

JOINT EXTERNAL EVALUATION  
OF IHR CORE CAPACITIES  
of the

**REPUBLIC OF  
NORTH MACEDONIA**

**Mission report:**  
**11–15 March 2019**





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- The WHO Regional Office for Europe.
- The Global Health Security Agenda Initiative for its collaboration and support.

# ABBREVIATIONS

<b>ACI</b>	Airports Council International
<b>AFP</b>	acute flaccid paralysis
<b>AEP</b>	airport emergency plan
<b>AIRSAN</b>	coordinated EU action in the aviation sector to control public health threats
<b>AMR</b>	antimicrobial resistance
<b>BCG</b>	Bacillus Calmette–Guérin
<b>CAA</b>	Civil Aviation Agency
<b>CAESAR</b>	Central Asian and Eastern European Surveillance of Antimicrobial Resistance
<b>CAPSCA</b>	Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation
<b>CLSI</b>	Clinical & Laboratory Standards Institute
<b>CMC</b>	Crisis Management Centre
<b>CoE</b>	centres of excellence
<b>CPH</b>	Centre for Public Health
<b>EFSA</b>	European Food Safety Authority
<b>EPI</b>	WHO Expanded Programme on Immunization
<b>EUCAST</b>	European Committee on Antimicrobial Susceptibility Testing
<b>FAO</b>	Food and Agriculture Organization of the United Nations
<b>FVA</b>	North Macedonia Food and Veterinary Agency
<b>GLASS</b>	WHO Global Antimicrobial Resistance Surveillance System
<b>GP</b>	general practitioner
<b>HACCP</b>	hazard analysis critical control point
<b>HCAI</b>	health care associated infection
<b>HPV</b>	human papillomavirus
<b>IAEA</b>	International Atomic Energy Agency

<b>IATA</b>	International Air Transportation Association
<b>ICAO</b>	International Civil Aviation Organization
<b>ILI/ARI</b>	influenza-like illness/acute respiratory infection
<b>INFOSAN</b>	International Food Safety Authorities Network
<b>IPC</b>	infection prevention and control
<b>IPH</b>	Institute of Public Health
<b>ISO</b>	International Organization for Standardization
<b>MALMED</b>	Macedonian Agency for Medicines and Medical Devices
<b>MCV</b>	measles containing vaccine
<b>MKFFIS</b>	Macedonia Forest Fire Information System
<b>MMR</b>	measles, mumps, rubella
<b>MOH</b>	Ministry of Health
<b>OIE</b>	World Organisation for Animal Health
<b>PHC</b>	public health centre
<b>PHEIC</b>	public health emergency of international concern
<b>POE</b>	point of entry
<b>PPE</b>	personal protective equipment
<b>PR</b>	public relations
<b>PRD</b>	Protection and Rescue Directorate
<b>RASFF</b>	Rapid Alert System for Food and Feed
<b>RSD</b>	Radiation Safety Directorate
<b>SOP</b>	standard operating procedure
<b>WAHIS</b>	World Animal Health Information System



# EXECUTIVE SUMMARY

The JEE team would like to express its appreciation to the Republic of North Macedonia for volunteering for a Joint External Evaluation. This shows a commitment, foresight and leadership from senior levels of government that will be critical to success in building and maintaining North Macedonia's core capacities under the International Health Regulations (IHR (2005)).

## Findings from the joint external evaluation

The Republic of North Macedonia acknowledges the importance of communicable disease control, surveillance and response, and regulates the area with comprehensive laws and by-laws. The country has a dedicated workforce that includes qualified medical and public health professionals, veterinarians, preparedness experts and laboratory specialists. There is multi-level, multisectoral, centrally coordinated capacity to respond to emergencies, and the country has international coordination mechanisms that have been developed under the IHR framework.

During the JEE mission, North Macedonia's capacities in 19 technical areas were evaluated through a peer-to-peer, collaborative process that brought subject matter experts together with members of the JEE team for a week of collaborative discussion and field visits. This process led to consensus on scores and priority actions in those 19 areas.

Once the JEE process is concluded, these priority actions should be captured in a National Action Plan for Health Security, with detailed costing of activities.

Four overarching recommendations emerged from the week. These are intended to address cross-cutting challenges affecting North Macedonia's capacities across many of the different technical areas that are explored in greater depth in the JEE process. These overarching recommendations are outlined below.

- 1. North Macedonia should develop and modernize its systems for health security, including through digitalization (for example of paper-based reporting), to improve efficiency and release human capacity. The development process should be based on a comprehensive needs mapping exercise, and funding should be increased gradually over time to ensure the implementation of key priorities to strengthen capacities under the IHR (2005).**
- 2. North Macedonia should secure the human and animal health workforce by providing wider access to up-to-date training and increased professional incentives, thereby strengthening capacity and reducing turnover.**

While the North Macedonian workforce is dedicated, there is insufficient human capacity across the majority of the assessed technical areas, and the country suffers from an ongoing brain drain of public health professionals. Although progress has been made in recent years to address staff shortages, there is a need to make the public health sector more attractive to graduates, through financial and other incentives. A comprehensive workforce strategy is needed, in which it will be important to modernize the workforce towards a multidisciplinary composition that can face new challenges and keep up with developments in—for example—surveillance, risk assessment and outbreak detection. In resource-limited settings, it is crucial to map how best to leverage existing resources for maximum benefit.

**3. North Macedonia should further develop multisectoral collaboration mechanisms and ensure that existing structures and mechanisms are operationalized, including through regular information sharing, joint training and joint simulation exercises.**

Multisectoral collaboration and coordination is needed at all levels: in shaping and implementing legislation; for high-level organization and coordination; and at operational, technical level. Intersectoral information sharing, joint risk assessment and joint incident management should be standard practice. As a short-term priority, North Macedonia should map current obstacles to multisectoral collaboration, and work to overcome existing barriers. Proven interventions to enhance health security include regular joint training of professionals working in human and animal health and other IHR-related hazards; joint field simulation exercises; and after-action reviews of both exercises and real responses to emergencies.

**4. Ensure that the national coordination of IHR relevant activities is rationalized, with a clear legislative basis and well-defined roles and responsibilities for all stakeholders.**

North Macedonia boasts an impressive range of legislation and operational guidance for health emergency and crisis management. Various directorates have closely related responsibilities for emergency response, and these directorates coordinate their actions and report directly and separately to the Prime Ministers' office. In order to create uniformity in the line of command and to streamline actions in a coordinated fashion, North Macedonia should review and rationalize where necessary, the distribution of managerial and operational responsibilities in case of emergencies. The health and other IHR-related sectors would benefit from a clear, uniform coordinating structure.

## **Republic of North Macedonia scores and priority actions**

The table below 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: [http://www.who.int/ihr/publications/WHO\\_HSE\\_GCR\\_2016\\_2/en/](http://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.

## SCORES AND PRIORITY ACTIONS

Technical areas	Indicator no.	Indicator	Score	Priority Actions
<b>PREVENT</b>				
National legislation, policy and financing	<b>P.1.1</b>	The State has assessed, adjusted and aligned its domestic legislation, policies and administrative arrangements in all relevant sectors to enable compliance with the IHR	<b>4</b>	Allocate a sufficient budget to the implementation of all IHR capacities, and increase visibility of funding related to IHR in all sectors. Allocate dedicated budget lines to IHR activities at the national and subnational levels in all relevant sectors. Conduct further assessment of IHR-related legislation, and identify and implement the adjustments required to achieve a complete legislative framework for the IHR (2005).
	<b>P.1.2</b>	Financing is available for the implementation of IHR capacities	<b>2</b>	
	<b>P.1.3</b>	A financing mechanism and funds are available for timely response to public health emergencies	<b>2</b>	
IHR coordination, communication and advocacy	<b>P.2.1</b>	A functional mechanism established for the coordination and integration of relevant sectors in the implementation of IHR	<b>3</b>	Strengthen intersectoral cooperation through regular exercises related to different IHR risks, involving all institutions and stakeholders, and testing the functionality of laws, legislation, policies and financial mechanisms. Incorporate lessons from multisectoral and multidisciplinary exercises into the relevant legislation and plans. Invest in a system for 24/7 epidemic intelligence, for monitoring risks.
Antimicrobial resistance	<b>P.3.1</b>	Effective multisectoral coordination on AMR	<b>3</b>	Adopt and implement the National Programme and Action Plan for the Control of Antimicrobial Resistance in all relevant sectors and disciplines.
	<b>P.3.2</b>	Surveillance of AMR	<b>3</b>	Implement strategies to increase the number and quality of samples.
	<b>P.3.3</b>	Infection prevention and control	<b>2</b>	Establish and implement a national infection prevention and control programme, including a strategy for the control and prevention of HCAI and additional guidelines for improving biosecurity in the veterinary sector.
	<b>P.3.4</b>	Optimize use of antimicrobial medicines in human and animal health and agriculture	<b>2</b>	Continue developing specific national and local guidelines for prudent antibiotic use for diseases of national importance in the public health sector, and initiate development for the veterinary sector. Ensure that the guidelines are implemented. Implement antimicrobial stewardship programmes.

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Zoonotic disease	P.4.1	Coordinated surveillance systems in place in the animal health and public health sectors for zoonotic diseases/ pathogens identified as joint priorities	2	Develop a joint, national multisectoral strategy for zoonoses, involving all stakeholders, including the environment and wildlife sectors. This should include a jointly developed list of priority zoonotic diseases and mechanisms for fully formalizing regular communication and cooperation between sectors.
	P.4.2	Mechanisms for responding to infectious and potential zoonotic diseases established and functional	2	Establish a joint coordinating body, with defined roles and responsibilities that meets routinely. Develop mutually agreed intersectoral contingency plans for priority and emerging zoonotic diseases, including operational plans for joint rapid response teams. Equip veterinary and human health professionals with the knowledge and skills required to conduct joint surveillance and response activities for zoonotic diseases, through regular multisectoral trainings, workshops and simulation exercises.
Food safety	P.5.1	Surveillance systems in place for the detection and monitoring of foodborne diseases and food contamination	3	Develop a joint list of priority foodborne diseases and hazards, based on a multisectoral assessment of the disease burden. Develop an electronic system that integrates information from the entire food-chain, and which includes timely and systematic information exchange, in order to improve understanding of risk and mitigation possibilities.
	P.5.2	Mechanisms are established and functioning for the response and management of food safety emergencies	3	Draw on the successful experiences of the brucellosis control programme to develop multisectoral collaboration in food safety. Continue improving laboratory capacities and the application of analytical epidemiology skills at regional and local level, in order to enhance situational awareness on causative agents and outbreak sources. Carry out regular simulation exercises for managing food safety emergencies, testing multisectoral cooperation and evaluating strengths and weaknesses.

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Biosafety and biosecurity	P.6.1	Whole-of-government biosafety and biosecurity system in place for all sectors (including human, animal and agriculture facilities)	2	<p>Conduct a training needs assessment to identify gaps and specific training needs.</p> <p>Nominate a multisectoral team of experts to review existing legislation, including elements of biosafety and biosecurity as outlined in the WHO biosafety manual (WHO, 2004) and WHO biosecurity guidance (WHO, 2006).</p>
	P.6.2	Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture)	1	<p>Expand the current monitoring system for isolation of pathogens to include data on storage/ destruction of pathogens, in order to develop an inventory of pathogens stored within facilities.</p> <p>Advocate for the nomination of reference laboratories for major pathogens under surveillance by the relevant ministries.</p> <p>Review funding needs for the establishment and maintenance of a national biosafety and biosecurity system in all biological laboratories in North Macedonia, including for infrastructure, staff, equipment and continuous training.</p>
Immunization	P.7.1	Vaccine coverage (measles) as part of national programme	3	<p>Conduct a vaccination coverage survey to validate current estimates and improve the quality of coverage information for evidence-based decision-making.</p>
	P.7.2	National vaccine access and delivery	4	<p>Perform a knowledge, attitudes and practices survey to improve understanding of issues around vaccine hesitancy and anti-vaccine attitudes.</p> <p>Conduct multisectoral action on vaccine hesitancy to build and maintain public trust, and develop a strategy for effective risk communication that highlights the importance of vaccination.</p> <p>Continue the development and implementation of the electronic immunization register.</p>
<b>DETECT</b>				
National laboratory system	D.1.1	Laboratory testing for detection of priority diseases	3	<p>Reference laboratories should be officially nominated by the MOH, with an open contest every five years. The nomination should contain the list of pathogens and core functions covered by each reference laboratory.</p>
	D.1.2	Specimen referral and transport system	3	
	D.1.3	Effective national diagnostic network	3	<p>Further strengthen the external quality assessment system and validation capacity for 10 core tests, and encourage labs to undergo the accreditation process for ISO 15189.</p> <p>Appoint a national coordination body for the microbiology laboratory system (both primary and reference laboratories) that will coordinate the network of laboratories, collect and analyse reports and encourage laboratories to implement external quality control and accreditation.</p>
	D.1.4	Laboratory quality system	3	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Surveillance	D.2.1	Surveillance systems	3	Finalize the digitalization of the electronic reporting system for communicable diseases, including with final classifications of reported cases and integration with the laboratory reporting system for confirmed pathogens.
	D.2.2	Use of electronic tools	2	Introduce enhanced surveillance for zoonoses and vector-borne diseases, as well as other prioritized diseases and/or diseases of interest.
	D.2.3	Analysis of surveillance data	3	<p>Improve intersectoral cooperation between the human and animal health sectors, including with regular formalized meetings and data sharing (under the One Health approach).</p> <p>Strengthen human resources at all levels simultaneously, providing continuous education in intervention epidemiology, risk assessment and risk management.</p>
Reporting	D.3.1	System for efficient reporting to FAO, OIE and WHO	3	A national SOP for coordination between the IHR NFP, the OIE delegate, the WAHIS national focal point and other relevant sectors should be written, implemented and tested.
	D.3.2	Reporting network and protocols in country	3	<p>Finalize reporting protocols for chemical, radiation and biological incidents.</p> <p>Establish a permanent team in the MOH for rapid risk assessment, which should be made up of top experts (e.g. epidemiologists, infectious disease clinicians, microbiologists, entomologists, etc.) and which can work with the Commission for Infectious Diseases to provide guidance to the NFPs.</p> <p>An integrated One Health surveillance and reporting system should be established that involves regular communication between the human, animal, wildlife, and environmental health sectors, in order to increase effectiveness and efficiency in reporting to international officials.</p>
Human resources (animal and human health sectors)	D.4.1	An up-to-date multisectoral workforce strategy is in place	2	Develop a long-term workforce strategy with tangible incentives in order to address projected staffing shortages.
	D.4.2	Human resources are available to effectively implement IHR	3	Include field epidemiology in the curriculum of the epidemiology specialization of the Medical Faculty by linking it with Institute of Public Health and Centres for Public Health knowledge hub.
	D.4.3	In-service trainings are available	2	Provide a field epidemiology training programme (FETP) to doctors and epidemiologists as part of the continuous medical education programme.
	D.4.4	FETP or other applied epidemiology training programme in place	3	<p>Engage non-medical health professionals in the FETP programme.</p> <p>Create joint education modules for the veterinary and human health sectors (e.g. on investigating foodborne outbreaks, analytical models, etc.).</p>

Technical areas	Indicator no.	Indicator	Score	Priority Actions
<b>RESPOND</b>				
Emergency Preparedness	R.1.1	Strategic emergency risk assessments conducted and emergency resources identified and mapped	3	<p>Adopt the national multisectoral multi-hazard risk assessment, and develop and test national and subnational multi-hazard, multisectoral emergency preparedness and response plans.</p> <p>Define clear roles and responsibilities between the Crisis Management Centre (CMC) and the Protection and Rescue Directorate (PRD), and improve their coordination and capacities through trainings and regular exercises.</p>
	R.1.2	National multisectoral multi-hazard emergency preparedness measures, including emergency response plans, are developed, implemented and tested	3	<p>Establish an electronic platform for better exchange of information between the CMC and other sectors, and to improve access to national risk assessments and mapping.</p> <p>Adopt a unified national risk assessment methodology, and develop standard operating procedures accordingly.</p> <p>Include relevant sectors, such as animal and environmental health, in the CMC steering committee.</p>
Emergency response operations	R.2.1	Emergency response coordination	3	<p>Establish a small public health emergency operations centre (PHEOC) in the IPH in a multipurpose space (e.g. a meeting or training room), using existing human resources where possible. The PHEOC should be capable of activating during outbreaks within 120 minutes, based on national preparedness plans for the health sector.</p> <p>Engage all stakeholders in assigning response activities for all identified hazards, and update national preparedness plans accordingly.</p> <p>Implement the lessons identified in evaluations of the responses of specific institutions and services during both exercises and real emergencies.</p> <p>Engage with the CMC and the PRD to ensure that ongoing organizational restructuring achieves one unified coordination mechanism for emergencies that ensures clear roles and responsibilities.</p>
	R.2.2	Emergency operations centre (EOC) capacities, procedures and plans	2	
	R.2.3	Emergency Exercise Management Programme	4	
Linking public health and security authorities	R.3.1	Public health and security authorities (e.g. law enforcement, border control, customs) linked during a suspect or confirmed biological, chemical or radiological event	3	<p>Organize joint training and simulation exercises (with a focus on biological and chemical threats) at national level, including all stakeholders in the crisis management system. Cascade the training programme to the regional level.</p> <p>Carry out periodic assessment and testing of existing communication protocols between the public health, veterinary health and security sectors, based on exercises or real events.</p> <p>Map out needs for material resources, and increase capacity accordingly.</p>

Technical areas	Indicator no.	Indicator	Score	Priority Actions
Medical counter-measures and personnel deployment	R.4.1	System in place for activating and coordinating medical countermeasures during a public health emergency	3	<p>Prepare an overview of entities responsible for managing or intervening in a health emergency response at State, regional and/or local level, and disseminate it to all relevant stakeholders, including health facilities, public health bodies, emergency medical teams (EMTs), Red Cross of North Macedonia, relevant NGOs, etc.</p> <p>Develop procedures and State regulations for receiving foreign expertise and EMTs during a public health emergency.</p> <p>Review the roles and responsibilities within the MOH for dealing with medical countermeasures during crises, and ensure that systems are in place to perform the necessary actions when required.</p> <p>Amend the Health Care Law to allow for the formation and recognition of paramedical services.</p>
	R.4.2	System in place for activating and coordinating health personnel during a public health emergency	3	
	R.4.3	Case management procedures implemented for IHR relevant hazards	4	
Risk communication	R.5.1	Risk communication systems for unusual/unexpected events and emergencies	3	<p>Invest in training for communication staff, in order to develop new competencies in strategic communication planning, community engagement and press relations.</p> <p>Develop knowledge and tools for social media monitoring in order to improve understanding of perceptions, emotions and behaviour in the population.</p> <p>Develop strategies to address wrong perceptions, risky behaviours and misinformation and to identify best practices.</p>
	R.5.2	Internal and partner coordination for emergency risk communication	3	
	R.5.3	Public communication for emergencies	3	
	R.5.4	Communication engagement with affected communities	2	
	R.5.5	Addressing perceptions, risky behaviours and misinformation	2	

Technical areas	Indicator no.	Indicator	Score	Priority Actions
<b>IHR-RELATED HAZARDS AND POINTS OF ENTRY</b>				
Points of entry	PoE.1	Routine capacities established at points of entry	4	<p>Integrate existing operational plans (e.g. the Airport Emergency Plan and the protocol for handling and reporting from an international airport entrance point) into finalized national strategic plans (e.g. the National Aviation Contingency Plan and the National Emergency Response Plan).</p> <p>By 2021, create and implement a port-specific, multi-year, multisectoral training and exercise plan that incorporates the lessons of previous exercises.</p> <p>Integrate appropriate data management and reporting of records captured during entry and exit screening into the public health surveillance system.</p> <p>Develop criteria to evaluate the success of multisectoral responses to biological threats or other incidents of concern (e.g. chemical and radiological incidents) at points of entry.</p>
	PoE.2	Effective public health response at points of entry	4	
Chemical events	CE.1	Mechanisms established and functioning for detecting and responding to chemical events or emergencies	2	<p>Identify capacity gaps across all relevant sectors. Develop national capacity building priorities for preventing, detecting and responding to chemical events.</p> <p>Assign an entity, committee or agency to lead the development of IHR capacity for chemicals across sectors.</p> <p>Establish a national chemicals profile and a risk map/register for chemicals (e.g. production, storage, use, waste, contaminated land, etc.).</p> <p>Increase surveillance capacity and the analytical scope (for detection and verification) of laboratories regarding chemicals and their health effects.</p> <p>Improve capacity for dealing with chemical events and casualties. Emergency response planning and risk assessment should also consider the potential for the presence of multiple hazards, including chemicals, and incorporate appropriate precautions and management.</p>
	CE.2	Enabling environment in place for management of chemical events	2	
Radiation emergencies	RE.1	Mechanisms established and functioning for detecting and responding to radiological and nuclear emergencies	4	<p>Establish a national repository for storing radioactive waste.</p> <p>Develop a comprehensive multisectoral training plan to address the needs and criteria of the National plan on Radiological Emergencies.</p> <p>Provide adequate protective materiel, decontamination equipment and personal protective equipment for personnel exposed to radiation sources.</p>
	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 IHR (2005) provide obligations and rights for States Parties. In some States Parties, implementation of the IHR (2005) may require new or modified legislation. Even if new or revised legislation may not be specifically required, States may still choose to revise some regulations or other instruments in order to facilitate IHR implementation and maintenance. Implementing legislation could serve to institutionalize and strengthen the role of IHR (2005) and operations within the State Party. It can also facilitate coordination among the different entities involved in their implementation. See detailed guidance on IHR (2005) implementation in national legislation at [http://www.who.int/ihr/legal\\_issues/legislation/en/index.html](http://www.who.int/ihr/legal_issues/legislation/en/index.html). In addition, policies that identify national structures and responsibilities as well as the allocation of adequate financial resources are also important.

#### Target

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

### LEVEL OF CAPABILITIES

The Republic of North Macedonia has comprehensive laws, legislation and policies in place for all relevant sectors to enable compliance with the IHR (2005). These include the Constitution of the Republic of North Macedonia; laws on crisis management, public health, protection of the population against communicable diseases, food safety, veterinary health, animal feed safety and protection against chemicals and radiation; the Aviation Act; and an order on civil aviation facilitation measures and procedures.

The country is a candidate for European Union (EU) membership and expects to commence membership negotiations soon. Candidate status was granted in 2005, and since then all IHR relevant laws and by-laws have been harmonized with EU legislation.

In 2013, within the framework of the biennial collaborative agreement with WHO, an assessment and analysis of domestic legislation in relation to implementation of the IHR (2005) was performed. The required adjustments have been identified and implemented, with the involvement of all relevant sectors. Further assessment and the identification of necessary adjustments in all areas and sectors should be continued in order to sustain capacity for IHR implementation.

The Law on Public Health legalizes the implementation of basic public health functions and tasks, the workings of the public health system, preparation for and response to public health emergencies, and public health financing. The law stipulates that the Ministry of Health (MOH) decides whether public

health emergencies and/or urgent circumstances reported by the country's regional public health centres (PHCs) are of international importance. The Institute of Public Health (IPH) has been given the defined roles and responsibilities of the IHR (2005) National Focal Point (NFP).

In accordance with the Law on Crisis Management, a crisis management system has been set up for the prevention, early warning and handling of crises (other than a state of war or state of emergency) that represent risks to the goods, health and lives of people and animals, and which are the result of natural disasters and epidemics or other risks and dangers that directly jeopardize the constitutional order and the security of the Republic of North Macedonia, or a part of it.

Although there is no dedicated budget line available for IHR-related capacities, funds related to the implementation of the IHR (2005) and the crisis management system are provided from the State budget as well as from other sources. However, the municipality bodies and the city of Skopje must provide funds for the crisis management system from their own resources as well as from the State budget.

When a crisis is declared, there is a legal option to secure additional financing for crisis response through a decision by the Government of the Republic of North Macedonia.

Funding for the implementation of the IHR (2005) remains a challenge. There is a need to increase funding for IHR implementation, and for human resources recruitment and IHR-related capacity building in all sectors, as an integral part of national policy.

## 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 4**

#### *Strengths and best practices*

- There is comprehensive legislation in place for implementation of the IHR (2005).
- A defined system is in place for crisis management at the national level.
- Protocols exist for IHR implementation (e.g. on biological risks, ionizing radiation, chemicals, points of entry, etc.).
- Protocols exist for cooperation between the IPH, the State Sanitary and Health Inspectorate (SSHI) and the Food and Veterinary Agency (FVA).
- The FVA has prepared an operational plan for food safety management in crisis conditions.
- Hospitals have crisis preparedness and response plans focused on pandemic influenza.

#### *Areas that need strengthening and challenges*

- Intersectoral cooperation for the implementation of the IHR (2005) should be strengthened.
- A budget should be allocated for implementing the legal framework for the IHR (2005).
- There is a lack of human resources and a lack of available training to provide the necessary IHR-related capacities in a range of different areas.
- There is a need for more joint planning and monitoring of activities.

### **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 for essential public health functions related to health security (including disease control).
- IHR relevant sectors are strengthening IHR capacities using their own budgets. In cases of emergency/crisis additional funds can be provided from the State budget.

*Areas that need strengthening and challenges*

- There is a need to increase funds, and the visibility of funds, for activities related to IHR implementation.
- There is a need to increase funding for human resources recruitment and strengthening.
- There should be specific budget lines for IHR implementation in all relevant institutions.

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

- Funds related to IHR implementation are provided by more than one institution.
- The State budget provides a “permanent reserve” for dealing with the consequences of crises and natural disasters.
- In the case of a declared state of emergency, mechanisms are in place to provide additional funds through a decision of the Government of the Republic of North Macedonia for quick and adequate responses to emergencies/crises.

*Areas that need strengthening and challenges*

- There is a need to increase funds and the visibility of funds related to IHR implementation.
- Each ministry/institution should have hazard specific contingency funding plans for specific emergency situations.

**Recommendations for priority actions**

- Allocate a sufficient budget for the implementation of all IHR capacities, and increase the visibility of funding related to IHR in all sectors.
- Allocate dedicated budget lines to IHR activities at the national and subnational levels in all relevant sectors.
- Conduct a further assessment of IHR-related legislation, and identify and implement the adjustments required to achieve a complete legislative framework for the IHR (2005).

# IHR COORDINATION, COMMUNICATION AND ADVOCACY

## INTRODUCTION

The effective implementation of the IHR requires multisectoral/multidisciplinary approaches through national partnerships for efficient alert and response systems. Coordination of nationwide resources, including the designation of a national IHR focal point, which is a national centre for IHR communications, is a key requisite for IHR implementation.

### Target

*Multisectoral/multidisciplinary approaches through national partnerships that allow efficient, alert and responsive systems for effective implementation of the IHR (2005). Coordinate nationwide resources, including sustainable functioning of a national IHR focal point – a national centre for IHR (2005) communications which is a key requisite for IHR (2005) implementation – that is accessible at all times. States Parties provide WHO with contact details of national IHR focal points, continuously update and annually confirm them.*

## LEVEL OF CAPABILITIES

North Macedonia has clear, well-structured standard operating procedures (SOPs) used by general practitioners (GPs) and hospitals to alert their local PHC in case of a suspected public health emergency. Local centres alert their regional counterparts, who will in turn inform the MOH and the IPH, including the NFP. The MOH assesses the situation and decides whether the health emergency is of international concern. If so, it asks the IPH to notify WHO. All actors involved seem to have a clear understanding of their roles and responsibilities and of the importance of notifying possible threats to public health.

Coordination, communication and advocacy have been built into SOPs and accompanying legislation, creating awareness about the importance of the IHR (2005). The need to cope with serious natural disasters and crises in the past has reinforced this awareness of, and attention to, the importance of the IHR. The same bottom-up system of communication for notifying possible threats is used in a top-down manner when managing a crisis situation.

The national Law on Crisis Management contains the mechanisms for managing a crisis situation by activating a dedicated headquarters at the national CMC, and bringing together all the national ministries, agencies, directorates and stakeholders necessary to mitigate and manage the situation. The same structure and composition is copied at regional level, where local headquarters – including in the municipalities – are set up.

Operational coordination and information exchange is described in detail in a by-law (2018) and in the 2017 Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters and is designed to ensure the intersectoral cooperation and participation of all institutions. With a Steering Committee and Risk Assessment Group installed within the CMC, decision-making takes place at the highest level from the start of an emergency situation and guarantees a whole-of-government approach. The legal possibility of convening a National Coordinating Body for health emergency preparedness and response further guarantees a multisectoral approach. Examples of such an approach include the clear rules that exist for notifying cases of zoonotic diseases in humans and zoonoses in animals.

A somewhat separate procedure is in place under the Law on Veterinary Health. According to this law, the FVA is responsible for conducting surveillance, diagnosis, eradication and prevention of zoonoses and communicable diseases in animals and fulfilling national and international reporting obligations. The law also describes how the FVA cooperates with ministries and other institutions in the case of a serious risk to human or animal health or to the environment. Although both procedures are well detailed, integration into the same system might further raise efficiency and speed of operations.

Field exercises are organized regularly by the main institutions, although not all partners seem to be involved in every exercise. Added value could be created without much additional investment by creating a more common approach to planning, organizing and evaluating exercises. This could make them truly multisectoral and multidisciplinary and lessons could be incorporated into the already very comprehensive plans and legislation.

## Indicators and scores

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

#### *Strengths and best practices*

- An NFP has been appointed.
- A regulatory framework for coordination, communication and reporting is in place.
- A comprehensive plan for health system preparedness and response provides for intersectoral cooperation and involvement of all relevant institutions of the health system.
- There is continuous communication and cooperation/connection with the system for protection and rescue and the system for crisis management.
- IHR implementation is evaluated through simulation exercises (for example, at the Skopje International Airport, or testing border security in the context of Ebola).
- Joint working groups were in place during preparation of the protocols for IHR implementation.

#### *Areas that need strengthening and challenges*

- Intersectoral cooperation should be strengthened.
- There is a lack of personnel and of training related to the IHR (2005).
- There is a need for true 24/7 monitoring of risks by the IPH (thereby strengthening epidemic intelligence).
- Regular IHR-related simulation exercises should be held.
- There is a need for a clear memorandum of understanding (MOU) between the institutions involved in IHR implementation.

### **Recommendations for priority actions**

- Strengthen intersectoral cooperation through regular exercises related to different IHR risks, involving all institutions and stakeholders, and testing the functionality of laws, legislation, policies and financial mechanisms.
- Incorporate lessons from multisectoral and multidisciplinary exercises into the relevant legislation and plans.
- Invest in a system for 24/7 epidemic intelligence, for monitoring risks.

# 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

*Support work coordinated by the Food and Agriculture Organization of the United Nations (FAO), OIE and WHO to develop an integrated global package of activities to combat antimicrobial resistance, spanning human, animal, agricultural, food and environmental aspects (i.e. a One Health approach). Each country has: (i) its own national comprehensive plan to combat antimicrobial resistance; (ii) strengthened surveillance and laboratory capacity at the national and international levels following international standards developed as per the framework of the Global Action Plan; and (iii) improved conservation of existing treatments and collaboration to support the sustainable development of new antibiotics, alternative treatments, preventive measures and rapid point-of-care diagnostics, including systems to preserve new antibiotics.*

## LEVEL OF CAPABILITIES

Antibiotics are widely used in North Macedonia in both the human and animal health sectors. Antimicrobial resistance (AMR) levels are generally high throughout the country, and above the EU average. Data show an overall low number of isolates and suggest disproportionate sampling of infections in more severely ill and pre-treated patients.

The Minister of Health initiated a multisectoral committee on the subject in 2009, followed by a multisectoral commission in November 2018. A first national strategy for the control of AMR 2012–2016 was adopted in 2011. In 2016 a new national strategy for 2017–2021 was adopted by a multidisciplinary team working on the issue, but this has not yet been adopted by the government as national strategy.

A system for surveillance of AMR in human isolates is in place and includes a national network of 30 laboratories that monitor the susceptibility of invasive isolates of bacteria from blood. Although there are two laboratories both working in a fashion similar to that of a national reference laboratory (NRL), there is currently no formally designated NRL for the human health sector.

North Macedonia is a member of the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network and AMR data have been included in CAESAR annual reports since 2013.

In the veterinary sector AMR surveillance is managed by the Faculty of Veterinary Medicine in Skopje, which is also the designated NRL. Until 2018, AMR surveillance targeted only *E. coli* and *Salmonella*; extended AMR surveillance was initiated in 2018 and includes sampling at slaughterhouses and at the retail level, and reporting of AMR results to the European Food Safety Authority (EFSA).

National programmes for the prevention, detection, notification, control and eradication of infections exist in the public health and veterinary sectors. There is no national infection prevention and control (IPC) programme. Hand hygiene campaigns have been in place since 2014, but compliance is not monitored. Guidelines to improve biosecurity on farms are only partly implemented.

By law, antibiotics are available only by prescription in both the public and animal health sectors. The Macedonian Agency for Medicines and Medical Devices (MALMED) ensures that medicines for both human and veterinary use meet prescribed quality, efficiency and safety requirements. Some national guidelines on prudent antibiotic use have been published for several infections in the public health sector.

## Indicators and scores

### P.3.1 Effective multisector coordination on AMR – Score 3

#### *Strengths and best practices*

- The MOH formed a multisectoral AMR committee in 2009, and a new multisectoral AMR commission was formed in November 2018. The commission has a defined job description and commission members are involved in the antibiotic awareness week and national CAESAR meetings.
- A first national strategy for the control of AMR 2012–2016 was adopted in 2011. In 2016 a new national strategy for 2017–2021 was developed and adopted by a multidisciplinary team (though not nationally); its strategic goals are harmonized with the WHO global action plan on AMR.

#### *Areas that need strengthening and challenges*

- The national strategy 2017–2021 should be adopted by the government, with clarification of the funding and human resources for implementing it.
- The multisectoral committee does not hold meetings at regular intervals; in future it should hold regular meetings of all members.
- The agriculture and environment sector should be included in the multisectoral commission.

### P.3.2 Surveillance of AMR – Score 3

#### *Strengths and best practices*

- A network of 30 microbiological laboratories manages the AMR surveillance system in the public health sector. Since 2013, the network has been part of the CAESAR network, and it joined WHO's Global Antimicrobial Resistance Surveillance System (GLASS) in 2017.
- The AMR surveillance system in the veterinary sector is managed by the Faculty of Veterinary Medicine in Skopje, which is also the designated NRL for the veterinary sector. Since 2018, extended surveillance activities have been initiated at slaughterhouses and at the retail level, and AMR results reported to EFSA.
- Consumption of antibiotics in human medicine is monitored by the national health insurance fund.
- Data on the distribution of veterinary antibiotics are monitored through annual sales reports.

#### *Areas that need strengthening and challenges*

- Although there are two laboratories carrying out the functions of an NRL for the human health sector, no such NRL is formally designated. There is a need to formally nominate reference laboratories for AMR.
- The low number of isolates in the public health sector and the overrepresentation of more severely ill and pre-treated patients receiving tertiary care indicate a need for training and guidelines for when and how to take samples and guidelines on reporting AMR.
- Molecular typing is only currently performed by the microbiological laboratory at the Faculty of Veterinary Medicine; these methods should also be introduced in the public health sector.

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

#### *Strengths and best practices*

- National programmes for the prevention, detection, notification, control and eradication of infections exist in the public health and veterinary sectors.
- Hand hygiene campaigns have been in place since 2014 and educational materials are available. Training materials and visuals are distributed to all hospitals and are available on the IPH website.
- There is a national commission for the control of health care associated infections (HCAIs), underpinned by the necessary laws and regulations.
- There are national and local commissions for the control of HCAIs and a person responsible for infection control. All PHCs prepare annual plans for IPC measures and all hospitals should have such a commission.
- Guidelines for improving biosecurity have been developed and distributed for some species.

#### *Areas that need strengthening and challenges*

- A national IPC programme should be developed and implemented.
- A strategy for the control and prevention of HCAIs should be developed and implemented. This should include the stipulation that the national commission for the control of HCAIs develops defined goals and a strategy, and that hospital commissions are functional everywhere. It should also take into account the need for measures to address stigmatization around reporting HCAIs.
- All hospitals should have professionals trained in the prevention and control of HCAIs on their staff and a relevant national training programme should be developed.
- A system should be established to measure implementation of hand hygiene.
- Guidelines for improving biosecurity should be strengthened.
- Guidelines should be developed for good farming practices in the veterinary sector.

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

#### *Strengths and best practices*

- MALMED ensures that medicines on the market for both human and veterinary use comply with prescribed quality, efficiency and safety requirements.
- The use of antibiotics as a growth promoter in animal feed is prohibited.
- By law, antibiotics are available by prescription only in both the public health and animal sectors.
- National guidelines on the appropriate use of antibiotics in public health have been developed for several diseases.
- General guidelines for the appropriate use of antibiotics have been developed for the veterinary sector.
- Several studies have been done on antibiotic use in health care facilities.

#### *Areas that need strengthening and challenges*

- There is a need to build professional knowledge and understanding of AMR and effective management of antibiotic use.
- There is a need to enforce the requirement for a prescription when acquiring antibiotics.
- Antimicrobial stewardship programmes should be established at both hospital and community levels.
- National guidelines on the appropriate use of antibiotics for specific diseases should be developed for the veterinary sector.
- A programme should be established to increase the responsible use of antibiotics.

- Multisectoral working groups must be nominated to revise the national guidelines for diagnosis and treatment of specific diseases.
- Multisectoral teams should be established to work on the rational and responsible use of antibiotics in hospitals. These teams should develop a protocol for the rational prescription and use of antibiotics, including a national roadmap.
- National AMR data should be used in the preparation of national and local guidelines for therapy.
- There is a need to enhance control over the prescribing habits of doctors and the requirement for a prescription in order to release antibiotics.
- There is a need for further education of the institutions responsible for controlling prescriptive habits and to establish mechanisms for the direct education of those who do not follow the guidelines.
- Hospital pharmacists should be trained in implementing AMR surveillance.

### Recommendations for priority actions

- Adopt and implement the National Programme and Action Plan for the Control of Antimicrobial Resistance in all relevant sectors and disciplines.
- Implement strategies to increase the number and quality of samples.
- Establish and implement a national IPC programme, including a strategy for the control and prevention of HCAs and additional guidelines for improving biosecurity in the veterinary sector.
- Continue developing specific national and local guidelines for prudent antibiotic use for diseases of national importance in the public health sector and initiate development for the veterinary sector. Ensure that the guidelines are implemented.
- Implement antimicrobial stewardship programmes.

# 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 is of animal origin; and approximately 60% of all human pathogens are zoonotic.

### Target

*Adopted measured behaviours, policies and/or practices that minimize the transmission of zoonotic diseases from animals into human populations.*

## LEVEL OF CAPABILITIES

North Macedonia has a comprehensive regulatory and organizational framework for zoonoses in both the human and animal sectors. There is no national multisectoral policy or strategy on zoonoses. There is traditionally good cooperation between the health and veterinary sectors, and this has been formalized in recent years by intersectoral Memoranda of Cooperation in 2013 and 2015. Multisectoral committees/bodies include the Committee for Communicable Diseases at the MOH and the National Centre for Disease Control at the FVA, and these meet ad hoc to implement coordinated activities, including joint risk assessments for zoonotic disease and other events.

There is no official list of priority zoonotic diseases agreed jointly between the animal health and public health sectors. Zoonotic diseases are listed in laws and by-laws for human and animal health, and are included within routine human and animal health surveillance systems. Additional project surveillance programmes are planned and implemented by both sectors. There are links between the FVA information system and the laboratory information system.

Routine epidemiological reports (weekly, monthly and annually), as well as situational awareness reports and reports of potential disease outbreaks, are shared regularly with the FVA by the IPH and regional centres for public health (CPHs), but only on request will the FVA share reports with the IPH. The exception is for brucellosis, for which all reports and surveys are exchanged routinely between the two sectors. There is effective but largely informal communication between the IPH, the FVA, the SSHI and the staff of the CPHs on zoonotic disease outbreaks, and for collaboration on national and international projects.

All laboratories are obliged to report isolates of all zoonoses and foodborne diseases to the IPH, the MOH, the SSHI and the FVA within 48 hours. There is no routine process for sharing biological specimens or surveillance reports between the public health and animal health laboratories, except for in unexpected or emergency situations (such as the outbreaks of listeriosis in 2014 and hantavirus in 2017).

Prevention and control policies exist for brucellosis and rabies, and are carried out in accordance with separate laws and by-laws. Only brucellosis is regulated by a separate annual programme, and the prevalence of bovine brucellosis has decreased significantly. There is an existing action plan for managing vector-borne diseases, with a focus on West Nile fever.

The MOH has developed a multisectoral pandemic influenza preparedness plan that includes avian influenza, and the FVA has an Urgent Measures Plan. No other joint plans or strategies exist for responding to zoonotic diseases. No exercise has occurred in the last two years involving investigation of and joint response to a zoonotic event. Previous exercises conducted for avian influenza and food safety and the tularaemia outbreaks in 2010 and 2015/6 involved effective information sharing and joint response. These responses included public health epidemiologists, the FVA, the SSHI and microbiologists.

## 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 2\***

\*North Macedonia has zoonotic disease surveillance in place for the zoonotic diseases of greatest public health concern, which would merit a score of 3, but has yet to reach multisectoral agreement on five priority zoonotic pathogens. The score of 2 was agreed on the understanding that this activity is planned, and will be carried out in the near future.

#### *Strengths and best practices*

- There is comprehensive separate legislation in the human and veterinary health sectors, and related laws, rulebooks, action plans and programmes.
- There is a dedicated programme for brucellosis, with specific surveillance systems and laboratory networks in both the human and animal sectors, and good intersectoral collaboration.
- There is an existing action plan for managing vector-borne diseases (with a focus on West Nile fever), for which measures and activities continue to be applied.
- There was excellent multisectoral management of the listeriosis outbreak in 2014, with early laboratory confirmation, timely response in the field and quick, effective identification of the source.

#### *Areas that need strengthening and challenges*

- There is no official list of priority zoonotic diseases of greatest national public health concern that has been agreed among sectors.
- Common strategic documents and operational plans for both sectors need to be developed.
- Intersectoral cooperation agreements need to be updated in line with the current situation, clearly defining roles, responsibilities and goals.
- The exchange of epidemiological and laboratory data and other information between the human and animal health sectors needs to be enhanced. Multisectoral exchanges should be routine and regular and should not only take place in outbreak/emergency situations.
- There are insufficient reagents and equipment for laboratories because procurement is not timely.

### **P.4.2 Mechanisms for responding to infectious and potential zoonotic diseases established and functional – Score 2**

#### *Strengths and best practices*

- Multisectoral expert/professional bodies are in place as mechanisms for response to zoonotic diseases: the Commission for Infectious Diseases (at the MOH) and the National Centre for Disease Control (at the FVA).
- Sector-specific SOPs, guidelines, protocols and other documents are shared between sectors during outbreaks or when required.
- Effective informal intersectoral collaboration and communication takes place for international projects, training and exercises and during outbreaks.
- The veterinary sector has a relatively satisfactory level of human and material resources.

#### *Areas that need strengthening and challenges*

- There is a strong need to implement a documented multisectoral national policy/strategy on zoonotic disease.
- Formalized functional intersectoral cooperation and coordination are required (including cooperation agreements for the regulation of all relevant areas, prompt exchange of data and information between both sectors and coordinated investigation by joint rapid response teams).

- Mutually agreed SOPs, guidelines and instructions need to be developed, including operational plans for joint responses involving both sectors.
- Regular intersectoral training and simulation exercises should be held.
- Human and material resources are inadequate throughout the public health sector.

### Recommendations for priority actions

- Develop a joint, national multisectoral strategy for zoonoses, involving all stakeholders including the environment and wildlife sectors. This should include a jointly developed list of priority zoonotic diseases and mechanisms for fully formalizing regular communication and cooperation between sectors.
- Establish a joint coordinating body with defined roles and responsibilities, which meets routinely.
- Develop mutually agreed intersectoral contingency plans for priority and emerging zoonotic diseases, including operational plans for joint rapid response teams.
- Equip veterinary and human health professionals with the knowledge and skills required to conduct joint surveillance and response activities for zoonotic diseases, through regular multisectoral training, workshops and simulation exercises.

# FOOD SAFETY

## INTRODUCTION

Food- and waterborne 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

*Surveillance and response capacity among States Parties for food- and waterborne disease risks or events by strengthening effective communication and collaboration among the sectors responsible for food safety, and safe water and sanitation.*

## LEVEL OF CAPABILITIES

Under the Law on Food Safety, the FVA is the designated central competent authority for food safety. The FVA is responsible for the prevention, early detection, notification and eradication of zoonoses in animals, including diseases transmitted by food of animal origin.

The MOH is responsible for the national annual public health programme and hosts an active contact point for the International Food Safety Authorities Network (INFOSAN). That contact point communicates with the NFP for rapid notification and alerts for food and feed, which communicates with the EU's Rapid Alert System for Food and Feed (RASFF). The process of communication is guided by SOPs.

The SSHI sits within the MOH, with the main purpose of organizing, monitoring and inspecting the implementation of legislation. In the case of foodborne outbreaks, SSHI inspectors are members of the response teams.

The IPH is responsible for monitoring, investigation and analysis of the epidemiological situation, and solving problems related to infectious diseases.

The food institute within the Faculty of Veterinary Medicine is responsible for research, education, development and application of hygiene measures and technology with reference to food products of animal origin. Their laboratory tests food and feed, including the use of molecular typing of microbiological isolates in food.

The FVA implements an annual programme for monitoring food safety focusing on certain microbiological (Salmonella, Listeria monocytogenes) and chemical (residues of pesticides, heavy metals, mycotoxins) hazards. There are regular annual plans for the eradication of brucellosis that are implemented in a process coordinated jointly by the health and veterinary sectors.

One of the 10 goals of the public health programme is to reduce the burden of diseases that are transmitted by food and water.

There is an established system of surveillance and monitoring of foodborne diseases; however, some points in this system – especially at the regional and local level – could be improved. For example, a joint list of priority hazards does not exist.

Coordination mechanisms and rapid information exchange for foodborne outbreaks have been established, but there is no clear, formalized procedure for routine information exchange for multisectoral cooperation, and no national mechanism for collecting and sharing relevant information for collective evaluation.

## Indicators and scores

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

#### *Strengths and best practices*

- The competent authorities have defined food safety responsibilities that are established in a legal and institutional framework.
- There is an established system for surveillance and monitoring of foodborne diseases.
- Epidemiologists, laboratory staff and inspectors are appropriately trained.
- Laboratories are capable of performing the necessary tests, and molecular typing can be performed by the microbiological laboratory at the Faculty of Veterinary Medicine.
- Every year, the FVA implements a programme for monitoring food safety, focusing on certain microbiological and chemical hazards and which includes a programme for the reduction of brucellosis.
- One goal of the national annual programme for public health is the reduction of food- and waterborne diseases.
- There is an operation protocol for competent institutions in the case of suspicion and occurrence of alimentary infections and intoxications.
- In December 2018, a national protocol for cooperation in foodborne disease outbreaks, specifying the tasks and obligations of all stakeholders, was harmonized and signed.

#### *Areas that need strengthening and challenges*

- A list of priority diseases and hazards related to foodborne pathogens and chemicals should be jointly developed by an intersectoral working group.
- Rates of some pathogens causing food- and waterborne diseases are grossly below EU averages, suggesting a major underestimation of the disease burden. A system should be developed to improve the isolation and detection of foodborne agents.
- Improvement of laboratory capacities and the application of analytical methods at regional and local levels should be continued.
- The implementation of molecular typing for outbreak investigations should be evaluated.
- Certified training for all relevant stakeholders (food inspectors, sanitary inspectors, etc.) is needed, including joint training for health care workers and inspectors from SSHI and FVA around reporting events related to unsafe food.

### P.5.2 Mechanisms are established and functioning for the response and management of food safety emergencies – Score 3

#### *Strengths and best practices*

- A national and operational plan for crisis management for food and feed safety was in place for 2014–2018, and a new one for 2019–2024 has been adopted. The plan has procedures for response, definitions and thresholds for alarms and warnings, coordination mechanisms and clear roles and responsibilities. All relevant stakeholders were included in the process of developing and adopting the general and operational plans.
- Coordination mechanisms for foodborne outbreaks have been established and there are mechanisms for rapid information exchange.
- At least one representative from the microbiological laboratory is a member of the team for rapid response to outbreaks.
- North Macedonia has contact points for food safety (i.e. the NFP, the INFOSAN emergency contact point and the RASFF national contact point) and related SOPs are in place.

*Areas that need strengthening and challenges*

- Routine information exchange and liaison between the epidemiology service, reference laboratories and sanitary and veterinary inspectorates is limited and should be improved.
- Food safety procedures are legally defined, but there is no clear formalized procedure for routine information exchange for multisectoral cooperation and no national mechanism for collecting and sharing relevant information for collective evaluation. The multisectoral processes dealing with brucellosis should be taken as a good example for developing processes for other foodborne diseases.
- No simulation exercises have been conducted on food safety emergencies. A simulation exercise with unsafe food should be held to test coordination mechanisms between different sectors.
- A national database should be developed for food safety and should be sent testing data from all laboratories.
- There should be regular analysis and evaluation of food safety data, followed by recommendations for future work.
- There should be a regular evaluation of foodborne diseases at least once a year, carried out by an intersectoral expert group.

**Recommendations for priority actions**

- Develop a joint list of priority foodborne diseases and hazards, based on a multisectoral assessment of the disease burden.
- Develop an electronic system that integrates information from the entire food-chain and which includes timely and systematic information exchange, in order to improve the understanding of risk and mitigation possibilities.
- Draw on the successful experiences of the brucellosis control programme to develop multisectoral collaboration in food safety.
- Continue improving laboratory capacities and the application of analytical epidemiology skills at regional and local level, in order to enhance situational awareness of causative agents and outbreak sources.
- Carry out regular simulation exercises for managing food safety emergencies, testing multisectoral cooperation and evaluating strengths and weaknesses.

# BIOSAFETY AND BIOSECURITY

## INTRODUCTION

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

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

### Target

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

## LEVEL OF CAPABILITIES

The Republic of North Macedonia has a strong legislative basis for its public health system, and biosafety is no exception. Preventive measures and immunization of workers are covered by a rulebook on the minimum health and safety criteria for workers for risks connected to exposure to biological agents. There is a law on Genetically Modified Organisms (2008, 2013) and there are guidelines for the safe management of medical waste.

Laws governing biosecurity are not as well established. The practice of biosafety is left to individual laboratories, and not all laboratories have written guidance documents for biosafety procedures. During medical education and specialized training, medical staff are well-trained and follow good biosafety practice, but there is no mechanism to monitor overall practices at the laboratory level. The microbiology laboratory at the IPH is undergoing accreditation as the National Influenza Centre and as part of this process is required to document its biosafety procedures.

While there is no regular relevant national training following initial qualifications, some individual staff members are accessing external training offerings, such as: the South Eastern European Influenza Laboratory Management Course (two persons); the Centers for Disease Control and Prevention/ Association of Public Health Laboratories Southeast Europe Biosafety Course (two persons); and training on chemical, biological, radiological and nuclear (CBRN) threats (three persons). They also access other national training courses, such as the Knowledge Development and Transfer of Best Practices on Biosafety/Biosecurity/Biorisk Management; training offered within the framework of the EU CBRN Centre of Excellence Project 3 (applicable to mixed laboratories, microbiological, biochemical and veterinary laboratories, and laboratories for food investigation and forensics); and internal biosafety training for staff at the IPH. The NRL for the veterinary sector conducts regular training on request, and could be used as a resource for continuing education in laboratory biosafety and biosecurity, with appropriate funding allocated for the purpose.

There are currently two national systems for laboratory accreditation. The first is offered by the Institute for Accreditation, from which laboratories can request and pay for accreditation. The health insurance scheme reimburses costs for laboratory services from accredited laboratories. Very few laboratories have taken up this option due to the expense.

The other option is offered by the Agency for Accreditation and has just been introduced as part of an overall programme to accredit all institutions in the health sector. At the time of writing in March 2019, hospitals are being accredited; later the programme will move to accredit laboratories. This accreditation process will be free. Under this scheme laboratories should be evaluated every year, although it is not yet stipulated what this evaluation will examine. Staff training and biosafety protocols could be included in this evaluation.

In terms of biosecurity, laboratories need to report on the causative agents of communicable disease as per the list of 56 agents subject to obligatory reporting, or whenever a bacterium with unusual resistance to antibiotics is isolated. Records are kept in a special Isolated/Confirmed Causative Agents Log, and reports are sent within 48 hours to the appropriate PHC, the IPH, the MOH and the SSHI. For zoonotic agents, reports are sent to the FVA. Each of the participating institutions in this system must keep records. The IPH uses the SPSS Statistics program for inputting, processing and evaluating laboratory isolates, and monthly reports are prepared that contain analysed data on isolated/confirmed causative agents. These are later published in the Bulletin for the Spread of Communicable Diseases, as well as in quarterly reports. This system could form the basis for an inventory of potential pathogens in the country, with the addition of information on whether the isolate has been stored or destroyed. The veterinary laboratory has a biosafety officer, and pathogenic isolates are kept in a locked facility at -80°C.

Research projects involving the use of pathogens must undergo clearance by an ethics committee.

## 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*

- Existing legislation covers most of the principles related to biosafety (but is less comprehensive for biosecurity).
- The Law on Health Care provides for accreditation of laboratories, and the implementation of a system by which to do this is in progress. According to the law, the laboratories should be evaluated at least once a year.
- Health care workers in laboratories apply biosecurity procedures in most cases, although this is not documented through records, nor is it required by a written document.

#### *Areas that need strengthening and challenges*

- There is no active monitoring and/or development of updated records and there is no inventory of pathogens within facilities that conserve or treat dangerous pathogens and toxins.
- Laboratory licensing and pathogen control measures, including requirements for physical containment, are not in place.
- There is no policy or agreement for dangerous pathogens and toxins to be consolidated into a minimum number of facilities.
- There is no compliant list of dangerous pathogens that should be stored in the facilities.
- Implementation of biosafety and biosecurity measures is poorly monitored.

## **P.6.2 Biosafety and biosecurity training and practices in all relevant sectors (including human, animal and agriculture) – Score 1**

### *Strengths and best practices*

- Staff have access to external training programmes.
- Relevant internal training has also taken place (particularly around CBRN practice).

### *Areas that need strengthening and challenges*

- Biosafety and biosecurity training are not in place across all facilities.
- There is no sustained academic training in institutions for those who maintain or work with dangerous pathogens and/or toxins.
- There are no financial resources and/or capacities to carry out training on biosafety and biosecurity.
- There is no established mechanism to ensure and monitor staff competence and standards of training at all laboratories.

### **Recommendations for priority actions**

- Conduct a training needs assessment to identify gaps and specific training needs.
- Nominate a multisectoral team of experts to review existing legislation, including elements of biosafety and biosecurity as outlined in the WHO Laboratory Biosafety Manual (WHO, 2004) and WHO Laboratory Biosecurity Guidance (WHO, 2006).
- Expand the current monitoring system for the isolation of pathogens to include data on the storage/destruction of pathogens, in order to develop an inventory of pathogens stored within facilities.
- Advocate for the nomination of reference laboratories for major pathogens under surveillance by the relevant ministries.
- Review funding needs for the establishment and maintenance of a national biosafety and biosecurity system in all biological laboratories in North Macedonia, including for infrastructure, staff, equipment and continuous training.

# 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.

### Target

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

## LEVEL OF CAPABILITIES

The Republic of North Macedonia has a long-standing tradition of immunization, and has had compulsory immunization (with a strong legal basis) since the 1960s. Immunization is free-of-charge for children aged 0–18 years, and the current programme targets 11 diseases: acute hepatitis B; tuberculosis (Bacillus Calmette–Guérin (BCG) vaccine); Haemophilus influenzae type b; diphtheria; tetanus; pertussis; poliomyelitis; measles, mumps and rubella (MMR); and human papillomavirus (HPV).

The country has a National Immunization Strategy for 2012–2020, with a multiyear plan adopted by the government. There is a dedicated line in the State budget for the MOH's immunization programme, with two-year centralized vaccine procurement.

Mandatory vaccinations are administered at vaccination centres. The monitoring of the programme is conducted by 10 regional CPHs, the IPH in Skopje, the SSHI and MALMED. BCG coverage is monitored by the Institute for Lung Disease and Tuberculosis. There are appointed coordinators for the Expanded Programme on Immunization (EPI) in each of the CPHs. Control of adverse events following immunization has been established by the IPH and MALMED, and is based on pharmacovigilance and the work of an expert body at the University Children's Hospital.

Vaccination coverage is monitored using the administrative method, where the denominator is based on administrative reports of the number of children of relevant age in the subnational areas. Coverage surveys to validate the estimates derived from administrative records have not yet been conducted. There is a plan in place to develop an electronic immunization register, which would further increase understanding of actual coverage. According to the 2017 Annual Report on the Implementation of Mandatory Immunization, measles containing vaccine (MCV) coverage at national level is 82.6%.

## Indicators and scores

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

#### Strengths and best practices

- Immunization is regulated by comprehensive laws and by-laws.
- There is a network of health institutions at the primary level.
- There is a network of public health institutions.
- Vaccination is provided free-of-charge and is not related to health insurance.
- All vaccines are planned for all vaccination points according to the immunization calendar.
- Centralized procurement of vaccines is done by the MOH and financed by a special State budget.

- An immunization strategy is in place for 2012–2020, with a multiyear plan adopted by the government.
- New vaccines are introduced based on the recommendations of a designated expert body.
- Vaccination points are established at PHCs.
- The immunization of marginalized population groups is organized through dedicated campaigns.
- The CPH network and regional EPI coordinators provide coordinating and supervisory functions.
- Coverage is monitored through quarterly, six-monthly and annual reports on the implementation of the immunization programme.
- Coverage (estimated using the administrative method) is over 90% for all vaccines except MMR and HPV.

#### *Areas that need strengthening and challenges*

- There is a need to harmonize legislation for new diseases and ensure multisectoral involvement in drafting the legislation.
- A multisectoral approach is required to deal with anti-vaccination activities.
- Immunization of school children should be strengthened.
- There is a need to strengthen human resources – there is a current lack of immunization teams and the necessary supporting medical teams.
- Studies are required to examine the attitudes of parents and family doctors towards immunization (especially MMR vaccination). More general research is required on public perceptions of vaccination.
- Measures should be taken to gain public trust and improve parents' knowledge of vaccination.
- Continuous medical education programmes and the immunization education programme for doctors should be strengthened.
- Development and implementation of the electronic immunization register should be completed.
- A seroprevalence study should be carried out on vaccine-preventable diseases.
- A risk communication strategy is required for immunization.
- First dose MMR coverage should be increased.

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

#### *Strengths and best practices*

- National vaccine access and delivery is regulated by comprehensive laws and by-laws.
- There is a network of health facilities at primary health care level.
- There is a dedicated State budget line for vaccine procurement.
- In 2018/2019, North Macedonia introduced free-of-charge flu vaccines for a specific group (those over 65 years with average or less than average income).
- There is centralized vaccine storage, and quarterly and monthly distribution by contracted wholesalers throughout the whole country.
- There is two-year public procurement of vaccines at the central level, sufficient to meet the needs of the entire country and provide a six-month reserve for all vaccines.
- Information is received from wholesalers after each delivery.
- The immunization services provide an annual inventory and notification of the status of reserves.

### *Areas that need strengthening and challenges*

- There is a need to enhance cold chain capacity at primary immunization services.
- There is a need to strengthen systems by which CPHs can procure vaccines according to epidemiological indications (e.g. for travellers and non-compulsory immunizations).
- Free-of-charge seasonal influenza vaccines should be procured for all risk groups.
- Additional State budget funds are required for central procurement of consumables and the establishment and strengthening of a prequalified cold chain.
- There is a need to develop the electronic immunization system for better control, distribution and forecasting of vaccine needs.
- Every refrigerator or other cooling device in which vaccines are stored at primary health care level should be fitted with a generator or an aggregator.

### **Recommendations for priority actions**

- Conduct a vaccination coverage survey to validate current estimates and improve the quality of coverage information for evidence-based decision-making.
- Perform a knowledge, attitudes and practices survey to improve understanding of issues around vaccine hesitancy and anti-vaccine attitudes.
- Conduct multisectoral action on vaccine hesitancy to build and maintain public trust, and develop a strategy for effective risk communication that highlights the importance of vaccination.
- Continue the development and implementation of the electronic immunization register.

# DETECT

## NATIONAL LABORATORY SYSTEM

### INTRODUCTION

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

#### Target

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

### LEVEL OF CAPABILITIES

The national laboratory system of the Republic of North Macedonia is well serviced, with 32 human health microbiology laboratories covering the needs of 2 081 000 inhabitants in eight districts. There are two laboratories for the analysis of veterinary specimens.

A tiered system operates on two levels – national and regional. The regional laboratories provide primary diagnostic services by performing basic bacteriology, serology and parasitology; national laboratories perform both primary and confirmatory testing. Five out of 10 core tests are performed: polymerase chain reaction for influenza, serology for human immunodeficiency virus (HIV), microscopy for *M. tuberculosis*, bacterial culture for *Salmonella enterica* serovar Typhi, and rapid testing for *Plasmodium* spp. Testing for polio culture is not performed in North Macedonia (WHO has declared North Macedonia a polio-free country and assigned a reference laboratory in Bulgaria to test any suspected polio specimens from North Macedonia). The final four core tests are still not defined. The laboratory system is able to cover a comprehensive range of 52 out of 56 notifiable diseases, in accordance with the Law on Protection of the Population against Communicable Diseases.

Reporting within 24 hours is obligatory under the law for any laboratory confirmed case of any of the 56 notifiable communicable diseases, but the system of notification is still mostly paper based. Animal diseases are subject to mandatory reporting requirements as well. Linkages between human and animal health laboratories are situation-based: they are in contact when an outbreak occurs, but in other cases contact is optional. Electronic data exchange exists between these institutions for brucellosis and tuberculosis only.

National guidelines for clinicians are published by the MOH, although they are still not in general use. Diagnostic guidelines are prepared by the Macedonian Microbiological Society and are considered reference documents for microbiologists. There are no standard SOPs, but some laboratories have their own internal SOPs. The methodology of EUCAST (the European Committee on Antimicrobial Susceptibility Testing) is used in all laboratories, with the exception of two that still use the Clinical and Laboratory Standards Institute standard.

A national external quality assessment (EQA) programme has been established, and although it is compulsory for public health laboratories under the law, it is still not fully functional. The microbiology laboratories are enrolled in EQA programmes. An NRL for veterinary medicine operates in accordance with the activities of the EU Reference Laboratories for defined pathogens, and also participates in annual EQAs and interlaboratory comparison testing.

Accreditation is voluntary and is offered by two public institutions. The Institute for Accreditation of the Republic of North Macedonia is currently in charge of laboratory accreditation under ISO 15189. The Agency for Accreditation of Health Institutions has recently been established to take over the accreditation process for the public laboratory system. This accreditation, when operational, will be free-of-charge.

Most of the laboratories are at biosafety level (BSL)1 or BSL2. A BSL3 laboratory is under construction and will be established in October 2019.

The microbiology system is funded by two financial sources: the National Insurance Fund for all activities, and an MOH fund for National Preventive Programmes, which covers reference activities for a number of specific pathogens (e.g. measles, rubella and influenza).

## Indicators and scores

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

#### *Strengths and best practices*

- A tiered national laboratory system is in place and is capable of conducting five out of 10 core tests. Performance of culture for polio is secured by contract with a reference laboratory in Bulgaria.
- The system conducts diagnostics for 52 out of 56 notifiable communicable diseases.
- One virology laboratory is recognized by WHO for influenza, measles and rubella.
- The laboratories performing tests for AMR have issued a set of algorithms aligned with international standards, accompanied by the EUCAST protocols for AMR.
- There is a well-established laboratory system for antimicrobial susceptibility testing. Protocols are in accordance with EUCAST standards, enforced by a national plan for detection and reporting to the CAESAR team for invasive isolates, and to the MOH, IPH, CPHs and FVA for food isolates.

#### *Areas that need strengthening and challenges*

- The outstanding four country-specific tests must be defined as a part of the 10 core tests.
- Validation of testing for each core test must be ensured.
- Funding is often disrupted, and this has an impact on timely laboratory testing for both human and animal specimens. This must be improved by timely planning of procurement.

### D.1.2 Specimen referral and transport system – Score 3

#### *Strengths and best practices*

- A transportation system is in place for specimens that are sent to laboratories in Skopje for primary or confirmatory diagnostic testing.
- The transportation of specimens by rail and road is supported by law. Air transport is not yet covered.
- A referral system is in place for specimens that are analysed in all public microbiology laboratories, which is covered by the National Insurance Fund. It is obligatory to refer all suspected measles, rubella, HIV, influenza, West Nile virus and orthohantavirus specimens, and any other specimens as required by the National Priority Programmes. The referral system is funded by the MOH.

#### *Areas that need strengthening and challenges*

- North Macedonia should consolidate all SOPs and national guidelines for specimen collection, packaging and transport with the relevant international standards.

- Funding for transportation should be provided from the State budget.
- There is a need to establish a laboratory information system for submitting laboratory results and meeting legal reporting obligations for communicable diseases.
- Laboratory staff should be regularly trained on the transportation system.

### D.1.3 Effective national diagnostic network – Score 3

#### *Strengths and best practices*

- A tier-specific diagnostic system exists, but needs to be expanded to perform a broader spectrum of tests at primary level.
- Point-of-care testing for human microbiology and veterinary medicine is partially in place.
- Veterinary laboratories are well equipped to test zoonotic agents, but this capacity is not used as expected because specimens are not being sent to the laboratories.

#### *Areas that need strengthening and challenges*

- Point-of-care testing should be strengthened in order to provide timely diagnostics for both human and animal specimens.
- The system is financially limited, which has consequences for the procurement of tests and reagents.

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

#### *Strengths and best practices*

- The national EQA system for AMR has been established and is functional for the majority of laboratories.
- Twelve out of 13 laboratories that are testing food and water safety are accredited according to ISO 17025 (these include both veterinary and human microbiology laboratories).
- The MOH is in charge of laboratory licensing.

#### *Areas that need strengthening and challenges*

- National EQA is mandatory under the law, and is in place for virology and AMR, but should be improved for other areas too.
- Implementation of corrective measures after receiving EQA results should be mandatory.
- Accreditation according to ISO 15189 is poorly established. As soon as the financial situation allows, it should be introduced into the rest of the microbiology system.
- A national authority should be appointed and given responsibility for the quality control of all laboratories.

## Recommendations for priority actions

- Reference laboratories should be officially nominated by the MOH, with an open contest every five years. The nomination should contain the list of pathogens and core functions covered by each reference laboratory.
- Further strengthen the EQA system and the ability to validate the 10 core tests, and encourage laboratories to undergo the accreditation process for ISO 15189.
- Appoint a national coordination body for the microbiology laboratory system (both primary and reference laboratories) that will coordinate the network, collect and analyse reports and encourage laboratories to implement EQA and accreditation.
- Establish the linkage between the clinical, epidemiological and laboratory sectors for public health purposes by introducing an information system.

# 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 biological 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 subnational, national and international levels of authority regarding surveillance of events of public health significance; and (3) improved country and intermediate level regional capacity to analyse and link data from and between, strengthened, early warning surveillance, including interoperable, interconnected electronic tools. This would include epidemiologic, clinical, laboratory, environmental testing, product safety and quality and bioinformatics data; and advancement in fulfilling the core capacity requirements for surveillance in accordance with the IHR and OIE guidelines.*

## LEVEL OF CAPABILITIES

In North Macedonia, public health surveillance is strongly regulated by specific, comprehensive legislation. The competent institutions have been established according to legal acts, with co-funding from the national budget through priority national health programmes and the national health insurance fund. The system of communicable disease prevention and control is based on an established network of 10 regional centres of public health. Both indicator-based and event-based surveillance have been in place for several years.

Notifiable diseases are defined (63 diseases and one condition), and there is mandatory reporting of all notifiable diseases within 24 hours of diagnosis; however no prioritization is done. This system is supplemented by a mandatory syndromic surveillance system that covers eight syndromes. Syndromic data are reported to the electronic ALERT system weekly and published along with analyses of trends.

Sentinel surveillance systems are in place for acute flaccid paralysis (AFP)/polio and influenza. The routine passive system is complemented by urgent suspected case-based reporting for nine defined diseases of public health importance, with immediate reporting requirements. Event-based surveillance is done by reviewing notification reports and information collected from other sources, on a daily basis, at local, regional and national levels. A weekly teleconference of regional epidemiologists has been recently introduced.

Clinicians and specialists in microbiology are generally aware of notifiable diseases and reporting requirements. The majority of communicable disease cases are, however, based on presumptive diagnoses by reporting clinicians, and are rarely laboratory confirmed. Due to the insufficient use of microbiological testing, several diseases are under reported, and the true burden of disease is not known. Furthermore, the separate existing systems of disease reporting and pathogen reporting produce differences in numbers of cases, as data are neither integrated nor systematically validated. The surveillance system, which is basically comprehensive and which is intended to be sensitive, does not therefore efficiently support monitoring of most disease.

Diseases and pathogens are reported to the network of epidemiologists in CPHs, who report mostly aggregate data to the IPH on a weekly and monthly basis. The use of epidemiological surveillance methods is limited, and restricted mainly to the national level. This impairs effective analysis, interpretation of data and risk assessment. Data are not routinely shared between sectors.

Even though there is no formal cooperation between the human and animal sectors, informal collaboration works well on a day-to-day basis. In the case of a suspected outbreak, a multidisciplinary team is established.

An electronic national surveillance system for public health is in development. A patient management system called "My Term" has the potential to support notification of suspected and confirmed cases of communicable diseases. Electronic systems for all notifiable diseases are expected to be fully functional by the end of 2019. In the veterinary sector, electronic systems have been in use for several years.

## Indicators and scores

### D.2.1 Surveillance systems – Score 3

#### *Strengths and best practices*

- Legislation defines the notifiable diseases (but these are not prioritized).
- One legally regulated system is in place for routine indicator-based and event-based surveillance. This system is supplemented by a mandatory syndromic surveillance system and sentinel surveillance systems.
- Action plans and public health programmes are in place with special emphasis on surveillance of certain diseases/conditions (AFP/polio, measles/rubella, tuberculosis and HIV/AIDS).
- Instructions, SOPs, guidelines and protocols are in place for the surveillance of communicable diseases, conditions and syndromes.
- There is systematic, immediate reporting within 24 hours of mandatory diseases and conditions.
- Capability is in place for diagnostics/laboratory confirmation for over 90% of the mandatory notifiable diseases in human health laboratories, and there are reference laboratory capacities (for measles, influenza, HIV, arboviruses and malaria) available at the IPH.
- Some cross-border activities are ongoing, including informal arrangements with neighbouring countries for the exchange of surveillance data and control of public health emergencies of international concern (PHEICs), e.g. with Albania concerning influenza, and participation in the EpiSouth and EpiSouth Plus capacity-building projects.

#### *Areas that need strengthening and challenges*

- There is a need to develop technical guidelines and SOPs to support event-based surveillance, in which systematic media monitoring and/or other sources could be included.
- There is a need to evaluate the completeness and timeliness of the surveillance system.
- Case definitions should be included in practice around the classification of cases.
- More clinical cases should be laboratory confirmed.
- Laboratory capacities need to be enhanced at the local level (in terms of human and material resources and training and education), and clinicians should be encouraged to send samples for confirmation.
- Clinicians and other health professionals should be trained on the importance of reporting.
- There is a need to strengthen intersectoral cooperation between the human and animal health sectors.

### D.2.2 Use of electronic tools – Score 2

North Macedonia is aiming for a score of 3 in the national use of electronic tools. The current score indicates the need to finalize implementation of the electronic reporting system for public health. North Macedonia exceeds this score in the animal health sector, where electronic reporting has been in use since 2013.

**Strengths and best practices**

- There is an integrated electronic health data management system, "My Term", run by the Directorate for E-health.
- The necessary basic IT infrastructure is in place in the public health system, making the context favourable for digitalization of the surveillance system.
- The ALERT syndromic surveillance system is in place for electronic reporting, and was implemented as a pilot scheme in 2005.
- Electronic reporting of influenza-like illness and acute respiratory infection has been partly implemented since the 2018/2019 influenza season.
- The module for reporting infectious diseases in "My Term" is expected to become fully functional during 2019, and will provide the possibility for the electronic linking of clinical, epidemiological and laboratory data.
- The electronic information system in the veterinary sector is functional, and has integrated IT tools for data processing and analysis. It collects data from the programme on animal health protection and the monitoring programme for certain infectious diseases.

**Areas that need strengthening and challenges**

- There is a need for faster flows of relevant data from the local/regional levels to the national level.
- There is a need to improve the completeness and timeliness of reporting by replacing paper-based reporting with an electronic reporting system.
- Epidemiological and laboratory data should be integrated.
- Reported surveillance data should be systematically validated.

**D.2.3 Analysis of surveillance data – Score 3****Strengths and best practices**

- Developed human capacities are in place for analysing data and carrying out descriptive analysis.
- Knowledgeable and competent staff are present at a national level to undertake data and risk analysis.
- Reports on communicable diseases and other topics are produced at the national level, mainly in the IPH.
- Regular weekly reports, monthly bulletins and annual reports including all notifiable diseases are publicly available.

**Areas that need strengthening and challenges**

- There is a need for further improvement of public health staff skills for the implementation of analytical methods in the detection and investigation of outbreaks at all levels, but particularly at the local level.
- Capacities for risk assessment should be further strengthened.
- There is a need for multisectoral coordination in public health and epidemic research.

**Recommendations for priority actions**

- Finalize the digitalization of the electronic reporting system for communicable diseases, including the final classification of reported cases and their integration with the laboratory reporting system for confirmed pathogens.
- Introduce enhanced surveillance for zoonoses and vector-borne diseases, as well as other prioritized diseases and/or diseases of interest.
- Improve intersectoral cooperation between the human and animal health sectors, including by regular formalized meetings and data sharing (under the One Health approach).
- Strengthen human resources at all levels simultaneously, providing continuous education in intervention epidemiology, risk assessment and risk management.

# 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 PHEIC to WHO and listed diseases to OIE, and will be able to rapidly (within 24/48 hours) respond to communications from these organizations.

### Target

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

## LEVEL OF CAPABILITIES

Under the IHR (2005), the IPH became North Macedonia's NFP for reporting the occurrence of a PHEIC. The IPH maintains constant communication with the PHCs throughout North Macedonia and with WHO.

The Director of the FVA is the OIE delegate and the World Animal Health Information System (WAHIS) NFP. There are a number of deputy focal points for redundancy and in order to maintain continuous coverage and contact.

Under the law, every doctor is responsible for immediate reporting, either by personal reporting card or by phone, the existence or suspicion of a communicable disease to the relevant PHC (i.e. its regional unit). This reporting must be done at the moment of examination or no later than 24 hours thereafter. A dual communicable disease reporting system is established within North Macedonia and includes individual reporting of a contagious disease through a reporting card with a list of 48 diseases, as well as an aggregate system (referred to as ALERT within North Macedonia) that reports based on defined syndromic conditions, once a week, using group cards.

With the incidence of a disease cluster, notification is immediate by telephone to the PHC. The chain of reporting proceeds from the PHC to the IPH. In the event of zoonoses, the PHC concerned will report to the veterinary services in the affected territory. A cluster is defined as two or more cases with identical or similar clinical presentation and an unusually acute form of the disease with unforeseeable progression, or an incidence of a disease of special interest.

On the veterinary side, testing results and syndromic surveillance data are submitted electronically via the FVA's information system, in which data are compiled into a database and sent to the national level for analysis. Diseases that must be reported to the OIE and FAO are submitted to the OIE NFP.

Once notification of a disease of public health, agricultural or food safety significance reaches the national level, the multisectoral committee convenes at the MOH to discuss whether it meets the respective thresholds for reporting to WHO, OIE and/or FAO. If the multisectoral committee agrees that it does, the appropriate NFP submits the required information through the established chains.

## Indicators and scores

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

#### *Strengths and best practices*

- All cases of zoonoses and foodborne and/or waterborne diseases (positive isolates) are reported to the FVA, which reports to the EFSA and OIE.
- Through the IPH, North Macedonia participates in TESSy, the communicable disease reporting system of the ECDC.
- Regulations are in place to support official controls of salmonella and other specific alimentary intoxications.
- Regulations are in place to support reporting of communicable diseases and microbial agents.

#### *Areas that need strengthening and challenges*

- The IHR NFP and the OIE delegate have not undergone any official training.
- Official bilateral mechanisms have not been established for cooperation and communication with other regional IHR NFPs. There are informal mechanisms for communication and cooperation in place, but these are not specifically related to the IHR (2005).

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

#### *Strengths and best practices*

- Legal support is in place for crisis management through the CMC.
- The CMC functions as the emergency call centre (received through the 195 and 112 phone numbers), provides official notification of possible risks, and is responsible for submitting notification of a PHEIC to WHO.
- National and regional operational centres use an organogram containing the necessary contact information to contact the relevant authorities as required.
- A multidisciplinary, multisectoral full-scale exercise based on a traveller infected with Ebola took place at Skopje International Airport in 2014. A PHEIC was submitted for this exercise.
- A notice was submitted to the OIE in 2018 as part of an exercise on foot and mouth disease.

#### *Areas that need strengthening and challenges*

- A national SOP is required for coordination between the IHR NFP, the OIE delegate, the WAHIS NFP and other relevant sectors.
- Functional mechanisms need to be established for coordinating relevant sectors in the implementation of the IHR (2005) – including points of entry, security authorities, surveillance units, laboratories and other sectors involved with zoonotic risks and events.

### Recommendations for priority actions

- A national SOP for coordination between the IHR NFP, the OIE delegate, the WAHIS NFP and other relevant sectors should be written, implemented and tested.
- Finalize reporting protocols for chemical, radiation and biological incidents.
- Establish a permanent team in the MOH for rapid risk assessment, which should be made up of top experts (e.g. epidemiologists, infectious disease clinicians, microbiologists, entomologists, etc.) and which can work with the Commission for Infectious Diseases to provide guidance to the NFP.
- An integrated One Health surveillance and reporting system should be established that involves regular communication between the human, animal, wildlife and environmental health sectors, in order to increase effectiveness and efficiency in reporting to international officials.

# HUMAN RESOURCES

## INTRODUCTION

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

The recommended density of doctors, nurses and midwives per 1000 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).*

## LEVEL OF CAPABILITIES

The Republic of North Macedonia has a thorough understanding of its human resources capacities and needs. It compiles updated information on workforce numbers on an annual basis: each facility provides information on its own resource gaps every year, and this goes into the annual recruitment profile.

Future predictions indicate that with the average age of health care employees being 56 (at the time of writing in March 2019), two thirds of professional staff will retire in the next five years. In addition, there is a loss of staff from the public to the private sector, and an outflow of professionals from the country.

There is a particular shortage of IT specialists. With the introduction of electronic surveillance systems and other digital platforms, this will become a major issue and it needs to be addressed in the short term.

Several measures have been undertaken to address staff shortages. These measures include the introduction of new jobs, increasing the salaries of health workers, introducing monthly fees for private residencies, and changing the postgraduate specialization and subspecialization programmes by creating more opportunities for enrolment, particularly in courses that will help fill identified capacity gaps. Additional options could include measures such as providing inducements for expatriate staff to return. While there is a four-year plan in place for human resources, there is no long-term succession planning to address future staffing shortfalls.

There is a well-established FETP in the country, provided with the collaboration of the Robert Koch Institute in Germany. Veterinary staff can also access this programme.

In collaboration with the ECDC, four IPH physicians have each received a two-year field epidemiology fellowship through the Mediterranean Programme for Intervention Epidemiology Training (MediPIET) project framework.

A number of legal barriers impede North Macedonia's ability to address some aspects of its problems around human resources for health. The current law indicates that only medically trained doctors can be employed as epidemiologists, although negotiations have commenced with the SSHI to allow non-medically trained staff with appropriate qualifications to take up the role of epidemiologist.

The Red Cross of North Macedonia has been training volunteers in first aid and more advanced skills, but there is no recognition of paramedics in the health system of North Macedonia.

Continuous medical education is compulsory, and there is a training simulation centre for doctors. North Macedonia has been training both rapid response teams and EMTs that are available 24/7.

Universities in North Macedonia offer Masters of Public Health and PhD programmes.

The FVA offers a wide range of training courses on request, and should be considered as a resource for use in the expansion of training programmes for the public health workforce. This would also serve to promote a One Health approach and utilize the resources of one agency for the benefit of others.

## Indicators and scores

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

#### *Strengths and best practices*

- A four-year programme is in place to meet the needs of specialist and subspecialist staff throughout North Macedonia's network of health care institutions, including the need for capacity in: epidemiology; hygiene with health ecology; medical microbiology with parasitology; and occupational medicine.
- Each public health institution has an organogram that includes job descriptions.
- There is a regulation governing the minimum requirements for protecting workers from risks associated with exposure to biological agents. This regulation is harmonized with EU Directive No. 2000/54/EC.
- In the last two years a significant number of new jobs in preventive medicine have been filled at national, regional and local levels.
- Salaries have been increased to motivate the current public health workforce and help recruit new staff.

#### *Areas that need strengthening and challenges*

- There is no long-term workforce strategy to address projected staff shortages.
- Public health jobs, and particularly those in preventive medicine, are not competitive with jobs in the private sector or throughout the EU.

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

#### *Strengths and best practices*

- All job profiles are available at both national and regional levels – although resources tend to be more accessible at the national level (e.g. epidemiologists, clinicians, biostatisticians, IT specialists, veterinarians, social scientists, laboratory specialists, etc.).
- There are 42 epidemiologists in North Macedonia (four epidemiologists per 200 000 people).
- The Public Health Programme for 2018 and 2019 provides for rapid response teams to be available 24/7.
- In collaboration with ECDC, four IPH medical doctors have received a two-year field epidemiology fellowship through the MediPIET project framework.

#### *Areas that need strengthening and challenges*

- Some regional/local authorities still do not have sufficient epidemiological capacity.
- Although increased, the number of epidemiology staff in the IPH is not sufficient to meet the needs of all programmes.
- The public health workforce is aging and two thirds of current employees are predicted to retire in the next five years.

**D.4.3. In-service trainings are available – Score 2***Strengths and best practices*

- A continuing medical education programme is mandatory for all medical doctors.
- Specialized epidemiology training is in place and is cascaded throughout the country.
- Joint training courses are carried out with the FVA, for example on brucellosis.

*Areas that need strengthening and challenges*

- Health care and other workers should be included in programmes for the FETP, and should be considered for employment as epidemiologists.
- There is a lack of biostatisticians. This should be addressed by targeted training programmes.
- Joint training programmes should be implemented for outbreak investigations involving both human and veterinary specialists.

**D.4.4 FETP or other applied epidemiology training programme in place – Score 3***Strengths and best practices*

- Epidemiology is recognized as a three-year specialization (residency) programme after graduation with a medical degree.
- Modules from the FETP are incorporated in the national programme for specialization.
- The IPH is recognized as a FETP (MediPIET) training centre and hosts MediPIET fellows from other countries.
- In 2017, four North Macedonian fellows and two supervisors graduated from the FETP.

*Areas that need strengthening and challenges*

- A “learning by doing” FETP should be developed.
- The current epidemiology specialization should be merged with the FETP, by linking the medical faculty and IPH as a teaching hub.
- Some form of FETP should be provided for health care workers other than doctors.

**Recommendations for priority actions**

- Develop a long-term workforce strategy with tangible incentives in order to address projected staffing shortages.
- Include field epidemiology in the curriculum of the epidemiology specialization of the Medical Faculty by linking it with the IPH/CPH knowledge hub.
- Provide a FETP to doctors and epidemiologists as part of the continuous medical education programme.
- Engage non-medical health professionals on the FETP programme.
- Create joint education modules for the veterinary and human health sectors (e.g. on investigating foodborne outbreaks, analytical models, etc.).

# RESPOND

## EMERGENCY PREPAREDNESS

### INTRODUCTION

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

#### Target

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

### LEVEL OF CAPABILITIES

The CMC was established in 2005. According to the law, the CMC is a coordinating body answerable to the Prime Minister’s office and responsible for organizing emergency preparedness, facilitating decision-making processes and use of resources, communicating with the public and conducting risk assessments throughout the country. It is also responsible for information gathering and assessment, situation analysis, determining objectives and tasks and developing and implementing the necessary actions for prevention, early warning and crisis response.

The CMC has an assessment group responsible for day-to-day technical operations and a steering committee (the higher decision-making body) led by the CMC Director and composed of members from the MOH, the Ministry of the Interior, the Ministry of Transport and Communication, the Ministry of Defence and the Ministry of Foreign Affairs. The steering committee meets regularly at the CMC headquarters, and invites other relevant sectors to their meetings depending on the situation and hazard at hand. There are similarly structured centres in all 34 municipalities and in the city of Skopje. To improve coordination and information sharing, the municipalities’ centres are further organized under eight regional centres.

The CMC, with contributions from other relevant sectors, is responsible for the development and coordination of strategic emergency risk assessments not only nationally but also locally, with the municipalities and Skopje city. The CMC gathers information from all municipalities and the city of

Skopje using a web-based platform called MKFFIS (Macedonia Forest Fire Information System). An all-hazards approach is used for national and local risk assessments. The CMC has concluded an up-to-date multi-hazard, multisectoral national risk assessment, which is waiting for government approval (at time of writing in March 2019).

In contrast to the very good system for assessing risks at national and local levels, there is no unified national multisectoral emergency preparedness and response plan. Ministries/sectors do, however, have their own emergency preparedness and response plans, in which resources are mapped and roles and responsibilities are defined. In 2017, as part of emergency preparedness measures, the health sector also developed a comprehensive emergency preparedness and response plan, with SOPs and clearly defined roles and responsibilities.

North Macedonia experienced a catastrophic earthquake in the city of Skopje in 1963, and since then several emergency preparedness measures have been taken by the government and its responsible institutions in order to build the required capacities.

Simulation exercises have been carried out to test the capacity of the system and its decision-making processes and operational performance.

## Indicators and scores

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

#### *Strengths and best practices*

- Multihazard risk assessments are conducted regularly at national and local levels.
- There is regular cooperation and exchange of information across sectors and at all levels during risk assessment and emergency response.
- North Macedonia participates in international simulation exercises.
- A plan is in place for managing and distributing stockpiles.
- A web-based platform (MKFFIS) has been established to collect information and analyse data.

#### *Areas that need strengthening and challenges*

- There is a need to operationalize SOPs in the context of the updated national risk.
- Allocate a sufficient budget to the implementation of all IHR capacities and increase visibility of funding related to IHR in all sectors.
- Allocate dedicated budget lines to IHR activities at the national and subnational levels in all relevant sectors.
- Conduct a further assessment of IHR-related legislation and identify and implement the adjustments required to achieve a complete legislative framework for the IHR (2005) assessment.
- SOPs should be adopted for communication, coordination and cooperation in accordance with the Law for Crisis Management.
- There is a need to address resource constraints affecting the CMC.
- Roles and responsibilities are not clearly defined between the CMC and the PRD.
- There is no unified national risk assessment.

**R.1.2 National multisectoral multi-hazard emergency preparedness measures, including emergency response plans, are developed, implemented and tested – Score 3**

*Strengths and best practices*

- Multi-hazard health sector emergency preparedness plans are in place.
- Contingency plans are in place for certain specific hazards, such as floods.
- Regular training is provided on emergency plans and simulation exercises are held periodically.

*Areas that need strengthening and challenges*

- There is a need for a national, multisectoral, multi-hazard emergency preparedness and response plan.
- Additional relevant sectors (such as animal health) should be involved in the CMC steering committee as standing members.
- There is a need for sustainable funding to the relevant sectors to support the coordination and implementation of emergency preparedness measures.

**Recommendations for priority actions**

- Adopt the national multisectoral multi-hazard risk assessment and develop and test national and subnational multi-hazard, multisectoral emergency preparedness and response plans.
- Define clear roles and responsibilities between the CMC and the PRD and improve their coordination and capacities through training and regular exercises.
- Establish an electronic platform for the better exchange of information between the CMC and other sectors and to improve access to national risk assessments and mapping.
- Adopt a unified national risk assessment methodology, and develop SOPs accordingly.
- Include relevant sectors, such as animal and environmental health, in the CMC steering committee.

# 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 EOC functioning according to minimum common standards; maintaining trained, functioning, multisectoral rapid response teams, and trained EOC staff capable of activating a coordinated emergency response within 120 minutes of the identification of an emergency.*

## LEVEL OF CAPABILITIES

North Macedonia has a strong legal framework and cross-cutting interministerial coordination for emergency response at all levels. The approach to emergency response is centralized with a clear chain of command from central teams for crisis assessment and outbreak investigation.

The Crisis Management Law (2005) establishes a crisis management system with the purpose of: "... prevention, early warning and handling crises ... that are the result of natural disasters and epidemics".

The national CMC and an additional eight regional and 34 municipal CMCs distributed throughout the country work together to coordinate risk management activities. A single communication and information system is currently being established whereby one phone number (112) will be applicable for all emergencies. All State administrative bodies are obliged to report all incidents and emergencies to the CMC, and there is intersectoral exchange of the key information and data required for response activities.

The PRD – equivalent to civil protection in other jurisdictions – is part of the national security system. It has a headquarters for protection and rescue (including an intersectoral expert committee) and manages the implementation of preventive and operational measures during natural disasters and other hazards. The PRD also includes subnational units for protection and rescue that coordinate local activities and each of these contains a permanent member from the public health sector. A review of the civil protection mechanism found some overlapping activities between the CMC and PRD (in practice but not in legislation) and therefore the government is currently discussing organizational reforms of the security structure.

A unit at the MOH, directly subordinate to the State Secretary for Health, was created to coordinate the health response to events and emergencies. A National Plan of Preparedness and Response of the Health System in Emergency Situations (2017) includes SOPs for coordinating and managing the health care sector. A Commission for Infectious Diseases is responsible for declaring nationwide epidemics (based on epidemic intelligence and risk assessment by the IPH). A multisectoral crisis response committee has further defined roles and responsibilities, including coordination and cooperation with emergency response units and other stakeholders; IHR implementation; managing cooperation with the CPHs; and managing health crises including epidemics.

For outbreaks of communicable disease, a public health EOC is activated on an ad hoc basis, using the premises of existing offices. There is limited office space and no reliable information, communications and technological equipment or dedicated plans, SOPs or resources for this structure. Public health events requiring intersectoral collaboration are escalated to the CMC.

Coordination with the PRD and civil society organizations such as the Red Cross is established in the Health Care Law. Coordination with the national crisis management system is assured by the participation of the MOH and the IPH in the steering committee of the CMC. Investigating outbreaks is a subnational responsibility, and intersectoral investigation teams are organized for field responses.

A number of exercises have been carried out in recent years relating to natural disasters (flood, fire and mass traffic accidents) and infectious disease (an Ebola case at the airport). Plans and procedures have also been tested in real emergency situations, including in responses to fires in 2005, the migrant crisis in 2015–16 and flooding in 2016.

The lessons learnt during the evaluation of the specific responses of various institutions and services – whether to real emergencies or to exercises – need to be implemented.

## Indicators and scores

### R.2.1 Emergency Response Coordination – Score 3

#### *Strengths and best practices*

- There is a well-established, multi-level, multisectoral, centrally coordinated operational capacity for emergency response. The MOH and the PRD/CMC have their own management structures and functions, which in the event of emergencies are coordinated by the competent headquarters.
- There is a clear chain of command. The roles and responsibilities of the emergency management units are clearly prescribed, and there is a system for grading and escalating the response.
- The CMC is governed by two bodies: a steering committee and an assessment group. Members of these bodies are high-level intersectoral representatives of key ministries and other authorities.
- There are multisectoral government bodies and committees responsible for different aspects of emergency response. One has been established for emergency responses to zoonotic diseases and includes representatives from the health, veterinary and environmental sectors.
- The national intersectoral mechanism for protection and rescue and crisis management was successfully activated during a natural disaster, which was declared a national emergency, in 2015/2016.

#### *Areas that need strengthening and challenges*

- In cooperation with all relevant institutions, it is necessary to update the National Emergency Protection and Rescue Plan, precisely defining each stakeholder's required response to all identified hazards.
- There is a need to improve inter-institutional cooperation and enactment of laws harmonized with EU Directives.
- Guidelines for emergency response should be developed based on the recommendations of relevant international organizations.
- The responses of specific institutions and response services need to be evaluated and the lessons learnt implemented.

### R.2.2 Emergency Operations Centre Capacities, Procedures and Plans – Score 2

#### *Strengths and best practices*

- An EOC has been established at the CMC in line with the National Plan of Preparedness and Response of the Health System in Emergency Situations. It can be activated within 24 hours and has plans, SOPs, trained staff, an ICT infrastructure and resources. It operates 24/7 during emergencies.
- There is national intersectoral exchange of key information and data for protection and rescue, which helps organize response activities. Situational analysis is conducted on data received from all levels and is shared with relevant bodies in order to facilitate correct and timely decisions.

- Both the CMC and PRD structures include a network of regional offices that coordinate with their national headquarters.
- Previous experiences of emergencies caused by different types of hazards have strengthened continuous high-level intersectoral communication.

#### *Areas that need strengthening and challenges*

- There is a need for a small public health EOC at the IPH for internal coordination of outbreaks limited to the health sector. This would be a component of the current network of EOCs under existing national disaster management authorities. When events required intersectoral coordination, they would be escalated from this public health EOC to the CMC.
- Roles and responsibilities should be described for EOC functions.
- Functional positions should be described and training provided for staff with roles in the EOC.
- There is a lack of financial and human resources for the further development of plans and procedures for the incident management system.
- Response plans (e.g. for protection and rescue, outbreak investigation, etc.) need to be updated at the local level.

### **R.2.3 Emergency Exercise Management Programme – Score 4**

#### *Strengths and best practices*

- An exercise was held to check the functionality of the draft of the National Plan for Protection and Rescue and the Plan for Preparedness and Response of the Health System in Emergency Situations. This exercise tested methods for activating emergency management, decision-making at the level of activation and readiness to respond.
- A number of national and international functional exercises have been conducted in recent years. These have mostly been in response to natural and man-made disasters (floods, fire, massive traffic accidents, etc.) but also to infectious disease risks (e.g. an Ebola case at the airport).

#### *Areas that need strengthening and challenges*

- There are gaps in the training (e.g. there are no command and coordination simulation exercises, staff management/decision-making courses, information management courses, etc.) and there is a need to organize training compatible with the EU civil protection training programme.
- An exercise needs assessment should be carried out, following which a sustainable intersectoral simulation exercise programme needs to be developed. This should include the participation of several institutions and plans, and should examine the dynamics of their implementation.
- There is a need for institutions to exchange information on the evaluation of exercises. It is critical that recommendations for improvements in response capabilities are then implemented.

### **Recommendations for priority actions**

- Establish a small public health emergency EOC in the IPH in a multipurpose space (e.g. a meeting or training room), using existing human resources where possible. This EOC should be capable of being activated during outbreaks within 120 minutes, based on national preparedness plans for the health sector.
- Engage all stakeholders in assigning response activities for all identified hazards and update national preparedness plans accordingly.
- Implement the lessons learnt in evaluations of the responses of specific institutions and services during both exercises and real emergencies.
- Engage with the CMC and the PRD to ensure that ongoing organizational restructuring achieves one unified coordination mechanism for emergencies that ensures clear roles and responsibilities.

# LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

## INTRODUCTION

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

### Target

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

## LEVEL OF CAPABILITIES

The Republic of North Macedonia has regulations that outline the obligations of different sectors to cooperate in emergency situations. There are several MOUs between the Ministry of the Interior – a stakeholder in emergency response – and the MOH.

The Ministry of the Interior and other State administrative bodies participate in prevention, early warning and response to the risks and dangers that can cause crisis situations, in accordance with the Law on Crisis Management and other relevant laws.

An MOU and Cooperation has been signed between the CMC and the MOH. SOPs are being prepared and drafted that will detail operational issues.

There have been several examples of joint operations over the past few years, including responses to the migrant crisis and a case of poisoning occurring in a factory.

The CMC receives regular signals from various sectors, and compiles a situational awareness report. This report is shared with all relevant stakeholders, including public health officials.

Security authorities have received relevant training, in particular in the field of radiation, but there are gaps in knowledge and procedures around chemical and biological hazards.

## Indicators and scores

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

#### *Strengths and best practices*

- Legislation and regulations provide a framework for cooperation between different sectors in emergency situations.
- Training, simulation exercises and command staff exercises are held in which the stakeholders in the crisis management system all participate, including the Ministry of the Interior, the MOH and other institutions. These are most often organized by the CMC.

### *Areas that need strengthening and challenges*

- There is a need to develop a joint curriculum for a training and education programme that builds continuous multisectoral cooperation and trust between partners in the crisis management system.
- The capacity of trained staff and the level of material resources in this area are currently insufficient.
- There is a need to implement periodic multisectoral simulation training for response to emergencies. Simulations should include both public health and the security authorities.
- Protocols and communication procedures should be developed for specific emergency situations that require multisectoral approaches. These procedures should include both public health and security authorities.
- There should be continuous cooperation and regular meetings between stakeholders in the crisis management system.

### **Recommendations for priority actions**

- Organize joint training and simulation exercises (with a focus on biological and chemical threats) at the national level, including all stakeholders in the crisis management system. Cascade the training programme to the regional level.
- Carry out periodic assessments and testing of existing communication protocols between the public health, veterinary health and security sectors, based on exercises or real events.
- Map out needs for material resources and increase capacity accordingly.

# 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, logistic and regulatory challenges to deployment of public health and medical personnel from one country to another. Case management procedures should be available to all staff, and implemented across the system during health emergencies due to IHR-related hazards.

### Target

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

## LEVEL OF CAPABILITIES

North Macedonia is divided into 10 public health regions, each of which has primary, secondary and tertiary health care services. The emergency medical services (EMS) and EMTs are part of the primary public health sector. There are 34 primary health centres with EMS/EMTs.

Outbreak detection and response is the responsibility of the epidemiology departments in the 10 CPHs and the IPH. All hospitals have prepared hospital safety indices and operational plans for crisis management and have emergency centres and services in place.

At the central level the PRD has teams for rapid response with medical personnel contracted separately. The Red Cross of North Macedonia is part of the response system, and provides teams for first aid. Veterinary experts are part of the rapid response teams deployed during outbreaks of foodborne disease and/or zoonoses.

In the case of an emergency requiring the activation of State countermeasures and deployment of personnel, the MOH coordinates its actions with the IPH, the CMC, the PRD, the Ministry of Internal Affairs, the FVA and the Radiation Safety Directorate (RSD).

In order to regulate the field of medical countermeasures, the Republic of North Macedonia has in place a range of laws, including relevant laws on: crisis management; protection and rescue; health care; health insurance; public health; food safety; radiation safety; and the role of the Red Cross of North Macedonia.

In addition, a number of operational plans are in place, including: the 2017 Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters; an operational plan on crises and disasters (February 2017); SOPs for the implementation of measures for emergency medical assistance; an operational plan and risk management manual for the occurrence of pandemic influenza in North Macedonia; an operational plan for crisis management in relation to food and feed; and an MOU between the PRD and the EU Civil Protection Mechanism.

There is a provision in procurement law to enable the country to fast track the procurement of drugs not on the essential medicines list, in the case of an emergency. This enables the fast tracking of the clearance process for these drugs and/or commodities when entering the country.

Foreign medical teams currently have to be registered in the country. North Macedonian health professionals who have moved elsewhere are allowed to come in and work immediately (if they have maintained their medical registration), but other expatriate staff have to go through a “fast track” registration process that can take up to 30 days. If North Macedonia became an EU Member State, this would change under EU provisions.

## Indicators and scores

### R.4.1 System in place for activating and coordinating medical countermeasures during a public health emergency – Score 3

#### *Strengths and best practices*

- There is regular training for EMTs, provided annually at a medical simulation centre for basic and advanced life-support training. The most recent training was in November 2018 (on flooding).
- An international field simulation exercise was carried out in 2017 (exercise “Krivolak”).
- All PHCs have stockpiles of commodities for emergencies upon which they can readily draw.

#### *Areas that need strengthening and challenges*

- The most recent restructuring of the MOH dismantled the department that deals with medical countermeasures during crises.
- There is a need to establish and practice the methodology for coordinating EMTs.
- There is a need to strengthen human resources capacity across the public health sector to support emergency responses.
- Preparedness plans should be updated regularly, including by updating lists of contact points and functions across different sectors.

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

#### *Strengths and best practices*

- EMTs are available at 34 primary level public health facilities.
- A network of public health facilities is in place, consisting of the IPH and 10 PHCs.
- The PRD has teams for rapid response.
- The Red Cross of North Macedonia provides first aid teams for disaster response.
- There is a connected network between EMTs and health facilities at primary, secondary and tertiary health care levels via the Tetra system.
- There is continuous medical education for EMTs provided annually at a medical simulation centre for basic and advanced life-support training.
- Training and gatherings outside the country are used for learning to strengthen skills relevant to IHR implementation.
- In 2015 an action plan was developed for the health sector to respond to large influxes of migrants.

#### *Areas that need strengthening and challenges*

- There is a need to build and maintain a well-trained cadre responsible for coordinating emergency response operations.
- There is a need to establish a pool of self-sufficient, well-coordinated medical teams trained and equipped to respond to a range of situations including outbreaks, displacements of large numbers of people and other emergencies.
- There is a need for clearly defined procedures for receiving foreign EMTs during a public health emergency.

- The capacities and efforts of the paramedical services should be recognized in the health care system.
- The availability of specialized staff in health centres should be ensured during emergencies.

#### **R.4.3 Case management procedures implemented for IHR relevant hazards – Score 4**

##### *Strengths and best practices*

- Protocols are in place for responses to biological, chemical and radiological hazards.
- There is an IHR algorithm for transporting patients from points of entry, and a protocol for transporting patients potentially suffering from a communicable disease.
- Legal regulations and by-laws are in place for protecting people and animals against infectious disease.
- The last field exercise involving the main stakeholders responsible for responding during floods was held in November 2018.
- The 2014 Ebola exercise provided an opportunity for many sectors to come together for emergency response.
- An international field simulation exercise took place in 2017.

##### *Areas that need strengthening and challenges*

- While there are protocols for biological, chemical and radiological hazards, case management procedures and training for high risk chemical events are only available at the toxicology centre in Skopje.
- There is a need to improve intersectoral coordination and cooperation related to IHR relevant hazards.
- There is a need for continuous training of clinical doctors, epidemiologists and clinical microbiologists that includes simulation exercises, interventional epidemiology for infectious diseases and multisectoral coordination in the field of public health and epidemic research.

#### **Recommendations for priority actions**

- Prepare an overview of entities responsible for managing or intervening in a health emergency response at the State, regional and/or local level and disseminate it to all relevant stakeholders, including health facilities, public health bodies, EMTs, Red Cross of North Macedonia, relevant NGOs, etc.
- Develop procedures and State regulations for receiving foreign expertise and EMTs during a public health emergency.
- Review the roles and responsibilities within the MOH for dealing with medical countermeasures during crises, and ensure that systems are in place to perform the necessary actions when required.
- Amend the Health Care Law to allow for the formation and recognition of paramedical services.

# RISK COMMUNICATION

## INTRODUCTION

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

### Target

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

## LEVEL OF CAPABILITIES

North Macedonia has a clear and comprehensive set of laws, preparedness and response plans and SOPs that define all the necessary roles, responsibilities and interactions concerning risk communication. They cover risk communication between government institutions, and between these institutions and stakeholders outside government. They include the Public Health Law, the Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters and several sets of SOPs describing the flow of information between different partners. The IHR NFP at the IPH is included in this legislation.

The MOH coordinates the flow of information with a range of government sectors, the IPH and the CMC. The CMC can call on a network of regional crisis centres to manage risk communication and disseminate information to the public about risks and the unfolding of events during an emergency. The FVA is responsible for communicating with the public about foodborne outbreaks or food safety problems, and the PRD plays an important role in communicating during natural disasters. As a nongovernmental partner, the Red Cross of North Macedonia plays another important role in promoting community resilience and protective measures among affected communities.

Although intersectoral cooperation and exchange of information is embedded in the system, the wide variety of communication channels (websites, social media platforms, information campaigns, etc.) is not streamlined and is managed separately by individual institutions and organizations, with varying degrees of success. This results in an information landscape that can be difficult for the public to navigate in an unfolding emergency.

Individual websites do, however, offer valuable, comprehensive and timely information about risks and preventive measures and present these messages in a professional and attractive manner. Social media platforms such as Facebook are used mainly to disseminate the same information, but most pages fail to engage or interact with their followers, resulting in low outreach and low impact of messages. An example of best practice in how to engage with followers can be found on the Red Cross Facebook page. The Facebook page managed by the PRD clearly invests in timely content, which is presented in

an attractive manner and which has the potential to become a valuable community. The MOH generates the best engagement on Twitter and has the highest number of followers on Facebook, but could generate more impact by interacting more with the public. Social media monitoring and the evaluation of communication activities are currently lacking, but could contribute to a better understanding of perceptions and behaviour among the public.

A high number of simulation exercises certainly help reinforce the competencies of all staff involved in risk communication activities. Testing risk communications should be an objective in every exercise scenario.

Although all institutions indicate that they have dedicated communications staff, the level of professionalism of these teams needs to be raised by training, helping them to create more added value. Competencies in strategic communication planning, community engagement and press relations need to be further developed.

Communications staff are currently charged mainly with producing and publishing communications materials, but could take on more responsibilities, and they deserve more trust from managers and experts.

Press relations are currently handled by technical experts, and sometimes by politicians. This not only takes up valuable expert time, but it might also lead to conflicting messages in serious emergency situations involving multiple institutions and partners. Strengthening the leadership and coordination of the communications staff at the CMC could prevent this, and help streamline and rationalize communications. Having professional spokespersons would create added value for most of the institutions involved in risk communication.

Establishing dedicated budgets for communications teams would allow them to invest in training, procure monitoring tools and obtain the necessary software and communications equipment.

## Indicators and scores

### R.5.1 Risk communication systems for unusual/unexpected events and emergencies – Score 3

#### *Strengths and best practices*

- Clear and well-developed legislation, protocols and SOPs guide the flow of information between actors and define risk communication roles and responsibilities.
- In the event of a crisis, the CMC headquarters are activated and coordinate risk communication, assuring the coordination of information flow with other entities involved in the crisis management system.
- Dedicated communication staff are available at the CMC.

#### *Areas that need strengthening and challenges*

- A dedicated budget should be created for risk communication.
- There is a need to invest in communications training for communications staff, with particular attention to local level staff.
- Dedicated communications staff should be appointed at the MOH, at the IPH and locally.
- Communication competencies should be strengthened through training and exchanges with international partners and institutions.

**R.5.2 Internal and partner coordination for emergency risk communication – Score 3***Strengths and best practices*

- The Law for Crisis Management and a governmental decree stipulate rules for communication, coordination and collaboration between all actors involved in crisis management.
- There is a clear mechanism for communication and coordination at the PRD.
- North Macedonia holds frequent simulation exercises.
- There is a law ratifying the relationship between the PRD and the Union of the Civil Protection Mechanism.

*Areas that need strengthening and challenges*

- There is a need to streamline and rationalize risk communication and messages between all partners involved in the management of a crisis, to avoid conflicting messages.
- There are no dedicated budgets for risk communication by external partners and affected stakeholders.

**R.5.3 Public communication for emergencies – Score 3***Strengths and best practices*

- There are dedicated public relations and communications teams at the CMC and the PRD.
- SOPs between the CMC and regional crisis management centres allow the verification of information at local level.
- There is media screening at the MOH.
- Guidelines are in place for the work of the regional CMCs.

*Areas that need strengthening and challenges*

- Target audiences should be analysed to create a better understanding.
- Social media should be used in crisis communication.
- A strategy should be developed for the proactive use of different media platforms.
- A coordinated approach to risk communication during an emergency should be developed.
- Staff should be trained in (social) media monitoring.
- Budgets for risk communication should be coordinated.

**R.5.4 Communication engagement with affected communities – Score 2***Strengths and best practices*

- The MOH and IPH have websites and Facebook pages for communicating advice to the public.
- The CPHs communicate with the public during local events, during outbreaks and around catch-up vaccinations.
- The Red Cross performs social mobilization work.

*Areas that need strengthening and challenges*

- No systematic analysis is conducted on baseline social data, and there is no intelligence and analysis on factors that could increase the population's risk from the top five hazards in the country. Such analysis should include mapping of languages, living conditions, religious and cultural practices, trusted channels of communication and influencers.
- There is no staff and no budget to monitor the effectiveness of risk communication in affected communities.

### **R.5.5 Addressing perceptions, risky behaviours and misinformation – Score 2**

#### *Strengths and best practices*

- The MOH website and Facebook page address events and issues case by case.

#### *Areas that need strengthening and challenges*

- There is no system for monitoring the effectiveness of public outreach in addressing unfounded beliefs or correcting misinformation.
- Communication feedback, including on perceptions and misinformation, is not taken into consideration in drafting messages.
- There is no information on public perceptions, unfounded beliefs, risky behaviour and misinformation.
- There is no evaluation of the efficiency of risk communication reactions to wrong perceptions, risky behaviours and misinformation.
- A strategy should be developed to address perceptions, risky behaviours and misinformation.
- There is a need for dedicated staff and skills for social media communication.
- North Macedonia has a problem with a large number of anti-vaccination advocates on social media.

#### **Recommendations for priority actions**

- Invest in training for communications staff, in order to develop new competencies in strategic communication planning, community engagement and press relations.
- Develop knowledge and tools for social media monitoring in order to improve understanding of perceptions, emotions and behaviour in the population.
- Develop strategies to address wrong perceptions, risky behaviours and misinformation and to identify best practices.

# IHR-RELATED HAZARDS AND POINTS OF ENTRY

## POINTS OF ENTRY

### INTRODUCTION

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

#### Target

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

### LEVEL OF CAPABILITIES

Skopje International Airport is North Macedonia's only designated point of entry under the IHR (2005). A robust, demonstrated multisectoral system of support and processes is in place for triaging passengers who arrive ill and for the inspection of conveyances. First line medical and emergency personnel are available on site 24/7 and are supported by local and State/national level on-call, offsite staff when a public health risk assessment or response is required. Onsite facilities exist for short-term isolation (for six people) and quarantine (for 200 people).

Service contracts are used for environmental health (water, air and noise), management of waste, management of hazardous materials, disinfection of baggage, cargo and containers, and vector control (disinsection and deratting). There is a concern that vector control will not be sustained in the area surrounding the airport, due to funding difficulties in the responsible municipal authorities.

By law, biological, chemical and radiological commodities are only allowed to enter North Macedonia through the IHR-designated port. Animal imports into Skopje are limited to personal pets and the occasional commercial shipment. Most commercial livestock move across land borders. Animal imports are permit-controlled and require pre-notification. Animal health assessments and control measures are provided by the FVA as needed.

Real-life events and exercises have shown that constant, routine education is required for all relevant sectors, as there is a large and consistent staff turnover. Protocols and procedural manuals need to be updated based on after-action reports and improvement plans generated by events (either real events or exercises), and then training and/or retraining should be conducted on a routine basis.

Additional education is needed for health authorities and port authorities on port procedures required or regulated by aviation agencies and organizations such as the Airports Council International (ACI), the International Air Transportation Association (IATA), the International Civil Aviation Organization (ICAO) and the Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation (CAPSCA).

Integration of operational plans into larger strategic documents is another area that requires increased intersectoral and interministerial coordination. For example, the Airport Emergency Plan (AEP) and the protocol for handling and reporting from an international airport entrance point should be reviewed from an intersectoral point of view and then annexed into national plans such as the National Aviation Contingency Plan and the National Emergency Response Plan (currently in draft).

## Indicators and scores

### PoE.1 Routine capacities established at points of entry – Score 4

#### *Strengths and best practices*

- Comprehensive national laws and operational plans are in place for individual carriers and ports, and protocols are in place for biological, chemical and radiological commodities entering the point of entry.
- There is 24/7 access to medical services and staff, diagnostics, equipment and transportation to the appropriate medical centres.
- Epidemiological support for assessment and response is available 24/7.
- Facilities are maintained at a high standard (following ISO standards and Hazard Analysis and Critical Control Point principles) to assure a healthy and safe environment for all passengers and employees.
- Participation in international training is supported, for example through CAPSCA Euro meetings and an AIRSAN (coordinated EU action in the aviation sector to control public health threats<sup>1</sup>) training course held in 2017.

#### *Areas that need strengthening and challenges*

- Communications and multisectoral cooperation need to be improved.
- There is a need for more frequent multisectoral training and regular exercises (i.e. one full-scale exercise every two years), including a focus on the proper use of personal protective equipment and on updated protocols and procedures. These exercises should be planned and carried out with consideration of limited resources and continuous turnover of staff.

### PoE.2 Effective public health response at points of entry – Score 4

#### *Strengths and best practices*

- There is communication, cooperation, coordination and collaboration between aviation and public health sectors during routine and emergency incidents.
- An established multisectoral response team coordinated through the CMC is available to respond to incidents.
- A multisectoral range of stakeholders took part in developing the response plans.
- National and service provider response plans are harmonized.
- Effectiveness of responses to public health events at points of entry has been evaluated and demonstrated, both after real events and in reviews of exercises.
- A multidisciplinary, multisectoral full-scale exercise based on a traveller infected with Ebola took place at Skopje International Airport in October 2014.

<sup>1</sup> The AIRSAN Project supports EU Member States in ensuring a well-organized and coherent response to public health threats in air transport.

### Areas that need strengthening and challenges

- There is a need to integrate operational plans into larger strategic documents.
- Training by the Civil Aviation Agency is required to educate relevant public health staff on aviation regulations. This should be implemented within 90 days of employment and staff should undergo annual refresher training.
- There is a need to improve distribution mechanisms to move preventive medicines from public health depots to port staff.
- Specific programmes are needed for monitoring and suppressing vectors at points of entry. These should include a focus on the areas surrounding the points of entry but not under their direct jurisdiction. These need to be evaluated, with particular emphasis on sustained funding for vector control carried out by the municipalities surrounding the airport.
- There is a need to develop faster assessment algorithms. Currently, assessment of an incident of public health concern can take up to three hours (one hour for an assessment team to be deployed and two hours for the assessment).

### Recommendations for priority actions

- Integrate existing operational plans (e.g. the AEP and the protocol for handling and reporting from an international airport entrance point) into finalized national strategic plans (e.g. the National Aviation Contingency Plan and the National Emergency Response Plan).
- By 2021, create and implement a port-specific, multiyear, multisectoral training and exercise plan that incorporates the lessons of previous exercises.
- Integrate appropriate data management and reporting of records captured during entry and exit screening into the public health surveillance system.
- Develop criteria to evaluate the success of multisectoral responses to biological threats or other incidents of concern (e.g. chemical and radiological incidents) at points of entry.

# CHEMICAL EVENTS

## INTRODUCTION

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

### Target

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

## LEVEL OF CAPABILITIES

North Macedonia was declared an EU candidate country in 2005, and has harmonized laws and by-laws to control and manage chemicals and protect health and the environment with the relevant EU Directives. International conventions and agreements have been ratified. There are, however, differences in the extent to which different stakeholders and sectors relevant to chemicals have implemented the legislation.

The Law on Public Health mandates national reporting procedures and notification of chemical events to WHO through the IHR NFP at the IPH.

The Department of Chemicals at the MOH is responsible for implementing the Law on Chemicals, including by regulating production and maintaining a register of chemicals. However, while a legal framework has been established a database has not been implemented.

National programmes exist for managing chemical risks within some relevant stakeholder areas (e.g. the work of the Ministry of the Environment) by maintaining information registers that include entities importing hazardous chemicals, priority contaminated sites, pollution prevention and control permits, etc. However, knowledge gaps remain. Neither a national chemicals profiling exercise nor a risk assessment has been undertaken in the last five years.

With regard to IHR capacity, responsibility for chemical management, response and surveillance is distributed among multiple agencies and ministries, but no single agency or entity has been established to lead the development of IHR capacity and increase awareness across different relevant areas/sectors. Where the areas of responsibility of various agencies or ministries have not been clearly defined, consensus on responsibilities has not been achieved.

The 2017 Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters describes the organizational structure and communication strategy linking multisectoral stakeholders in responses to emergencies, including chemical events. This plan describes the roles of the MOH, the IPH, the CMC and other stakeholders in responding to emergencies. The CMC coordinates risk assessment, collects and exchanges information, communicates with the public and coordinates a multiagency response. Responses to chemical events are determined by a multisectoral committee risk assessment team, and may include first responders, the PRD and/or the army. Guidelines and operating procedures for incident management and surveillance have been developed, but there is little knowledge of their implementation in a number of sectors.

Surveillance for chemicals and chemical events is managed by individual agencies and is limited. Indicator-based surveillance programmes exist for ambient air quality, water quality, food and non-food consumer products, with most analysis undertaken by the IPH. The IPH also provides commercial analytical services and has the potential to extend the scope of its analytical services to support other agencies. It was reported that the army has chemical detection capacity and analytical facilities for emergency response events. Neither event-based nor syndromic surveillance systems exist for chemical events. Membership of international chemical surveillance networks was not reported.

The Macedonian Toxicological Information Centre is part of the University Clinic of Toxicology in Skopje, and was reported to collect and process data on poisoning and adverse effects caused by chemicals and to provide a poisons information service. However, there was some uncertainty about its operational capabilities and ability to provide 24/7 services.

## Indicators and scores

### CE.1 Mechanisms established and functioning<sup>2</sup> and responding to chemical events or emergencies – Score 2

#### *Strengths and best practices*

- A national plan has been established for preparedness and response of the health system when dealing with emergencies, crisis situations and disasters.
- Guidelines and SOPs have been established for coordinating responses to events involving chemicals.
- National monitoring systems have been established for ambient air quality, water quality, food and non-food consumer products.
- The Macedonian Toxicological Information Centre collects data on health effects caused by chemicals and provides a poisons information service.

#### *Areas that need strengthening and challenges*

- Intersectoral stakeholder communication and cooperation should be improved, particularly during periods outside emergency event responses.
- Surveillance systems should be improved/established for a greater number of stakeholder sectors and should aim to include event-based and syndromic surveillance systems to facilitate early detection.
- There should be regular reporting of surveillance data.
- The analytical scope of laboratories should be increased to improve detection and verification capacity, utilizing existing resources where possible.
- Responses to chemical events should be tested and assessed regularly under realistic scenario conditions, through evaluation exercises.
- A chemical information system/database should be established and made accessible at all times.
- Civilian first responders and emergency medical staff should receive training, equipment and resources to deal with the casualties of chemical incidents.
- There is no civilian structure or capacity for response and decontamination following a chemical emergency (currently only the military has this capacity). Capacity for dealing with chemical events should be strengthened and should include planning for surge events.
- Emergency response planning and risk assessment should consider the potential for the presence of multiple hazards, including chemicals and should incorporate appropriate precautions and management.

<sup>2</sup> Detection capacity includes not only surveillance but also the laboratory capacity required for the verification of any events.

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

### Strengths and best practices

- Legislation has been enacted to control and manage chemicals and protect health and the environment. Relevant international conventions and agreements have been ratified.
- A national strategy has been established for preventing the proliferation of weapons of mass destruction and protecting against CBRN threats.
- A national preparedness and response plan for emergencies, crisis situations and disasters has been established and clearly defines the roles and responsibilities of stakeholders, a coordinating body and a communication process. SOPs have also been drawn up.
- Emergency funds are provided by central government or in cases of emergency, agreements have been made for provision of international support where required.
- Regulatory standards and registers are established for the control and management of chemical risks/sources in some sectors and applications (such as for major hazardous sites, land use planning, water and food quality, pollution prevention and control, etc.), but knowledge gaps remain. A register of entities working with chemicals/precursors has been established.
- A list of priority industrially contaminated sites has been prepared.
- Interdepartmental consultation/communication between the MOH and the Ministry of the Environment and Physical Planning is required when a land use planning application proposes development of an industrial facility.

### Areas that need strengthening and challenges

- Agency/sector roles, responsibilities and expectations relating to chemicals and IHR implementation should be clearly defined, to include raising awareness of the importance of each sector in a functional multisectoral system to protect health.
- An entity or committee to lead development of and/or strengthen capacity across the sectors should be considered.
- A national chemicals profile and a risk map/register for chemicals do not exist (e.g. for production, storage, use, waste, contaminated land, etc.).
- Intersectoral stakeholder communication and cooperation should be improved, particularly during periods outside emergency event response.
- There is a need to establish an integrated chemical information and registry system that is available at all times and which is regularly updated.
- There is a need to improve implementation and regulation of legislation relating to all sectors relevant to chemicals.
- Risk communication with the public should be improved.

### Recommendations for priority actions

- Identify capacity gaps across all relevant sectors. Develop national capacity-building priorities for preventing, detecting and responding to chemical events.
- Assign an entity, committee or agency to lead the development of IHR capacity for chemicals across sectors.
- Establish a national chemicals profile and a risk map/register for chemicals (e.g. production, storage, use, waste, contaminated land, etc.).
- Increase surveillance capacity and the analytical scope (for detection and verification) of laboratories regarding chemicals and their health effects.
- Improve capacity for dealing with chemical events and casualties. Emergency response planning and risk assessment should also consider the potential for the presence of multiple hazards, including chemicals and incorporate appropriate precautions and management.

# RADIATION EMERGENCIES

## INTRODUCTION

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

### Target

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

## LEVEL OF CAPABILITIES

The Republic of North Macedonia does not have a nuclear power plant, nor is it in possession of a nuclear research installation. As a result, there is no nuclear waste or fuel in the country. There is, however, a range of low level radiation sources in diagnostic and therapeutic devices used in the health sector and in industry.

According to the international standards of the International Atomic Energy Agency (IAEA) and a national by-law on threat categorization, North Macedonia has category III to category V threats in the country (Regulation on Categorization of Radiation and Nuclear Threats, Gazette of the Republic of Macedonia 162/09).

A number of laws, decrees and regulations support a solid system of response to radiation emergencies and the protection of workers and the population in general. Particular mention can be made of the Law on Ionizing Radiation Protection and Safety (Official Gazette of the Republic of Macedonia, no. 48/02, 135/07 with amendments), the long-standing Decree on the Ratification of the Convention on Early Notification of a Nuclear Accident (Official Gazette of SFRY 15/1989), and the more recent Radiation Emergency Plan in the Republic of Macedonia (Official Gazette of the Republic of Macedonia 84/2011).

The RSD is the relevant regulatory body in the Republic of North Macedonia. This entity reports directly to the Prime Minister and has a wide range of authoritative functions. It manages the licensing process for permits and control of sources of ionizing radiation; determines intervention levels and conditions for import and export of ionizing sources; intervenes and coordinates in cases of emergency; maintains the national registry of ionizing sources; and maintains a registry of persons exposed to ionizing sources in the context of occupational activity. The responsibilities of the IPH for radiation protection include providing regular information on perceived or known radiation levels in soil, water, air and food to the RSD. Furthermore, the RSD maintains close coordination with border authorities on radiation levels of goods entering the country.

National coordination of response actions in radiological emergencies or to threats of nuclear origin is managed by a tripartite platform consisting of the RSD, the CMC and the PRD. This platform coordinates its activities with other State entities, ministries and NGOs and prepares coordinated messaging and information for the public.

Operational staff working in radiation protection participate, on a selective basis, in regional and international events on radiation issues. There is a need for a more structured approach to training a cadre of professionals in this area, including through exposing them to international developments in the field of radiation protection and management – a point of particular concern.

## Indicators and scores

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

#### *Strengths and best practices*

- A national plan is in place on the Protection of the Population in Case of Radiation Emergency in the Republic of North Macedonia.
- Monitoring of radiation in the environment is supported by adequate laboratory capacity (for monitoring air, precipitation, river water and sediment, drinking water, land, food, animal feed and other goods controlled at border crossings).
- An early warning and notification system is in place (the European Radiological Data Exchange Platform).
- North Macedonia participates in exercises organized by the IAEA.
- The IPH reports annually on the monitoring of radiation in the territory of the Republic of North Macedonia.
- There is a government directorate for coordinating and managing radiological emergencies.

#### *Areas that need strengthening and challenges*

- There is a need for multisectoral training of operational and managerial professionals in accordance with the needs and criteria of the national plan on radiological emergencies.
- There is a need to improve the ability of the health care system to support responses to radiological incidents (building technical capacities, instituting SOPs for treatment of irradiated persons, providing up-to-date laboratory technology and stockpiles of the necessary drugs and medicines, etc.).

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

#### *Strengths and best practices*

- A National Coordinating Body is in place to deal with radiation and nuclear emergency situations.
- A government decree (April 28, 2018) determines the response plan for radiological accidents.
- There is multisectoral involvement during such responses, with delegated responsibilities for operations, communications, management and decision-making during an emergency.

#### *Areas that need strengthening and challenges*

- A structured approach is required for national simulation exercises, including protocols for requesting international assistance where needed.
- No formal site for storage of radioactive waste has been defined; current deposits are outside the country.

### Recommendations for priority actions

- Establish a national repository site for storing radioactive waste.
- Develop a comprehensive multisectoral training plan to address the needs and criteria of the national plan on radiological emergencies.
- Provide adequate protective materiel, decontamination equipment and personal protective equipment for personnel exposed to radiation sources.

# APPENDIX 1: JEE BACKGROUND

## Mission place and dates

Skopje, Republic of North Macedonia, 11–15 March 2019.

## Mission team members:

- Jussi Sane (Team Lead), Finnish National Institute for Health and Welfare
- Peter J. Mertens (Team Co-Lead), independent consultant
- Haydn Cole, Public Health England
- Jan Eyckmans, Belgian Federal Public Service Health
- Dagmar Heim, World Organisation for Animal Health
- Ivana Kelic, Institute of Public Health of Serbia
- Abebayehu Mengistu, WHO Regional Office for Europe
- Taina Niskanen, European Centre for Disease Prevention and Control
- Mark Nunn, independent technical writer
- Adrienne Rashford, WHO Regional Office for Europe
- Andreas Reich, Robert Koch Institute, Germany (observer)
- Kendra Stauffer, US Centers for Disease Control and Prevention, USA
- Hannah Lewis Winter, Robert Koch Institute, Germany

## Objective

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

## The JEE process

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

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

## Limitations and assumptions

- The evaluation was limited to one week, which limited the amount and depth of information that could be managed.
- It is assumed that the results of this evaluation will be publically available.
- The evaluation is not just an audit. Information provided by North Macedonia 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

- Suzana Andonova
- Zoran Atanasov
- Angelina Bacanovic
- Zoran Blazevski
- Golubinka Bosevska
- Bojan Boskovski
- Agron Buxhaku
- Biljana Celevska
- Emilija Chutanovska
- Lendita Dika
- Biljana Georgievska Dimitrievski
- Vesna Dimitrovska
- Mirjana Dimovska
- Adnan Dzaferoski
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- Vesna Gerasimovska
- Svetislav Gjoirgjevic
- Dragan Gjorgjev
- Kristina Hristova
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- Shaban Memeti
- Vladimir Mikic
- Grozdanka Naumovska
- Lidija Nikolovska
- Greta Nikolovska
- Dance Gudeva Nikovska
- Dugagjin Osmani
- Boris Palcevski

- Nikola Panovski
- Milena Petrovska
- Dusko Petrovski
- Svetlana Petrusevska
- Perivoje Popov
- Gordana Ristovska
- Iskra Sadikario
- Lidija Savic
- Afrodita Shalja
- Zaklina Sopova
- Keterins Stavric
- Kristina Stavridis
- Milena Stevanovic
- Biljana Strojmenska
- Ljubica Tasheva
- Jihane Tawilah
- Maja Timovska
- Goran Trajkov
- Romel Velev

## Supporting documentation provided by host country

### NATIONAL LEGISLATION, POLICY AND FINANCING

- Constitution of the Republic of Macedonia (Official Gazette of the RM)
- Law on Crisis Management (Official Gazette of the RM no. 29/2005,36/2011,41/2014, 104/2015, 39/16 and 83/18)
- Law on Public Health (Official Gazette of the RM no. 22/10, 136/11, 144/14, 149/15 , 37/16}
- National Public Health Programme (Official Gazette of the RM no. 16/2018)
- Law on Protection of Population against Communicable Diseases (Official Gazette of the RM no. 66/04, 139/08, 99/09,149/14, 150/15 and 37/16)
- A Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters (iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf)
- Public Health Action Plan
- Law on Food Safety (Official Gazette of the RM no. 157/10, 53/11 and 1/12)
- Law on Veterinary Health (Official Gazette of the RM no. 113/07, 24/11, 136/11 and 123/12)
- Law on Animal Feed Safety (Official Gazette of the RM no. 145/10, 53/11 and 1/12)
- Law on Medicinal Products and Medical Devices (Official Gazette of the RM no. 106/2007, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16 and 113 G/2018)
- Law on Chemicals (Official Gazette of the RM no. 145/10, 53/11, 164/13, 116/15, 149/15 and 37/2016)
- Plan for Protecting the Population Against the Harmful Effects of Ionizing Radiation (Official Gazette of the RM, no. 84/2011)
- Aviation Act (Official Gazette of the RM no. 14/2006, 24/2007, 103/2008, 67/10, 24/12, 80/12, 155/12, 42/14, 97/15,152/15 and 31/2016)
- Order on Civil Aviation Facilitation Measures and Procedure (Official Gazette of the RM no. 50/11, 36/2013)

## IHR COORDINATION, COMMUNICATION AND ADVOCACY

- Law on Crisis Management (Official Gazette of the RM no. 29/05, 36/11, 41/14, 104/15, 39/16 and 83/18)
- Decree determining the operational procedures for mutual communication, coordination, cooperation and acting of the entities in the crisis management system (Official Gazette of the RM no. 27 of 09.02.2018)
- SOPs drafted and signed by the CMC Director, for everyday use in by the CMC staff
- SOP-Work on Duty in the State Operations Centre (no. 14-1305/2 from 24.04.2017)
- SOP for the work of 8 regional centres (7/24), no. 14-2554/1 of 22.09.2015
- SOP for the work of the regional centres (5/8) no. 14-2555/1 of 22.09.2015

## ANTIMICROBIAL RESISTANCE

- Law on Food Safety
- Law on Medicinal Products and Medical Devices
- Law on Protection of Population against Communicable Diseases (Official Gazette of the RM no. 66/2004, 139/2008, 99/2009, 149/2014, 150/2015 и 37/2016)
- Law on Veterinary Health
- Law for Health Care (Official Gazette of the RM no. 43/2012, 145/2012, 87/2013, 164/2013, 39/2014, 43/2014, 132/2014, 188/2014, 10/2015, 61/2015, 154/2015, 192/2015, 17/2016 and 37/2016}
- Law for Medicines and Medical Devices (Official Gazette of the RM 106/2007, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, and 113/18)
- Law for Health Insurance (Official Gazette of the RM no. 25/00, 34/00)
- Law for Sanitary and Health Inspection (Official Gazette of the RM no. 71/2006, 139/2008, 88/2010, 18/2011, 53/2011, 164/2013, 43/2014, 144/2014, 51/2015, 150/2015 и 37/2016)
- Regulation on the detailed criteria for prevention and treatment of intrahospital infections (Official Gazette of the RM no. 25/2008)
- Regulation on the manner and procedure for carrying out official controls on products of animal origin intended for human consumption (Official Gazette of the RM, no. 157/2015)
- Regulation on the manner of performing official controls and procedures for monitoring zoonoses
- Regulation on the manner of performing official controls of Salmonella and other specific alimentary intoxications (Official Gazette of the RM no. 34/2015)
- Regulation on the manner of reporting and the form and content of the forms for reporting communicable diseases and microbial agents
- Regulation on the necessary space, equipment and professional staff for establishing, starting operations and conducting health care activities in health care institutions
- Regulation prescribing the manner and procedure for reporting diseases
- Regulation on specific requirements relating to microbiological criteria of foodstuffs (Official Gazette of the RM no. 100/2013, 145/2014, 37/2017)
- Regulation on the manner of reporting and the form and content of the forms for reporting communicable diseases and microbial agents (Official Gazette of the RM no. 46/2009)
- CAESAR reports until 2018
- Programme for antimicrobial resistance for the period 2017–2021
- Plan for Antimicrobial Resistance Surveillance

- National control plan to reduce the presence of salmonellosis in laying hens, breeding flocks, broilers, incubation stations (*Gallus gallus*) in the Republic of Macedonia
- Strategy for the Control of AMR 2017-2021
- Annual Order on Animal Health Care
- Decision for plans on emergency measures
- Quarterly and Annual Reports of Pharmaceutical Inspectors from MALMED
- Rulebook for prescription and distribution of medicines (Official Gazette of the RM no. 94/2016)
- Rulebook on detailed criteria for prevention and suppression of intrahospital infections (Official Gazette of the RM no. 25/2008)
- NHIF's Rulebook on realization of the insurers rights based on compulsory health insurance (Official Gazette 1 of the RM 8/15, 64/15, 96/15, 125/15, 191/15 and 187/16)
- Rulebook for reporting and report forms (report form no. 8) (Official Gazette of the RM no. 46/2009)
- National Strategy with action plan 2012-2016 [http://zdravje2020.mk/index\\_en.php?page=ebiblioteka](http://zdravje2020.mk/index_en.php?page=ebiblioteka); <http://www.who.int/antimicrobialresistance/national-action-plans/library/en/>
- List of essential medicines (Official Gazette of the RM no. 19/2015 (according WHO list))
- National reimbursing (positive) list of medicines (Official Gazette of the RM no. 17/15)
- Medical map – health care facilities included in reimbursement system – NHIF contracts the health care providers from the Medical map (Official Gazette of the RM 17/15 81/12, 169/13, 21/14, 90/14, 161/14, 2/16, 144/16, 187/16, 223/16 and 188/18)

## ZOOONOTIC DISEASE

- Law on Protection of the Population Against Communicable Diseases (Official Gazette of the RM no. 66/2004,139/2008,99/2009,146/2014,150/2015,37/2016)
- Law on Public Health (Official Gazette of the RM no. 22/2010,136/2011,144/2014,149/2015, 37/2016)
- Law of Sanitary and Health Inspection (Official Gazette of the RM no. 71/06, 139/08, 88/11, 53/12, 164/13, 43/14, 51/15, 37/16)
- Law of Inspection Surveillance (Official Gazette of the RM no. 50/10, 162/10, 157/11, 147/13, 41/14, 33/15, 193/15, 53/16, 11/18, 83/18, 120/18)
- Regulation on the manner of reporting and the form and content of the forms for reporting communicable diseases and microbial agents (Official Gazette of the RM no. 46/2009)
- Regulation of criteria for case definitions of communicable diseases (Official Gazette of the RM no. 10/2011, updated in Official Gazette of the RM no. 19/2018)
- Programme for examining the emergence, prevention and suppression of brucellosis in the population in the Republic of Macedonia (Official Gazette of the RM no. 4/2019, last)
- National Annual Public Health Programme of the Republic of Macedonia (Official Gazette 6/2019)
- Law on Veterinary Health (Official Gazette of the RM no. 113/07, 24/11, 136/11, 123/12, 154/15, 53/16)
- Law on Food Safety (Official Gazette no. 157/10, 53/11, 1/12, 164/13, 187/13, 43/14, 72/15, 84/15)
- Annual Order for Animal Health Protection (Official Gazette of the RM no. 3/2019)
- Regulation on the manner and procedure for reporting rabies in domestic animals and wildlife and measures to be taken for the treatment and eradication of rabies (Official Gazette of the RM 155/2012)

- Programme for treatment and eradication of brucellosis in sheep and goats
- Programme for elimination of the rabies in foxes (2008)
- Memorandum of coordination of works and competences related to food safety and public health between FVA and IPH (November 2013)
- Cooperation Agreement between FVA and MOH (May 2015)
- National protocol for the handling of competent institutions in case of suspicion and occurrence of alimentary infections and intoxications between SSHI and FVA (December 2018)
- Decision to establish a Committee for Communicable Diseases, last in 2018
- FVA Forming a National Centre for Diseases Control (Peste des petits ruminants), July 2018

## FOOD SAFETY

- Law on Population Protection Against Communicable Diseases
- Law on Public Health
- Law on Food Safety
- Law on Sanitary and Health Inspection
- Law on Veterinary Health
- Regulation on criteria for defining cases of communicable diseases (Official Gazette of the RM no.19/2018)
- Regulation on the manner of reporting and the form and content of the forms for reporting communicable diseases and microbial agents (Official Gazette of the RM 46/2009)
- Regulation for specific requirements for microbiological criteria for food products (Official Gazette 100/2013 173/2018)
- Regulation for general requirements for food safety related to maximum levels for certain contaminants (Official Gazette of the RM 175/2018, 102/2013}
- Plan for preparedness and response of the health care system in dealing with emergency, crisis situations and disasters, 2017
- National plan for crisis management for food and feed safety for the period 2014–2018
- National plan for crisis management for food and feed safety for the period 2019–2023
- Programme for examining the emergence, prevention and treatment of brucellosis in the population in the Republic of Macedonia (Official Gazette of the RM 17/2018, last)
- National Annual Public Health Programme of the Republic of Macedonia (Official Gazette of the RM 16/2018 last)
- Programme for monitoring food safety for 2018 year (Official Gazette of the RM 17/2018, last)
- National Operation Protocol of competent institutions in cases of suspicion and occurrence of alimentary infections and intoxications
- Report for communicable diseases for 2017 year, Institute of Public Health of Republic of Macedonia
- Report for alimentary intoxication in Lear Tetovo. Institute of Public Health.
- Monthly newsletters for infectious diseases, prepared by the IPH and submitted to the MOH; SSHI; FVA; CPH, published on the website of IPH
- Former Yugoslav Republic of Macedonia, The Trends and Sources of Zoonoses and Zoonotic Agents In Foodstuffs, Animals and Feed Stuffs, including information on foodborne outbreaks, antimicrobial resistance in zoonotic and indicator bacteria and some pathogenic microbiological agents, 2017, EFSA Zoonoses monitoring

## BIOSAFETY AND BIOSECURITY

- Law on Protection of the Population Against Communicable Diseases (Official Gazette of the RM no. 66/2004, 139/2008, 99/2009, 149/2014, 150/2015 and 37/2016)
- Regulation on reporting and the form and content of the forms for reporting communicable diseases and microbiologically confirmed causative agents (Official Gazette of the RM no. 46/2009). Form no. 8, Form no. 9
- Guidelines for safe management of medicinal waste ([iph.mk/wp-content/uploads/2014/09/Priracnik\\_bezbednosno\\_upravuvanje-Medicinski\\_otpad\\_2009.pdf](http://iph.mk/wp-content/uploads/2014/09/Priracnik_bezbednosno_upravuvanje-Medicinski_otpad_2009.pdf))
- Guidance on regulations for the transport of infectious substances 2017–2018 ([apps.who.int/iris/bitstream/handle/10665/254788/WHO-WHE-CPI-2017.8-eng.pdf](http://apps.who.int/iris/bitstream/handle/10665/254788/WHO-WHE-CPI-2017.8-eng.pdf))
- Information on the first biosafety/biosecurity/ biodiversity workshop on the IPH website (<http://www.iph.mk/odrzana-prvata-rabotilnica-na-tema-razvoj-na-znaenja-i-prenos-na-najdobri-praktiki-za-biosigurnost-biobezbednosti-upravuvanje-so-biorizik-vo-republika-makedonija/>)
- Law for Health Protection
- Rulebook for minimum criteria for safety and health at work of workers from risk connected to exposure to biological agents (Official Gazette of the RM no. 170 /2010 -no. 07-9041/1)

## IMMUNIZATION

- Law on Protection of the Population Against Communicable Diseases (Official Gazette of the RM no.37/2016)
- Rulebook for immunoprophylaxis, chemoprophylaxis, people subject to these measures, means of realization and keeping records and documentation (Official Gazette of the RM, no. 177/15 )
- Compulsory Immunization Programme for the population in the Republic of Macedonia for 2018 (Official Gazette of the RM no. 16/2018)
- National Annual Public Health Programme (Official Gazette of the RM no.16/2018 )
- National Immunization Strategy 2012-2020
- Law on Health Care (Official Gazette of the Republic Macedonia no. 43/12, 145/12, 87/13, 164/13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15, 192/15, 17/16 and 37/16),
- Annual Report on the Implementation of Mandatory Immunization for 2017 – [http://www.iph.mk/wp-content/uploads/2018/05/Immunization – Izvestaj-2017\\_final\\_12.03.pdf](http://www.iph.mk/wp-content/uploads/2018/05/Immunization_-_Izvestaj-2017_final_12.03.pdf)
- [http://malmed.gov.mk/wp-content/uploads/28-Pravilnik\\_za\\_prijavuvanje\\_nesakani\\_reakcii-Sl.Vesnik-br.93-2008.pdf](http://malmed.gov.mk/wp-content/uploads/28-Pravilnik_za_prijavuvanje_nesakani_reakcii-Sl.Vesnik-br.93-2008.pdf)
- Law on Medicines and Medical Devices <http://malmed.gov.mk/wp-content/uploads/19-Zakon-za-izmenuvanje-i-dopolnuvanje-na-Zakonot-za-lekovi-i-meidcinski-sredstva-br.-245-od-2018.pdf>
- ECDC Technical Assessment Report: The former Yugoslav Republic of Macedonia assessment of country capacities in communicable diseases surveillance, prevention and control, 2016

## NATIONAL LABORATORY SYSTEM

- Law on Protection of the Population Against Communicable Diseases 2004 (Official Gazette of the RM no. 66/2004)
- Rulebook on reporting of infectious diseases and specific health issues – Article 5 defines notifiable infectious diseases, as well as specific health issues (health care-related infections and antimicrobial resistance)
- Law on Health Care (Official Gazette of the RM no. 43/2012)
- Law on Veterinary Health (Official Gazette of the RM no.113/07, 24/11, 136/11, 123/12, 154/15 and 53/16)

- Regulation on the reporting manner and procedure for diseases subject to mandatory reporting and a list of animal diseases subject to mandatory reporting (36/17) Veterinary Directorate has identified the priority animal diseases in cooperation with the EU, OIE and countries in the region, and established a procedure for determining the priority diseases (2005).
- Law on Health Care / Rulebook on detailed conditions for performing health care activities in health institutions
- Regulation on the programme for the protection of health of the population against infectious diseases defines priority objectives in the field of epidemiology, microbiology
- Technical assessment report for the Former Yugoslav Republic of Macedonia, ECDC, 2016

## SURVEILLANCE

- Law on Protection of Population from Communicable Diseases
- Law on Public Health
- Law on Electronic Health Records
- Samples of surveillance reports used by public health decision-makers in the country
- Listing of core syndromes indicative of a public health emergency
- Plans for enhancing syndromic surveillance
- Plans for developing or enhancing EBS
- OIE reports (WAHIS)
- Surveillance databases and forms
- ECDC Technical assessment report

## REPORTING

- Decision to nominate an IHR NFP from 2018 (Document no. 13 in Annex)
- Law on Communicable Diseases
- Law on Food Safety
- Law on Public Health
- Law on Protecting the Population from Contagious Diseases (Official Gazette of the RM no. 66/04)
- Regulation on the manner of performing official controls and procedures for monitoring zoonoses and zoonotic agents and a list of zoonoses and zoonotic agents that are regularly monitored
- Regulation on the manner of performing official controls of salmonella and other specific alimentary intoxications
- 2017 Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises And Disasters
- Regulated case definitions, synchronized with ECDC, published in the Official Gazette of the RM no. 10/2011, updated in Official Gazette of the RM no. 19/2018
- WHO IHR 2005 Annex 2 Decision Instrument for The Assessment and Notification of Events That May Constitute A Public Health Emergency of International Concern

## HUMAN RESOURCES (ANIMAL AND HUMAN HEALTH SECTORS)

- A programme for the needs of specialist and subspecialist staff (postgraduate trainees) according to the network of health care institutions 2015-2018 (Official Gazette of the RM no. 69/15)
- Occupational Health and Safety Strategy for Health Care Professionals (40)([iph.mk/wp-content/uploads/2019/01/Стратегија-здравствени-работни-ци.pdf](http://iph.mk/wp-content/uploads/2019/01/Стратегија-здравствени-работни-ци.pdf))

- Regulation on the minimum requirements for the protection of workers from risks related to exposure to biological agents at work
- Health map of the Republic of Macedonia 2016 (<http://iph.mk/wp-content/uploads/2017/12/EN-Zdravstvena-karta-2016-del-1.pdf>)
- Weekly EPI reports, Monthly EPI Bulletin, Reports from epidemiological investigations, Outbreak notification report, EPItel report, CMC daily information
- Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters

## EMERGENCY PREPAREDNESS

- Law on Protection and Rescue (Official Gazette of the RM no.93/12)
- Assessment of the threat of the Republic of Macedonia from natural disasters and other disasters" Official Gazette of the RM no. 117/07
- Methodology for the content and method of assessment of the threat and planning of protection and rescue (Official Gazette of the RM no. 76/06)
- Decree on the type, size and organization of the protection and rescue forces
- Decision on the formation of the protection and rescue forces established by the Republic
- Decision for provision of material reserves for the needs of protection and rescue
- SOP for the measure Emergency Medical Assistance no. 01-2964/1 from 2010
- National Protection and Rescue Plan
- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters (February 2017),
- SOP for the measure Emergency Medical Assistance no. 01-2964/1 from 2010
- SOP for the measure Evacuation of the population
- SOP for the measure Assanation in the field. no. 01-2963/1 from 2010
- SOP for the measure Car accidents protection and rescue. no. 01-2966/1, 2010
- SOP for the measure Assanation in the field. no. 01-2963/1 from 2010
- SOP for the measure Protection and rescue of animals and products of animal origin. no. 01-2965/1 from 2010
- Participation in the field exercise Modex 2017 Apell-EuroModex Civil Protection of the European Union, military camp Pepelishte, RM
- Workshops CMEP 2016/2017 preparation of scenario for exercise and exercise
- Participation in exercises and other activities, according to approved plans and programs
- participation in international exercise Cro – Floods 2017
- Training plans and programmes
- Elaborates for held exercises
- Evaluations from the held trainings for 2017
- Protection and rescue plans at the local level
- Simulation exercise of the employees of Alkaloid ad Skopje on the topic: Evacuation of employees in case of fire.
- Participation in exercises and other activities, according to approved plans and programs
- Participation in international exercise Cro – Floods 2017
- Training plans and programmes
- Elaborates for held exercises

- Evaluations from the held trainings for 2017
- Participation in Exercise – Ipa Floods International Exercise, Germany
- Participation in a workshop CMEP-Scenario Planning Workshop – Geospatial Disaster Response Preparations
- Training evaluation of the spatial forces for protection and rescue
- Training evaluation of the universal unit for protection and rescue
- Decree on methodology for assessment of the threat to the security of the Republic of Macedonia from all risks and dangers, its content and structure, the manner of keeping and updating, as well as determining the entities in the crisis management system to which a complete or statement of assessment is provided
- Law on Crisis Management
- Decree for determining the operational procedures for communication, coordination, cooperation and conduct of the subjects in the system for crisis management
- Decree for the type of data and information, and procedure for its delivery to the Centre for Crisis Management
- Methodology for preparing the assessment, its content, structure storing and updating and determine the subjects in the system for management of crisis to whom the Assessment is given in full or in part
- Decree for organization, planning and conducting exercises/trainings, content of the certificates for the exercises/trainings as well as procedures that are mandatory in the system for the crisis management.
- Elaborates for the organization and conducting of the regular international exercises in the organization of CMC and other exercises and trainings for human resources development in the crisis management system

## EMERGENCY RESPONSE OPERATIONS

- Law on Protection and Rescue (Official Gazette of the RM no. 93/12)
- Plans of the EOC, and listing of available equipment
- Decision on the Establishment of the General Headquarters for Protection and Rescue (Official Gazette of the RM no. 63/18)
- Decision on Established Regional Protection and Rescue Headquarters
- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters (February 2017)
- Exercise MODEX 2017
- Law for the Red Cross of Macedonia (Official Gazette of the RM 41/94) <http://ckrm.org.mk/zakon-za-crveniot-krst-na-republika-makedonija/>)
- Statute of Red Cross in Macedonia, Skopje March 2017 <http://ckrm.org.mk/statut-na-crven-krst-na-republika-make/>
- Training plans for emergency operations staff
- Exercise plan, including evaluation and corrective action plan, if available
- Activation plan for emergency response, such as roster of emergency operations staff and role
- Reports and minutes from meetings held
- Law on Crisis Management
- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters

- Operational centre plans, and lists of available equipment
- Training plans for personnel in charge of emergency operations
- A plan of exercises, including evaluation and a corrective action plan, if available
- Emergency response activation plan, as a list of employees responsible for emergency operations and their roles
- Decree for determining the operational procedures for communication, coordination, cooperation and conduct of the subjects in the system for crisis management
- Decree for the type of data and information, and procedure for its delivery to the Centre for Crisis Management
- Methodology for preparing the Assessment, its content, structure storing and updating and determine the subjects in the system for management of crisis to whom the Assessment is given in full or in part
- Decree for organization, planning and conducting exercises/trainings, content of the certificates for the exercises/trainings as well as procedures that are mandatory in the system for the crisis management.
- Elaborates for the organization and conducting of the regular international exercises in the organization of CMC and other exercises and trainings for human resources development in the crisis management system.
- Memoranda of collaboration Centre for Crisis Management – Ministry of Health
- Operational procedures – Organigrams of the working process of the Regional Centres for Crisis Management
- Rising public awareness and education of the public for minimizing the risks of disasters: Key Messages 2017 (Funded by Austrian Red Cross, Austrian Development Cooperation, Red Cross of North Macedonia, International Federation of Red Cross and Red Cross Societies) <http://ckrm.org.mk/wp-content/uploads/2017/07/Podiganje-na-javna-svest-l-educacija-na-javnost-na-rizici-od-katastrofi-klucni-poraki.pdf>
- Early Warning System in the Community: Guiding Principles 2012 <http://ckrm.org.mk/wp-content/uploads/2017/07/Sistem-za-rano-predupreduvanje-vo-zaednicata-vodecki-principi.pdf>
- Rising public awareness and education of the public for minimising the risks of disasters: The Guide <http://ckrm.org.mk/wp-content/uploads/2017/07/Podiganje-na-javna-svest-l-educacija-na-javnost-na-rizici-od-katastrofi-upatstvo.pdf>
- Annual Programme of Red Cross <http://ckrm.org.mk/publikacii-cat/godishni-programi/>
- Annual Report <http://ckrm.org.mk/publikacii-cat/godishni-izveshtai/>
- Raising public awareness and education for reducing risks of catastrophes: key messages, 2017 (funded by Austrian Red Cross, Austrian Development Cooperation, Red Cross of North Macedonia, International Federation of Red Cross and Red Cross Societies). <http://ckrm.org.mk/wp-content/uploads/2017/07/Podiganje-na-javna-svest-l-educacija-na-javnost-na-rizici-od-katastrofi-klucni-poraki.pdf>
- Community Early Warning System: Guiding Principles, 2012. <http://ckrm.org.mk/wp-content/uploads/2017/07/Sistem-za-rano-predupreduvanje-vo-zaednicata-vodecki-principi.pdf>
- Raising public awareness and educating the public on disaster risk reduction: guidance. <http://ckrm.org.mk/wp-content/uploads/2017/07/Podiganje-na-javna-svest-l-educacija-na-javnost-na-rizici-od-katastrofi-upatstvo.pdf>
- Annual program <http://ckrm.org.mk/publikacii-cat/godishni-programi/>
- Annual Report <http://ckrm.org.mk/publikacii-cat/godishni-izveshtai/>

## LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

- Law on Crisis Management (Official Gazette of the RM, no. 29/2005)
- Law on Internal Affairs (Official Gazette of the RM, no. 42/2014)
- National Concept of Security and Defence (June 2003)
- Strategic Defence Review (July 2018)
- National Platform for Disaster Risk Reduction (2011)

## MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters (February 2017)
- Operational plan and risk management manual for the occurrence of pandemic influenza in Macedonia
- National Preparedness Plans for Biological, Radiological, Chemical, Food and Veterinary events.
- Memorandum of understanding between Protection and Rescue Directorate and Union for Civil Protection Mechanism of the EU
- Law regulation for sending and receiving medical assistance (equipment and drug/medicines)
- Law on Protection and Rescue (Official Gazette of the RM' no. 93/12)
- Law on Crisis Management (Official Gazette of the RM, no. 29/05, 36/11, 41/14, 104/15, 39/16, 83/18)
- Law on Public Health (Official Gazette of the RM no. 22/2010 и 136/2011)
- National Annual Programme for Public Health in the Republic of Macedonia for 2018 (Official Gazette of the RM no. 16/2018)
- Guidelines for the operation of the State Operational Centre in the Centre for Crisis Management in the Republic of Macedonia and procedures for the enforcement agents in operational matters – Standard Operating Procedures
- Decree on the manner and procedure for obtaining consent, as well as the criteria for fulfilling the personnel and material and technical conditions for participation in protection and rescue. no. 44/06
- Guidelines for compulsory reporting on emergencies, events and cases in the area of protection and rescue
- Decree on the methodology for assessment of the threat to the security of the Republic of Macedonia from all risks and dangers, its content and structure, the manner of keeping and updating it, as well as the determination of the entities in the crisis management system that will receive a complete or partial assessment (Official Gazette of the RM no. 13/2011)
- Decree on the establishment of operational procedures for mutual communication, coordination, cooperation and handling of the entities from the crisis management system (Official Gazette of the RM, no. 27 from 09.02.2018)
- Guidelines for the work of the Regional CMCs in the Republic of Macedonia
- Law of Macedonian Red Cross (Official Gazette of the RM no. 41/94 from August 05, 1994) <http://ckrm.org.mk/zakon-za-crveniot-krst-na-republika-makedonija/>
- Statute of the MRCC, Skopje, March 2017 <http://ckrm.org.mk/statut-na-crven-krst-na-republika-make/>
- Annual programme <http://ckrm.org.mk/publikacii-cat/godishni-programi/>
- Annual Report <http://ckrm.org.mk/publikacii-cat/godishni-izveshtai/>

## RISK COMMUNICATION

- Law on Protection and Rescue (Official Gazette of the RM no. 93/12)
- Decree on the manner and procedure for obtaining consent, as well as the criteria for fulfilling the personnel and material and technical conditions for participation in protection and rescue. no. 44/06
- Guidelines for compulsory reporting on emergencies, events and cases in the area of protection and rescue
- Standard operating procedures for communication, coordination and cooperation between the subjects of the protection and rescue system
- [www.dzs.gov.mk](http://www.dzs.gov.mk)
- Law on Crisis Management (Official Gazette of the RM, no. 29/05, 36/11, 41/14, 104/15, 39/16, 83/18)
- Decree on the establishment of operational procedures for mutual communication, coordination, cooperation and handling of the entities from the crisis management system (Official Gazette of the RM, no. 27 from 09.02.2018)
- Decree on the type of data and information and the manner and procedure for their submission to the Crisis Management Centre no. 19-6823/1 from 23.01.2007
- Standard operational procedures for communication, coordination and cooperation between entities in the crisis management system in the declared crisis situation – August 2014
- Decision to appoint specific trade companies for emergency work. Government of the RM (Official Gazette no. 167 from 02.12.2013)
- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters (February 2017)

## POINTS OF ENTRY

- Law on Health Care
- Law on Public Health Article 25
- Law on Protection of Population against Communicable Diseases
- Law on Veterinary Health (2014)
- Law on Protection and Rescue
- Aviation Law (airports, an ordinance for providing emergency medical assistance at airport)
- National plan for natural and other types of accidents
- Preparedness and response plan of the health care system when coping with emergencies, crises and disasters
- ACI and ICAO Airport preparedness guidelines for outbreaks of communicable disease
- IATA medical manual
- ICAO relevant annexes and other documents for public health include the following (Annex 6 – Operations, Annex 9 – Facilitation, Annex 11 – Air Traffic Services, Annex 14 – Aerodromes, requires airports to have an aerodrome emergency plan, including procedures for public health emergencies).
- Procedures for Air Navigation Services – Air Traffic Management
- Annex 18 (Doc 9284) – Technical Instructions for the Safe Transport of Dangerous Goods by Air (Cargo manual)
- Guide to Hygiene and Sanitation in Aviation – Third Edition 2009
- Acting and reporting from the entry point International Airport Skopje

- In the case of public health emergency of international concern biological in nature
- AEP Airport Emergency Plan Revision 4 from 17.08.2015
- Action plan for the health sector in response to crisis and emergency situations
- Plan for IHR protocol for biological hazard – points of entry
- CAPSCA Checklist\_0
- WHO Handbook for the Management of Public Health Events in Air Transport
- WHO PoE Core Capacity Assessment Tool
- WHO Handbook for the Management of Public Health Events in Air Transport

## CHEMICAL EVENTS

- Law on Chemicals (Official Gazette of the RM 53/2011 refined text; 164/2013; 116/2015; 149/2015 and 37/2016) with the sublaws
- Law on Precursors (Official Gazette of the RM 37/04) with the sublaws
- Law on Crisis Management (Official Gazette of the RM 29/05, 36/11, 41/14, 104/15, 39/16 and 83/18)
- Law on Protection and Rescue (Official Gazette of the RM 36/04 with amendments)
- Law on Environment (Official Gazette of the RM 53/05 with amendments and additions)
- Law on Public Health (Official Gazette of the RM 37/2016 refined text)
- Law on Health Protection (Official Gazette of the RM 37/2016 refined text)
- Laws on Ratification of Legally Binding Agreements and Voluntary Documents
- Law on Health Insurance (Official Gazette of the RM 142/2016 refined text)
- Law on Product Safety (Official Gazette of the RM 33/2006 with amendments)
- Law on Food Safety (Official Gazette of the RM 157/10 with amendments and additions)
- Law on Dangerous Goods Transportation in Road and Railroad Transport (Official Gazette of the RM 92/2007 with amendments and additions)
- Law on Cosmetic Products Safety (Official Gazette of the RM 55/07; 47/11; 150/15)
- Law on Market Surveillance (Official Gazette of the RM 48/10; 79/13)
- Law on Occupational Health and Safety (Official Gazette of the RM 53/13 refined text)
- Law on Medicinal Products and Medical Devices (Official Gazette of the RM 106/07 with amendments and additions)
- National Annual Programme for Public Health (Official Gazette of the RM 9/2019)
- Rulebook on children's toys safety (Official Gazette of the RM 149/10)
- Rulebook on data kept for each chemical in the chemicals register (Official Gazette of the RM бр. 67/12 and 120/12)
- Report on air quality in RM for the period 2005-2015 ([http://air.moepp.gov.mk/?page\\_id=299](http://air.moepp.gov.mk/?page_id=299))
- Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters. Ministry of Health 2017
- Standard operative procedures for Communication, coordination and cooperation among the crisis management system entities in a situation of declared emergency (second amended edition). August 2014. The Crisis Management Centre

## RADIATION EMERGENCIES

- Law on Ionizing Radiation Protection and Safety (Official Gazette of the RM, no. 48/02, 135/07 with amendments)
- Law on Crisis Management (Official Gazette of the RM br.29/05 and 36/11}
- International instruments (binding and non-binding)
- Law on ratification of the Convention on Assistance in a Case of Nuclear Accidents and Radiological Emergency (Official Gazette of the SFRJ, no. 4/1991)
- Law on ratification of the Convention on Early Notification in Case of Nuclear Accidents (Official Gazette of the SFRJ, no. 15/1989)
- National Radiation Emergency Response Plan, published in official gazette (24.06.2011)
- Article 13, paragraph 3, Article 18 paragraph 4 and Article 24 of Law on Crisis Management (Official Gazette of the RM no.29/05 and 36/11}



JOINT EXTERNAL EVALUATION  
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NORTH MACEDONIA**

**Mission report:**  
**11–15 March 2019**