

NEW PUBLIC HEALTH LAW - second version, 13 April 2009

This second version by Kees Schaapveld and Miroslav Trajanovski incorporates the results of the meeting with the Working Group on 7 March and of the workshop on 10 March 2009, and subsequently has been translated into “legal language”. Some issues are open for discussion; they will be presented in a separate handout for the workshop in May 2009.

Chapter 1 General provisions

Subject matter of the Law

Article 1

This Law shall regulate the basic public health functions and tasks, the public health emergencies, funding of public health programs [listing of main chapters/ sections of the law]

Purpose of the law

Article 2

The purpose of this Law shall be:

- a) to preserve and improve the health of the population;
- b) to enable implementation of the International Health Rulebook 2005;
- c) to regulate specific public health issues which are not or not adequately regulated by existing legislation.

Definitions

Article 3

Specific terms used in this Law shall have the following meaning:

1. „Public health” is the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society. Public health analyses and monitors the health status of the population, and tries to improve this health status by influencing the known determinants of health (also known as risk factors) such as environmental and microbiological causes, lifestyle and socio-economic factors
2. „Essential public health functions,, are a set of fundamental activities that address the determinants of health, protect a population’s health, and treat diseases of public health significance. They prevent and manage the major contributors to the burden of disease by using effective technical, legislative, administrative, and behaviour-modifying interventions or deterrents, and thereby provide an approach for intersectoral action for health.
3. „Public health emergency” is an occurrence or imminent threat of a situation that can cause wide-spread mortality or serious morbidity from a natural disaster,

infectious agent, biological toxin, or chemical or nuclear release.

4. „Public health emergency of international concern” is an extraordinary event that may constitute a public health risk to other states through the international spread of disease, and that potentially requires a co-ordinated international response

5. „ An epidemic of a communicable disease” is a sudden increase in the usual occurrence of that disease in a certain time or place.

Principles

Article 4

Public health shall be rooted in the following principles:

1. Responsibility for public health for which the state shall have the leading role in preservation and improvement of the health of the population;
2. Wide-ranging measures and activities focused on the entire population, and on social-economic health determinants and risk factors.
3. Multidisciplinary basis and intersectoral cooperation
4. Comprehensiveness of data collection by the means of qualitative and quantitative methods and
5. Partnership with population

Correlation with other laws

Article 5

The provisions of this Law shall have a subsidiary application and shall be applied only if not otherwise prescribed by another law.

Chapter II

Public health functions and tasks

Essential public health functions

Article 6

The essential public health functions are:

1. Surveillance and assessment of the population’s health and well-being.
2. Identification, prediction, investigation and mitigation of health problems and health hazards in the community.
3. Health protection: technical assessment of needs and actions required to ensure health protection;
4. Disease prevention: applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Development and enforcement of laws and regulations that protect health and ensure safety.
7. Assuring a competent multidisciplinary public health workforce.

8. Initiation, support and carrying out of health-related research.
9. Initiation, development and planning of public health policy.
10. Preparedness and management of public health emergencies, including prevention, response and mitigation of consequences.
11. Ensuring intersectoral partnership and community participation to improve health and reduce inequalities.

The basic functions of paragraph 1 of this article, in addition to the fact that are addressed in this Law, are also regulated by the legislation addressing environment, professional health and safety, food safety, blood safety, protection against communicable diseases and crisis management.

This Law shall limit the regulation of EPHF 7, 8 and 10 in those activities for which responsibility lies within the public health service/sector under the Ministry of Health. Those activities addressing the clinical sector and activities which are outside the healthcare sector which are not considered a part of these EPHF of article 6, point 7,8 and 10 shall be regulated with separate laws.

Essential tasks of public health

Article 7

Republic of Macedonia shall be responsible for public health by means of the following:

1. Providing policy and strategy of public health;
2. Monitoring the health status of the population and identification of health problems in the community;
3. Planning, establishing priorities, passing special public health programmes, as well as passing regulations in this area;
4. Implementation of taxation, economic and other policies that stimulate healthy life styles;
5. Providing conditions for health education and empowerment of the population to take care of their own health;
6. Providing a system of quick response in extraordinary situations such as epidemics, physical and chemical accidents, and natural disasters;
7. Development of a health information system;
8. Support for communities and development of intersectoral co-operation in solving health problems;
9. Evaluation of effectiveness, quality, accessibility and efficiency of health care services and programmes oriented towards the individual and the population;
10. Strengthening of laws and regulations protecting health and providing security and safety of people;
11. Provision of competence in public health human resources through training and continuing education;
12. Researching new approaches and innovation of measures in solving health problems of the population;

Chapter III

Competent authorities for implementation of the Law

Competent ministries

Article 8

The implementation of the tasks of article 7 of this Law shall be carried out by the Ministry of Health and by other ministries in cooperation and coordination with other ministries and institutions requiring inter- sectoral cooperation.

National Institute for Public Health

Article 9

National Institute for Public Health (hereinafter: Institute), in addition to provisions stipulated in another law, shall perform the following:

1. Provide expert/ professional assistance to the Ministry of Health in preparation of medium-term and long-term public health plans, including the programs for public health in healthcare, health promotion, screening of the population, monitoring and control of communicable and non- communicable diseases.
2. Prepare annual national reports on relevant aspects of the population's health;
3. Standardise, co-ordinate, inform and monitor the operation of the Centres for Public Health (hereinafter Centers);
4. Act as a reference laboratory for the Centers;
5. Develop and provide programmes for continuous professional development in the field of public health for its own staff, staff of the Centers, and other target groups, in co-operation with the School of Public Health, the Centers, the Medical Faculty, and other educational establishments in Macedonia;
6. Participate in the implementation and shall coordinate public health measures in case of epidemics and other emergencies, together with other ministries and organisations indicated by the Crisis Management Law;
7. Participate in international co-operation in the field of public health, shall provide health data to international organisations in accordance with law;
8. Organise and implement research in the field of public health;
9. Conduct testing of pharmaceuticals;
10. Assist the Ministry of Health and the other responsible ministries on issues stipulated in article 6 of this Law;
11. Other tasks at the request of the Ministry of Health.

Entries of paragraph 1 of this article shall be carried out by the means of analysis, planning and assessment, promotion of health, prevention of diseases and research in the area of public health in the area of mother and child health, communicable and non-communicable diseases as well as preparation of emergencies.

Centers for Public Health

Article 10

Tasks of public health for the area of two or more municipalities shall be provided

and coordinated by the Centers.

A Center can be established in the area of a group of municipalities of combined number of inhabitants of at least [...] and the most [...].

Provisions of paragraph 2 of this article shall not apply to the Center in Skopje.

[Note: the name “Center for Public Health” has not been officially adopted]

Article 11

The Centers, in addition to provisions in other laws and in order to address the needs of the municipalities in which are founded shall perform the following issues;

1. Preparation of medium-term public health plans and annual plans and implementation programs;
2. Preparation of annual reports on the population’s health;
3. Maintain records and collections of data as defined by law;
4. Monitoring of environmental and sanitary conditions;
5. Implementation of measures and activities from the public health programs;
6. Microbiological, physical- chemical laboratory services;
7. Implementation of measures in cases of epidemics and other emergencies;
8. Perform other services stipulated in law and requested by the Ministry of Health;

In addition to items in paragraph 1 of this article, the Center, on the basis of an approval obtained by the Ministry of Health, can carry out certain specialized activities.

Pursuant to the case in paragraph 2 of this article, the Center for Public Health shall serve as the leading institution to the other Centers (we should consider better phrasing)

[The SSHI will propose a text about the relation between the SSHI and the Institute /Centres.]

Coordination and cooperation

Chapter IV

System of public health

Article 12

The system of public health that provides conditions for preservation and improvement of the population’s health is comprised of citizens, families, employers and employees, educational and other institutions, humanitarian, religious, sport and other organisations, associations, public health and health care institutions, health insurance funds, as well as municipalities and the Government of the Republic of Macedonia, and other state and non-state organisations and institutions.

The partners in paragraph 1 of this Article are responsible for participating in the implementation of the essential public health functions from Article 6 of this law.

The provision and implementation of the public health functions in the country shall be the right and responsibility of Republic of Macedonia, the Ministry of Health, the Institute, the Centers, the State Sanitary and Health Inspectorate, ministries in charge of education, environmental protection, social care/ protection, science, sports, culture, traffic, agriculture, economy, labor and other authorities and bodies as

stipulated in this and other laws.

The Institute and the Centres have the leading role in the system of public health, as well as in the implementation of the essential public health functions of article 6 of this Law.

Competencies and tasks of other participants in the system of public health are determined by other laws and regulations.

In the course of implementing the public health functions of article ____ of this Law, the following shall participate: citizens, families, employers and employees, educational and other institutions, humanitarian, religious, sport and other organisations, associations, public health and health care institutions, health insurance funds, as well as municipalities and the Government of the Republic of Macedonia, and other institutions as well as non- governmental organizations.

In addition to the Ministry of Health, other ministries engaged in areas of education, environmental protection, social care/ protection, science, sports, culture, traffic, agriculture, economy, labor shall secure delivery of the public health functions pursuant to this and other laws.

Article 13

The Institute and the Centres shall position the delivery of operations stipulated in article ____ and article ____ of this Law in the following principles:

1. Clearly defined public health purpose.
2. Public health procedures based on modern, scientifically sound principles and evidence.
3. Well-targeted public health interventions by involving the optimal number of persons as required by public health.
4. Undertaking public health intervention which is least restrictive to rights and interests of individuals in the course of protecting public health;
5. Undertaking public health intervention which will not in an unlawful manner discriminate individuals on the basis of their race, ethnicity, nationality, religious beliefs, sex, sexual orientation, or disability status.
6. Respect the dignity of each individual during a public health intervention

National Council for Coordination of Public Health

Article 14

The Government of Republic of Macedonia shall establish a National Council for Public Health (hereinafter: Council) as an advisory body dealing with public health issues of shared competency scope of two or more ministries.

The Council shall study the public health issues and policies, shall prepare opinions, initiatives and/or proposals to submit to the competent authorities for the implementation of this law.

The National Council of paragraph 1 of this article shall be comprised of _____ representatives from the Ministry of Health, Ministry of Environment and Physical Planning, Ministry of Labor and Social Policy, Ministry of Education and Science, the Institute, in the course of which one should consider an equal representation of the entire population in Republic of Macedonia.

The coordinative body shall be chaired by the Minister of Health.
The coordinative body of paragraph 1 of this article shall adopt Rules of Procedure.

Article 15

Each Centre will establish an Intersectoral Public Health Advisory Committee that will advise the Centre and the municipalities on its territory, upon their request and also at its own initiative, on all public health matters that involve other partners than the Centre. (this is a solution is questionable)

The Committee of paragraph 1 of this article shall comprise of at least 7 members, of which at least 3 shall represent the municipalities on whose territory the Center is established, and other 2 members coming from the public health independent exerts community.

Out of the Committee's constituency/membership, the members shall elect a chairperson.

The mandate of the members of the Committee shall be 5 years.

The Committee shall adopt rules of procedure for its operation.

The municipalities under the inter-municipal cooperation can establish an intersectoral Public Health Committee as an advisory body for the municipalities.

The Committee of paragraph 1 of this Article shall be comprised of _____ members, representatives from the municipalities and _____ members, representatives from the Centers.

The Committee shall be chaired by _____.

The Committee of paragraph 1 of this article shall adopt Rules of Procedure.

Public health emergencies

Chapter V

Public health emergencies causes by infectious disease epidemics

Article 16

In case of an epidemic of communicable disease on the territory of located one or more Centres, the Centre(s) will inform the Ministry of Health and the Institute.

If there is a risk of the epidemic spreading beyond the borders of the Republic of Macedonia, the National Focal Point will inform the Contact Point of the World Health Organisation..

The Ministry of Health will decide if the epidemic is a public health emergency that warrants the involvement of the Crisis Management Centre.

If the epidemic does not represent a public health emergency, the epidemic control measures will be undertaken by the Ministry of Health and agencies thereof.

Public health occurrence of international concern

Article 17

In cases of suspected public health occurrence of international concern prescribed by the International Health Regulations, the Centre/Centres shall inform the Ministry of

Health and the Institute.

The Ministry of Health shall decide if the public health occurrence is of international concern, in accordance with the decision-making assessment instruments stipulated in the International Health Regulations.

In cases of public health occurrence of international concern prescribed in the International Health Regulations, the National Focal Point shall inform the Contact Centre in the World Organization according to notification instrument appropriate for such instances, set forth in the International Health Regulations.

Public health emergencies of a non- infectious nature
Article 18

In case of a public health emergency of a non-infectious nature, the Crisis Management Centre will be in charge of control of the emergency according to the Crisis Law, in co-operation with the Ministry of Health and the Institute.

If the public health emergency of paragraph 1 of this article is of international concern pursuant to the International Health Regulations, the Institute shall inform the Contact Center of the World Health Organization within 24 hours following the assessment of the public health information.

Application of the International Health Regulation
Chapter VI

National Focal Point
Article 19

The Institute shall be the National Focal Point for the application of the health measures from the International Health Regulation.

Acting in instances of suspicion of a presence of an onboard infectious disease
Article 20

The captain of an aeroplane in an international flight who wants to land at the airport, and who knows or seriously suspects that one or more passengers on board of the aircraft show signs of an infectious disease that may endanger public health, must inform the air traffic controller or the operator at the airport immediately after discovering and before landing.

The air traffic controller must immediately inform the operator of the airport whereas the later shall inform the responsible person of the medical team of the airport
The responsible person of the medical team of the airport shall immediately inform the State Sanitary and Health Inspectorate and the Institute of Public Health of Republic of Macedonia.

General declaration of the aircraft and other information
Article 21

Pursuant to a request by the State Sanitary and Health Inspectorate, the captain of the

airplane in charge of the international flight shall prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations.

In addition to the Health Part of paragraph 1 of this Article the State Sanitary and Health Inspectorate can ask the captain for additional information about the airplane regarding the health situation of the passengers on board.

Entry point Article 22

The Minister for Transport following an opinion stated by the Minister of Health shall designate the airport(s) which is/are to be the entry point(s) to which the International Health Regulations apply.

The airport(s) of paragraph 1 of this article is/are obliged to develop its/their capacities as prescribed by the International Health Regulation.

In case of accepting notification of Article 20, or if suspicion of a potential public health danger on board of an aeroplane has arisen otherwise, the Minister of Transport, after consultation with the Minister of Health, can determine at which airport the aeroplane should land.

State Sanitary Inspectorate actions Article 23

In case of article 18 of this law, the State Sanitary and Health Inspectorate shall submit a list of measures to be applied upon arrival of the airplane in the airport.

In case of a direct threat of an epidemic of an infectious disease, the State Sanitary and Health Inspectorate will decide on measures which must be taken regarding the admission of crew and passengers of the aeroplane.

In cases of paragraphs 1 and 2 of this Article, the captain of the aeroplane will assure that after landing of aircraft, nobody is to enter or exit the aircraft, and no goods will be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained.

The State Sanitary and Health Inspectorate, upon request, shall submit a list with the names, address, sex, age and destination of the passengers to the captain of the aircraft.

Article 24

The State Sanitary and Health Inspectorate can order the operator of the airport:

- a) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- b) to assist the Institute or the State Sanitary and Health Inspectorate with the investigation of departing or arriving passengers for the presence of an infectious disease with a risk of serious danger to the public health;
- c) to carry out technical-hygienic measures for the prevention of contamination, if there is a well-founded risk of contamination;
- d) to close buildings or sites, or parts thereof, for the control of contamination.

Article 25

The State Sanitary and Health Inspectorate can order the operator of an aircraft:

- a) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- b) to carry out technical-hygienic measures on the aircraft and its cargo for the prevention of contamination, if there is a well-founded risk of contamination;
- c) to check an aircraft and its cargo for the presence of contamination;
- d) to disinfect an aircraft and its cargo for the control of contamination, including the destruction of vectors.

Road border crossings **Article 26**

Aspects of the International Health Regulations that pertain to designated ground border crossings shall be regulated by the Law on Infectious Diseases.

Active and passive immunization **Article 27**

Active or passive immunisation of persons in order to obtain an internationally valid certificate as described in the International Health Regulations will be provided according to the provisions of the Law on Infectious Diseases.

Shape and content of the certificates of paragraph 1 of this article are prescribed by the International Health Regulations.

The Minister of Health will designate institutions that can provide immunisation against yellow fever and other types of immunisation not used for the entire population.

Airport Operators Costs **Article 28**

The operators of airports as well as operators of aircrafts shall cover all costs for the implementation of the measures of this law and the International Health Regulations.

Article 29

The Minister for Health shall publish the International Health Regulations.

Special provisions **Chapter 7**

[Regulation of food risk management; the Food Directorate will propose a text.]

Article 30

An entrepreneur who is not a medical doctor and who performs activities that penetrate the skin of his clients needs a permit from the Ministry of Health. Activities of paragraph 1 of this article include tattooing, piercing, permanent make-up and acupuncture.

Article 31

A natural person or legal entity can perform skin work such as tattooing, piercing, permanent make-up and acupuncture if adequate facilities, equipment, skilled staff and appropriate materials are secured.

Tattooing or piercing except in the earlobe is prohibited for persons under the age of 16.

For persons above the age of 16 and under the age of 18 a written parental or guardian's approval is required for tattoos on head, neck, wrists or hands, and for genital piercing (boys and girls) and nipple piercing (girls only).

For persons receiving a piercing or a tattoo a prior elaboration of possible consequences is compulsory.

Tattooing, piercing, permanent make-up and acupuncture can be performed only in premises prescribed by the Minister of Health.

Modalities regarding the facilities, equipment and skilled staff shall be prescribed by the Minister of Health.

Article 32

Minister of Health shall assess if the requirements of article ____ of this Law have been met, and shall adopt a decision for authorizing/ permitting work.

The work permit of paragraph 1 of this Article can be revoked if changes occur as a cause of which significant deviation according to article _____ of this law have been performed.

Article 33

The persons having a tattoo or a piercing must have the potential consequences elaborated in advance.

Article 34

[Other public-health issues which are currently insufficiently regulated?]

Financing Chapter

Sources of financing

Article 35

Sources of financing for the Institute and Centers are:

- funds from the Budget of Republic of Macedonia;
- individual/ own income resources;
- funds by the Fund for Health Insurance of Republic of Macedonia under conditions stipulated in this law;
- donations and

- other sources of revenue regulated in another law.

Funds from the Budget of Republic of Macedonia

Article 36

The current operation of the Institute and the Centers is financed by the Budget of Republic of Macedonia, on the basis of annual work programs.

The work programs of paragraph 1 of this article are adopted by the Institute or the Centers the latest of 31 December of the year in progress for the following year. Consent for the programs of paragraph 1 and 2 of this article is provided by the Government of the Republic of Macedonia, following a previously submitted opinion by the Ministry of Health.

Funds for capital investments are secured externally to the funds envisaged for current operation.

Own income resources

Article 37

The Institute can generate income by providing services to natural persons and legal entities, provided such services can not be provided by the Centers.

In cases when the Centers provide diagnostic-laboratory services to individually insured patients according to a referral, the expenses for such services are to be covered by the Health Insurance Fund of Republic of Macedonia.

The pricing of paragraph 1 and 2 of this article shall be defined according to a tariff book.

The tariff book of paragraph 4 of this article shall be adopted by the Minister of Health.

Donation revenues

Article 38

Financial or material items can constitute a donation.

Donors could be domestic and international natural or legal entities.

The purpose and modality of use of donations are to be regulated with a contract between the donor and the Institute, or the Center.

Supervision

Chapter

Article 39

Supervision over the application of this Law shall be carried out by the Ministry of Health.

Inspection supervision over the implementation of the provisions of this Law shall be carried out by the State Sanitary and Health Inspectorate compliant to the Law on Sanitary and Health Inspectorate.

Penal provisions

Chapter

Article 40

Transitional and final provisions
Chapter_____

Institute for mother and child care
Article 41

On the day of entering into force of this Law, the Institute for Mother and Child Care as such shall cease to exist.

All employees, equipment and other assets of the Institute for Mother and Child Care are to be taken on by the Institute.

Enactment
Article 42

This Law shall enter into force on the eight day following the publication in the “Official Gazette of Republic of Macedonia”