

MINISTRY OF HEALTH OF THE REPUBLIC OF MACEDONIA

HEALTH SECTOR MANAGEMENT PROJECT

CONSULTANCY ON DEVELOPMENT OF A NEW PUBLIC HEALTH LAW

PROGRESS REPORT (draft)

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Skopje/Rotterdam, 20 February 2009

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1 ACTIVITIES 12 JANUARY – 20 FEBRUARY 2009

The consultants submitted their inception report on 12 January 2009. They presented it to the Working Group on 13 January, although the Working Group had not yet been installed officially on that day.

The Working Group had a clear preference for a so-called “umbrella law” for public health, but some members would like to see a more detailed description of specific areas, such as health promotion, the control of non-communicable diseases, mother & child care, and the health aspects of disaster preparedness.

The law should regulate public health within the health sector, but refer to intersectoral activities and laws from other sectors. The establishment of an intersectoral public health council would be useful.

The Health Care Law will remain the key law for the health sector, but other recent health laws should also be referred to.

The Working Group wants the consultants to base the new law on all Essential Public Health Functions (EPHFs), although for some EPHFs the legislation could be limited to public health only, that means excluding the curative sector. The Working Group would like to see involvement of local authorities in public health, but realises the problems in that area. There was a discussion about the extent to which “quality assurance in health care” (EPHF 6) should be a subject of the new law; it seems that it would be better to regulate this in another law, and to limit the planned public health law to quality assurance in public health.

There is still debate about the future of the 16 national programmes and their division into clinical programmes (financed by the Health Insurance Fund) and public health (budget-financed) programmes.

The planned study tour should cover both legislation and organisation & financing of public health.

The consultants met with the Minister of Health, the deputy Minister of Health, the director and staff of the State Sanitary and Health Inspectorate (SSHI), and the head of the sector for EU integration.

The Minister approved the intersectoral approach of the new law and will discuss it with his colleagues. The new law should be before Parliament in June 2009. The Deputy Minister discussed the planned amendments in the Health Insurance law, but the content of the benefit package(s) has not yet been decided.

The SSHI explained their responsibilities and activities, also in relation to other agencies (Food Directorate, Public Health Institutes, Ministry of Interior). They are responsible for the supervision of 31 laws. At present, some modifications in the Law on the SSHI and the Law on Infectious Diseases are being prepared. Their actual staff of 40 inspectors and 21 administrators (with 15 branch offices) is deemed insufficient.

The head of the European Union (EU) integration department discussed the public health initiatives in the South East European region, and some important existing laws for public health such as the Law on Medical Data (also known as Law on Evidence) and the Law on Protection of Personal Data.

The second workshop of this consultancy was organised in the Stone Bridge Hotel on 16 January 2009. The agenda of the workshop, the presentations by the consultants and the report of the workshop are presented in Annexes A-D of this progress report.

2 ANALYSIS OF MACEDONIAN HEALTH LEGISLATION

The Law on Healthcare (“Official Gazette of Republic of Macedonia”, No. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07 and 77/08) which regulates the system and the organisation of health care in Republic of Macedonia, captures the public health approach in the overall health care system. Thus the general provisions of the Law define the scope of health care, the organised measures, activities and procedures for maintaining health and the environment – both living and working, rights and obligations exercised in health insurance as well as the measures, activities and procedures undertaken by health care facilities for protection and improvement of health of people, prevention and suppression of diseases, injuries and other health disorders, early detection of disease and health conditions, timely and effective treatment and rehabilitation by the utilisation of professional medical measures, activities and procedures. This approach is contained in Article 32 of the Law according to which specific measures and activities directed towards protection of health to the overall population are envisaged and on the basis of which a number of preventive programmes funded by the Budget of Republic of Macedonia are developed.

Chapter 7 of the Law – Health care facilities, regulates the types of health care facilities and their scope, and in addition, the scope shall include the preventive measures and the health improvement measures. The public health function of the Institutes for Public Health and the National Institute for Public Health arises from the provisions of the Law. The Institutes as public healthcare facilities shall monitor, investigate and study the medical condition of the population, the reasons for emergence and spread of infectious diseases of a social and medical significance, as well as the influence of environmental factors over health; also shall propose and undertake measures for protection and improvement of health of the population. The Law also regulates the issues of management and governance of institutions.

The Law on Medical Data (“Official Gazette of SFRY”, No. 22/78, 18/88 and “Official Gazette of R.M”, 15/95) and the Law on Medical data (“Official Gazette of S.R.M”, No. 37/79 and "Official Gazette of R.M.", 15/95) regulate medical record-keeping. Concerning the fact that the above-stated laws are outdated and are lacking harmonisation with the new demands and terminology, a new Law on Medical Data has been prepared and is currently undergoing parliament procedure. This Law shall regulate record- keeping, data collections and medical registries, manner of collection, procession, archiving and storing data, publishing of data, securing quality of data and protection of data, as well as exercising rights and responsibilities related to medical record- keeping. The Law shall envisage electronic record- keeping and links to competent institutions possessing data collections and enable data exchange.

The Law on Protection of Population Against Communicable diseases (“ Official Gazette of Republic of Macedonia” No.66/04 and 139/08) regulates the protection against communicable diseases realised through planning, organising and continuous monitoring of the epidemiological conditions and implementation of prescribed measures, as well as through supervision and control over implemented measures. The implementation of measures for protection against communicable diseases shall hold a priority in relation to the implementation of other health protection measures and also in relation to securing material and other resources. This Law stipulates that the National Institute for Public Health shall monitor and study the epidemiological condition of infectious diseases on the territory of Republic of Macedonia and the epidemiological condition in the Republic, whereas the Institutes for Public Health shall monitor the epidemiological condition in the area of their

establishment and shall report the situation to the National Institute for Public Health, the municipalities and the city of Skopje. The Institutes of Public Health shall co-operate with the local self-government units and shall devise demand driven plans and programmes for specific public health issues of local importance. The municipalities and the city of Skopje shall monitor the condition and movement of infectious disease within their designated area through exchange of information with the competent Institutes for Public Health compliant to this and another law. The forthcoming period anticipates amendments to the Law in the communicable diseases part which will be subject to mandatory reporting in agreement with the EU directives.

Food safety is regulated with the Law on Food Safety and Products and Materials in Contact with Food ("Official Gazette of Republic of Macedonia" No. 54/02 and 84 /07) and numerous secondary legislation transposing the regulations of the EU in this domain. In addition to this Law, the animal origin food is regulated in the veterinary health legislation.

The public health approach is contained in the Law on professional health and safety ("Official Gazette of Republic of Macedonia", No. 92/07) which, among other issues defines the measures of professional safety and health as well as the preventive measures against professional hazards, elimination of hazardous factors influencing accidents, reporting, consulting, training of workers and their representatives and their participation in the planning and undertaking measures for professional safety and health.

Numerous other regulations (Law on Protection of Population against Communicable diseases, Law on Ionising Radiation Protection and Safety, Law on Ambient Air Quality, Law on Waters, Law on Environmental Protection against Noise etc.) regulate measures and activities directed towards protecting the health of the population. In their essence they are intersectoral and impose the need of an organised and coordinated approach in the course of their implementation.

As a result of the analysis of the current health legislation, one might conclude that not a single regulation clearly defines the public health functions. The various aspects of public health are regulated in a wide array of regulations, however they lack the co-ordinated and integrated approach in the implementation of activities. Such approach is contained in the Law on Crisis Management that in a separate chapter stipulates the organisation and operation of the authorities and bodies within the crisis management system (the Steering Committee and Assessment Group, co-ordination among institutions). This might serve as a model for intersectoral co-ordinated work in the public health domain (and shall apply for IHR issues).

Multiple laws convey the authorities of the local self-government units and the commitments for preparation of plans and programmes for specific public health segments. However, the local level lacks co-ordinated work of adjacent municipalities in addition to the opportunity for inter-municipal co-operation stipulated in the Law on Local self-government.

The legislation, in addition to the fact that public health (protection of the health of population) is considered to be a public good falling under the authority of the state, does not contain explicit provisions that funding of this sector should be secured by the State Budget. The Law on Healthcare contains a provision which lists all sources of funding for healthcare facilities as well as a provision that the preventive measures and activities of the programmes are funded by the State Budget, however no clear distinction is made as to the selection of public health functions and manner of payment for particular public health functions. This shall particularly apply for the Institutes of Public Health.

Good approach is provided for in the new Law on Medical Data according to which funds for implementation of the law are allocated by the State Budget on account of a programme adopted by the Government, by the Health Insurance Fund of Macedonia for basic medical documentation record keeping and by legal entities and natural persons for processing of data and material costs for submission of record-keeping system medical data upon request.

In all, pursuant to public health, it might be said that the health legislation addresses issues related to the tasks, responsibilities and the institutions within the health sector.

A more detailed overview of Macedonian legislation relevant for public health is presented in Annex E.

3 PUBLIC HEALTH REFORM: PROGRESS AND CHALLENGES

A comprehensive report on public health reform has been written by consultant Thomas Novotny in May 2008, with a thorough analysis and recommendations for reform. Some reform measures for the public health sector have also been described in the Health Strategy 2020 of February 2008.

At the time of writing of this progress report, there are a number of outstanding issues that will be briefly described below. All of them have been discussed by Novotny and in the Health Strategy, and all of them are dealt with in the draft public health law (Annex F).

National programmes

The responsibility for the 16 national programmes has been discussed for several years. There are typical community-oriented public health programmes (e.g. AIDS or brucellosis), typical medical care programmes for individual patients (e.g. dialysis and uninsured patients), and mixed programmes (e.g. tuberculosis and mother & child care). Many programmes have both community-oriented prevention activities and treatment of individual patients, and many provide payment for treatment of uninsured patients and/or co-payments. The general idea is that a) public health activities should be carried out under the responsibility of the National Institute of Public Health and the Centres for Public Health and paid from the state budget, and b) that medical treatment should be carried out by primary and secondary care providers and either paid by the Health Insurance Fund or by patients themselves or by the budget if patients are uninsured or exempted. However, the division of the 16 programmes and the allocation of responsibility and funds proves to be a complicated task.

Financing of public health

The general idea is that paying for public health activities is a (national or local) government responsibility, contrary to paying for medical care which is mostly an insurance matter. For individual prevention activities such as immunisation of children or even for treatment of patients with certain communicable diseases, it is arbitrary if it will be paid as a public health activity or as part of the Basic Benefits Package. Novotny's report has a large chapter on the financing of public health.

The incorporation of Mother & Child Health in the National Institute of Public Health

This seems to be more or less accepted, but the modalities have to be worked out.

The responsibilities of the National Institute of Public Health and the Centres for Public Health.

The draft of the new public health law proposes a description of the official tasks of both, and the relationship between both levels. The general idea is that the National Institute leaves the routine public activities to the Centres, and focuses on typical national and international tasks including supervision, evaluation, planning, co-ordination, and training. The Centres are independent legal entities as a consequence of decentralisation, but they should be standardised, supervised and assisted by the National Institute.

Involvement of local authorities in public health

According to article 22 of the Law on Local Self-Government, local authorities - i.e. municipalities - have a responsibility for public health. In reality, this has not yet materialised for lack of funds and capacity. The draft of the new law proposes some regulation that would involve municipalities in public health. It is hoped that municipalities gradually become more interested in this field and devote some local budgets to it.

Intersectoral co-operation

As public health is essentially intersectoral, it is important to create a forum for co-ordination. The draft law proposes an Intersectoral Public Health Co-ordination Council at national level, and Public Health Advisory Committees at local level. This is not to say that intersectoral co-ordination does not exist, see for example the subject of food safety. The implementation of the International Health Regulations also requires intersectoral co-operation.

Strengthening health promotion

The main cause of morbidity and mortality is not infectious disease but chronic non-communicable disease. This requires a shift in focus of public health professionals towards health promotion and health education for health problems such as cardiovascular disease, cancer, diabetes, obesity and for lifestyle issues such as smoking, physical exercise, safe sex, and the use of drugs. This is not to say that vigilance in the control of infectious disease should diminish. Health promotion is a typical example of the need for an intersectoral approach.

Public health data

There is always a call for strengthening data collection and analysis, but health systems, health professionals and citizens should not be overburdened by data to be submitted. It is sometimes better to reduce the number of data to be collected and to collect more targeted data of better quality. Data should not only go up in the pyramid, but there should also be a return flow in the form of consolidated reports, for example from the National Institute of Public Health to the Centres for Public Health, and from the Centres to municipal authorities and medical care providers. The modalities of the public health information system should be dealt with in a separate chapter of the new public health law.

Norms for public health facilities

Norms for the National Institute of Public Health and the Centres for Public Health will probably need revision in secondary legislation. How many Centres for Public Health does Macedonia need? What types and numbers of staff are needed, e.g. in view of strengthening planning capacity and health promotion activities? Should the institutions and the laboratories be accredited, and if so, how? A resource allocation formula for public health institutions can also be seen as a sort of norm.

4 PREPARATION OF THE STUDY TOUR

A delegation from the Republic of Macedonia will visit two countries in the European Union between 31 March and 10 April 2009 with the purpose of:

- a) studying the legal basis of public health activities, with special attention to recently developed general Public Health laws and their relation to other relevant legislation, including legislation developed by other ministries (inter-sectoral co-ordination of Public Health);
- b) studying the organisation and financing of public health activities, with emphasis on those activities that in Macedonia involve the Ministry of Health;

in order to be better prepared to draft a new Macedonian public health law that regulates the whole Macedonian public health sector effectively and efficiently, and is compatible with EU legislation and the International Health Regulations 2005.

The Ministry of Health of Macedonia has selected the Netherlands because it recently passed a new general public health law, and because of the existing co-operation between Macedonia and the Netherlands in various fields. As the other EU country, Belgium is a good choice because it is a neighbouring country with a very different system of organising and financing public health activities.

Consultant Kees Schaapveld has been asked to organise the programme for the study tour, based on the requirements and needs of the Macedonian participants.

So far (17 February 2009), the following organisations have expressed their willingness to receive the Macedonian delegation:

Netherlands

- * Ministry of Health, Welfare and Sport (VWS) in The Hague;
- * National Institute of Public Health (RIVM) in Bilthoven;
- * Food and Consumer Product Safety Authority (VWA), head office in The Hague and branch office/laboratory in Zwijndrecht;
- * Regional Public Health Service (GGD) of Zuid-Holland Zuid in Dordrecht;
- * Department of International Public Health of Maastricht University.

Belgium

- * Federal Public Service Health, Food chain safety, and Environment, Brussels;
- * (Federal) Scientific Institute of Public Health, Brussels (WIV/ISP);
- * Flemish Ministry for Welfare, Public Health and Family, Brussels (WVG).

With these organisations, discussions about programme and timing are taking place.

A few other organisations (including a Belgian provincial Institute of Hygiene) still have to agree to participate in the study tour.

The study tour will take place from Wednesday 1 April until Thursday 9 April 2009. Tuesday 31 March and Friday 10 April (a national holiday in the Netherlands and Belgium) are travel days. Provisionally, 1-3 April is reserved for the Netherlands, and 6-8 April for Belgium, with 9 April available for either country.

All participants of the study tour speak English, there will be no translation from and to Macedonian.

5 DRAFTING OF THE NEW PUBLIC HEALTH LAW

The incomplete draft of the new public health law in Annex F is the key element of this progress report. It has been based on the discussions of the various stakeholders with the consultants in December 2008 and January 2009, including the discussions with the Working Group and during the workshops, and on the analysis of Macedonian and international legislation. Annex F should be the main topic of discussion during the next meeting(s) with the Working Group and the third workshop in March 2009. Important items for the discussion are:

- * Description of tasks of the National Institute of Public Health and the Centres for Public Health (Articles 3.2 and 3.6).
- * Organisational structure of the National Institute of Public Health and the Centres for Public Health (Articles 3.4 and 3.7).
- * In which cases and how to refer to existing legislation (Articles 3.8, 3.9, 4.4-7; Chapters 6 and 7).
- * The establishment of an Intersectoral Public Health Co-ordination Council (Article 4.2).
- * The involvement of local authorities in public health (Article 4.3).
- * What to add about food risk management (Article 4.4); a proposal from the Food Directorate is expected here.
- * The powers of public health officials (Article 5.2).
- * What new regulation will be needed for public health emergencies (Chapter 6).
- * What new regulation will be needed for data management (Chapter 7).
- * What new regulation will be needed for land border crossings (Article 8.10).
- * The difficult issue of financing of public health activities.

The draft in Annex F is a proposal by the consultants and will be further explained by them during the discussions. It is obvious that the discussions will be intense and time-consuming, so that the Working Group should reserve sufficient time and the planned workshop should last a full day.

6 CONCLUSIONS

The analysis of existing Macedonian legislation (chapter 2 and Annex E) shows that many adequate laws regulate the public health sector, but that an over-arching or unifying general public health law based on the internationally accepted public health functions is missing. Also, there is ambiguity about the financing of public health activities and the role of local authorities in public health, and there is a need to incorporate the new International Health Regulations 2005 into Macedonian legislation. Fortunately, there appears to be broad consensus in Macedonia about the contribution of a new public health law to the sector, and about the general outline of such a law.

A new public health law should codify agreed mechanisms in public health. This requires agreement on outstanding public health issues (chapter 3). A study tour to two EU countries (chapter 4) can generate ideas, but there is no ideal model of organising and financing public health in any country: within the EU, public health legislation (except for EU regulations and directives) and public health systems vary widely.

The draft for a new public health law presented in Annex F is incomplete, but nonetheless gives a fair picture of what the final draft may look like. The discussion of the draft in Annex F will require intensive attention from the Working Group, the Ministry of Health, the Institutes of Public Health, and all other stakeholders in Macedonian public health (see chapter 5). The consultants are available for such discussions during the two weeks of 2-13 March 2009, and of course by e-mail before and after that period. A full-day workshop will be needed as well during that period, to prepare for the next stage: a rather complete draft of the new public health law as soon as possible after the study tour, i.e. in April-May 2009. It will be possible to present a new public health law to Parliament before the summer of 2009 if indeed timely agreement is reached on the outstanding issues in organising and financing public health, and on the definitive content of the law.

ANNEX A - AGENDA OF THE WORKSHOP OF 16 JANUARY 2009

Second workshop on Friday 16 January 2009, 10.00 a.m. – 14.00 p.m.

Venue: Stone Bridge Hotel, Skopje

Objective of the workshop

To discuss central issues in the development of a new public health law for the Republic of Macedonia between the Public Health Law Working Group, other major stakeholders, and two external consultants.

Participants

- * Members of the Public Health Law Working Group
- * Ministry of Health
 - State Sanitary and Health Inspectorate
 - Department of European Integration
 - Food Directorate
 - Health Sector Management Project
- * Representatives from the Ministries of Agriculture, Environment, Local Self-Government
- * Representative(s) from the Health Insurance Fund
- * Representatives from the regional Institutes of Public Health
- * Representative from the WHO Country Office
- * External legal consultant and public health consultant

Agenda

- 10.00-10.15 Opening by the chairman, Prof. Vladimir Popovski
- 10.15-10.30 Existing public health legislation in Macedonia in relation to the new public health law, by Miroslav Trajanovski, legal consultant
- 10.30-11.00 Suggestions for the development of the new public health law, by Kees Schaapveld, public health consultant
- 11.00-13.45 Discussion about the shape and content of the new public health law

- * How to use the Essential Public Health Functions to describe the field of public health?
- * To what extent should EPHF 6 (quality assurance), 7 (research), 9 (disaster preparedness) and 10 (human resources) be included and excluded from the new law?
- * How should we include EHPF 8 (public health planning) into the new law?
- * How should the 16 “national (special) programmes” be regulated in the law?
- * How should we integrate the IHR 2005 into the new law?
- * Should an intersectoral public health advisory (or co-ordination) council be established? Also at regional level?
- * How should the Law on Infectious Diseases and the new public health law relate to each other?
- * To what extent should the roles of the Food Directorate and the State Sanitary and Health Inspectorate be regulated by the new law and by existing laws?

- 13.45-14.00 Summary and conclusions by the chairman
- 14.00 Snacks and drinks

ANNEX B - PRESENTATION BY MIROSLAV TRAJANOVSKI

Јавното здравје во постојното македонско законодавство и новиот закон за јавно здравство

Уставна поставеност

- * На секој граѓанин му се гарантира правото на здравствена заштита.
- * Граѓанинот има право и должност да го чува и унапредува сопственото здравје и здравјето на другите.
- * Секој човек има право на здрава животна средина.

Интердисциплинарен карактер на јавното здравје

- * Јавното здравје како интердисциплинарен пристап кон **унапредувањето** на здравјето и **превенцијата** од болести опфаќа поширок дијапазон на мерки и активности на општеството.
- * Тргувајќи од тоа дека клучната детерминанта на здравјето не е само здравствениот сектор, туку и социјалните и економски фактори, јавното здравје, иако кај нас сеуште сфатено како медиализирано јавно здравје, е уредено со голем број на прописи (законски и подзаконски акти).

Предмет на уредување на Законот за здравствената заштита

- * Со овој закон се уредуваат правата од здравствена заштита на граѓаните и системот и организацијата на здравствената заштита.
- * Согласно овој закон, мерките и активностите кои се насочени кон заштита на здравјето на населението опфатени се со превентивни програмим кои ги донесува Владата на РМ, а се финасираат од централниот буџет.
- * Организираниот систем на здравствени установи (јавни, приватни и мешовити) освен што акцентот го ставаат на поединецот и на лечењето на болестите, спроведуваат **превентивни мерки и мерки на унапредување на здравјето** на целата популација, со посебен акцент на посебни (ранливи) групи на населението, како што се мајките и децата

Предмет на уредување на Законот за здравствената заштита

- * Со овој закон, како посебен вид на здравствени установи предвидени се заводите за здравствена заштита, кои се организирани како Републички завод за здравствена заштита и 10 регионални центри.
- * Основната дејност на овие заводи е превентивната здравствена заштита од специјализиран вид (следење, истражување и проучување на здравствената состојба на населението, причините за појава на заразни болести од социјално-медицинско значење, влијанието на еколошките фактори и предлагање и преземање мерки за заштита и унапредување на здравјето на луѓето).

Предмет на уредување на Законот за здравствената заштита

Освен заводите за здравствена заштита, согласно Законот за здравствената заштита, специјализирана превентивна заштита врши и Институтот за медицина на трудот на Македонија, како и службите за медицина на трудот, кои согласно Законот за безбедност и здравје на работа се ориентирани кон превентивни активности за заштита и безбедност на здравјето на вработените и здрави работни услови.

Законска регулатива за унапредување на здравјето на целата популација

- * Превентивните мерки и мерките на унапредување на здравјето на населението, освен во Законот за здравствената заштита, содржани се во широк спектар на закони, со кои особено се уредуваат областите на : Контролата на безбедноста на храната;
- * Безбедноста и здравјето на работното место;
- * Контролата на заразните и незаразните заболувања;
- * Контролата на здравствените ризици на животната средина (вода, воздух);

Здрава животна средина

- * Закон за животната средина
- * Закон за квалитетот на амбиенталниот воздух
- * Закон за снабдување со вода за пиење и одведување на урбани отпадни води
- * Закон за водите
- * Закон за заштита од бучавата во животната средина

Друга законска регулатива

- * Закон за безбедноста на храната и производите и материјалите што доаѓаат во контакт со храната
- * Закон за ветеринарното јавно здравство
- * Закон за заштита на населението од заразните болести
- * Закон за заштита и спасување
- * Закон за управување со кризи

Носител на јавното здравје и извори на средства за финасирање

- * Во Република Македонија, и покрај започнатиот процес на децентрализацијата, сеуште централната власт е главниот носител на јавната одговорност, како што е впрочем и во областа на јавното здравство
- * Финансиски средства воглавном се обезбедуваат од централниот буџет
- * Потреба од вклучување на единиците на локалната самоуправа

Интерсекторски пристап во јавното здравје

- * Министерство за здравство
- * Републички завод за здравствена заштита
- * Државен санитарен и здравствен инспекторат
- * Институт за медицина на трудот на Македонија
- * Министерство за животна средина и просторно планирање
- * Министерство за земјоделство, шумарство и водостопанство
- * Ветеринарна управа
- * Министерство за труд
- * Министерство за локална самоуправа
- * Министерство за финансии

Закон за јавно здравје

- * Umbrella law или Lex Generalis (... покрај одредбите од овој закон се применуваат и одредбите на законите....)
- * Упатни одредби на посебните закони
- * Престанување на важење на одреденои одредби од посебните закони
- * Подзаконски акти
- * Препораки за изменување и дополнување на одделни посебни закони

ANNEX C - PRESENTATION BY KEES SCHAAPVELD

A NEW PUBLIC HEALTH LAW FOR THE REPUBLIC OF MACEDONIA

second workshop

Skopje, 16 January 2009

by consultant Kees Schaapveld

Possible scheme for the new public health law

- ch.1: purpose, definitions, terminology
- ch.2: public health functions and tasks
- ch.3: public health infrastructure and responsibilities
- ch.4: partnerships in public health
- ch.5: public health authorities/powers
- ch.6: public health emergencies
- ch.7: public health information system
- ch.8: financing of public health activities

Purpose of the new Dutch Public Health Law

- * to enable implementation of International Health Regulations
- * to improve the control of infectious diseases
- * to achieve a coherent and comprehensive single law for public health
- * to improve data collection in public health for children and adolescents

Purpose of the new Scottish Public Health Law

- * to restate and amend the [previous] public health law
- * to implement the obligations under the International Health Regulations
- * to make provision about mortuaries and the disposal of bodies
- * regulation of sun beds
- * control of nuisances

Definition of Public Health - Netherlands

Public Health means health protection and health promotion measures for the whole population or specific groups, including the prevention and early detection of diseases.

Definition of Public Health - Scotland

Public Health means the protection of the community (or any part of the community) from infectious diseases, contamination, or other such hazards which constitute a danger to health. This includes the prevention, the control, and the provision of a public health response to such diseases, contamination, or other hazards.

Ch. 2: public health functions and tasks

- * based on 10 Essential Public Health Functions
- * for (parts of) some EHPF: reference to other laws / ministries
- * some of the 16 national (special) programmes
- * International Health Regulations 2005 (or separate chapter?)
- * control of infectious diseases (or separate chapter or separate law?)
- * non-communicable diseases, including health promotion and screening
- * some mother and child services

Ch. 3: public health infrastructure and management (linked to ch. 2)

- * Ministry of Health
- * National Institute of Public Health
- * Regional Institutes of Public Health
- * State Sanitary and Health Inspectorate?
- * Food Directorate?
- * human resources and/or expertise
- * physical infrastructure
- * governance based on Health Care Law

Ch. 4: partnerships in public health

- * intersectoral public health advisory (or co-ordination) committees, national and regional
- * joint management of specific public health areas, e.g. food safety or IHR 2005
- * involvement of local authorities (article 22)
- * role of Non-Governmental Organisations
- * public-private partnership probably not relevant

Ch. 5: public health authorities/powers

- * epidemiological investigations
- * compulsory testing and treatment
- * notification
- * quarantine
- * searches, inspections, closures, destruction
- * fines
- * human rights and privacy issues

Ch. 6: public health emergencies

- * International Health Regulations 2005
- * see recent Crisis Law
- * epidemics
- * bioterrorism
- * additional powers for public health authorities

Ch. 7: public health information system

- * responsibilities of the various partners for data collection, analysis and reporting
- * data protection / confidentiality
- * maintenance of registries

Ch. 8: financing of public health

- * public health is government responsibility
- * national government and local government
- * separating 16 special programmes into individual medical services and public health
- * clinical diagnostic tests \neq public health
- * official payments (tests, certificates, etc.)
- * market revenues

Also in the new public health law:

- * amendments in existing laws
- * repeals of existing laws
- * to be followed by secondary legislation in specific cases mentioned in the law

Discussion

- * Is this an acceptable approach to a new comprehensive general public health law?
- * Are we missing any essential aspects of public health and public health management?

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ANNEX D - SHORT REPORT OF THE SECOND WORKSHOP

This short report on the second workshop on the development of a new public health law is not a full account of all contributions by the participants, but rather a summary of their opinions and conclusions, which were not always unanimous.

For the agenda of the second workshop, see Annex A.

The workshop started with a short introduction by the chairman, Prof. Vladimir Popovski, who informed the participants about the preparation for the new law since December 2008, the planned study tour to two EU countries, the need for conformity of the new law with EU legislation and the International Health Regulations 2005, and the new Law on Health Information that was passed this same day.

The introduction was followed by presentations given by consultants Miroslav Trajanovski (see Annex C) and Kees Schaapveld (see Annex D).

The second half of the workshop was chaired by the co-ordinator of component 1 of the Health Sector Management Project, Katerina Venovska.

Most participants appeared to agree to the rough outline of the new law presented in Annex D. The new law should begin with its purpose and with a good definition of public health.

All wanted the law to be based on the internationally accepted list of Essential Public Health Functions (EPHF) which should be elaborated into tasks and activities.

It is clear to all that there exists already a vast amount of public health legislation in Macedonia, some of it quite recent. The new public health law should not repeat or take over what has been regulated well in other laws. In the opinion of most, this is also true for the Law on Infectious Diseases, although some disagree because the control of infectious diseases is usually a key element in general public health laws in other countries.

There is a preference for a concise umbrella law rather than a law burdened by too many detailed regulations. The new law should refer to existing public health legislation where possible.

The activities of the National Institute of Public Health and the regional Centres for Public Health and their mutual relationship must constitute an important part of the new law. It will be important to standardise the tasks and activities of these institutes. Some said that the present relationships between the Centres for Public Health, the State Sanitary and Health Inspectorate, and the Food Directorate were not always clear, and that the new law should clearly describe those relationships. However, others denied that there was overlap or lack of co-ordination at the moment.

Most participants were of the opinion that the new public health law could not be the vehicle for a comprehensive regulation of quality assurance in health care (EPHF 6). It would suffice to describe the quality assurance of the public health activities by the institutes under the Ministry of Health. Some Centres for Public Health are already accredited by a Slovenian agency. There is already a law for one aspect of quality assurance: patients' rights. However, most participants would like to see a new comprehensive law on quality of health care to be developed in the near future. As with EPHF 6, the subjects of medical and health research (EPHF 7), disaster preparedness (EPHF 9) and formation and development of human resources (EPHF 10) should be limited to the field of public health. If some public health aspects will be found lacking – e.g. in the recent Crisis Law – they can be introduced in the new public health law.

There appears to be consensus that the new law should pay attention to non-communicable diseases and measures to control them (health promotion, screening, etc.).

About EPHF 8 – the task of preparing public health plans – there appeared to be agreement that this is needed and must be regulated by the new law. At present, some annual planning is done but this should be improved and become more long-term, taking into account the National Health Strategy 2020 and existing national action plans (e.g. tobacco control and alcohol). Plans for emergency situations will also be needed.

Although article 22 of the Law on Local Self-Government describes a role of local authorities in public health, the question of involvement of local authorities in public health proved to be difficult. Most participants would like to see this involvement, although some doubt if sufficient capacity exists in smaller municipalities. It is a problem that officially regions do not exist. Solutions could be forms of inter-municipal co-operation, focussing on those municipalities where Centres for Public Health are located, and providing useful public health information for municipalities as an incentive. The draft of the new public health law should formulate ideas in this area, taking into account that some administrative and financial mechanisms must be changed in order to achieve a local contribution to public health.

All participants recognised public health as an interdisciplinary field, and supported the establishment of a national public health advisory (or co-ordination) council with a clear mandate. Such councils would also be useful at regional level, but here we find again the problem that regions do not exist officially. The contribution of Non-Governmental Organisations to public health was regarded as beneficial by some and dubious by others.

The consultants should propose a solution for the management, financing and evaluation of the 16 national (special) programmes. Some of them are clearly public health programmes that will require (sufficient) funding from the State budget. Other national programmes are individual medical care programmes that could be included into the Basic Benefit Package (BBP) or receive budget funding separate from the funds for public health. Unfortunately the discussion on the BBP and on the role of the Health Insurance Fund on paying for prevention programmes has not yet been concluded.

It was clear that implementation of the International Health Regulations 2005 (IHR) will require a major effort from the field of public health and its partners. The IHR and its annexes provide information about how to act at border crossings or in case of emergencies. According to the representative of the World Health Organisation (WHO), the IHR are in fact simpler and more efficient than existing Macedonian legislation. Therefore, existing legislation would have to be amended or specific articles would have to be introduced in the new public health law. The WHO has already done some analysis of existing legislation related to IHR.

Specific topics were mentioned by several participants

Although there is a new Food Safety Law, food safety *management* is not well regulated at the moment, and should find its way into the new public health law. It may be necessary to establish an intersectoral “food chain commission”.

The health risks from unprofessional beauty parlours etc. should be regulated in the new law, because such legislation is lacking at present.

The new law should specify who will be responsible for the supervision of the correct application of the new public health law.

It would be an option to include occupational medicine in the package of responsibilities of the regional Centres for Public Health.

Sports and recreation was mentioned as an important subject for public health legislation.

It was suggested to expand the number of Centres for Public Health to the same number as exists in the network of the State Sanitary and Health Inspectorate.

It should be mentioned that during the workshop the representatives of the Ministries of Environment and Agriculture declared themselves satisfied with the preparation of the new public health law so far.

Immediately after the workshop, the Working Group on the Development of a New Public Health Law met to discuss the work plan for the coming weeks and months. It was decided that:

- * the consultants will submit their progress report on 20 February 2009;
- * comments on the 16 national programmes or any other comments useful for the development of the new law can be sent to Katerina Venovska and/or to the consultants;
- * the next visit of the international consultant will take place from 1 to 13 March 2009;
- * the study tour should start on 24 March 2009 (note: this date was later changed into 31 March).

Note from the consultants: this would mean a meeting with the Working Group between 3 and 6 March and a third workshop on Thursday 12 March.

ANNEX E - ANALYSIS OF THE MACEDONIAN PUBLIC HEALTH LEGISLATION

Law on Healthcare (Health Protection Law) (“Official Gazette of Republic of Macedonia”, No. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07 and 77/08),

Subject matter

This Law regulates the healthcare rights of the population and the system and organization of healthcare.

The general provisions, despite the term- healthcare, regulate the healthcare scope of activities to be performed solely in healthcare organizations by healthcare workers and medical associates that fulfill the requirements stipulated in this Law; the healthcare scope shall act as a public interest activity and the professional operations shall be subjected to supervision.

In line with the Law, the healthcare organization can be founded as public, co-operative, shared and private.

Healthcare organizations, dependent on the nature of performed healthcare scope and type of provided healthcare service can be founded or organized as practice, polyclinic, diagnostic laboratory, dental laboratory, emergency medical center, mental health center, clinical hospital, healthcare facility (station), healthcare home, general and special hospital, institute, university clinic, university clinical center, institute for public health and a pharmacy.

For each type of healthcare organization, the Law addresses all scope of activities which is to be provided by the respective type of healthcare organization.

The license for start of operation of the healthcare organizations (public, co-operative, shared or private) shall be given by the Minister of Health.

The organized system of healthcare organizations shall comprise of healthcare organizations on three levels: primary, secondary and tertiary healthcare. All types of healthcare organizations, irrespective of whether they are public, private or shared shall implement, among other things, preventive measures and measures for improvement of population’s health. In parallel, particular emphasis is placed on implementation of the measures on healthcare for special (vulnerable) groups of population such as women, pregnant women, infants, preschool and school children, youth and the elderly.

The Law on Healthcare identifies the Institutes on Public Health as well as the National Institute of Public Health as separate types of healthcare organizations performing preventive specialized type of healthcare.

Thus, the Institutes of Public Health in accordance with the Law on Healthcare shall act as principal healthcare organizations for monitoring, investigation and study of the health condition of the population, the rational behind emergence and spread of diseases of social and medical importance as well as the influence of the environmental factors over the health; also propose and undertake measures for protection and improvement of the health of the population.

The healthcare shall secure financial resources from the Health Insurance Fund of Republic of

Macedonia (MHIF) as referred to in the Law on Health Insurance, or from another insurance company provided voluntary insurance is established; directly from the beneficiary of healthcare services for those services not covered by the compulsory health insurance, co-payment, or from other organizations providing contract-signed healthcare services, from selling market services and products and from interest rates, dividends, copyrights, patents, inheritance, gifts and other sources.

According to the amendments of the Law dated 2004, an opportunity has presented itself to transform the public healthcare organizations in primary healthcare and pharmacy activities so as to enable stock auctioning and lease.

Competent authorities

Supervision over the legality of operation of healthcare organizations and over the professional work of healthcare workers and healthcare organizations is performed by the Ministry of Health.

Healthcare organizations have a mandatory responsibility to organize internal supervision over the professional work of the healthcare workers.

Inspection services are performed by the State Sanitary and Health Inspectorate.

Law on Health Insurance (“Official Gazette of R. Macedonia“ No. 25/2000, 34/2000, 96/2000, 50/2001, 11/2002, 31/2002, 84/2005, 37/2006, 18/2007 and 36/2007 and 82/08);

Pursuant to the Law on Health Insurance, the healthcare organizations are obliged to plan the financial resources needed to cover a particular scope of healthcare services and within the planned funds, each year MHIF designs a Plan and a Program for healthcare services which are to be funded by the compulsory healthcare insurance funds.

MHIF acts shall define the criteria according to which contracts with the healthcare organizations as well as the method of payment of healthcare services are to be performed, certainly bearing in mind the number of beneficiaries, the defined price of healthcare services, the programs for particular types of healthcare and other criteria.

The Law does not differentiate between the public and the private healthcare organizations as regards to concluding contracts with the MHIF.

In order to deliver the healthcare services, MHIF concludes contracts with the healthcare organizations in which the scope, the type, the quality and timeline for delivery of the healthcare service(s) are defined, as well as the method of calculation, the cause and conditions under which a contract might be terminated.

MHIF maintains control over the funds of the healthcare facilities disbursed by the Fund for an earmarked and cost- effective use of the funds.

The disputes between the healthcare organizations and the MHIF are to be resolved by a competent court according to the rules of the litigation procedure.

Law on Protection of Population against Communicable Diseases (“Official Gazette of R. Macedonia” No. 66/04 and 39/08)

Subject matter

This Law shall define the measures for preventing the appearance, for early detection, prevention of spreading and suppressing communicable diseases and infections, the rights and responsibilities of the healthcare organizations and natural persons as well as supervision over the implementation of the measures in order to protect the population against communicable diseases.

Each person has the right to protection of communicable diseases and the responsibility to protect oneself and others from infections. The protection against communicable diseases is realized through planning, organizing and continuous monitoring of the epidemiological conditions and implementation of measures prescribed by this Law, as well as through supervision and control over implemented measures. The implementation of measures for protection against communicable diseases shall hold a priority in relation to the implementation of other health protection measures and also in relation to securing material and other resources.

The measures for protection against communicable diseases encompass general and specific measures for preventing the emergence, for early detection, preventing spread and suppressing communicable diseases and infections and are directly implemented by the healthcare organizations and the healthcare workers.

Competent authorities

The Ministry of Health shall monitor the movement of communicable diseases in Republic of Macedonia and internationally and shall report the findings to the competent authorities, shall adopt programs for protecting the population against communicable diseases, shall align activities and define measures for implementation of programs.

The National Institute for Public Health shall monitor and study the epidemiological condition of the communicable diseases in the territory of Republic of Macedonia and shall regularly report the national epidemiological condition findings to the Ministry of Health.

Institutes for Public Health shall monitor the epidemiological condition of communicable diseases for the area of their jurisdiction and report the situation to the National Institute for Public Health and the municipalities and the city of Skopje.

Supervision over the application of this Law and regulations adopted thereof shall be carried out by the Ministry of Health.

Inspection supervision over the implementation of this law and regulations adopted thereof shall be carried out by the State Sanitary and Health Inspectorate.

The municipalities and the city of Skopje shall perform supervision over the state and movement of the communicable diseases within their jurisdiction through exchange of information with the competent Institutes for Public Health pursuant to this and another law.

In the course delivery of supervision the State Sanitary and Health Inspectorate shall

cooperate with the Institute for Public Health.

Law on Crisis Management (“Official Gazette of Republic of Macedonia” No.29/05)

This Law shall regulate the crisis management system in Republic of Macedonia as follows: the organization and functioning, decision- making and utilization of resources, communication, coordination and cooperation, assessment of jeopardized security within the Republic, planning and financing, as well as other issues related to the crisis management system.

The crisis management system is organized and functional for the purposes of prevention, early warnings and crisis management involving risk to goods, health and life of people and animals, caused by natural disasters and epidemics or other hazards directly influencing and endangering legal order and security in the overall territory of R.M. or to a part thereof, and for which no circumstance exists to declare state of emergency or war.

The crisis management system includes collection of information, assessment, analysis of the condition, defining aims and tasks, development and implementation of necessary preventive actions, early warnings and handling of crisis.

Planning the development, operational and ongoing short term, mid term and long term planning of the crisis management system shall be performed by authorities in power to handle crisis, whereas the funds shall be secured by the Budget of Republic of Macedonia.

Competent authorities

The crisis management system shall be carried out by the state administration and state authorities (Parliament, President and Government), the armed forces such as the Army of Republic of Macedonia, protection and rescue forces, and authorities of municipalities and the city of Skopje.

Public enterprises, public institutions and services and companies, can participate in the prevention, early warning and handling of crisis in accordance with this Law.

Also the citizens, the citizens’ associations and the Red Cross of Republic of Macedonia, the non-governmental and humanitarian organizations, the public information services as well as other legal entities can participate in the prevention, early warnings and handling of crisis in a voluntary and responsible manner.

Ministries and other state administration bodies can participate in prevention, early warning and handling of crisis, in accordance with a law regulating their competencies/ authorities, whereas the municipalities and the city of Skopje, within their powers as referred to in a law, shall have the obligation to conduct risk and threats assessment on a local level for their own purposes, or for a more efficient prevention and early detection of potentially hazardous situations.

The Army can participate in cases of crisis, and the protection and rescue forces shall participate in disposal of remains.

In the crisis management system an independent body of the state administration shall be

established acting as a directorate in position and function, and as a legal entity in property. The title of the independent body of the state administration shall be the Crisis Management Center.

The inspection for implementation of this law and other regulations adopted thereof shall be carried out by the Center via crisis management inspectors.

Law on Sanitary and Health Inspection (Official Gazette of Republic of Macedonia No. 71/06 and 139/08)

Subject matter

This Law shall regulate the authorities and organization of the Sanitary and Health Inspection, the nomination of the sanitary and health inspectors, the competencies and procedures for inspection.

The Sanitary and Health Inspection shall address all inspections over the implementation of the laws and regulations adopted thereof in the area of sanitary – hygiene, epidemiological and health protection to population, health insurance and medical record- keeping.

The competencies in the area of sanitary – hygiene and epidemiological protection, as well as in healthcare and health insurance, and the opportunities to initiate a procedure for professional supervision of professional work in the healthcare organizations, shall be conducted in accordance with the Law on Healthcare.

The provisions addressing the organization of the SSHI regulate the issues related to the director of the SSHI, the state sanitary and health inspectors, the annual work program and annual report on the work of the Inspectorate, the responsibilities of the director, the organizational structure act of the Inspectorate, the official identification, the professional development of the inspectors and the obligation of the legal entities and natural persons to enable continuous and unobstructed delivery of inspections.

Types of supervisions and their scope, the minutes, adoption of decision, oral command of measures, the right to a complaint, the request for instigating misdemeanor procedure, or the criminal act complaint and the costs of the inspections during procedures shall also be the subject matter of this Law.

Law on Institutions (“Official Gazette of Republic of Macedonia” No. 32/05 and 120/05)

This Law shall regulate the conditions and the manner of providing public services of public interest, institutions and other forms and scopes in which these services are provided in education, culture, health sector, social protection, child care as well as in other scopes referred to in law as public services, as well as ownership transformations.

Subject matter shall be the requirements and procedures for founding institutions and status features thereof, granting and revoking licenses for conducting business, supervision, status changes and termination, development, operation funds, investments of funds, statute and other acts, organizational units and forms of cooperation and association of institutions.

The Law on Institutions shall also define the legal framework for ownership transformation (privatization) of institutions founded with public or state capital, organizations of associated

labor or other organizations performing activities among others in the health sector.

This Law shall have a subsidiary application and shall be applied provided another law does not stipulate otherwise.

Law on Food Safety and Products and Materials in Contact with Food (“Official Gazette of Republic of Macedonia” No. 54/02 and 84 /07)

Subject matter

This Law shall regulate the requirements for obtaining safety of food and of products and materials in contact with food, the production and marketing, the right and responsibilities of natural persons and legal entities that manufacture or market, in order to protect peoples’ health, to protect consumers from deceits and to safeguard free trade in internal and external markets.

The food that is produced and marketed in accordance with Law must be in line with the demands as referred to in the Macedonian Codex on Food. The Macedonian Codex on Food comprises of all regulation of food which is produced and marketed in Republic of Macedonia.

Competent authorities

In order to perform activities within the area of safety of food and products and materials in contact with food, the Law shall stipulate an establishment of a Food Directorate as a function within the Ministry of Health.

Operations addressing food of animal origin shall be conducted by the Ministry of Agriculture, Forestry and Water Economy – the Veterinarian Directorate, in accordance with the Law on Veterinary Health („Official Gazette of Republic of Macedonia No. 114/07) and the general requirements prescribed by this Law.

For the operation of the Macedonian Codex on Food, the Minister for Health shall form a committee of 15 members, as an expert advisory body.

The general issues on food safety as well as the specific requirements for safety of particular types of food in accordance with the general food safety requirements, shall be prescribed by the Minister for Health, whereas the special animal origin food safety requirements in line with the general requirements referred to in this Law shall be prescribed by the Minister for Agriculture, Forestry and Water Economy.

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

Control of food and products and materials in contact with food shall be carried out in all production and marketing stages by the Directorate, through food inspectors.

Inspection over the animal origin food shall be carried out by the Veterinarian Directorate in accordance with the regulations on veterinary health and the general requirements prescribed by this Law.

Law on Veterinary Public Health (“Official Gazette of Republic of Macedonia” No.114/07)

This Law shall regulate the general and specific requirements for conducting public veterinary health and healthcare of animals related to public veterinary health as follows: the responsibilities of food operators, registration and approval of food and facility operators, food import and export, official controls of food and funding thereof, monitoring of residues and prohibited substances, zoonosis agents, antimicrobial resistance, as well as all other issues significant to veterinary public health.

The competent authority for the implementation of this Law shall be the Veterinary Directorate within the Ministry for Agriculture, Forestry and Water Economy of Republic of Macedonia;

Law on Environment (“Official Gazette of Republic of Macedonia” No. 53/05, 81/05 and 24/07)

Subject matter

This Law shall act as a framework law and thus shall regulate the rights and responsibilities of Republic of Macedonia and the local self- government units, as well as the rights and responsibilities of legal and natural persons in securing conditions for protection and improvement of the environment for the purposes of exercising populations’ right to a healthy environment.

For the purposes of protection and improvement of quality and conditions of environment media: soil, water, air, of biological diversity and other natural riches, as well as protection of the ozone layer and protection against negative impact of men to climate, in addition to the provisions of this law, provisions of the laws on separate environment media and domains (separate laws) shall also be applied.

Measures and activities for the protection and improvement of the environment are of public interest.

The Government of Republic of Macedonia shall be obliged to secure funds from the Budget of Republic of Macedonia for protection and improvement of the environment. The municipality, the city of Skopje and municipalities thereof shall be obliged to secure funds for protection and improvement of the environment from the budget of the municipality, the budget from the city of Skopje and from Skopje municipalities’ budget.

Competent authorities

The supervisions over the application of this Law and regulations adopted thereof shall be carried out by the authority of the state administration in charge of environmental activities.

The inspection over the application of this Law and the regulations adopted thereof shall be conducted by the State Inspectorate for Environment, through the state environment inspectors and the nature protection inspectors.

For the operations within the power of the municipalities, of the city of Skopje and the municipalities of the city of Skopje as referred to in this Law, the inspection over the implementation of this law shall be carried out by authorized inspectors for environment of the municipality, authorized inspectors for environment of the city of Skopje and authorized inspectors for environment of the municipalities in the city of Skopje.

Inspection over the application of this Law in the area of marketing products, semi- products, raw materials, chemical substances, packaging and labeling of products and packaging containing information of the environmental impact shall be carried out by the State Market Inspectorate, through the state market inspectors, the State Sanitary and Health Inspectorate by using the state, sanitary and health inspectors, the Phytosanitary Directorate by using the pytosanitary inspector and the State Agricultural Inspectorate through the state inspectors for agriculture.

Inspection over the implementation of this Law in the area of marketing products, semi – products and raw materials for human consumption (food and drink) and their packaging and labeling containing information of environmental impact shall be carried out by the Food Directorate by using the food inspectors.

Law on Quality of Ambient Law (“Official Gazette of Republic of Macedonia” No.67/04 and 92/07).

Subject matter

This Law shall regulate the measures for avoiding, preventing or reducing the adverse effects of polluted ambient air over human health, as well as adverse effects over the entire environment by determining the ambient air quality limit values and warning thresholds, limit values in emissions, forming a universal system of monitoring and control of the ambient air and monitoring the sources of emissions, a comprehensive management system of the quality of the ambient air and the sources of emissions, the information system as well as all other protective measures from natural persons and legal entities which might have a direct or indirect impact over the quality of the air.

The objectives of this Law, among others are avoidance, prevention and reduction of adverse effects over human health and the entire environment.

In order to avoid, prevent or reduce the adverse effects over human health and entire environment, the Law shall prescribe limit values.

For the monitoring of the ambient air quality, as an integral part of the overall environmental monitoring, across the territory of Republic of Macedonia, the Government of Republic of Macedonia shall set up a network for ambient air quality monitoring.

Competent authorities

The assessment of the ambient air quality shall be performed by the state administration authority responsible for the environmental issues.

Assessment of health hazards related to the ambient air quality shall be carried out by the state administration authority responsible for the health issues.

Supervision over the implementation of this law and the regulations adopted thereof shall be carried out by the Ministry of Environment and Physical Planning.

Inspection over the application and implementation of this Law and the regulations adopted thereof shall be carried out by the State Inspectorate for Environment through the environment inspectors. The issues for which the municipalities and the city of Skopje hold jurisdiction as referred to in this Law, and the inspection over the application and implementation of this Law shall be carried out by the municipal inspectors for environment and authorized environment inspectors of the city of Skopje.

Law on Ionizing Radiation and Protection and Safety (“Official Gazette of Republic of Macedonia” No. 48/02 and 135/07)

Subject matter

This Law shall regulate the system of control over all sources of ionizing radiation, as well as the **protection** of the population and environment from exposure or potential exposure to ionizing radiation.

Under protection from ionizing radiation as referred to in this Law, shall be considered a set of activities and means undertaken in order to protect the life and health of people and the environment from the adverse effects of ionizing radiation.

Competent authorities

The general conditions for protection against ionizing radiation and securing the sources of ionizing radiation should safeguard normal exposure within the limit values prescribed by the Directorate for Ionizing Radiation.

The Directorate for Radiation Safety is established by this Law in order to carry out administrative and expert activities in the area of ionizing radiation.

The Directorate shall form a Committee on Radiation Safety as an advisory body for particular issues in the area of protection against ionizing radiation and preparation of proposals and decisions within its powers.

The National Institute for Public Health upon request and under requirements prescribed by the Directorate, among others shall perform activities related to:

- 1) preparation of standards in the area of radiation safety in accordance with the standards of the international organizations and the European Union;
- 2) submitting reports to the Directorate in relation to the improvement of protection in utilization ionizing radiation sources and the control thereof;
- 3) participation in the delivery of training for safe handling and management of ionizing radiation sources;
- 4) measuring the level of exposure to ionizing radiation of persons working with radiation sources, as well as of the population
- 5) monitoring the content of the radionuclides in the air, soil, waters and food;
- 6) evaluation of the level of exposure of ionizing radiation during work and
- 7) continuous medical control and record keeping for persons which are professionally

exposed to ionizing radiation and

The National Institute for Public Health upon request and under requirements prescribed by the Directorate, among others shall perform the following activities:

- 1) preparation and proposal of technical basis for the preparation of the secondary legislation and standards in the area of radiation protection in accordance with the standards of the international organizations and the European Union;
- 2) submitting reports to the Directorate as regards to improvement of protection in use of sources of ionizing radiation and the control thereof;
- 3) participation in implementation of training on safe handling and management of ionizing radiation sources;
- 4) measurements on degree of exposure to ionizing radiation of persons working with radiation sources as well as of the population;
- 5) perform assessment as to the level of exposure to ionizing radiation during work;
- 6) perform continuous medical control and keep records on persons professionally exposed to ionizing radiation;
- 7) perform calibration on measurement instruments for radiation protection and
- 8) perform other works in the area of ionizing radiation protections.

The Directorate might ask professional services from other expert institutions necessary for the implementation of this Law, authorized by the Ministry of Environment and Physical Planning, the Ministry of Health, the Directorate and the Ministry of Agriculture, Forestry and Water Economy.

Supervision over the application of this law and the regulations adopted thereof shall be carried out by the Directorate.

Activities of inspection over the implementation and application of this Law and the regulations adopted thereof shall be carried out by the Directorate through ionizing radiation inspectors.

Law on Waters (“Official Gazette of Republic of Macedonia” No. 4/98, 19/2000, 42/2005 and No.46/06).

Subject matter

Provisions of this Law shall address the spring, running, still and ground waters, the run-off rain waters, drinking waters and waste waters, riverbeds and banks of run off flows and torrents, lakes and reservoirs, as well as thermal and mineral waters, unless a separate law stipulates otherwise.

This Law shall, among other things regulate the conditions and manner of utilization and consumption of drinking waters, the protection against adverse effects of waters, as well as protection of waters against pollution for the purposes of enabling unobstructed utilization of waters, protection of populations’ health, protection of the environment and the nature, and the flora and fauna.

Protection of waters against pollution shall be carried out in accordance with the National Action Plan for Protection of the Environment of Republic of Macedonia and the action plans for protection and improvement of the environment and natural surroundings of the municipalities and the city of Skopje.

Provisions of Article 50 of the Law prescribe the responsibility of legal entities which supply drinking water and legal entities which utilize drinking water from individual sources to disinfect the water and to undertake measures which will safeguard continuous and regular investigation as to the quality and sanitary safety of waters and the water supply capacities and facilities and submit and report on findings to the Ministry of Health.

Water utilized or intended for populations' consumption, the industry that requires water with drinking properties and the mineral waters intended for human consumption, in accordance with article 51 of the Law shall not contain harmful substances of adverse effect to the health of the people exceeding permitted limits, and as regards to the physical, chemical, biological and radiological properties must comply with the prescribed requirements in line with the regulations on sanitation safety of foodstuffs.

Competent authorities

The Ministry of Health shall prescribe the manner of disinfection, the scope, type and methodology of drinking waters examination and shall designate a legal entity of appropriate equipment and appropriate expert staff to conduct analysis of the drinking waters, also shall define the limits above which the drinking waters must not contain harmful or dangerous substances.

Ministry of Health for the purposes of protection of peoples' health can ban the use or consumption of the drinking water in cases and under circumstances prescribed in the regulations for sanitary safety of foodstuffs.

Ministry of Health in accordance with the Minister for Agriculture, Forestry and Water Economy, can ban the use or consumption of the waters for bathing, sports or recreation.

The Republic Hydrometeorological Institute shall establish and maintain a cadastre of potential water pollutants as well as of water protection facilities. The Republic Hydrometeorological Institute shall continuously and regularly submit the data on the condition and modifications of the quality of waters to the Ministry of Agriculture, Forestry and Water Economy and to the Center for processing and utilization of data on monitoring the environment and nature quality within the Ministry of Urban Planning, Construction and Environment.

Supervision over the implementation of this Law and the regulations adopted thereof shall be carried out by the Ministry of Agriculture, Forestry and Water Economy.

The inspection over the implementation of this Law shall be carried out by water management inspectors.

Law on Drinking Water Supply and Drainage of Urban Wastewaters (“Official Gazette of Republic of Macedonia” No.68/04, 28/2006 and 103/08)

Subject matter

This Law shall regulate the conditions and the manner of supply of drinking water, termination of the drinking water supply and drainage of urban waste waters in the recipient

through the water supply and sewage system, construction, maintenance, protection and attachment to the water supply and sewage systems, the relations between the provider and beneficiary of services as well as monitoring over the implementation of this Law.

The objectives of this Law are as follows:

- * Accessibility to sufficient quantities of sanitary safe and clean drinking water for the needs of the service beneficiaries, in accordance with the requirements, the standards and the water quality properties.
- * Supply of sanitary healthy drinking water, and in cases of its contamination, ban or consumption limitations
- * Appropriate information to the beneficiaries of the service on the quality of the drinking water and undertaking measures for obtaining quality of drinking water
- * Appropriate treatment of industrial waste waters prior to their release into the recipient and
- * Through drainage of urban waste waters to secure protection against adverse affect of drainage.

Competent authorities

Inspection over the application of this law and the regulations adopted thereof, shall be carried out by the authorized communal municipal inspector, and the authorized communal inspector of the city of Skopje, the State Inspectorate for Environment and the State Sanitary and Health Inspectorate as well as other inspections, within the competencies as referred to in this Law.

The State Sanitary and Health Inspectorate and the municipal inspectors and the city of Skopje during inspection shall confirm if the service provider:

- * Performs examinations for sanitary safety of the drinking water, and
- * Supplies the beneficiaries of the services with the needed quantity of drinking water in instances when water supply via the water supply system for a continuous period over 12 hours, is disabled.

Law on Protection and Rescue (“Official Gazette of Republic of Macedonia” No.36/04 and 49/04).

Subject matter

This Law shall regulate the protection and rescue of people and material goods against natural disasters, epidemics, epizooties, epiphytotics, and other catastrophes in peace time and war time and against military actions in Republic of Macedonia (hereinafter: the Republic).

Protection and rescue of people shall be a work of public interest for the Republic.

Competent authorities

Protection and rescue in the Republic shall be carried out by the state administration functions, the local self government units, the public enterprises, and services, the companies, the citizens’ associations, the citizens and the protection and rescue forces, pursuant to in this Law, the regulations adopted thereof, as well as according to the norms, standards and technical practice rules.

For the purposes of performing protection and rescue against natural disasters, epidemics,

epizooties, epiphytotics, and other catastrophes, a Directorate for Protection and Rescue has been established and functioning as an independent state administration body with the capacity of a legal entity.

Inspection over the implementation of the provisions of this law and other regulations in the area of protection and rescue shall be carried out by a protection and safety general inspector.

Law on Professional Health and Safety (“Official Gazette of Republic of Macedonia” No.92/07).

Subject matter

This Law shall define the professional health and safety measures, the obligations of the employer and the rights and responsibilities of the employees in the area of professional health and safety as well as the preventive measures against professional hazards, removal of misfortune risk factors, information, consulting, training of workers and their representatives as well as their participation in the process of planning and undertaking professional health and safety measures..

The provisions of this Law shall be applied in all aspects of the public and private sector, shall be applied for all insurees against injuries on the job, or professional diseases according to the regulations on pension, disability and health insurance and for all other persons engaged in the work processes. The provisions of this Law shall not be applied to the scope of activities provided another regulation addresses this subject mater (armed forces, police, and in some cases the protection and rescue forces.). The provisions of this Law shall not apply to house keepers.

Competent authorities

The Government of Republic of Macedonia shall establish a Council for Professional Health and Safety (hereinafter: the Council), as an expert advisory body consisted of 15 members.

The supervision over the implementation of the provisions of this Law shall be carried out by the Ministry of Labor and Social Policy, whereas the inspection in the professional health and safety area shall be conducted b the State Labor Inspectorate pursuant to the Law on Labor Inspection.

Law Proposal on Medical Data

Subject matter

This Law shall regulate the record- keeping, data compilations/collections and medical registries, manner of collection, procession, archiving and storing data, publishing of data, securing quality of data and protection of data, as well as exercising rights and responsibilities related to medical record- keeping.

The application of the Law shall have the following purpose:

- * Full automated processing of health and medical data,
- * Partial automated processing of health and medical data, and
- * Manual processing of health and medical data which are a part of a permanent collection of

health or medical data or are to become a part of a collection of medical and personal data.

Subject matter of the Law are the obligations to maintain a record-keeping system and to submit reports, individual records, collective records, data forms, medical registries, single/unique methodological principles and statistical standards (definitions, classifications and nomenclatures) as well as standards procedures for designing and keeping compilations of data, the central medical data base, sources of funding of the implementation of this Law.

Also the Law shall regulate collection of data, purposes of medical data use, maintaining basic medical documentation, exchange of data between data compilations, record-keeping means, commitment of healthcare facilities to submit reports to Public Health Institutes, responsibility of the healthcare facilities to familiarize the individual with collected medical and personal data, disclosure of medical and personal data of the individual for the purposes of healthcare provision, statistical and research purposes in processing of medical and personal data and the committee for monitoring and improving medical records.

Healthcare organizations shall have the obligation to undertake measures for securing personal and medical data in their possession, in accordance with this Law and the regulations on personal data protection and to establish and maintain a security system.

The Republic Institute for Public Health in the process of conforming to the international obligations and in cooperation with the authorized statistical stakeholders shall cooperate, mediate and exchange data with other countries which have established protection of data as well as with international organizations.

Competent authorities

Supervision over the implementation of the Law, the inspection over the implementation of the organizational and technology procedures and measures for protection of medical and personal data, as well as keeping of medical records in instances when performed manually shall be carried out by the State Sanitary and Health Inspectorate.

ANNEX F - OUTLINE OF THE NEW PUBLIC HEALTH LAW

This is an incomplete draft of 11 February 2009 by Kees Schaapveld and Miroslav Trajanovski. Text between [square brackets] means: not yet ready, or open for discussion, or questions.

Chapter 1: General provisions

Scope of the law

Article 1.1

This law shall regulate [enumeration of the main issues/chapters of the law]

Article 1.2

The purpose of this law is threefold:

- a) to regulate the public health sector with the aim of maintaining and improving the health of the population;
- b) to enable implementation of the International Health Regulations 2005;
- c) to regulate specific public health matters that are not [adequately] regulated by existing legislation.

Article 1.3

The terms used in this law shall have the following meaning.

Public health is “the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society” [or: “the science and art of preventing disease, prolonging life and promoting physical health and efficiency through organised community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organisation of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health”.] [or: yet another definition]

A Public Health emergency is the 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.

[option: insert article 3 of the Serbian draft law here]

[insert glossary]

Article 1.4

Public health is described [or: defined] according to the internationally adopted list of Essential Public Health Functions (EPHFs), which 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. The EPHFs 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; Development and enforcement of laws and regulations that protect health and ensure safety.
4. Disease prevention: Applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Evaluation of the quality and effectiveness of personal and community health services.
7. Initiation, support and carrying out of health related research.
8. Initiation, development and planning of public health policy.
9. Preparedness and management of public health emergencies.
10. Assuring a competent public health and personal health care workforce (including evidence-based culture and communication skills).

Chapter 2: Public health functions and tasks regulated by this law

Article 2.1

Existing legislation that regulates parts of certain EPHFs [especially EPHFs 3 and 9] will remain in force, more specifically in the fields of environmental protection, safety & health at work, food safety, blood safety, control of infectious diseases, and disaster preparedness.

Article 2.2

This law limits the regulation of EPHFs 6, 7, 9 and 10 to activities for which the public health sector under the Ministry of Health is responsible. Activities in the medical (clinical) sector and activities outside the health sector that can be considered part of these 4 EPHFs will be regulated by special laws.

Article 2.3

The implementation of the International Health Regulations 2005 falls under several EPHFs and is regulated in Chapter 8 of this law.

Article 2.4

The determination, organisation and financing of national (special) programmes in the field of public health is regulated by this law.

Article 2.5

Specific public health matters that are not [adequately] regulated by existing legislation are presented in Chapter 9 of this law.

Chapter 3: Public Health responsibilities and infrastructure

Article 3.1

The following tasks are included in the responsibility for public health at the level of the Republic of Macedonia:

1. providing policy and strategy of public health [EPHF 8];
2. monitoring the health status of the population and identification of health problems in the community [EPHF 1 and 2];
3. planning, establishing priorities, passing special public health programmes, as well as passing regulations in this area [EPHF 3 and 8];
4. implementation of tax and economic policies that stimulate health life styles;

5. providing conditions for health education and empowerment of the population to take care of their own health [EPHF 5];
6. providing a system of quick response in extraordinary situations such as epidemics, physical and chemical accidents, and natural disasters [EPHF 9];
7. development of a health information system [EPHF 1 and 6];
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 [EPHF 6];
10. strengthening of laws and regulations protecting health and providing security and safety of people [EPHF 3];
11. provision of competence in public health human resources through training and continuing education [EPHF 10];
12. researching new approaches and innovation of measures in solving health problems of the population [EPHF 7];
13. building, equipping and creating conditions for a rational network of Centres for Public Health.

The responsible ministry for the tasks mentioned in this Article is the Ministry of Health [except tasks 4 and 6]. [Here we should mention which other ministries are responsible for specific tasks.]

Article 3.2

The National Institute of Public Health is responsible for advising and assisting the Ministry of Health [and other relevant ministries] in the tasks mentioned in Article 3.1. Specific tasks of the National Institute of Public Health are:

1. to prepare medium-term and long-term public health plans, including the development and co-ordination - also intersectorally - of national public health programmes to be agreed by the Ministry of Health, and their budgets; these programmes are in the areas of health protection, health promotion, population screening, control of communicable diseases, and mother & child health;
2. to prepare annual national reports on relevant aspects of the population's health;
3. to standardise, co-ordinate, inform, and supervise the professional work of the Centres for Public Health;
4. to act as a reference laboratory for the Centres for Public Health;
5. to develop and provide education programmes in the field of public health for its own staff, staff of the Centres for Public Health, and other target groups, in co-operation with the School of Public Health, the Centres for Public Health, and the Medical Faculty;
6. to co-ordinate public health measures in case of epidemics and other emergencies, together with other ministries and organisations indicated by the Crisis Law;
7. to function as the Focal Point for the International Health Regulations 2005;
8. to co-ordinate international co-operation in the field of public health, provide health data to international organisations, and represent the Republic of Macedonia in international meetings and projects;
9. to organise and implement research in the field of public health;
10. other tasks at the request of the Ministry of Health.

Article 3.3

The governance of the National Institute of Public Health and the Centres for Public Health is according to the provisions of the Health Care Law and the Public Institutions Law [is this

sufficient?]

Article 3.4

The National Institute of Public Health will be organised in the following departments:

1. Management and administration;
2. Department of analysis, planning, and evaluation;
3. Department of health promotion;
4. Department of mother and child health;
5. Department of disease control and prevention (of specific communicable and non-communicable diseases; including emergency preparedness).
6. Department of environmental protection [alternative name: environmental health].
7. Department of reference laboratory services.

The National Institute of Public Health will employ staff with at least the following expertise: [.....].

Staffing, space, equipment and accreditation norms (or minimum requirements) will be established by secondary legislation adopted by the Minister of Health.

Article 3.5

Public health services for the territory of one, two or more municipalities are provided and coordinated by Centres for Public Health. Each Centre for Public Health will serve a group of municipalities with a combined number of inhabitants of at least [...] and at most [...], the Centre for Public Health of the city of Skopje being an exception to this numerical rule.

Article 3.6

The Centres for Public Health provide the following services:

1. to prepare medium-term public health plans and annual implementation plans for the territory covered by the Centre;
2. to prepare annual reports on the population's health in the territory covered by the Centre, based on the regular collecting of prescribed data and on ad hoc collection of specific relevant data; contribute the required data to the National Institute of Public Health;
3. monitoring of environmental and sanitary conditions in the territory covered by the Centre;
4. microbiology and physicochemical laboratory services;
5. local implementation of the national public health programmes in the areas of health protection, health promotion, population screening, control of communicable diseases, and mother & child health, together with other local authorities and organisations where relevant;
6. local implementation of the International Health Regulations 2005, the Law on Infectious Diseases, and other relevant public health laws;
7. to prepare for and contribute to public health measures in case of epidemics and other emergencies, together with other local authorities and organisations, under the coordination of the National Institute of Public Health;
8. participation in education programmes in the field of public health for the staff of the Centres;
9. other public health services agreed with local authorities.

A Centre for Public Health may be specialised for certain activities, and, if it is, serve as the leading institution for other Centres for Public Health.

Article 3.7

The Centres for Public Health will be organised in the following departments:

1. Management and administration;
2. Department of analysis, planning, and evaluation;
3. Department of health promotion (including mother and child health);
4. Department of disease control and prevention (of specific communicable and non-communicable diseases; including emergency preparedness).
5. Department of environmental protection [alternative name: environmental health].
6. Department/laboratory of microbiology.

The Centres for Public Health will employ staff with at least the following expertise:

[.....]

Staffing, space, equipment and accreditation norms (or minimum requirements) will be established by secondary legislation adopted by the Minister of Health.

Article 3.8

The public health responsibilities and tasks of the State Sanitary and Health Inspectorate are regulated by the Law on the State Sanitary and Health Inspectorate.

[Do we need this article? Should something be added here? Is the relation between the SSHI and the Institute/Centres for Public Health clear?]

Article 3.9

The safety of blood and blood products is regulated by [name of law(s)].

[We suppose that blood safety is sufficiently regulated. Do we need this article?]

Chapter 4: Partnerships in Public Health

Article 4.1

1. The system of public health that provides conditions for preservation and improvement of the population's health consists 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.
2. The partners mentioned in paragraph 1 of this Article are responsible for participating in the implementation of the public health functions from Article 1.4 of this law.
3. The Government of the Republic of Macedonia is responsible for the overall provision and implementation of public health functions in the country. Responsibility for public health is, apart from the Ministry of Health, divided between other ministries for different social areas: education, protection of the environment, social care, science, sport, culture, traffic, agriculture, economy, labour, and other.
4. The National Institute of Public Health and the Centres for Public Health have the leading role in the system of public health, as well as in the implementation of the public health functions from Article 1.4 of this law.
5. Tasks of other participants in the system of public health are determined by other laws and regulations.

Article 4.2

1. The Government will establish an Intersectoral Public Health Co-ordination Council that

will advise the Minister of Health and other relevant ministries, upon their request and also at its own initiative, on all public health matters that involve the domain of more than one ministry.

2. The Council is chaired by the Minister of Health or his/her representative, and will have [...] members. [details about the Council to be filled in later]

Article 4.3

1. Each Centre for Public Health will have 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 for Public Health.

2. The committee is chaired by [details about membership and tasks to be filled in later]. The committee will have at least [3] representatives from municipalities covered by the Centre for Public Health [because public health is also a municipal responsibility according to Article 22 of the Law on Local Self-Government] .

[Does existing legislation stipulate that local authorities must be represented on the Board of a Centre for Public Health?]

[Instead of Article 4.3, we could also modify the tasks and composition of the existing Boards of the Centres which are established according to the Public Institutions Law (see Article 3.3). However, Board and intersectoral advisory committee are quite different concepts.]

Article 4.4

1. Food safety is an important intersectoral public health subject that is regulated by [Food Safety Law and other laws]. [The Food Safety Law does not mention the Institute/Centres for Public Health, do they have a role in food safety?]

2. In addition, the *management* of food safety risks is regulated by Articles [9.1 and following] of this law.

Article 4.5

Safety and health at work is an important intersectoral public health subject that is regulated by [.....].

[We suppose that this subject is sufficiently regulated by its new law]

Article 4.6

Protection of the environment is an important intersectoral public health subject that is regulated by [.....].

[need for any additional regulation?]

Article 4.7

Disaster preparedness is an important intersectoral public health subject that is regulated by the Crisis Law. Articles [....; Chapter 6] of this Public Health Law specify further regulation of health aspects of disasters and emergencies.

Chapter 5: Powers of the Public Health authorities

Article 5.1

The National Institute of Public Health and the Centres for Public Health are authorised to use the powers and provisions set forth in this Chapter to prevent, control or ameliorate conditions of public health importance. In carrying out these powers, they will be guided by the

following principles:

1. The public health purpose must be clear.
2. Procedures must be followed that are based on modern, scientifically sound principles and evidence.
3. The intervention must be well-targeted, that means not involving more persons than is necessary for the public's health.
4. The intervention should be the least restrictive alternative, that means that least infringes on the rights and interests of individuals, while still protecting the public's health.
5. The intervention should not in an unlawful manner discriminate individuals on the basis of their race, ethnicity, nationality, religious beliefs, sex, sexual orientation, or disability status.
6. The intervention should respect the dignity of each individual.

Articles 5.2 and following

[To some extent, the following items are regulated by the Law on Infectious Diseases, and possibly by the Law on the State Sanitary & Health Inspectorate, but is it sufficient?

- * epidemiological investigations
- * notification
- * compulsory testing, immunisation, and treatment
- * isolation/quarantine
- * searches, inspection, closures, disinfection, destruction
- * fines
- * privacy and human rights issues]

Chapter 6: Public Health emergencies

[Examples of a public health emergency are an epidemic of atypical influenza, contamination of the drinking water supply, or an accident in a chemical factory.]

[Additional powers for public health authorities in case of epidemics are already regulated by articles 57-58 and 64 of the Law on Infectious Diseases, but there is no link with the Crisis Law, and not all public health emergencies are of infectious origin. The Crisis Law sets a framework for disaster preparedness and response. This presumably includes public health emergencies as defined in Article 1.3. The new public health law should say if all public health emergencies should be controlled via the Crisis Law. In that case, the roles of the Steering Committee, the Assessment Group, and the Crisis Management Centre should be clear. These organisations should have members with public health expertise, preferably from the National Institute of Public Health. It would also be possible to describe specific public health emergencies that do not require the use of the Crisis Law, for example a case of food poisoning involving a large number of persons.]

Chapter 7: Public Health information system

[The Law on Medical Records (also known as Evidence Law) regulates many aspects of collecting, storing, using, transmitting and sharing of health (care) data, including data protection and confidentiality aspects. The emphasis appears to be on health care data. The Law on Infectious Diseases does *not* sufficiently regulate these aspects for infectious diseases, and the Law on the State Sanitary and Health Inspectorate does not deal with these aspects.]

There are also other data than health (care) data used in public health: financial and economic data, demographic data, survey data, and environmental data (including sanitation and food). These are not the subject of the Law on Medical Records.

The new public health law will refer to the Law on Medical Records, but it could (should?) add articles on the specific tasks and responsibilities of the National Institute of Public Health, the Centres for Public Health, and the Ministry of Health (including Food Directorate and State Sanitary and Health Inspectorate).]

Chapter 8: International Health Regulations 2005

Article 8.1

1. The Minister of Health designates to which airports the Articles of this chapter apply [IHR article 20].
2. A civil airport will be designated jointly with the Minister of Transport.
3. A military airport will be designated jointly with the Minister of Defence.

Article 8.2

A bylaw will specify which facilities the airports must have at their disposal, and with which standards these facilities must comply. Such facilities and standards may differ between airports.

The owner [operator] of the airport is obliged to implement the provisions of the bylaw.

Article 8.3

1. The captain of an aeroplane that makes an international journey who wants to land at one of the airports 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 at the airport as soon as possible, but in any case before landing.
2. The air traffic controller immediately informs the owner [operator] of the airport, the Centre for Public Health on which territory the airport is located, and the Focal Point of the National Institute of Public Health.

Article 8.4

1. Without prejudice to Article 8.3, the captain of an aeroplane that makes an international journey will provide the Centre for Public Health with the Health Part of the Aircraft General Declaration according to article 38 of the International Health Regulations if so requested.
2. If the Health Part mentioned in the first paragraph of Article 8.4 calls for additional information, the captain of the aeroplane should provide such information about the health situation on board to the Centre for Public Health.
3. The Minister of Health will inform the aircraft operators or their agents of these requirements.

Article 8.5

In case of a notification as described in Article 8.3, 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.

Article 8.6

1. In case of a notification as described in Article 8.3, or if suspicion of a potential public health danger on board of an aeroplane has arisen otherwise, the National Institute of Public

- Health will decide which measures must be taken after arrival or the aeroplane at the airport.
2. In case of a direct threat of an epidemic of an infectious disease mentioned in Annex 2 of the International Health Regulations [or a more restricted list of infectious diseases], the National Institute of Public Health will decide which measures must be taken regarding the admission or non-admission of crew and passengers of the aeroplane.
 3. In a situation as described in paragraphs 1 and 2 of this Article, the captain of the aeroplane will assure:
 - a) that after arrival, nobody will enter or leave the aircraft and no goods will be loaded or unloaded, until permission of the National Institute of Public Health is obtained, and
 - b) that, if requested, the National Institute of Public Health will receive a list with the names, address, sex, age and destination of the passengers, in so far as known by the captain.
 4. The National Institute of Public Health applies these measures only as long as needed to carry out its investigation to ascertain the seriousness of the risk.

Article 8.7

The National Institute of Public Health can order the owner [operator] of an airport:

- a) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- b) to assist the Centre for Public Health or the National Institute of Public Health 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 8.8

The National Institute of Public Health 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.

Article 8.9

1. Active or passive immunisation of persons in order to obtain an internationally valid certificate as described in article 36 of the International Health Regulations will be provided according to rules established by the Minister of Health.
2. The certificates will have the model of Annex 6 of the International Health Regulations.
3. The Minister of Health will designate persons of institutions that can provide immunisation against yellow fever.

Articles 8.10 and following

[on land border crossings, if not regulated elsewhere]

Chapter 9: Specific public health matters

Articles 9.1 and following

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

Article 9.x and following

1. Quality assurance activities in the National Institute of Public Health and the Centres for Public Health will consist of developing and following agreed professional standards and guidelines, continuing professional development of staff, accreditation of laboratories, and peer review.
2. The National Institute of Public Health and the Centres for Public Health are themselves responsible for assuring the quality of the services they provide according to jointly developed guidelines. In their annual reports they will describe their efforts and results in this field in the past year and their commitments for the coming year. The National Institute of Public Health will supervise the activities of the Centres for Public Health according to a jointly developed protocol.
3. The National Institute of Public Health will provide reference laboratory services for the laboratories of the Centres for Public Health according to a jointly agreed schedule.
4. The National Institute of Public Health and the Centres for Public Health will provide sufficient opportunities for continuing professional development to their technical and academic staff to maintain the required level of expertise. The National Institute of Public Health will assist the educational activities of the Centres for Public Health as required.
5. The laboratories of the National Institute of Public Health and the Centres for Public Health must be accredited according to [.....].

Article 9.y

1. An entrepreneur who performs activities that penetrate the skin of his clients and who is not a medical doctor needs a permit from the Ministry of Health. Such activities include tattooing, piercing, permanent make-up and acupuncture.
2. It is not allowed to provide a tattoo or piercing (except in the earlobe) to persons under the age of [16]. A person under the age of 18 needs parental approval for tattoos on head, neck, wrists or hands, and for genital piercings (boys and girls) and nipple piercings (girls only).
3. Persons receiving a piercing or tattoo must be informed in advance about the possible consequences.
4. Tattoos, piercings, permanent make-up and acupuncture can only be provided in special rooms for this purpose.
5. Modalities of the permit and the requirements for the treatment room and the materials to be used will be established by secondary legislation adopted by the Minister of Health.
6. The implementation of this Article will be supervised by the State Sanitary and Health Inspectorate [or by the Centre for Public Health?].

Article 9.z

[Other public health issues that are insufficiently regulated at present?]

Chapter 10: Financing of Public Health activities

Article 10.1

1. For the execution of its tasks according to Article 3.2, the National Institute of Public Health will receive funding from the state budget at a level annually to be determined by the Minister of Health after consultation with the Institute on the basis of a submitted business plan.
2. The National Institute of Public Health is allowed to accept funding for public health projects from national and international sources. Such projects must be compatible with the

national and international mission of the Institute and have no commercial purpose.

3. The National Institute of Public Health will not receive funding from the Health Insurance Fund for any of its activities.

4. The National Institute of Public Health will not enter into contracts with government, parastatal or private entities for testing and monitoring activities that can be executed by Centres for Public Health.

Article 10.2

1. For the execution of their tasks according to Article 3.6, the Centres for Public Health will receive funding from different sources.

2. The Centres for Public Health will receive basic funding from the state budget according to a resource allocation formula established by the Minister of Health. Per capita funding according to the number of inhabitants in their territory will be an important element of this formula. The total funding available for all Centres for Public Health will be decided annually by the Minister of Health after consultation with the Centres on the basis of submitted business plans. The state funding will include the cost of implementing the official public health programmes.

3. The Centres for Public Health will be paid by the Health Insurance Fund for diagnostic laboratory services for individual insured referred patients, on the basis of an annually agreed fee-for-service tariff. [What about uninsured patients?]

4. The Centres for Public Health will be paid by public entities [municipalities, drinking water companies, etc.] for specific public health activities according to a mutually agreed contract.

5. The Centres for Public Health will be paid for legally required tests and certificates by the clients according to the official tariff established by the Ministry of Health.

6. The Centres for Public Health can conclude contracts with private companies [e.g. food industry] for public health activities. The revenues from private sources shall not be more than [...] % of the total revenues of a Centre.

Article 10.3

Investment costs for the National Institute of Public Health and the Centres for Public Health will be paid from a separate budget of the Ministry of Health on the basis of submitted investment plans.

Article 10.4

All costs of activities that are required from airport owners [operators] and aircraft operators for the implementation of the International Health Regulations will be borne by themselves.

Article 10.5

The cost of implementing food safety activities is regulated by the Food Safety Law.

Article 10.6

The cost of implementing sanitary inspections is regulated by the Law on the State Sanitary and Health Inspectorate [is this true?].

Chapter 11: Miscellaneous

[items:

- * Amendments that will be required in existing laws.
- * Repeals of existing laws or provisions of existing laws that are not needed anymore.
- * Who will be responsible for the supervision of the implementation of the new law?

- * Overview of secondary legislation that will follow specific cases in this new Public Health Law.
- *]