification and control of hospital infections.
- National plans are available for infection prevention and control in animal health care.
- Hand hygiene guidelines are developed at the national level, and all healthcare facilities have a safe water supply.

#### Areas that need strengthening and challenges

- National guidelines for Infection and Prevention Control in animal production should be available and disseminated.
- Veterinary staff should receive continuing education on prevention and control of animal diseases.
- An education programme should be financed and implemented for animal keepers and food and feed business operators to improve their basic knowledge of communicable animal diseases and zoonoses and animal husbandry conditions.
- A national monitoring system for hand hygiene compliance should be implemented.

### P.3.4 Optimize use of antimicrobial medicines in human and animal health and agriculture – Score 2

### Strengths and best practices

- Antibiotics are available by prescription only.
- National guidelines on the appropriate use of antibiotics in public health are developed for several diseases.
- The use of antibiotics as a growth promoter in animal feed is prohibited.

### Areas that need strengthening and challenges

- Guidelines for the use of antibiotics in animals and crops in line with FAO and OIE standards should be developed.
- Quality testing for antimicrobial quality is needed.
- A national committee should be set up to develop a list of recommended antibiotics based on local antibiograms.

- Establish a national committee to develop a list of recommended antibiotics and national guidelines for rational use of antibiotics in public health.
- Establish a national laboratory for AMR surveillance of animal and food isolates.
- Extend the National Action Plan for AMR to include agriculture and environmental protection.
- Develop a national strategy for the prevention and control of hospital infections.

### **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.* 

### MONTENEGRO LEVEL OF CAPABILITIES

Montenegro's legislative framework for surveillance, control and reporting of zoonotic and foodborne diseases is harmonized with EU legislation. The management of zoonotic diseases as part of IHR implementation covers both human and animal sectors, which share responsibility for disease detection, surveillance, and reporting. In the human health sector, that responsibility lies with the IPH at the central level, and locally with hygiene and epidemiological services. In the animal health sector, responsibilities are shared by the Ministry of Agriculture and Rural Development (MARD), Directorate for Food Safety, Veterinary and Phytosanitary Affairs and the Specialist Veterinary Laboratory. The control of zoonoses is based on comprehensive legislation in both animal and human health.

Rulebook on monitoring zoonoses and causes of zoonosis divides them into two groups: Group A deals with zoonoses that are directly monitored and Group B with those monitored depending on their epidemiological situation.

The Programme of Food and Feed Safety Measures monitors Listeria monocytogenes, campylobacteriosis and their causes, Salmonella in food and Escherichia coli (in shells), among others.

The National Infectious Diseases Commission being established by the MoH has as a multi-sectoral working group for infectious diseases, including zoonoses. Multi-sectoral teams and committees were established for avian influenza and the flu pandemic in 2005, for Ebola in 2014 and a Commission for Rabies set up in 2011.

At the end of each year, the DFSVPA adopts an Annual Programme of Mandatory Measures of Animal Health for the following year. The programme prescribes in detail the required measures for supervision and control of certain diseases of public importance. Of the 21 prescribed animal health measures and activities, nine are directly related to the control of specific zoonotic diseases.

The IPH uses an electronic reporting system that collects data about infectious diseases and zoonoses and generates reports weekly, monthly and annually. These are shared with the DFSVPA, which then reports back on them. Data exchange, exchange of information and collaboration between animal and human health sectors takes place regularly but mostly informally. More formalized intersectoral communication should be established, including between the SVL and the IPH.

To document the timeliness and efficiency of intersectoral operational mechanisms, evidence and records of joint investigation and tracking of zoonotic diseases incidents need to be improved.

### **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

- The existing legislative framework for surveillance, control and reporting of zoonotic and foodborne diseases is harmonized with EU legislation.
- The National Commission for Infectious Diseases provides a multi-sectoral approach and coordinated surveillance systems between animal and public health sectors.
- There is an exchange of information and cooperation between public health and animal health sectors, with formal and informal systems for mutual reporting on zoonosis and zoonotic agents.
- Multi-sectoral teams for avian influenza and flu pandemic, Ebola and rabies have been established.
- The obligation to report diseases to the European Commission and the OIE is fulfilled.

### Areas that need strengthening and challenges

- A separate, dedicated multi-sectoral commission for zoonoses should be established.
- National coordination and reporting on zoonoses should be improved at all levels and include an electronic solution for surveillance and intersectoral communication and reporting.
- Joint human and veterinary investigation and tracing is needed in suspected cases of zoonotic disease, for analysis and evaluation as well as for documentation and reporting.
- Awareness campaigns should be developed for zoonotic diseases both for the general public and for more targeted groups.

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

### Strengths and best practices

- The Annual Programme of Mandatory Measures of Animal Health includes nine zoonoses.
- Accredited laboratory capacities exist for both animal and human health that can detect, isolate and identify causes of zoonotic diseases and instruction for sampling for animal diseases.
- The DFSVPA has an animal identification and registration database and possibility for traceability.
- Epidemiological and epizootiological surveys and questionnaires have been developed for zoonotic diseases.

#### Areas that need strengthening and challenges

- Specific training is needed to improve skills and knowledge among staff engaged in collecting samples, assessment and risk evaluation.
- Simulation exercises and training should be held with the participation of all stakeholders.
- Software in the existing PHI information system should be improved and adapted.
- The Veterinary Information System (VIS) requires upgrading.
- SOPs, manuals and guidebooks in all areas related to IHR should be developed.
- Funds are needed to recruit more staff and provide continuing education in both human and veterinary sectors.
- Provide training and information to animal owners and food entities to help them improve living conditions for animals, expand their knowledge about infectious animal diseases and zoonoses, apply biosafety measures, and improve manufacturing practices and animal welfare.
- Laboratories should be equipped to apply new diagnostic methods.

- Strengthen human resources for surveillance and control of zoonoses in human and veterinary sectors through training and simulations.
- Develop an IT interface between human and animal health surveillance and reporting on zoonotic diseases.
- Implement activities for surveillance of zoonoses in line with legislation, based on epidemiological factors in the risk assessment and develop SOPs and manuals.

### 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.

### **MONTENEGRO LEVEL OF CAPABILITIES**

Montenegro has an integrated surveillance and monitoring system that includes priority foodborne diseases as well as priority hazards (chemical and microbiological). This, to a significant extent, ensures all potential food-related dangers that may pose a threat to human health are monitored. However, regional and local implementation is a challenge, due to a lack of skilled food safety specialists, epidemiologists and veterinarians.

The legal framework for undertaking measures at all stages of food production and processing, from primary production (fields, stables) to table is laid down in regulations, but a national food safety emergency plan still needs to be finalized and implemented. The food safety emergency plan is being developed and its draft form was submitted to the mission. The plan is being developed with expert support (IPA 2014: Strengthening of the Veterinary Service), and according to the Government Plan for Montenegro's EU accession, the adoption of this document is planned for the IV quarter of 2019. Standard operating procedures, instructions, management guides, etc. are part of the draft - they can be found in the aforementioned food safety emergency plan (with expert support of the same IPA 2014 project), and they will be applied after the adoption of the plan. The plan and these documents will be tested before adoption through a simulation exercise, scheduled for September/October 2019 (through the IPA 2014 project).

As Montenegro is a small society, experts know each other and make informal arrangements. There is an informal, extremely effective communication between institutions, which should certainly be channeled into formal procedures. Although this system can function very well, it also can create risks when there is an emergency and some key persons are not available. It is advised to transform these informal processes into SOPs.

A designated INFOSAN Emergency Contact Point should also be appointed and could actively coordinate with local and national authorities and the OIE delegate during food safety emergencies.

Those responsible for maintaining high food safety standards in Montenegro are finding them challenging to maintain in the face of tight budgets and a loss of human capital through emigration. A challenge is the lack of staff, especially in the field of veterinary medicine, which is substituted by cooperation with competent institutions (European Commission, European Food Safety Authority (EFSA), OIE, BfR). In

addition to that, the DFSVPA has formally signed technical agreements on cooperation with the Ministry of Health of Italy in the field of veterinary medicine and food safety, as well as with the German Federal Institute for Risk Assessment (BfR). Trainings for employees, as well as scholarships for veterinary medicine students are provided in order to attract quality staff to work for the DFSVPA. Continuous education on risk assessment is provided through BTSF trainings that are constantly available to Montenegro, as well as trainings organized by EFSA and via participation in EFSA scientific networks. Also, through the OIE trainings, there are ONE HEALTH concept trainings available to the employees of the Directorate. The DFSVPA Director is a permanent observer at the EFSA's Advisory Forum and the Vice-President of the OIE Regional Commission for Europe, therefore continuous education for DFSVPA employees is continuously available and used.

### **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

- A legal framework is in place fully compliant with EU legislation.
- A surveillance and monitoring system of priority foodborne diseases is established, as well as priority hazards (chemical and microbiological); the system entails inspection and health surveillance, case definitions for each reported food disease, health records and teams dealing with outbreak of foodborne or epidemic diseases.
- Food control plans and food monitoring programmes (such as microbiological criteria, pharmacological residues, contaminants, and pesticides) are in place.
- Control and monitoring programmes are regularly funded.
- There are competent laboratories for regular food testing, as well as during epidemics or contamination.
- Efficient formal and informal mechanisms for rapid information exchange between stakeholders and relevant sectors are in place in case of a suspected outbreak or an investigation of events.
- There is transparent reporting on laboratory food testing.
- There is rapid notification of food safety accidents to the European Rapid Alert System for Food and Feed (RASFF-EU).

### Areas that need strengthening and challenges

- It is necessary to establish formal procedures for communication and multi-sectoral cooperation of participants in the supervision/competent bodies.
- The food safety and veterinary sectors needs to continue strengthening the professional and administrative capacities especially taking into account a clear lack of veterinarians in the country.
- Staff require expanded skills and knowledge in sampling i.e., selection of samples and transportation during a foodborne disease outbreak to help them identify disease causes.
- An effective response to foodborne diseases requires management tools, information sharing and communication as well as SOPs, instructions, procedures and guides.
- Evaluation and feedback after each emergency, in order to use evaluations of earlier events when defining measures in the event of a new event occurring are needed.

### P.5.2 Mechanisms are established and functioning for the response and management of food safety emergencies – Score 1

#### Strengths and best practices

- A general contingency plan is under development and almost finalized.
- The response of health institutions, laboratories and food inspectors in crises is aligned appropriately as mandated by law.
- Instructions are in place for rapid alert and notification actions following legal procedures.
- The DFSVPA is the National Contact Point for the exchange of information with the European Rapid Alert System for Food and Feed.
- The DFSVPA is the National Contact Point for OIE.
- Dedicated and competent staff are in regular contact with European food safety experts.

### Areas that need strengthening and challenges

- There is a lack of clearly defined tasks and procedures for exchanging information during a foodborne disease event of major concern.
- A national food safety emergency plan should be developed.
- Following the adoption of the national food safety emergency plan, a simulation exercise on crisis management in food and feed should be organized.

- Finalize and implement a national food safety emergency plan.
- Expand rapid risk assessment capacity by attracting specialists through adequate job facilities, continuing education and yearly simulation exercises.
- Improve SOPs, instructions, procedures and guides required for management, information exchange and communication to an effective response to foodborne diseases.

### **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 multi-sectoral 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.

### MONTENEGRO LEVEL OF CAPABILITIES

Montenegro has laws and regulations on biosafety and biosecurity which require greater attention and further improvement, and has a developed laboratory system with many biosafety and biosecurity practices in place. However, not all types of organism are addressed, and biosecurity issues and dual use research of concern are not covered under one single ordinance.

A process has been initiated to monitor and develop up-to-date records and inventories of pathogens within facilities that preserve or process dangerous pathogens, toxins and cultivated organisms. A laboratory licencing procedure exists in the country, but mainly for technical equipment, infrastructure and personnel. Procedures are in place for access control and other security measures to secure laboratories, in accordance with requirements of the International Organization for Standardization (ISO) 9001 and ISO 17025. However, not all laboratories are accredited. Pathogen collections are only stored in certain laboratories, although no list of pathogens of concern exists at a central level. The veterinary sector has no storage for strain collections and has written procedures for their proper destruction. The country does not have a biosafety level (BSL) 3 laboratory facility.

A multi-sectoral biosafety and biosecurity system is not adequately developed, and a risk-based approach is not in place for classifying frontline diagnostics for Risk Group 4 microorganisms.

Transport regulations are compatible with international regulations. The MoH issues approvals for the transport of infectious substances beyond the borders of the country, and personnel from the Centre for Medical Microbiology have attended WHO training for the transport of infectious substances and patient specimens.

There is no national training programme on biosafety and biosecurity in Montenegro, although basic training is provided in the Faculty of Medicine. Personnel in most facilities, including those that preserve

or work with dangerous pathogens and toxins, receive information and training on biosafety and biosecurity locally. However, there are no national records of who has undergone training.

### 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 partial legislation on biosafety and biosecurity which require more attention and further improvement and some, but not all elements of a comprehensive biosecurity and biosafety system are in place.
- Procedures are in place regarding physical security measures for laboratories certified for ISO 9001 or accredited for ISO 17025.
- At the national level, the army of Montenegro has the capacity to manage emergency biological situations.

#### Areas that need strengthening and challenges

- There are no common biosafety and biosecurity requirements or licensing conditions for all laboratories.
- There is no defined policy of using diagnostic tests to eliminate the need for cultivation of dangerous pathogens.
- No lists of selected agents of concern exist at a national level and there is no centralized inventory of these dangerous pathogens and toxins.

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

#### Strengths and best practices

- Personnel in most facilities, including those that preserve or work with dangerous pathogens and toxins, receive information and training on biosafety and biosecurity.
- There is sufficient availability and proper use of personal protective equipment.
- Biosafety and biosecurity training is provided and documented locally by the institution.

#### Areas that need strengthening and challenges

- There is no national record of personnel training and testing in the field biosafety and biosecurity procedures.
- The capacity to organize training sessions and oversee competences of personnel on biosafety and biosecurity should be improved.
- There is no comprehensive and sustainable academic training in institutions, including within those that presently train employees who work with dangerous pathogens and toxins.

- Develop a list of dangerous pathogens and toxins and a licensing procedure to regulate and control pathogens of concern in all relevant sectors.
- Implement national biosafety and biosecurity licensing requirements for all laboratories working with agents defined in the list.
- Provide systematic and effective education and training on biosafety and biosecurity management at a national level.
- Establish a joint biosafety and biosecurity body at the national level, which would cover activities in all sectors, both public and private.

### **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.

### MONTENEGRO LEVEL OF CAPABILITIES

The management of immunizations as a part of IHR in Montenegro is the responsibility of the IPH. An organized immunization programme started after World War II and Montenegro maintains good immunization practice, which is part of their public health tradition. Programmes such as smallpox (19th century) and tuberculosis (20th century) were also launched in neighbouring countries.

Vaccinations in Montenegro are mandatory and entirely subsidized by the government. Overall target coverage across all vaccines is 95% and mandatory vaccines include diphtheria, tetanus, pertussis, polio, BCG, measles, mumps, rubella, hepatitis B and influenza.

Electronic monitoring of vaccine coverage takes place in real time. Given the effectiveness of realtime monitoring by the IPH, special attention is paid to communication including immunization perceptions, media promotion of vaccination, anti-vaccine lobbies and groups and other vaccinerelated media activities.

Montenegro also has the capacity for ring immunization upon notification of single imported cases and has access to hard-to-reach populations.

Monitoring takes place through the National Electronic Immunization Registry, which monitors data on all vaccines and antigens used in the immunization programme, in real time, at all vaccination points and healthcare centres.

The cold chain system for storing and distributing vaccines is organized at central and local levels. Centralized multi-year procurement of vaccines and bio-immune products has been in effect since 2018-2019. Global market monitoring takes place through collaboration between the state-owned 'Montepharm' and the IPH.

### **Indicators and scores**

### P.7.1 Vaccine coverage (measles) as part of national programme – Score 1

#### Strengths and best practices

- Monitoring takes place through the National Electronic Immunizations Registry and there is routine analysis or monitoring or coverage.
- Public healthcare institutions have a good networking system and there is consistent institutional communication and cooperation.
- A functional pharmacovigilance system is in place.
- There is clear MoH and IPH leadership.
- Vaccination points are readily available and there are home visitation services.
- Vaccines are free of charge, available in schools, and for hard-to-reach populations.

### Areas that need strengthening and challenges

- More communication is needed with parents as well as among healthcare professionals.
- Modern communication and mobilization campaigns should be implemented, for example through social networks.
- Work is needed to counter anti-vaccination misinformation.
- Providers are too flexible in accommodating parental requests to postpone the measles, mumps and rubella (MMR) vaccine.

#### P.7.2 National vaccine access and delivery – Score 4

#### Strengths and best practices

- An effective centralized approach is in place and includes a well-organized national vaccine storage system, central procurement and a professional and methodical approach to vaccine access and delivery.
- The country has a three-year vaccine procurement programme.
- Montenegro has developed and disseminated a national Cold Chain Guide.
- The number of hot-spots has been reduced by addressing previous distribution shortages.

### Areas that need strengthening and challenges

- Temperature monitoring should be improved for transport and storage at healthcare centres.
- Vaccine maintenance equipment is lacking in healthcare centres.
- Funds are needed for an Effective Vaccine Management (EVM) study, for procurement of continuous temperature loggers and for equipment procurement.

- Increase coverage of all vaccines from the Immunization Programme, with special emphasis on the measles, mumps and rubella (MMR) vaccine, by developing a communication strategy or social mobilization strategy focusing on vaccine promotion.
- Implement an Effective Vaccine Management (EVM) study with related action plan for capacity building and improved practices for vaccines storage and distribution.
- Introduce a remuneration system for providers who are effective in increasing immunization uptake and adherence to the immunization schedule.

# 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.

# MONTENEGRO LEVEL OF CAPABILITIES

Montenegro's national laboratory system is well serviced, with 13 public and 7 private microbiology laboratories for human specimens. They cover the needs of 620 079 inhabitants in 24 municipalities. The IPH has four reference laboratories for influenza, measles, rubella and AMR. The country has one Specialist Veterinary Laboratory, which is public and analyses animal samples, food and feed.

The public health microbiology system operates on local and national levels. At local level, laboratories are located in primary health centres and general hospitals. They mostly provide primary diagnostic services by performing basic bacteriology and parasitology. National-level laboratories are located at both the IPH and the Tuberculosis Laboratory of the Dr Jovan Bulajic Specialist Hospital for Lung Diseases.

The national laboratory system performs 5 out of 10 core diagnostic tests: polymerase chain reaction (PCR) for influenza, serology for HIV, microscopy for M. tuberculosis, culture for Salmonella enteritidis serovar Typhi, and rapid test for Plasmodium spp... The 10 core diagnostic tests for the analysis of human specimens are still not defined, although the laboratory system can cover 42 out of 53 diseases notifiable under EU law. The IPH has signed a five-year Memorandum of Understanding for specialized testing not available in-country with the Lazzaro Spallanzani National Institute for Infectious Diseases in Italy.

There is no electronic system to share results between the microbiological laboratory system and the surveillance system.

Diagnostic guidelines are published for clinical bacteriology and are in use. Formal SOPs have not been published, but some laboratories have their internal SOPs. European Committee for Antimicrobial Susceptibility (EUCAST) methodology for AMR has been introduced in most laboratories.

With the exception of AMR, no national external quality assessment (EQA) is in place, although some laboratories participate in EQA schemes. The SVL tests samples in accordance with OIE standards.

Accreditation is voluntary and is conducted by one public institution. The IPH is certified to ISO 9001:2015 standards, and its food and water laboratory to ISO 17025, as is the SVL that tests food and feed. These two laboratories are the only ones accredited by the state for food testing.

Most laboratories can handle pathogens that require biosafety levels 1 and 2, but the system is unable to handle pathogens that require BSL 3.

## **Indicators and scores**

### D.1.1 Laboratory testing for detection of priority diseases - Score 3

### Strengths and best practices

- The IPH's centre for microbiology is well equipped with up-to-date technology and has qualified staff to test most communicable diseases.
- Reference laboratories for influenza, measles and rubella are recognized by WHO.
- The SVL services the entire system of animal specimens, food and feed in accordance with OIE standards and is accredited to ISO 17025.

### Areas that need strengthening and challenges

- Four country-specific tests should be defined as a part of 10 core diagnostic tests.
- There are no official national diagnostic algorithms or prescribed standard methods for providing complete human microbiological diagnostics.
- Although there are sufficient microbiological laboratories, the network of laboratories is not clearly defined.
- There is no AMR tracking system in veterinary medicine or in routine human diagnostics.

### D.1.2 Specimen referral and transport system – Score 2

### Strengths and best practices

- An electronic specimen referral system exists between the IPH and doctors in health centres but the remainder of the referral system is paper-based.
- Primary and secondary healthcare levels and the IPH are linked electronically to the Health Insurance Fund, which also collects data.
- The SVL has a laboratory information system.

### Areas that need strengthening and challenges

- Specimen transportation is ad hoc for example by automobile or handheld refrigerator; transportation conditions should be improved and supported financially by the MoH.
- No specially defined specimen referral network related to human microbiology exists, nor is there a document that describes the network clearly.
- There is no authorized courier service for referral of potentially communicable samples to laboratories outside Montenegro.

### D.1.3 Effective national diagnostic network – Score 2

### Strengths and best practices

- A tier-specific diagnostic system as well as point-of-care diagnostics exist.
- The SVL is responsible for diagnostic testing of communicable animal diseases throughout Montenegro and routinely performs serological, microbiological and molecular testing in line with OIE recommendations.

### Areas that need strengthening and challenges

- Although Montenegro does not have a specific strategy for point-of-care based diagnostics, the type of testing conducted at the primary, secondary and tertiary healthcare levels is formally defined.
- The state has no strategy for specific diagnostics and none is under development, yet this is important for emerging infectious diseases, for example pathogens which require a BSL 3 laboratory.
- Microbiological laboratories in healthcare centres perform only basic bacteriological and parasitological testing.

### D.1.4 Laboratory quality system – Score 3

#### Strengths and best practices

- National authorities are in charge of laboratory licensing and accreditation and a national regulatory authority is responsible for the qualification or registration of in vitro diagnostic devices.
- There is a quality assurance system for water and food safety and for veterinary diagnostics.
- A national EQA system is established for AMR.

#### Areas that need strengthening and challenges

- National EQAs should be organized for all laboratories and coordinated by the IPH.
- Participation in the EQA system must be strengthened for core tests.
- Laboratories are not accredited to ISO 15189 but the standard should be introduced if the funds are available.

- · Adopt a set of standard diagnostic methods and develop national diagnostic algorithms.
- Develop strategies for specific diagnostics, especially for emerging infectious diseases, such as pathogens that require biosafety level 3 (BSL3).
- Ensure the Ministry of Health undertakes a leading role in establishing the network of microbiological laboratories, thereby improving the system's capacity.
- Create a national specimen referral network and transportation system.
- Establish national EQA system and strengthen participation in international EQA programmes.

# **REAL-TIME 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.

### MONTENEGRO LEVEL OF CAPABILITIES

Montenegro has a continuous and comprehensive notification system that covers 83 mandatorily notifiable diseases. A legal basis for notification is in place and aligned with EU regulations.

Montenegro has several different surveillance systems. Mandatorily notifiable diseases are notified by physicians through an electronic system developed in 2013. Notification by laboratories is still paperbased and data is not automatically merged with the existing electronic system (indicator-based surveillance). In addition, functioning event-based and syndromic surveillance systems are in place, for example through twice-monthly epidemiological teleconferences.

An early warning and emergency response system that takes IHR (2005) Annex 2 as a reference has been established.

The IPH is responsible for final verification and consolidation of surveillance data made available through the electronic surveillance system and through laboratory notification, as well as for data analysis. Epidemiological surveillance capacity is also based on international collaboration and participation in regional and international networks such as the Network for Communicable Disease Control in Southern Europe and Mediterranean Countries (EpiSouth), EpiSouth Plus and the Mediterranean Programme for Intervention Epidemiology Training (MediPIET). Surveillance data is routinely transmitted to international networks and organizations such as the European Surveillance System (TESSy) and the European Legionnaires' Disease Surveillance Network (ELDSNet).

Surveillance of communicable diseases is conducted by trained epidemiologists. Weekly, monthly and annual reports, epidemiological bulletins based on the mandatory notification, reports from event-based surveillance system and additional reports according to epidemiological requirements are produced and disseminated among stakeholders.

Electronic data on infectious disease morbidity from the Clinical Center of Montenegro, specialized hospitals and private health facilities as well as from the veterinary and the food safety sectors should be integrated into the established electronic surveillance system.

# **Indicators and scores**

### D.2.1 Surveillance systems – Score 4

### Strengths and best practices

- Primary and secondary legislation of mandatory notification for physicians and laboratories is aligned with EU regulations.
- A continuous and comprehensive electronic indicator-based surveillance system is in place.
- Various types of event-based and syndromic surveillance are established.
- There is international collaboration and participation in regional and international networks.

#### Areas that need strengthening and challenges

- Electronic data from clinical centres, specialized hospitals and private health facilities, as well as from the veterinary and the food safety sector, should be integrated into the existing surveillance system.
- Intersectoral cooperation between the public health and veterinary sectors should be strengthened.
- Documents defining roles and responsibilities of stakeholders from different sectors should be developed.

### D.2.2 Use of electronic tools – Score 3

#### Strengths and best practices

- Electronic case notification is integrated into the patient management system of medical practices.
- Real-time monitoring of infectious diseases is in place.
- A set of integrated data processing and analysis tools allows for the production of weekly, monthly and annual reports.

### Areas that need strengthening and challenges

- Notification from laboratories, specialized hospitals and private health facilities should be integrated into the surveillance system.
- An electronic system for the notification of infectious diseases in animals and for foodborne diseases in the veterinary sector should be established, preferably integrated in to existing surveillance system.

#### D.2.3 Analysis of surveillance data – Score 4

#### Strengths and best practices

- There are qualified and dedicated staff for the analysis of epidemiological data in both human and veterinary sectors.
- Weekly, monthly and annual reports, epidemiological bulletins based on mandatory notification, reports from event-based surveillance and ad hoc reports based on epidemiological requirements are produced and disseminated among stakeholders and to the public.

#### Areas that need strengthening and challenges

- Capacity for data analysis should be strengthened through joint continuing education of experts from human and veterinary sectors and should include risk assessment.
- Training should be provided in statistical methods for advanced data analysis, including outbreak investigation.

- Integrate electronic data from clinical centres, specialized hospitals and private health facilities within the established surveillance system.
- Establish an electronic notification system for communicable diseases in animals, including foodborne diseases.
- Integrate electronic data from laboratory diagnostics within the established surveillance system at local and national levels.

# 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.* 

# MONTENEGRO LEVEL OF CAPABILITIES

The IHR NFP is established within the Institute for Public Health. As Montenegro is an OIE member, the OIE Contact Point is within the Directorate for Food Safety, Veterinary and Phytosanitary Affairs. Both the National IHR Focal Point and OIE Contact Point are available 24 hours a day.

National legislation already supports collaboration between the public health and animal health sectors and applies a multi-sectoral all-hazard approach. Dedicated and trained staff is ready to use the IHR (2005) Annex 2 to fulfil required obligations.

So far, no PHEIC has affected Montenegro but exercises have demonstrated that reporting of potential events to WHO would be based on a risk assessment by the NFP staff and requires no formal approval that could delay reporting. While the NFP has the capacity to notify WHO of biological threats within 24 hours, this might not be the case for all potential hazards. The OIE Contact Point is also able to report within 24 hours to OIE.

Multi-sectoral collaboration, for example between human and animal health and the food safety sector or between human health and transportation sectors, has been tested in various exercises involving cross-border events. Based on existing and reliable surveillance systems, including early warning and response systems, the NFP is alerted to a potential PHEIC by the IPH.

## **Indicators and scores**

### D.3.1 System for efficient reporting to FAO, OIE and WHO - Score 3

### Strengths and best practices

- The NFP and OIE Contact Point are established.
- The functionality of the NFP has been demonstrated in exercises.
- The NFP benefits from close collaboration with the IPH.

### Areas that need strengthening and challenges

- Information exchange between the veterinary and human sectors should be improved, and procedures covering a multi-sectoral all-hazard approach developed.
- A multi-sectoral evaluation of events should be conducted for reporting.

### D.3.2 Reporting network and protocols in country – Score 3

#### Strengths and best practices

- Existing surveillance systems, including early warning and response, ensure early detection of a
  potential PHEIC in the country.
- National legislation supports a multi-sectoral all-hazard approach.

### Areas that need strengthening and challenges

- A list of contact details for all IHR stakeholders in the country should be compiled, updated and distributed regularly.
- NFP human resources need strengthening.
- A simulation exercise should be conducted to test the functioning of existing procedures, such as for risk assessment or communication with WHO.

- Raise public awareness on the implementation of the One Health approach and the allhazard approach, including development of agreed protocols and SOPs.
- Improve communication between human and veterinary sectors by exchanging best practices, training and exercises with all partners involved in detecting and reporting relevant events.
- Establish an electronic system to support the reporting of a potential PHEIC in the veterinary sector.

# **WORKFORCE DEVELOPMENT**

### **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, paraveterinarians, epidemiologists, IT specialists etc.

The recommended density of doctors, nurses and midwives per 1,000 populations 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).

## MONTENEGRO LEVEL OF CAPABILITIES

Montenegro has a human resources plan for 2013-2022 for health workers in the human health sector and an employment needs plan for professionals in veterinary medicine. The human health sector has enough appropriately qualified staff, according to WHO recommendations, but this is not necessarily the case in the animal health sector.

The human and animal health sectors collaborate effectively, for example by participating in joint committees and agencies or in an ad hoc manner for foodborne disease outbreak investigations or for regular data exchange.

The legal framework and a clear organizational structure for setting up epidemiological field teams for the surveillance, prevention and control of communicable infections are in place. However, this is not necessarily the case for other hazards such as chemical, radiological or nuclear events.

The government has also committed to implementing the human resources plan, which contributes to personnel recruitment and to the continuing education programme for public health professionals.

Programmes are in place for ongoing in-service training in immunization and infectious diseases surveillance in the human health sector as well as cascade training in animal welfare. In-service training in both human and animal health sectors also takes place, for example through staff participation in short- and long-term qualification courses conducted by international organizations such as WHO, European Centre for Disease Prevention and Control (ECDC), OIE and Better Training for Safer Food (BTSF) or partner countries including Serbia, Croatia, Bosnia and Herzegovina, Greece and Germany.

A three-year academic specialization programme in epidemiology is available. In addition, Field Epidemiology Training Programme (FETP) capacity building is in place through participation in MediPIET. Further training can also be obtained in analytical methods for human field epidemiology by collaborating with partners in other countries or in animal health through international organizations.

# Indicators and scores

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

### Strengths and best practices

- A human resources plan for the human health sector for 2013-2022 for health workers and an employment needs plan for professionals in veterinary medicine are in place.
- Additional epidemiologists and hygiene specialists have been employed in the past decade.
- There is effective collaboration in the area of foodborne diseases between the public health and veterinary health sectors.

#### Areas that need strengthening and challenges

- A multi-sectoral workforce strategy should be developed, and reviewed and updated regularly.
- Collaboration between the public health and animal health sectors should be strengthened in the areas of food safety and zoonoses.

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

Note: The score of developed capacity, meaning that appropriate human resources are available at national (and intermediate) level, applies only to biological hazards and does not include other hazards.

### Strengths and best practices

- The legal framework for setting up epidemiological teams for the surveillance, prevention and control of infections in hospitals is in place.
- A clear organizational structure with established coordination mechanisms at the national level and a network of operational field teams at the local level is available in both public health and animal health sectors.
- The government, including the MoH, is committed to implementing the human resources plan, which helps recruit personnel and contributes to ensuring enough young epidemiologists can replace those who reach retirement age.
- Veterinary inspectors receive a bonus to compensate for difficult working conditions in the field.

### Areas that need strengthening and challenges

- The number of veterinarians employed by the Directorate for Food Safety, Veterinary and Phytosanitary Affairs needs to be increased.
- Additional financial incentives are needed to attract and retain highly qualified health professionals and veterinarians in the public sector.

### D.4.3. In-service trainings are available – Score 2

#### Strengths and best practices

- The government has expressed its commitment to support the continuing education programme for public health professionals.
- The public health sector has continuing education programmes in immunization and infectious diseases surveillance, as well as cascade training in animal welfare.
- Public health and veterinary staff attend professional meetings and short- and long-term qualification courses conducted by international organizations or partner countries and often share their knowledge with colleagues upon their return to Montenegro.

### Areas that need strengthening and challenges

- Plans and content of continuing professional education need improvement and funding and should take greater account of the One Health approach.
- Expert and educational in-service training capacities of the IPH and DFSPVA need to be strengthened.
- Joint food safety and zoonoses training programmes for epidemiologists and veterinarians should be developed and should include the One Health approach.

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

#### Strengths and best practices

- A three-year academic specialization programme in epidemiology is in place, with a clear structure and legal and financial support.
- Capacities in infectious disease epidemiology have been strengthened through participation in MediPIET.
- Intensive in-service training in animal health is in place, supported by international organizations.

#### Areas that need strengthening and challenges

- In addition to existing epidemiology training programmes, an FETP should be established within the future Public Health School.
- Adequate personnel and financial support is needed to implement and sustain an FETP in Montenegro.

- Ensure jobs are filled with high-quality personnel in public health and animal health sectors through positive selection of personnel and prevention of employee turnover.
- Improve the quality of postgraduate education and continuing professional education.
- Develop a multidisciplinary and multi-sectoral approach to support teamwork in the fields of surveillance, prevention and control of infectious diseases.

# 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 multi-sectoral emergency response operations for outbreaks and other public health emergencies.

### MONTENEGRO LEVEL OF CAPABILITIES

The Directorate for Emergencies, which is based in the Ministry of Interior, is responsible for risk management, protection and rescue in emergencies. It also manages the consequences of these emergencies.

The directorate is responsible for a number of key tasks. It manages protection and rescue activities in natural and technological disasters or in cases of accidents due to chemical, biological, radiological and nuclear contamination. It also oversees the work of appropriate authorities by coordinating and managing the work of state-level institutions, down to local and individual levels in the event of an emergency. The directorate's protection and rescue work recognizes three phases: prevention, rescue and consequence removal phases.

Through its 112 Emergency Operations Centre (EOC), the directorate handles continuous collection and submission of data related to an emergency in affected areas. It is also responsible for international cooperation and exchange of information and data with counterparts worldwide and with informing citizens in an emergency.

Prevention activities include vocational training and development of operational protection and rescue units, as well as supervision of their functioning and equipping; preventive work (fire protection, trade and

transport of hazardous substances such as explosive substances, poisons and radioactive materials); fire prevention and extinction activities around natural and forested areas as well as industrial, residential and other facilities, including rescue of persons and property threatened by fire. The directorate also works to prevent threats to the health of citizens and the environment that might result from radiological, chemical, nuclear and biological contamination.

## **Indicators and scores**

# **R.1.1** Strategic emergency risk assessments conducted and emergency resources identified and mapped – Score 2

### Strengths and best practices

- A protection and rescue system is established with plans at national, municipal and entrepreneurial levels, for all types of risks.
- A standardized EOC 112 has been fully operational since 2015.
- In 2017, the government adopted a Strategy for Disaster Risk Reduction and an implementation plan for 2018-2023.
- A working group has been established to develop a national risk assessment.
- Exercises have taken place at the national level (IPA MNE QUAKE 2014, Montenegro 2016).
- There was successful cross-sectoral cooperation in developing the Disaster Risk Reduction
   Strategy

### Areas that need strengthening and challenges

- The national risk assessment should be finalized.
- Risk maps and resource maps should be created at the national level.
- Financial resources are needed to upgrade material and technical resources.

# **R.1.2** National multi-sectoral multi-hazard emergency preparedness measures, including emergency response plans, are developed, implemented and tested – Score 2

- Strengths and best practices
- The DDR Strategy is now developed.
- Twelve national protection and rescue plans are developed.
- There are updated plans for fires and earthquakes.
- An influenza pandemic preparedness plan is in place.
- There was successful cross-sectoral cooperation in developing the Disaster Risk Reduction Strategy.
- Two national plans have tested on real events: floods and fires.

### Areas that need strengthening and challenges

- Protection and rescue plans for individual accidents should be developed.
- Training sessions and exercises should be organized to implement national plans.
- A preparedness plan for infectious diseases should be finalized.

- Develop a national disaster risk assessment.
- Develop local disaster risk assessments.
- Develop national protection and rescue plans for different types of risks.
- Develop a national plan of readiness and response in the health system.
- Map resources at the national level in public health, veterinary and other relevant sectors.

# **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, multi-sectoral rapid response teams, and trained EOC staff capable of activating a coordinated emergency response within 120 minutes of the identification of an emergency.

### MONTENEGRO LEVEL OF CAPABILITIES

The Directorate for Emergencies, which is based in the Ministry of Interior, is responsible for risk management, protection and rescue in emergencies, and manages the consequences of these emergencies.

The directorate is responsible for a number of key tasks. It manages protection and rescue activities in the event of natural and technological disasters or in cases of accidents arising from chemical, biological, radiological and nuclear contamination. It also oversees the work of appropriate authorities by coordinating and managing the work of state level institutions, down to local and individual levels in the event of an emergency. The directorate's protection and rescue work recognizes three phases: preventive, rescue and consequence removal phases.

Through its 112 Emergency Operations Centre, the directorate handles continuous collection and submission of data related to an emergency in affected areas. It is also responsible for international cooperation and exchange of information and data with counterparts worldwide and with informing citizens in the event of an emergency.

A number of exercises have been held since 2013 to plan for emergencies and accidents. These include a biological accident simulation, a regional South Eastern Europe Simulation (SEESIM) exercise, a NATO exercise on flooding and a chemical accident, regional and national chemical, biological, radiological and nuclear (CBRN) scenarios, earthquake response and a table-top exercise on communicable diseases inflight. These exercises required a high level of cooperation both among ministries in Montenegro and with external and international partners.

A major regional exercise, Project 44, helped strengthen CBRN capacity and cooperation and provided equipment for a team of rescuers from the Podgorica Protection Service. Additionally, the project held two national and two regional training events to test CBRN response and interagency and inter-regional cooperation. The exercise also tested reporting and notification procedures for accidents with transnational impacts including EOC 112 and existing cooperative and emergency assistance arrangements.

### R.2.1 Emergency Response Coordination – Score 4

### Strengths and best practices

- A standardized EOC 112 has been fully operational since 2015.
- A protection and rescue system is established with plans at national, municipal and entrepreneurial levels, for all types of risks.
- Coordination teams (a national coordination team, municipal teams and operational HQ) have been set up.
- In 2017, the government adopted a Strategy for Disaster Risk Reduction and an implementation plan for 2018-2023.
- A national disaster risk reduction platform and disaster risk reduction committee were established within the Directorate for Emergencies in 2014, with the support of regional and international initiatives; five disaster reduction conferences have been held in the country since the launch.
- The Agreement on the Civil Protection Mechanism is signed and facilitates civil protection cooperation in the event of major natural, technical, technological and other emergencies.
- Montenegro received international support from the North Atlantic Treaty Organization (NATO) and the European Response Coordination Centre (ERCC) during severe floods and massive wildfires. This tested coordination, protection and rescue, and the reliability of international emergency assistance.
- Coordination is handled through the EOC 112 as well as local centres in Bar and Bijelo Polje.

### Areas that need strengthening and challenges

- There is no medical operation centre available 24/7 to deal with threats.
- EOC 112 procedures are needed for CBRN, technical and technological accidents, provision of international assistance and other requirements.
- The national risk assessment should be finalized; to date, dominant risks in Montenegro have been defined and a 50-expert working group established.
- Inter-institutional and international cooperation with such entities as Interpol and the Centers for Disease Control and Prevention (CDC) need to be improved.

### R.2.2 Emergency Operations Centre Capacities, Procedures and Plans – Score 4

### Strengths and best practices

- A standardized EOC 112 has reliable communications. In 2018 it received 105 395 calls and participated in 40 mountain operations that rescued 88 persons.
- Eight SOPs are in place and more are planned.
- Three regional reporting and information centres are established.
- EOC employees are trained regularly.

### Areas that need strengthening and challenges

- A plan for staff expansion for the EOC 112 (40 staff are now employed) should be developed.
- SOPs for CBRN and technical and technological accidents should be developed.
- Procedures for sending and receiving assistance in case of emergencies should be improved.
- Protection and rescue plans are needed at the municipal and entrepreneurial levels.
- Local strategies based on the action plan for disaster risk reduction should be developed.
- Financial resources should be increased and budgets allocated to develop plans, procedures and the national risk assessment.

### R.2.3 Emergency Exercise Management Programme – Score 3

#### Strengths and best practices

- A number of exercises have been held since 2013 to plan for emergencies and accidents.
- A workshop on coordination of emergency responses to multi-injury road accidents was organized.
- The Institute for Emergency Medical Assistance (IEMS) is involved in a number of maritime emergency activities (pollution prevention, search and rescue and firefighting).
- Montenegrin security capacity was enhanced and collaboration among allies strengthened with an exercise simulating a coordinated attack on the US Embassy.
- Activities were implemented around the response to emergency diseases resulting from air traffic.
- The IEMS has its own centre to train employees in the care of injured persons at the pre-hospital level.
- A major regional exercise, Project 44, helped strengthen CBRN capacity and cooperation.

#### Areas that need strengthening and challenges

- A joint programme should organize regular multi-day exercises with national and local institutions.
- Regular exercises to test response at the national and local levels should be strengthened.
- Access is needed to a range of institutional budgets to support joint exercises.
- Post-exercise information exchange among institutions should be strengthened to improve implementation of recommendations and exercise outcomes

- Develop a comprehensive Emergency Preparedness and Response Plan for all participants in protection and rescue for relevant risks at national and local levels.
- Improve capacity of municipal protection and rescue services by equipping and training them to respond to different types of risks, particularly in chemical, biological, radiological and nuclear protection (CBRN).
- Increase the number of employees in CBRN protection.
- Develop a programme and plan of exercises at national and local levels in the protection and rescue system.
- Establish the National Training Centre for Protection and Rescue.

# 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, multi-sectoral 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.

# MONTENEGRO LEVEL OF CAPABILITIES

Montenegro's Law on Protection and Rescue outlines the rights and responsibilities of different sectors, along with coordination mechanisms, for country preparedness and crisis management.

Under the law, all government administration bodies must ensure their timely preparedness. The Ministry of Interior regularly receives data and information from various sectors of importance to protection and rescue and compiles a situation report. This report is shared with all relevant stakeholders, including public health officials.

The country has detailed operational guidelines for specific situations that are in line with legislation. Over the past few years, several joint training sessions have taken place on investigation and response to health threats. The Directorate for Emergencies under the Ministry of Interior organized and took part in exercises on CBRN hazards, with the participation of multiple operational and rescue bodies, the IPH and international assistance.

SOPs on joint risk assessment during events of public health and security significance are not in place, although event-specific SOPs exist. Specific events include disease outbreaks and food contamination, which may require security sector support to implement public health measures.

# **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

- There is a legal and regulatory framework for cooperation among sectors in case of emergencies.
- An operational team for protection and rescue is convened in cases of threats or anticipated or random events.
- Several training events on preparedness for public health and security authorities have taken place.

#### Areas that need strengthening and challenges

- Periodic multi-sectoral simulation exercises and training sessions should be held on preparedness and response to public health threats.
- Multi-sectoral SOPs are needed for communication and response in cases of public health threats.

- Map out needs for human and material resources, and increase capacity accordingly.
- Organize simulation exercises at national and local levels with international assistance.
- Develop multi-sectoral SOPs or formal agreements for information sharing to respond to public health threats.

# 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.

# MONTENEGRO LEVEL OF CAPABILITIES

Montenegro has no plan in place that oversees procedures and decisions related to sending and receiving medical countermeasures during a public health emergency, although the Strategy for Disaster Risk Reduction provides for such a plan's development within the next five years. However, legislation provides for the establishment of a multi-sectoral coordinating team, led by the Prime Minister, in case of an emergency. That team would include several departments in charge of emergency management and an operational headquarters. Municipal teams would also be created.

The operational headquarters would make all procurement decisions. In addition to domestic financing, the law allows for funding through international assistance, businesses, legal entities and other sources. In an emergency, the formal procurement process can be bypassed and the law allows for direct purchase from the manufacturer or distributor.

The MoH has prepared guidelines for use during pandemics and a vaccine distribution plan. The IPH has several sets of personal protective equipment. Two hospitals in the north and south provide medical assistance for infected people in the case of outbreaks. The hospitals follow up on people coming from danger areas. The Ministry of Defence has the required human and equipment capacities for a CBRN accident and will cooperate with the Ministry of Interior. A plan that covers reaction to an event is in place and was developed as a result of field work.

The Ministry of Interior receives regular information from various sectors, which it collects and issues as daily bulletins. Compiling a report and sharing it with stakeholders would benefit coordination and cooperation. Also, responsible health officers should have access to information held within the ministry.

# **Indicators and scores**

# **R.4.1** System in place for activating and coordinating medical countermeasures during a public health emergency – Score 4

### Strengths and best practices

- A regulatory framework is in place.
- Montenegro, as a NATO member, can seek and provide equipment and personnel assistance in emergencies.
- Montenegro has signed 11 bilateral agreements, 2 multilateral agreements and 4 memorandums of cooperation in case of emergencies.
- The Directorate for Emergencies organized two military-civilian exercises, one for earthquakes and one for floods in which all relevant institutions participated.
- Guidelines for Ebola outbreaks and awareness activities have been in place since 2014.
- A preparedness plan for an influenza pandemic exists.

### Areas that need strengthening and challenges

- A transportation plan for medical staff during emergencies should be developed.
- Preparedness plans should be updated regularly, along with lists of contact points.
- The overall system's functionality should be tested regularly.

# **R.4.2** System in place for activating and coordinating health personnel during a public health emergency – Score 3

### Strengths and best practices

- National and local staff working in primary, secondary and tertiary health care during emergencies cooperates and communicate effectively.
- Field teams are well staffed and include epidemiologists, infectious disease specialists, microbiologists, epizootiologists, hygiene specialists, sanitary inspectors, food inspectors and other relevant professionals.
- Many experts have extensive experience in the public health care sector.
- Training organized by MediPIET was held in 2017 with the participation of staff from the Ministry of Interior, the Directorate for Emergencies and the army.
- A multi-country project, MediLab secure, is underway and will help strengthen human and veterinary microbiology, epidemiology and entomology in the field of arbovirus infections.

### Areas that need strengthening and challenges

- The capacity of staff to coordinate emergency response operations needs strengthening.
- A plan with defined procedures for the deployment of healthcare staff during a public health emergency should be developed.
- The department responsible for coordinating, planning and monitoring the deployment of healthcare staff should be designated.

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

### Strengths and best practices

- Procedures are in place to manage cases of priority illnesses that tend to turn into epidemics such as Ebola virus disease, pandemic influenza or vaccine-preventable diseases.
- Legislation exists that protects people and animals against infectious diseases.
- There are guidelines in place for referral and ambulance transport of patients to designated health facilities.

### Areas that need strengthening and challenges

- Guidelines to manage cases of priority illnesses and IHR-relevant hazards exist at all health system levels.
- There is a need to improve intersectoral coordination and cooperation related to IHR-relevant hazards.
- SOPs for intersectoral coordination and cooperation are only in place for specific events.

- Identify health care facilities and equipment to ensure first response for mass casualty events.
- Develop a plan with defined procedures for the deployment of medical staff during a public health emergency.
- Develop guidelines for case management of all IHR-related hazards.

# **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.

## **MONTENEGRO LEVEL OF CAPABILITIES**

The Ministry of Interior issues official communications about the dangers of emergencies, their scope, activities and protection and planned rescue measures. A representative of the Secretariat-General of the Government in charge of public relations sits on the Protection and Rescue Coordination Team. There is a public relations department within the Ministry of Interior. Also, the Directorate for Emergencies manages the EOC 112.

While there is both formal and informal communication coordination in the healthcare system, there are no common communication plans for all hazards.

There is no formal job position for risk communication, although the Ministry of Interior is in charge of communication about hazards, emergencies, activities and measures. No special budgetary item exists for communication in an emergency but funds from the budget reserve can be used if necessary.

Communication among those involved in the protection and rescue system is reviewed annually through internal and international exercises organized for certain types of risks. Depending on the emergency, there are specific mechanisms for prompt approval of communication content. However, risk communication at the prevention level is not coordinated, nor is a formal mechanism in place.

The Government of Montenegro has expanded its communication strategy, with the support of the UK Government, to include crisis communications.

Communication is provided in the languages of local communities, such as Albanian or Roma, depending on the areas affected.

A clearly defined hierarchy develops and approves communication messages in case of emergencies and partner organizations, such as the Red Cross, are included in the network.

# **Indicators and scores**

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

### Strengths and best practices

- Strategic guidance documents have been developed.
- An EOC is established.
- Public relations services are available when needed through formal and informal networks throughout the healthcare system.
- Response speed is high and messages can be disseminated and placed rapidly.
- Relations with the public are good and information is usually well received and trusted.

### Areas that need strengthening and challenges

- Internal communication mechanisms and SOPs should be developed.
- Communications should regularly be evaluated after public health events.
- The Intersectoral Team for Crisis Communication should be formalized.
- An all-hazard communication plan has not been written.
- An information mechanism should be created to communicate internal and external threats.
- The changing landscape of communication and information sharing should be taken into greater account, for example by using and monitoring social communication networks during an emergency to ensure accuracy of information to the public.

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

### Strengths and best practices

• In addition to state resources, the staff resources of local government bodies, private companies, NGOs and individuals are also pooled.

### Areas that need strengthening and challenges

- Spokesperson skills should be strengthened through formal and informal education.
- Social networks are not sufficiently or appropriately used.
- There is inadequate staff capacity for sustainability.
- There is insufficient computer literacy among communication staff.

### R.5.3 Public communication for emergencies – Score 4

### Strengths and best practices

- Information flows quickly in an emergency.
- Population coverage is broad.
- Media is open and available to cover these issues.

### Areas that need strengthening and challenges

- Efforts should be made to use all channels of communication, including social media, when the situation on the ground is rapidly changing.
- Staff employed with the emergency response services should receive additional training for effective communication.
- There is a lack of staff for crisis communication.
- Infrastructure deficiencies should be addressed.

### **R.5.4** Communication engagement with affected communities – Score 4

### Strengths and best practices

- Teams or working groups can be developed ad hoc during an emergency to focus on social mobilization, health promotion or community engagement as needed during a response.
- A number of departments including social mobilization, health promotion and community engagement departments are integrated within the overall health response and linked to the media staff and coordinated with key partners.
- Social mobilization, health promotion and community engagement are included in national protection and rescue plans.

### Areas that need strengthening and challenges

• Community partners should be trained to share information and work to strengthen partnerships and community action.

### R.5.5 Addressing perceptions, risky behaviours and misinformation - Score 3

### Strengths and best practices

- A formal communication function is in place to monitor, detect and address people's perceptions, unfounded beliefs, risky behaviours and misinformation.
- Information on people's perceptions, unfounded beliefs, risky behaviours and misinformation and strategies to address them should be shared regularly with other stakeholders.

### Areas that need strengthening and challenges

- Information on perception, risky behaviours and misinformation is not systematically used for shaping prevention measures and the response.
- There is no formal evaluation process.

- Formalize SOPs for the Intersectoral Team for Crisis Communication and improve internal communication.
- Use all communication channels, including social media, to disseminate information.
- Increase the number of staff available for risk communication as well as overall formal and informal education and promotion of spokespersons skills in the emergency response services.

# 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.

### MONTENEGRO LEVEL OF CAPABILITIES

Montenegro borders with Croatia, Bosnia and Herzegovina, Serbia and Albania. There are 28 points of entry (PoE) into Montenegro, including 19 ground crossings for international road transport, 2 for international railway transport at Tuzi and Bijelo Polje railway stations, 2 airports at Podgorica and Tivat and 5 ports for international maritime transport at Bar, Kotor, Zelenika, Budva and Tivat.

At the end of May 2019, none of these PoEs had been officially designated. The legal framework, however, has been developed and Montenegro has the necessary legislation for designation of PoEs.

Many of the required core capacities are already available at PoEs in normal times and during an emergency, although availability is greater in aviation than in the maritime or land transport sectors. Podgorica Airport will become a designated PoE with core capacities as required by Annex 1B of IHR (2005).

A number of those core capacities are already in place such as medical services, transport of ill travellers and assurance of a safe environment for travellers. An integrated public health emergency plan is also expected to come into effect.

In addition, training and exercises have demonstrated excellent collaboration between different sectors in the response to public health threats at airports and ports.

Due to Montenegro's lack of appropriate medical facilities to treat suspected cases of highly contagious infectious diseases, this extremely relevant core capacity cannot be fulfilled. In addition, capacities

to identify and handle chemical and radio-nuclear threats are not adequately developed at the PoEs, limiting the implementation of an all-hazard approach.

# Indicators and scores

### PoE.1 Routine capacities established at points of entry - Score 2

### Strengths and best practices

- A regulatory framework and efficient surveillance systems are in place.
- Good communication and collaboration among relevant stakeholders at local and national levels, including epidemiologists, are in place and have been demonstrated at PoEs.
- A number of required core capacities at PoEs are already in place, such as access to medical services, transport of ill travellers and assurance of a safe environment for travellers.

### Areas that need strengthening and challenges

- Protocols and SOPs are required for all PoEs except Podgorica Airport.
- A national vector control plan should be developed.
- Multi-sectoral awareness of IHR implementation should be strengthened through regular training and exercises in applying SOPs and involve all relevant stakeholders.

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

### Strengths and best practices

- Good communication and collaboration of relevant stakeholders at local and national levels are in place and have been demonstrated.
- Relevant stakeholders are trained in applying their individual procedures.
- SOPs are in place to implement measures if a highly contagious disease is suspected.

### Areas that need strengthening and challenges

- Integrated protocols and SOPs should be developed for the response to public health emergencies.
- Communication between decision-makers and implementers needs strengthening.
- All relevant stakeholders involved in emergency cases at PoEs should be trained regularly.
- A generic preparedness plan with a focus on public health threats should be developed.

- Finalize the designation of one airport in line with IHR (2005) requirements.
- Designate one port in line with IHR (2005) requirements and develop SOPs and guidelines to manage cross-border public health threats in the designated port.
- Develop a plan for ongoing training in public health emergencies, and implement exercises at PoEs to improve multi-sectoral preparedness, communication and response.
- Continue establishing appropriate facilities aligned with the core capacity requirements under Annex 1B of the IHR (2005).

# **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.

# MONTENEGRO LEVEL OF CAPABILITIES

While Montenegro does not have a developed chemical industry, a number of hazardous chemicals are imported and used, and hazardous wastes from former industrial activities are stored in the country. To ensure sound chemicals management, the country adopted the Law on Chemicals in 2017 and the Law on Biocidal Products in 2018. Legislation on environmental protection, occupational health, transportation of hazardous substances and inspections also includes items related to chemicals management.

Montenegro is a Party to the Basel, Rotterdam, Stockholm and Minamata Conventions, as well as the UNECE Convention on Transboundary Effects of Industrial Accidents. It also participates in the Strategic Approach to International Chemical Management (SAICM). In 2019, Montenegro adopted the National Chemicals Management Strategy and its supporting action plan for 2019-2022, which replaced the previous 2015-2018 strategy. The lack of human, technical and financial resources is seen as the main barrier to implementing the legislation and is addressed in the strategy.

A system for monitoring chemicals in air, waters and drinking water, soil, food and in some consumer products is in place but only for conventional chemicals.

Emergency situations are managed under the Law on Protection and Rescue and coordinated by the Ministry of Interior. Other ministries with responsibilities in emergencies include the Ministry of Sustainable Development, Environmental Protection Agency, Administration for Inspection Affairs, Ministry of Health, Ministry of Labour and Social Welfare, Directorate for Food Safety, Veterinary and Phytosanitary Affairs and their institutions. The National Plan for the Protection from Chemical Incidence defines the roles of all key institutions involved in chemical incidence response.

National legislation also covers requirements under the Seveso III Directive, such as registration of hazardous sites and their control, development of on-site and off-site emergency plans, siting and land use planning. A licencing system for enterprises dealing with hazardous substances is in place, as well as a registry of hazardous installations, although it is not available online to other agencies and institutions involved in managing chemical events or to the public.

Plans for management of acute events are being developed at all levels – national, local and enterprise. But there is no public health plan in case of chemical incidents. Mass poisonings and disease outbreaks caused by hazardous chemicals are not classified as chemical accidents and are not addressed properly in legislation on emergency prevention and response. Procedures to rapidly assess chemical risks during responses to chemical events have not been developed, mostly due to lack of capacity and expertise. While the register of chemical substances and mixtures has not been created yet and no registration system is in place, the National Chemicals Management Strategy envisages the registry's creation in 2021. The Environmental Protection Agency has some databases but they are not public. An inventory of reference healthcare facilities for the diagnosis and treatment of chemical poisoning cases is not available. There is insufficient communication with the public in cases of poisoning by consumer products, as well as gaps in the collection and availability of information needed for preparedness and response.

# **Indicators and scores**

# **CE.1** Mechanisms established and functioning for detecting and responding to chemical events or emergencies – Score 2

### Strengths and best practices

- Mechanisms are established as required by the Law on Protection and Rescue and the Law on Environment.
- Monitoring of chemicals in the environment is in place.
- Monitoring of chemicals in consumer products takes place through the Rapid Exchange of Information System (RAPEX).
- Good laboratory capacities are available.
- Under the Law on Environment, operators of Seveso installations or establishments with
  activities that involve one or more hazardous substances must take all necessary measures to
  prevent a chemical accident and to limit the impact of such an accident on humans and on the
  environment.

### Areas that need strengthening and challenges

- The Poison Control Centre should be established as the central point for receiving and consolidating information on poisoning and chemicals as potential causes of poisoning, with relevant information on prevention and response, adequate treatment and antidotes available to medical personnel and the public.
- Databases with adequate protocols on preparedness and response in case of poisoning are needed.
- A separate unit should be created within the Clinical Centre of Montenegro (CCMNE) to coordinate a network of health institutions that manage cases of poisoning and to handle communication with relevant healthcare institutions.
- Adequate staff specialized in emergency medicine and toxicology is needed.
- Administrative, technical and human capacities, both in number and expertise, should be strengthened by establishing a network of experts and ensuring they receive the necessary training in response to chemical events.

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

### Strengths and best practices

- A mechanism for management and coordination of protection and rescue is established at national, local and operator levels.
- Operators are developing prevention and response plans and safety reports in accordance with the Law on Environment and the Law on Protection and Rescue.
- Transport of hazardous substances is regulated.
- Implementation of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS) is underway.

- A national help desk has been set up within the Environmental Protection Agency, which provides customers with information and advice on chemicals and biocidal products.
- An EOC is functioning.
- Coordination teams, operational headquarters and municipal teams are established for protection and rescue in case of emergencies.
- A Seveso installations register has been created.
- Equipment is provided for one team of rescuers in the capital's Protection Service and so far, three exercises have tested the response to a chemical accident, two in the field and one simulation exercise.

#### Areas that need strengthening and challenges

- Cooperation should be formalized between the Environmental Protection Agency and scientific research institutions to adequately implement regulations and provide expert assistance in risk assessment of chemicals.
- Regular exercises to test different chemical accident scenarios should be carried out.
- A chemicals register should be established.
- The Protection and Rescue Plan should be updated in the event of a chemical accident, as envisaged in the Disaster Risk Reduction Strategy.
- More training and exercises should be held to capitalize on the experience acquired by Montenegro during its participation in table-top exercises and field training exercises for chemical accidents as part of the EU project "Capacity Building for the First Response to CBRN and Regional Cooperation of Southeast European Countries, South Caucasus, Moldova and Ukraine".
- Funds for 2014-2020 are available under the Instrument for Pre-accession Assistance and the 2020-2030 project proposal is prepared.

- Establish a poison control centre according to WHO guidelines.
- Strengthen administrative capacities to respond to different types of chemical event.
- Ensure collection, evaluation and availability of information needed to assess chemical risks, including rapid risk assessment for all stakeholders involved in management of acute chemical events.
- Establish a mechanism for coordination and cooperation in managing chemical events, including participation in chemical or toxicological networks.

# **RADIATION EMERGENCIES**

# **INTRODUCTION**

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

# Target

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

# **MONTENEGRO LEVEL OF CAPABILITIES**

Montenegro is a country without a nuclear industry, weapons, research reactors or any other facility producing radioactive and nuclear materials. Radioactive and nuclear materials, radioactive sources and sources of ionizing radiation are used in human medicine: for diagnostics; diagnostic and interventional radiology; radiotherapy; brachytherapy; nuclear medicine (diagnostics); in veterinary medicine, then for non-destructive testing (industry; portable and fixed-type gauge measurement, detection or analytical techniques; radioactive waste management; trade in sources of ionizing radiation and radioactive and nuclear materials, as well as in science and research.

National legislation covers management of radioactive and nuclear material, radioactive sources and sources of ionizing radiation in the Law on Protection against Ionizing Radiation and Radiation Safety (Official Gazette of Montenegro 56/09, 58/09, 40/11, 55/16). The process of drafting the new Law on Protection against Ionizing Radiation, Radiation and Nuclear Safety and Security is ongoing to achieve full compliance with EU directives and IAEA safety and security standards. Radiation safety is addressed in a number of strategic documents. The most important include the Strategy for Disaster Risk Reduction and implementation plan (2018-2023) and the Strategy on Ionizing Radiation Protection, Radiation Safety and Radioactive Waste Management (2017-2021) and its supporting action plan. Montenegro is a party to 26 international legal instruments in the area of radiation and nuclear safety and security.

Good laboratory capacities in Montenegro allow the systemic testing of radionuclides in air, soil, rivers, lakes and sea, solid and liquid precipitation, construction materials, drinking water, food and animal feed, as well as testing the concentration of radon activity in residential and work premises.

The Ministry of Sustainable Development and Tourism, Agency for Nature and Environmental Protection, Administration for Inspection Affairs, and the Ministry of Interior - Directorate for Emergencies are the competent institutions in the field of protection against ionizing radiation, radiation and nuclear safety and security.

A Protection and Rescue Coordination Team is established at the national level while municipal protection and rescue teams are established for the territories of municipalities. The Coordination Team is headed by the Prime Minister while its members are the director of the state administration body for protection and rescue and ministers (Ministries of Environment, Health, Social Welfare, Agriculture, Defence, Transport, Ministry of Foreign Affairs and others).

The Coordination Team manages the activities of protection and rescue participants when carrying out their tasks. Operational activities of protection and rescue participants are coordinated by the Operational Protection and Rescue Headquarters headed by the head of the state administration body responsible

for protection and rescue. The Operational Headquarters coordinates the implementation of measures and activities and protection and rescue actions and cooperates with the bodies of neighbouring states responsible for management and coordination in the fields of protection and rescue, and assesses the degree of threat and the possibility of a state of emergency arising.

In addition to the Ministry of Interior (MoI) - Directorate for Emergencies and the Agency for Nature and Environmental Protection, all activities include: the Ministry of Defence - the General Staff of the Armed Forces of MNE, Ministry of Health, (Clinical Centre of Montenegro, health centres, Emergency Centre, Institute for Public Health) and the Centre for Ecotoxicological Testing LLC.

Pursuant to the Law on Protection and Rescue, protection and rescue plans are developed at three levels: national, municipal and entrepreneurial (company-level). Municipal and company-level plans are in line with the National Plan of Action in case of a Radiological Accident. Holders of permits for performing radiological activity and permits for the management of radioactive waste storage are obliged, in accordance with the provisions of the Law on Protection and Rescue and the Law on Protection against lonizing Radiation and Radiation Safety, to have appropriate plans for emergency response, i.e., a radiological emergency preparedness and action plan (company-level plan).

Approval to the plans is given by the Mol's Directorate for Emergencies. The approval is submitted to the Agency for Nature and Environmental Protection for the purpose of issuing a radiological activity licence.

In order to better recognize and manage risks, the Mol's Directorate for Emergencies initiated the procedure of establishing a working group for the development of the Disaster Risk Assessment for Montenegro. About 50 experts from various state bodies, public administrative bodies, as well as academic community will participate in the development of the Assessment.

The risk assessment will include a detailed threat analysis of CBRN (chemical/biological/radiation/ nuclear) accidents, as well as of: earthquakes, extreme weather events, floods, fires, avalanches, landslides, epidemics, epiphytotics, epizootics, industrial accidents, traffic accidents, accidents at sea, civil aviation accidents, climate change, critical infrastructure protection, and terrorism.

In the past five years, no basic public health assessments have been made regarding radiation protection, taking into account morbidity and mortality. For the needs of such a research, it is necessary to start with the development and implementation of studies by the Institute for Public Health, which require time, expertise, necessary personnel and financial resources. However, an assessment of the radiological burden of the population has been conducted in Montenegro since 1998. In fact, the Agency for Nature and Environmental Protection performs an assessment of the radiological burden of the population based on the annual Programme of Systematic Radiation Testing, which is implemented by the authorized legal entity. The Programme of Systematic Radiation Testing in the Environment has been implemented since 1998 to determine the presence of radionuclides in the environment and to assess the levels of exposure of the population to ionizing radiation under normal conditions, in the event of a suspicion to a radiation accident and during a radiation accident. The information paper on the radioactivity monitoring including an estimate of radiological burden of population is developed by the Agency for Nature Protection and Environment, which is adopted annually by the Government of Montenegro on a proposal of the Ministry of Sustainable Development and Tourism, as well as the Information paper on the status of the environment which, in addition to the monitoring of radioactivity, includes other monitoring programmes.

Individual doses are measured within Montenegro, i.e. all professionally exposed persons wear dosimeters and only specific analyses to evaluate the exposure of those persons to radiation, such as chromosomal aberration analyses, are performed abroad. In accordance with the results of the national radioactivity monitoring programme, an assessment of the radiological burden on the population from radionuclides present in the environment, food and drinking water was last conducted in 2012.

Due to the lack of a legal person for performing vocational training in the field of protection against ionizing radiation, vocational training and periodic examination of professional qualifications in this area were carried out abroad. However, the new proposed Law regulates the system of vocational training and periodic examination of professional qualifications, which will be carried out in Montenegro, based on a license issued to the legal person which meets the requirements. It is envisaged that this licence as well as all other authorizations will be issued by the Environment and Nature Protection Agency to the legal entity that will conduct vocational training and periodic examination of professional qualifications.

Current human and financial resources are insufficient to implement policies and regulations in the field of ionizing radiation protection and their reinforcement is envisaged within the negotiating chapters covering that area. Bearing in mind the obligations from Negotiating Chapter 15 - Energy and other related negotiating chapters, as well as the obligations that Montenegro will have in the future in the field of nuclear and radiation safety and security and ionizing radiation protection, the strengthening of administrative and implementation capacities will continue in the form of constant training and by increasing the number of employees. Within the 2018-2020 Program of Accession of Montenegro to the European Union, it is planned to strengthen administrative capacities for all relevant institutions in this area, within the negotiating chapter 15 - Energy.

There is no inventory of designated healthcare facilities which can act in the event of a radiological emergency.

Montenegro has not joined the WHO Radiation Emergency Medical Preparedness and Assistance Network or the WHO Global Biodosimetry Network of Laboratories for Radiation Emergencies.

## **Indicators and scores**

# **RE.1** Mechanisms established and functioning for detecting and responding to radiological and nuclear emergencies – Score 4

### Strengths and best practices

- Mechanisms are established in compliance with strategic documents, existing laws and ratified international legal instruments.
- The system for management of radiation emergencies was reviewed in 2005 by the Radiation Safety and Security Infrastructure Appraisal (RASSIA), in 2008 by the Integrated Regulatory Review Service and in 2013 by the IAEA Advisory Mission (2013).
- The system has been tested through national and international exercises, which have helped increase national expertise.
- Obligations of license holders are clearly described and regulated.
- Planning takes place at national, municipal and entrepreneurial levels.
- Plans are moving forward and are updated based on a risk assessment.
- SOPs cover radiation events management and are implemented.
- A network of gamma dose rate stations (GDR) stations is established.
- Monitoring of radioactivity in environment, food, drinking water, feed, consumer products and construction material has been conducted as of 1998.
- Laboratory capacities are solid and enable monitoring of all natural and artificial radionuclides in the environment. Consequently, the concentration of cesium and iodine was observed during the Fukushima accident.
- Successful decontamination took place in Cape Arza in 2000-2003 (258 DU removed) and at Sipčanik Airport.
- An EOC 112 is established.

- Six Instrument for Pre-accession Assistance (IPA) projects were successfully implemented in cooperation with other Western Balkan countries.
- The Centre for Ecotoxicological Investigations (CETI) is a member of the IAEA's Analytical Laboratories for the Measurement of Environmental Radioactivity (ALMERA) network.

### Areas that need strengthening and challenges

- The professional training programme envisaged by the revised draft of the Law on Protection Against Ionizing Radiation, Radiation and Nuclear Safety and Security should be established, along with a legally designated entity to manage the programme.
- Capacities require strengthening.
- Equipping teams to act with dosimeters that meet safety standards in radiological emergencies.
- Medical services that can provide emergency radiological situations response should be identified.
- There is a need for regular simulation exercises at all levels, multi-sectoral training and exercises that test national and local responses to radiological emergency situations.
- The possibility of creating pharmaceutical stockpiles to use as countermeasures in a radiation emergency should be examined.

### RE.2 Enabling environment in place for management of radiation emergencies - Score 4

### Strengths and best practices

- The management and coordination of protection and rescue is established and implemented at national, local and enterprise level.
- License holders are required to develop entrepreneurial plans.
- Safe transportation of Class VII hazardous substances is ensured.
- Protection and rescue are managed through a coordination mechanism, dedicated operational headquarters, a municipal team and a CBRN team.
- Nature and Environment Protection Agency issues licences and keeps a register of licences and professionally exposed persons and develops information papers on radioactivity monitoring in the environment.
- The CBRN team is equipped to ensure adequate response to radiation emergencies.

### Areas that need strengthening and challenges

- Stronger cooperation is needed among institutions if they are to implement regulations and undertake new obligations.
- The proposed Law on Protection Against Ionizing Radiation, Radiation and Nuclear Safety and Security provides for a clear information exchange mechanism that would include the requirements detailed in the law.
- Medical institutions should be strengthened to better respond to a radiation emergency.
- More exercises are needed to test national, municipal and entrepreneurial plans.
- Equipment and adequate training should be provided for health sector specialists and first responders in a radiological emergency.
- Awareness should be raised among the public and among employees at risk of ionizing radiation exposure on the consequences of exposure and protective procedures to follow in a radiological emergency.
- Montenegro should consider joining the following: the WHO Radiation Emergency Medical Preparedness and Assistance Network (REMPAN), the WHO Global Network of Biodosimetry Laboratories for Radiation Emergency Situations (BioDoseNet) and the IAEA Response and Assistance Network (RANET).

- Organize and promote simulation exercises to test responses to radiological emergencies at the national and local levels.
- Develop a joint programme with exercises to respond to different scenarios involving participants from relevant institutions at the national and local levels.
- Strengthen administrative and technical capacities and procedures including improving the mechanism for information collection and exchange.
- Identify healthcare facilities and personnel and equip them to respond to radiological emergency situations.

# ANNEX: JEE BACKGROUND

# **Mission place and dates**

Podgorica, Montenegro; 27 to 31 May, 2019

# **Mission team members:**

- Ran Adelstain, Department of Emergency Situations, State of Israel Ministry of Health (team lead)
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- Siri Laura Feruglio, Norwegian Institute of Public Health, Kingdom of Norway
- Maleeka Glover, United States of America Centers for Disease Control and Prevention
- Janusz Janiec, National Institute of Public Health, Republic of Poland
- Ivana Kelic, Institute of Public Health of Serbia, Republic of Serbia
- Astrid Milde-Busch, Robert Koch Institute, the Federal Republic of Germany (team co-lead)
- Henk Jan Ormel, Food and Agriculture Organization of the United Nations
- Irina Zastenskaya, the WHO European Centre for Environment and Health

# Objective

To assess Montenegro's capacities and capabilities relevant to the 19 technical areas of the JEE tool for providing baseline data to support Montenegro'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 publicly 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

### 1. Working group for national legislation, policy and financing:

- Milica Skiljevic, Ministry of Health of Montenegro
- Dr Miro Knezevic, Ministry of Health of Montenegro
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#### 17. Working group for points of entry:

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- Dr Jadranka Pajkanovic, Administration for Inspection Affairs, Sanitary Inspection;
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- Dr Tatjana Djurickovic, Agency for civil aviation
- Mirjana Popovic, Property Administration

## 18. Working group for chemical events:

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- Branimir Vulevic, Ministry of defense;
- Maja Mijovic, Ministry of labor and social welfare;
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# Supporting documentation provided by host country

# National legislation, policy and financing

- Rulebook on measures for prevention of outbreaks, detection, suppression and eradication of avian flu (Official Gazette of Montenegro, No. 70/2015)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Law on Wellbeing of Animals (Official Gazette of Montenegro, Nos. 014/08 and 47/15)
- Rulebook on classification of infectious animal diseases, procedure of notification of outbreak and suspicion and cessation of infectious animal diseases (Official Gazette of Montenegro, No. 92/2017)
- Programme of mandatory measures of animal health protection in 2019 (Official Gazette of Montenegro, No. 10/19)
- Majority of by-laws which closely define measures for control of certain animal diseases, and the import conditions per animal species (including quarantine and measures in quarantine)
- Rulebook on conditions for import of birds (Official Gazette of Montenegro, Nos. 79/2016 and 2/2018)
- Rulebook on detailed conditions for import and transit of aquatic animals and their products (Official Gazette of Montenegro, Nos. 60/2017 and 1/2019)
- Rulebook on detailed conditions for trade and import of poultry for farming or production (Official Gazette of Montenegro, No. 48/2018)
- Rulebook on measures for prevention, suppression and eradication of animal anthrax (Official Gazette of Montenegro, No. 56/2017)
- Law on Protection of Population from Infectious Diseases (Official Gazette of Montenegro, No. 12/2018)
- Law on Health Protection (Official Gazette of Montenegro, Nos. 003/2016, 039/2016, 002/2017)
- Veterinary Law (Official Gazette of Montenegro, No. 11/2004)
- Law on Wellbeing of Animals (Official Gazette of Montenegro, Nos. 014/2008, 47/2015, 040/2011, 047/2015)
- Rulebook on classification of animal diseases, procedure of notification reporting on infectious animal diseases (Official Gazette of Montenegro, No. 5/2008)
- Programme of mandatory animal health measures in 2018 (Official Gazette of RS, No. 11/2018)
- Rulebook on measures for prevention of outbreaks, detection, suppression and eradication of avian flu\* (Official Gazette of Montenegro, No. 70/2015)
- Law on Medicines (Official Gazette of Montenegro, Nos. 56/2011 and 6/2013)
- Laboratory diagnostics in clinical bacteriology; National Guidelines on Good Clinical Practice 2016, Ministry of Health
- Law on Budget and Fiscal Responsibility (Official Gazette of Montenegro Nos. 20/14 and 56/14)
- Law on Transport of Hazardous Goods (Official Gazette of Montenegro, Nos. 33/14 and 13/17)
- Law on Waters (Official Gazette of Montenegro, Nos. 27/2007 and 32/2011, 47/2011 correction, 48/2015, 52/2016, 2/2017 state law, 80/2017 state law, 55/2016 state law and 84/2018)
- Law on Food Safety (Official Gazette of Montenegro, No. 57/2015)
- Law on Protection against Ionizing Radiation and Radiation Safety (Official Gazette of Montenegro, Nos. 056/2009, 058/2009, 040/2011, 055/2016)
- Health policies in the Republic of Montenegro until 2020 (Government of Montenegro at its session of 11 January 2001)
- Montenegrin Health Development Strategy (Ministry of Health, September 2003)
- Montenegrin Budget Law for 2019 (Official Gazette of Montenegro, No. 87/18)

- Action Plan for Implementation of IHR (2016-2018)
- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/2007, 005/2008, 086/2009, 032/2011, 054/2016)
- Strategy for Disaster Risk Reduction with dynamic plan of activities for implementation of strategy for 2018-2023

#### IHR coordination, communication and advocacy

- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/2007, 005/2008, 086/2009, 032/2011, 054/2016)
- Law on the protection of population against communicable diseases (Official Gazette of Montenegro, No. 012/18)
- Decision of the Ministry of Health on Establishing IHR National Team (22 November 2018)
- Operational Plan of Actions in Emergency Situations
- Government of Montenegro, Ministry of Interior, Directorate for Emergencies and Civil Protection information on floods in Montenegro for the period November December 2010 (9 February 2011)
- Decision of the Ministry of Health on Establishing Task Force to Monitor and Coordinate the Activities Related to the Outbreak of Swine Flu (H1N1) (15 May 2009)
- Decision of the Ministry of Health on Establishing Coordination to Monitor and Coordinate the Activities Related to the Outbreak of Quarantine Diseases Ebola (7 August 2014)
- Decision on Establishing the National Board for Communicable Diseases (19 April 2017)
- Rulebook on the list of communicable diseases with epidemiological supervision and against which measures are implemented aimed at preventing and suppressing communicable diseases and defining the cases of communicable diseases (Official Gazette of Montenegro, No. 020/2019)
- Rulebook on notifying about communicable diseases, hospital-acquired infections, states and death cases caused by these diseases (Official Gazette of Montenegro, No. 020/2019)
- Rulebook on monitoring of zoonoses and zoonotic agents (Official Gazette of Montenegro, Nos. 7/2015 and 2/2018)
- National Action Plan for protection against chemical, biological, radiological and nuclear threats and risks (CBRN) for 2016-2020
- Strategy on the Non-Proliferation of Weapons of Mass Destruction for 2016-2020
- Decision on the appointment of the Operational Headquarters for Protection and Rescue (Official Gazette of Montenegro, No. 52/17)
- Examples of recommendations sent to primary health care centres and competent epidemiological services in Ulcinj, Bar, Budva, Tivat, Kotor, Herceg Novi; General Hospitals in Bar, Kotor, Cetinje; Blood Transfusion Institute of Montenegro; Emergency Medicine Institute; Specialized Hospital Risan; Clinical Center of Montenegro
- Response Plan in case of outbreak of a communicable disease in air traffic posing a threat to public health draft

## Antimicrobial resistance

- Law on Medicines (Official Gazette of Montenegro, Nos. 56/2011 and 6/2013)
- Law on Pharmaceutical Activity (Official Gazette of Montenegro, No. 24/2019)
- Law on Protection of Population from Communicable Diseases (Official Gazette of Montenegro, No. 012/18)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Law on Food Safety (Official Gazette of Montenegro, No. 57/17)
- National Strategy for the Control of Bacterial Resistance to Antibiotics for 2017-2021

- National Strategy for the Control of Bacterial Resistance to Antibiotics for 2012-2016
- Rulebook on the monitoring of residues in animals and products of animal origin (Official Gazette of Montenegro, No. 3/17), transposing Directive No. 96/23 and Commission Decision No. 97/747 / EC
- Rulebook on the maximum allowed quantities of residues of pharmacologically active substances of veterinary medicinal products in products of animal origin (Official Gazette of Montenegro, No. 75/18)
- Rulebook on the method of monitoring zoonoses and zoonotic agents (Official Gazette of Montenegro, Nos. 7/15 and 2/18), transposing Council Directive 2003/99/EC and the Commission Implementing Decision 2013/652/EU
- Rulebook on the manner and measures for the control of salmonella in poultry and other specific food-borne zoonotic agents (Official Gazette of Montenegro, Nos. 36/15 and 92/17), transposing Regulation (EC) No. 2160/2003 and the Commission Regulation (EU) Nos. 200/2010, 517/2011, 1190/2012, 200/2012, 1177/2006
- Rulebook on the amendments to the Rulebook on Quality and Sanitary and Technical Requirements for Discharge of Wastewaters into Recipient and Public Sewerage (Official Gazette of Montenegro, No. 59/13)
- Rulebook on more detailed conditions for performing health care activities in hospitals and natural SPAs (Official Gazette of Montenegro, Nos. 74/08 and 32/10)
- Rulebook on monitoring and evaluation of results of quality and quantity of released effluent for municipal and biodegradable industrial waste water (Official Gazette of Montenegro, No. 078/17)
- Action Plan for the control of bacterial resistance to antibiotics in Montenegro for 2019-2020
- Rulebook on the list of communicable diseases subject to both epidemiological surveillance and measures of prevention and suppression of communicable diseases, and definitions of cases of communicable diseases (Official Gazette of Montenegro, No. 020/19)
- CAESAR Report for Montenegro (2016)
- National guidelines for the treatment of infections and the rational use of antibiotics for: respiratory infections, sepsis and septic shock, hand hygiene, Tonsillopharyngitis - diagnostics and treatment, antimicrobial therapy during acute gastroenteritis in children, diagnostics and treatment of urinary tract in children, diagnosis guide and treatment of acute uncomplicated urinary infections in adult patients in primary care, diagnostics and treatment of bacterial infections of skin and soft tissues in children, rational use of antibiotics in primary health care, antimicrobial prophylaxis in surgery, laboratory diagnostics in clinical bacteriology (www. mzdravlja.gov.me)
- Decree on the requirements for the production and placing on the market of medicated animal feed (Official Gazette of Montenegro, No. 51/2017)
- Decree on Food Hygiene (Official Gazette of Montenegro, Nos. 13/2016, 80/2016, 80/2018)
- Decree on Special Requirements for Hygiene for Products of Animal Origin (Official Gazette of Montenegro, Nos. 32/2016, 80/2016, 57/2017, 49/2018)
- Decree on Microbiological Criteria for Food Safety (Official Gazette of Montenegro, Nos. 26/2016 and 31/2018)
- Guide to good hygienic practices in food business for hospitality and trade sector and public catering facilities (Chamber of Commerce and Industry of Montenegro) (http://www.ubh.gov. me/vijesti/174162/Vodic-za-dobru-higijensku-praksu-u-poslovanju-sa-hranom.html)
- Decree on the Prohibition of the Use and Treatment of Animals Regenerated by Certain Substances and Veterinary Medicinal Products (Official Gazette of Montenegro, No. 76/2018)
- Food and Feed Safety Measures Programme- adopted annually
- Programme for monitoring residues in food of animal origin and animal feed adopted annually
- Programme of compulsory animal health measures adopted annually

- Adequate legal frameworks for the regime of issuing and selling antimicrobial drugs. Law on Medicines (Official Gazette of Montenegro, No. 56/2011)
- CMM Annual Work Report
- Report on the work of the Specialist Veterinary Laboratory
- Report on the work of the Directorate for Food Safety, Veterinary and Phytosanitary Affairs
- PVS Report (OIE)

## **Zoonotic diseases**

- The Law on Protection of Population from Infectious Diseases (Official Gazette of Montenegro, No. 12/2018)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Food Safety Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Rulebook on the method of reporting infectious diseases, hospital infections, conditions and deaths of persons suffering from these diseases (Official Gazette of Montenegro, No. 20/19)
- Rulebook on the List of Infectious Diseases under which epidemiological surveillance is being carried out and against which preventive and suppressive measures are being applied and definitions of infectious diseases cases (Official Gazette of Montenegro, No. 20/19)
- Rulebook on monitoring zoonosis and causes of zoonosis (Official Gazette of Montenegro, Nos. 7/2015 and 2/2018)
- Rulebook on method and measures to control salmonella at poultry and other specific causes of zoonosis transferred by food (Official Gazette of Montenegro, Nos. 36/2015 and 92/2017), transposing Regulation (EC) No. 2160/2003 Commission Regulations (EU) Nos. 200/2010, 517/2011, 1190/2012, 200/2012, 1177/2006
- Rulebook on classification of infectious diseases at animals, reporting procedure, i.e. reporting
  of a suspicion and signing of infectious diseases at animals (Official Gazette of Montenegro, No.
  92/17)
- Annual Programme of Mandatory Animal Health Measures
- Annual Programme of food and feed safety measures
- Report on acute infectious diseases in Montenegro
- Report on the work of Specialist Veterinary Laboratory
- Report on the work of Food Safety, Veterinary, and Phytosanitary Agency
- PVS report (OIE)
- Bylaws for prevention of occurrence, detection, suppression, and eradication of certain animal diseases (tuberculosis, brucellosis, anthrax, avian influenza, etc.)

## Food safety

- Law on Protection of Population from Communicable Diseases (Official Gazette of Montenegro, No. 12/18)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12 and 48/15)
- Food Safety Law (Official Gazette of Montenegro, No. 57/15)
- Rulebook on the manner of reporting communicable diseases, hospital infections, conditions and mortality from these diseases (Official Gazette of Montenegro, No. 20/19)
- Rulebook on the list of communicable diseases subject to epidemiological surveillance and application of prevention and suppression measures for communicable diseases and definitions of contagious diseases (Official Gazette of Montenegro, No. 020/2019)
- Rulebook on the method of monitoring zoonoses and zoonotic agents (Official Gazette of Montenegro, Nos. 7/2015 and 2/2018)

- Rulebook on the classification of communicable animal diseases, the manner of reporting outbreak or suspected appearance and the removal of contagious animal diseases (Official Gazette of Montenegro, No. 92/2017)
- Procedures for exchanging information on direct or indirect risks to human health from food or feed (Nos. 323/16-0101-5463 of 6 December 2016)
- Annual programme of mandatory animal health measures
- Food Safety Measures Programme for 2019
- Report on acute communicable diseases in Montenegro
- Report on the work of the Directorate for Food Safety, Veterinary and Phytosanitary Affairs
- EC report confirming good progress in food safety area for 2018
- Annual Plan of Official Food Control
- National Plan for Sustainable Use of Pesticides
- Post-registration control of plant protection products for 2019
- Reporting to the EC on the implementation of the annual program of residues of VMP and pesticides

## **Biosafety and biosecurity**

- Law on Safety and Health at Work (Official Gazette of Montenegro, Nos. 34/14 and 44/18)
- Rulebook on occupational safety measures against the risk of exposure to biological substances (Official Gazette of Montenegro, No. 062/17)
- Rulebook on the conditions to be met by a legal or natural person for the performance of professional work in the field of occupational safety and the procedure for determining the fulfilment of these conditions (Official Gazette of Montenegro, No. 79/04)
- SOP Instructions for Biosafety (Q3.5.4.01.03, of 4 April 2016), Centre for Medical Microbiology
- SOP Instructions for Biosecurity generic document
- SOP Instructions for Medical Waste Management (Q3.5.4.02.01, of 27 April 2016), Centre for Medical Microbiology
- Law on Transportation of Dangerous Substances (Official Gazette of Montenegro, No 05/08)
- Law on Waste Management (Official Gazette of Montenegro, Nos. 064/11 and 039/16)
- Laboratory Biosafety Manual, WHO, Geneva (Third Edition, 2004)
- SOP Rules of residence at the Centre for Medical Microbiology (UP1-CMM of 7 February 2017), Centre for Medical Microbiology
- SOP Instructions in case of spillage of biological materials (CMM-Z-008 of 3 October 2016), Centre for Medical Microbiology
- Biorisk Management: Laboratory biosecurity guidance, WHO, Geneva (September 2006)
- Programme for compulsory immunization of the population against certain infectious diseases in the territory of Montenegro (Official Gazette of Montenegro, No. 023/19)
- Law on the Control of Export of Dual-Use Goods (Official Gazette of Montenegro, No. 030/12)
- Rulebook on the Conditions, Manner and Procedure of Medical Waste Treatment (Official Gazette of Montenegro, No. 42/12)
- Medical Waste Management Plan in Montenegro with the Action Plan for 2016-2020, as well as the plans for managing medical waste for all healthcare institutions in Montenegro (http://www. mzdravlja.gov.me/rubrike/medicinski-otpad)

## Immunization

- Law on the Protection of Population from Infectious Diseases (Official Gazette of Montenegro No. 012/18)
- Pravilnik o uslovima i načinu sprovođenja obavezne imunoprofilakse i hemioprofilakse protiv određenih zaraznih bolesti ("Sl. list CG", br. 31/2010. godine od 04. 06. 2010. godine)
- Program obaveznih imunizacija stanovništva protiv određenih zaraznih bolesti na teritoriji crne gore za 2017. Godinu ("Službeni list Crne Gore", br. 004/17 od 20.01.2017)
- Vodič za planiranje nabavki, skladištenje i transportovanje vakcina uz održavanje režima hladnog lanca
- Godišnji izvještaji o sprovedenim imunizacijama
- Multiple indicators cluster survey (MICS) 2018; UNICEF & MONSTAT publikacija u pripremi
- Pravilnik o bližim uslovima u pogledu standarda, normativa i načina ostvarivanja primarne zdravstvene zaštite preko izabranog tima doktora ili izabranog doktora ("Službeni list RCG", br. 61/2005 od 19.10.2005. godine)
- JRF Joint Reporting Format on Immunizations and Communicable Diseases (WHO & UNICEF)
- Portal javnih nabavki Crne Gore trogodišnja nabavka vakcina

## National laboratory system

- Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 12/18)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Rulebook on the classification of communicable animal diseases, the manner of reporting outbreak or suspected appearance and the cancellation of contagious animal diseases
- Programme of mandatory animal health measures in 2019 (Official Gazette of Montenegro, No. 10/19)
- Rulebook on the list of communicable diseases subject to both epidemiological surveillance and measures for the prevention and control of communicable diseases and the definitions of cases of communicable diseases (Official Gazette of Montenegro, No. 020/19)
- Rulebook on the manner of reporting communicable diseases, hospital infections, conditions and mortality of persons diagnosed with these diseases (Official Gazette of Montenegro, No. 020/19); Law on Health Protection (Official Gazette of MNE, Nos. 3/2016, 39/2016, 2/2017, 44/2018)
- Law on Health Inspection (Official Gazette of MNE, No. 030/17)

## **Real-time surveillance**

- Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18.)
- Rulebook on the list of communicable diseases that are subject to epidemiological surveillance and prevention and control measures, and case definitions (Official Gazette of Montenegro, No. 020/19)
- Rulebook on the manner of reporting communicable diseases, hospital inspections, conditions and mortality caused by these diseases (Official Gazette of Montenegro, No. 020/19)
- Technical and methodological instructions for epidemiological surveillance of the flu in Montenegro with the SARI protocol
- Guide for the control of smallpox, rubella and congenital rubella syndrome in Montenegro 2010
- Guide for acute flaccid paralysis (AFP) active surveillance
- Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions

# Reporting

- International Health Regulations, 2005 [Annex 2]. WHO, Geneva, 2005
- Decision to nominate a National IHR Focal Point from 2009, 2016
- Law on the Protection of Population from Infectious Diseases (Official Gazette of Montenegro No. 012/18)
- Veterinary Law (Official Gazette of Montenegro, Nos. 30/12, 48/15, 52/16, 43/18)
- Rulebook on the classification of infectious animal diseases, manner of notifying the occurrence or suspicion to infectious animal diseases and notice of elimination thereof (Official Gazette of Montenegro, No. 92/17)
- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/07, 005/08, 086/09, 032/11, 054/16)
- A plan for responding to the occurrence of an infectious disease in air transport that poses a risk to public health (draft)

## Workforce development

- Human Resources Plan in the Health Sector for 2013-2022. Government of Montenegro, Podgorica 2013
- Programme of Accession of Montenegro to the European Union 2019-2020; Strategy for Transposition and Implementation of the EU Acquis Chapter 12, from 2016
- Rulebook on internal organization and systematization of the Directorate for Food Safety, Veterinary and Phytosanitary Affairs for 2019
- Overview of the state of personnel with permanent employment in the public health care institutions of out-patient and hospital health care in Montenegro in 2018. Institute of Public Health, Podgorica 2019
- Law on Data Collections in the Field of Health (Official Gazette of Montenegro, No. 80/08)
- Rulebook on Specializations (Official Gazette of Montenegro, No. 17/14)
- Rulebook on Specializations and Subspecializations of Health Workers and Health Associates (Official Gazette of the RS, Nos. 10/13 and 91/13)
- Rulebook on criteria and procedures for approval of specializations and the rights and obligations of candidates approved for specialization by a health care institution (Official Gazette of Montenegro, No. 22/16)
- Law on Protection of Population from Infectious Diseases (Official Gazette of Montenegro, No. 012/18)

# **Emergency preparedness**

- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/07, 005/08, 086/09, 032/11, 054/16)
- Law on Transport of Hazardous Substances (Official Gazette of Montenegro, Nos. 33/14 and 13/17)
- Law on Flammable Liquids and Gases (Official Gazette of Montenegro, Nos. 26/10 and 48/15)
- Rulebook on the contents and methodology of drafting, harmonizing, updating and keeping of risk assessment studies used for developing protection and rescue plans (Official Gazette of Montenegro, No. 31/17)
- Rulebook on more detailed contents and methodology of drafting, harmonizing, updating and keeping of protection and rescue plans (Official Gazette of Montenegro, No. 34/17)
- Strategy for Disaster Risk Reduction with an Activity Time Schedule for 2018-2023
- Report on the state of the protection and rescue system in Montenegro in 2010

- Report on the state of the protection and rescue system in Montenegro in 2011
- Report on the state of the protection and rescue system in Montenegro in 2017
- Information paper about the activities carried out during the 2017 summer fire season
- Information paper on floods in Montenegro for November-December 2010
- National earthquake protection and rescue plan (2018)
- National fire protection and rescue plan (2018)
- National biological accidents protection plan
- National chemical accidents protection plan
- National action plan in case of a radiation accident
- National flood protection and rescue plan
- National landslide protection plan
- National extreme weather protection plan
- National traffic accident protection plan
- National plan for protection against damage to power plants and hydraulic structures
- National plan for protection against technological hazards
- National plan of search and rescue in civil aviation accidents

## **Emergency response operations**

- SOP for earthquakes
- SOP for floods
- SOP for wildfires
- SOP for fire in closed facilities
- SOP for railway incidents
- SOP for road transportation incidents
- SOP for immediate threat or occurrence of risks with cross-border effects
- SOP for unexploded ordnance
- SOP for engagement of a helicopter
- 2017 Report on the status of the protection and rescue system of Montenegro
- 2018 Report on the status of the protection and rescue system of Montenegro
- 2018 National Plan for Fire Protection and Rescue
- 2018 National Plan for the Protection and Rescue from Earthquakes

## Linking public health and security authorities

- The Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/07, 005/08, 086/09, 032/11, 054/16)
- Report on the Protection and Rescue System 2014
- Report on the Protection and Rescue System 2016
- Report on the Protection and Rescue System 2017
- Report on the Protection and Rescue System 2018
- Response Plan in cases of a communicable diseases outbreak in air transport that represents a risk for public health
- Response Activity Algorithm in case of suspicion/outbreak of Ebola virus (EVO) (2014)
  - » Algorithm for conduct with passengers in international transport due to Ebola importation risk

- » Form for questioning a person that is ill or suspected to be ill from Ebola
- » Form for monitoring the health condition of a person placed under surveillance/quarantine
- » Possible Ebola outbreaks in Montenegro and Activity Algorithm
- » Sequence of procedures in terms of proper personal protective gear handling
- Personal protective gear in case of Ebola importation
- Interim recommendations for infection control and care of patients with suspected or confirmed Phylovirus Haemorrhagic Fever (Ebola, Marburg)
- Recommendations for vessels
- Recommendations for international air transport
- Preparedness and Response Plan for Pandemic Flu Outbreak in Montenegro
- Law on Protection of Population from Communicable Diseases (Official Gazette of Montenegro, No. 12/18)
- National Action Plan for Protection from Chemical, Biological, Radiological, and Nuclear Risks (CBRN) 2016-2020
- Strategy for Non-proliferation of Weapons of Mass Destruction for 2016-202
- Decree on the Appointment of Operational Team for Protection and Rescue (Official Gazette of Montenegro, No. 52/17)
- Draft Decision on setting up a National Coordination Body for Non-proliferation of Weapons of Mass Destruction
- Public Administration Law (Official Gazette of Montenegro, No. 078/18)

## Medical countermeasures and personnel deployment

- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 31/07, 5/08, 32/11, 54/16)
- Strategy for Disaster Risk Reduction with Activity Plan for 2018-2023
- Law on Budget and Fiscal Responsibility (Official Gazette of Montenegro, Nos. 20/14, 56/14, 70/2017)
- Law on Public Procurement (Official Gazette of Montenegro, Nos. 42/11, 57/14, 28/15, 42/17).
- Law on International Development Cooperation and Sending International Humanitarian Aid (Official Gazette of Montenegro, No. 38/18).
- Law on the Red Cross of the RoM (Official Gazette of the RoM, No. 28/06).
- Preparedness Plan for pandemic influenza
- Law on Labour (Official Gazette of Montenegro, Nos. 49/2008, 26/2009 88/2009, 26/2010, 59/2011, 66/2012, 31/2014, 53/2014, 4/2018)

# **Risk communication**

- News of the Institute of Public Health of the Ministry of Health (www.ijzcg.me)
- News of the Ministry of Health website (http://www.mzdravlja.gov.me/press-centar)
- Public Relations Department of the Ministry of Interior (http://www.mup.gov.me/press-centar)
- Action plan for the implementation of the strategy for disasters risk reduction for 2018-2019
- National plans for protection and rescue from various hazards

## **Points of entry**

- Border Control Law (Official Gazette of Montenegro, Nos. 72/09, 39/13, 17/19)
- State Property Law (Official Gazette of Montenegro, Nos. 21/09, 40/11)
- Law on Protection of Population from Communicable Diseases (Official Gazette of Montenegro, No. 12/18)

- Air Transport Law (Official Gazette of Montenegro, No. 30/2012) changes and amendments (Official Gazette of Montenegro, No. 30/2017)
- Rulebook on conditions and procedures for providing emergency medical assistance at airports (Official Gazette of Montenegro, No. 62/2012)
- Rulebook on provision of firefighting-rescue services at airports (Official Gazette of Montenegro, No. 47/2012)
- Integrated Border Management Strategy 2014-2018
- Special Agreement on setting up coordination teams for the implementation of the Integrated Border Management Strategy and related Action Plan
- House rules at points of entry
- Framework Action Plan for the implementation of Integrated Border Management Strategy 2014-2018
- Extension of the Integrated Border Management Strategy and related Action Plan for 2019
- Preparedness and Response Plan to Pandemic Flu Outbreak in Montenegro 2017
- Activity Algorithm for conduct in case of suspicion/illness from Ebola virus (EVO) /from 2014
- Contingency Plan in case of communicable disease outbreak in air transport, which represents a threat to public health (draft)
- National Contingency Plan for protection from bird flu and flu pandemic, October 2005

## **Chemical events**

- Law on Environment (Official Gazette of Montenegro, No. 52/16)
- Rulebook on Content of the Prevention Plan and the Accident Protection Plan (Official Gazette of Montenegro, No. 67/16)
- Rulebook on quantities of hazardous substances by categories that determine the degree of risk of Seveso plants (Official Gazette of Montenegro, No. 67/16)
- Law on Chemicals (Official Gazette of Montenegro, No. 51/17), Law on biocidal products (Official Gazette of Montenegro, No. 51/17)
- Law on the Ratification of the Stockholm Convention on Persistent Organic Pollutants (Official Gazette of Montenegro, International Agreements, No. 16/10, 4/14, 9/17)
- Law on the Ratification of the Rotterdam Convention on the Proceeding of Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade (Official Gazette of Montenegro, International Agreements, No. 3/11)
- Law on the Ratification of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Official Gazette of Montenegro, International Treaties", No. 2/99)
- Law on the Ratification of the Convention on the Transboundary Effects of Industrial Accidents (Official Gazette of Montenegro, International Agreements, No. 42/2009)
- 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, International Treaties, No. 2/99)
- Law on Ratification of the Minamata Convention on Mercury (Official Gazette of Montenegro, International Agreements, No. 3/19)
- Law on protection and rescue (Official Gazette of Montenegro, Nos. 13/07, 5/08, 32/11, 54/16)
- Rulebook on content and methodology of preparation, method of harmonization, updating and keeping of the risk assessment study on the basis of which are expressed the Protection and Rescue Plans (Official Gazette of Montenegro, No. 31/17)
- Law on the Transport of Dangerous Goods (Official Gazette of Montenegro, Nos. 13/07, 5/08, 32/11, 54/16)

- Law on Health and Safety at Work (Official Gazette of Montenegro, Nos. 34/14, 44/18)
- Rulebook on occupational health and safety at work on the risk of exposure to chemical substances (Official Gazette of Montenegro, Nos. 81/16, 30/17, 40/18)
- National strategy for chemicals management 2019-2022 with Action plan for 2019-2022 (http://www.mrt.gov.me/biblioteka/strategije)
- National plan for implementation Stockholm Convention 2014-2022
- National strategy on sustainable development 2030
- National Plan for Protection and Rescue on case of chemical incident
- Information on the condition of the environment (environmental monitoring data), Environmental Protection Agency of Montenegro (https://epa.org.me/informacije-o-stanju-zivotne-sredine/)
- Programme of measures on food and food safety for 2019 (Official Gazette of Montenegro, No. 8/19)
- Programme on monitoring the environment, food safety, pesticides, nitrates

#### **Radiation emergencies**

- Strategy for Disaster Risk Reduction and Action Plan for Implementation of the Strategy for 2018-2023
- Strategy for protection against ionizing radiation, radiation safety and radioactive waste management for 2017-2021, and Action Plan for 2017-2021
- National Security Strategy of Montenegro
- Defence Strategy of Montenegro
- Strategy for the Prevention and Suppression of Terrorism, Money Laundering and Terrorist Financing for the period 2015-2018 and Action Plan
- Strategy on Non-proliferation of Weapons of Mass Destruction (2016-2020)
- Action Plan for the Implementation of the Strategy on Non-Proliferation of Weapons of Mass Destruction (Action Plan for the implementation of the United Nations Security Council Resolution 1540 (2014-2018))
- National Action Plan for the Protection of Chemical, Biological, Radiological and Nuclear Threats and Risks (CBRN) for 2016-2020
- Integrated Nuclear Safety Support Plan (INSSP) and Action Plan for its implementation for 2017-2019
- Law on Protection against Ionizing Radiation and Radiation Safety (Official Gazette of Montenegro, Nos. 56/09, 58/09, 40/11, 55/16)
- List of all subordinate legislation supporting the implementation of the Law on Protection against Ionizing Radiation and Radiation Safety (Official Gazette of Montenegro, Nos. 56/09, 58/09, 40/11, 55/16)
- Law on Protection and Rescue (Official Gazette of Montenegro, Nos. 013/07 and 054/16)
- Law on Transportation of Hazardous Goods ("Official Gazette of Montenegro", Nos. 33/14 and 13/18);
- Decree on organization and manner of work of the state administration (Official Gazette of Montenegro, No. 087/18) (competences of the Ministry of Sustainable Development and Tourism and Environmental Protection Agency)
- European Union IPA Project "Strengthening Radiation Protection and Nuclear Safety in Montenegro through Improvement of Capacity of the Public Institution", Centre for Ecotoxicological Research of Montenegro
- Law on Environment (Official Gazette of Montenegro, No. 052/16)
- Environmental monitoring programme
- Information on the state of the environment

- Regulation on Ratification of the Convention on Early Notification of Nuclear Accidents (Official Gazette of FRY, International Treaties, No. 015 / 89-3)
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency Convention on Assistance in the Case of a Nuclear Incident or Radiological Hazard, Vienna (Official Gazette of FRY, International Treaties, No. 004/91-29)
- Law on the Ratification of the Agreement between the European Atomic Energy Community (Euratom) and non-member States of the European Union on the participation of the latter in the Community arrangements for the early exchange of information in the event of radiological emergency (Ecurie) (Official Gazette of Montenegro, International Treaties, No. 002/17)
- First national report on the implementation of obligations arising from the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
- Second National Report on the implementation of obligations arising from the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
- Third National Report on the implementation of obligations arising from the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
- First National Report on the implementation of obligations arising from the Convention on Nuclear Safety
- Convention on Early Notification of Nuclear Accidents 2007
- Vienna Convention on Civil Liability for Nuclear Damage 2007
- Convention on the Physical Protection of Nuclear Material 2007
- Nuclear Non-Proliferation Treaty 2007
- Agreement on the Prohibition of Experiments with Nuclear Weapons in the Atmosphere, Space and Underwater 2007
- Agreement on the Prohibition of the Placement of Nuclear and Other Weapons of Mass Destruction at the Seas and Ocean Sea and Their Underground 2007
- Contract for Comprehensive Nuclear Test Ban with Protocol 2007
- Joint Convention on Safety of Fuel Management and Radioactive Waste Management 2010
- Agreement on Protective Measures, Additional Protocol and Small Quantity Protocol 2010
- Protocol on Amendments to the Vienna Convention on Civil Liability for Nuclear Damage 2010
- Convention on the Supplementary Compensation for Nuclear Damages 2011
- Convention on Nuclear Safety 2015
- Amendments to the Convention on the Physical Protection of Nuclear Material 2016
- International Convention on the Suppression of Nuclear Terrorism Act 2007
- Agreement between the European Atomic Energy Community (EURATOM) and non-EU Member States on the participation of the latter in the Community Emergency Information Exchange System (ECURIE) 2017
- Joint Protocol on the Application of the Vienna Convention and the Paris Convention 2018
- Code of Conduct on Safety and Security of Radioactive Sources and Additional Guide on Import and Export of Radioactive Sources and Additional Guide to the Management of Utilized Closed Radioactive Sources
- Agreement on Privileges and Immunities of the International Atomic Energy Agency and the IAEA Statute



