

**MINISTRY OF HEALTH OF THE REPUBLIC OF MACEDONIA**  
**HEALTH SECTOR MANAGEMENT PROJECT**  
**CONSULTANCY ON DEVELOPMENT OF A NEW PUBLIC HEALTH LAW**

**INCEPTION REPORT (draft)**

Kees Schaapveld, public health consultant

and

Miroslav Trajanovski, legal consultant

Skopje, 12 January 2009

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## 1 INTRODUCTION

The terms of reference for this consultancy specify as its main aim “to assist the Ministry of Health and the Republic Institute for Health Protection in the development of a new Law on Public Health that would encompass the role of the state in providing public health services as public goods”. The Ministry of Health has engaged two consultants - the authors of this inception report - who should:

- \* provide an analysis of public health legislation in EU and non-EU countries;
- \* provide an inventory of relevant existing Macedonian legislation;
- \* propose - in various stages - a new Public Health Law that reflects the aspirations of public health in Macedonia and the goals of public health reform;
- \* organise a study tour to one or two EU countries for a group of Macedonian public health policy makers.

Although the consultants have been contracted for the period of 15 December 2008 until 30 June 2009, the Ministry of Health has expressed its wish that a full draft of the new Public Health Law be already available by the end of March 2009. It will depend on the co-operation of the many stakeholders and on the possibility to reach agreement on the content of the law if this deadline can be met. Also, a study tour needs at least two months of preparation and preferably more.

The consultants started their activities on the 15th of December, 2008. The first visit of the international consultant to Macedonia lasted until the 20th of December.

Meetings were held with the Deputy Minister of Health (who is also the principal co-ordinator of the Health Sector Management Project), the head of the Legal Department of the Ministry of Health, the Director of the Food Directorate of the Ministry of Health, and the Primary Health Care co-ordinator of the Ministry of Health.

A half-day workshop was organised on the 18th of December 2008 with the main stakeholders of the public health sector, to explain the purpose of the new Public Health Law and the role of the consultants, and to elicit a first round of comments. Stakeholders from outside the health sector (e.g. environment or local government) were not yet invited at this stage. The workshop was chaired by the Deputy Minister of Health who invited the public health consultant to give a presentation (see Annex A), and then asked the Director of the Republic Institute for Health Protection to comment. Many other participants also took the opportunity to voice their opinion. A short report on the workshop is presented in Annex B. The co-ordinator for the Policy Formulation and Implementation component of the Health Sector Management Project participated in all meetings and in the workshop.

The second visit by the international consultant will take place from 11 until 17 January, during which period also the second workshop will be organised.

## **2 INTERNATIONAL ASPECTS OF PUBLIC HEALTH LEGISLATION**

### **2.1 International comparison of public health laws**

When comparing public health laws from various countries – both within and outside the European Union – the first observation is that they are all quite different from each other, usually even very much so. We have studied 11 (draft) public health laws of which texts were available in English, Serbian or Dutch: those presented in Annex D, plus the public health laws of Estonia, Ireland and Moldova (the Moldovan law is not really a public health law in the sense being discussed here although it has public health elements). Some of these laws are “framework” or “umbrella” laws of 15-25 pages or so that set out general principles, to be followed up by secondary legislation. Others are quite detailed, especially in English-speaking countries, sometimes over 100 pages. The New Zealand public health law has nearly 300 pages!

Although most laws present an overview of what they see as the functions of public health, most of them do not use the list of Essential Public Health Functions (EHPF) developed by the World Health Organisation, except the United States Model Public Health Act, and – to some extent - the Serbian law. The Essential Public Health Functions are:

- 1 Surveillance and assessment of the population’s health and well-being.
- 2 Identification, prediction, investigation and mitigation of health problems and health hazards in the community.
- 3 Health protection: Technical assessment of needs and actions required to ensure health protection; 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).

The emphasis in the various public health laws is on quite different aspects of public health, sometimes excluding some aspects altogether because they are regulated in other laws. Food safety (included in EHPF 3), occupational health & safety (included in EHPF 3, 4 and 5), quality assurance in health care (EHPF 6), health related research (EHPF 7), disaster preparedness (EHPF 9), and development of human resources (EHPF 10) are important public health functions, but they always appear to be regulated by separate legislation.

Environmental hygiene or environmental protection (air, water, soil, various types of waste; EHPF 2 and 3) is included in general public health laws with varying intensity and sometimes nearly absent; this means that the control of the environment is usually regulated by separate legislation.

Public health laws are not usually intersectoral in the sense that various ministries appear to co-regulate public health and co-sign public health laws. General public health laws are usually signed by Ministries of Health. However, most laws clearly give a role to local authorities in implementing public health activities.

Little is being regulated about the financing of public health activities except in the Dutch law

that obliges the local authorities (municipalities) to cover most of the cost of the public health activities listed in the law. Some other laws state that specific tests are either free or should be paid by the consumers, but nothing else. Serbia and Moldova present some general statements on the financing of public health activities.

A majority of laws stipulate that national and regional/local authorities are obliged to make regular public health plans, and the laws prescribe the content of such plans.

Notwithstanding all these differences, all public health laws have some characteristics in common as well.

Nearly all begin with the purpose of the law, and with a definition of public health and a list of terminology to be used in the law. However, as public health is a complex subject that has been defined in various ways, different laws use different – but more or less equivalent - definitions. The same is true for technical terms such as “health protection”, “health promotion” and “disease prevention”.

All public health laws describe the tasks and responsibilities of the various actors in the field of public health, at least of those under the control of the Ministry of Health or equivalent Ministry responsible for health.

All public health laws put much emphasis on the control of communicable diseases, although only recent laws (e.g. the Netherlands, Scotland and New Zealand) were able to base this part on the International Health Regulations 2005. The new public health laws in the Netherlands and Scotland pay relatively much attention to quarantine regulation including human rights aspects. The control of non-communicable diseases (e.g. by early detection of risk factors) does not receive much attention, with some exceptions (e.g. New Zealand).

Most public health laws have a section (chapter) on penalties for infringements against the articles of the law, and a section (chapter) on existing legislation to be amended or repealed.

## **2.2 Public health legislation of the European Union**

Apart from treaties, the core of European legislation is based on regulations and directives. Regulations are binding texts for the member states, whereas directives must be incorporated into national legislation. In European Union parlance, regulations and directives are called secondary legislation (whereas treaties are primary legislation), which can be confusing because in national legislation the term of secondary legislation is usually reserved for by-laws and decrees based on laws.

There are approximately 200 regulations and also approximately 200 directives in force that are related to public health; they can be found in the EUR-LEX database. More than half of these regulations and nearly half of these directives are important for public health but they clearly belong to the fields of agriculture, environment, and health & safety at work. The regulations and directives more directly related to human public health are presented in Annex E. The vast majority of these regulations and directives belongs to the food safety category, and as such should be covered by the Macedonian Food Safety Law and its secondary legislation. Other regulations and directives are covered by other existing Macedonian legislation (see chapter 3), but this must be checked carefully to identify gaps, duplications and contradictions. The planned new public health law can be used to refer to

certain EU regulations and to incorporate EU directives for which no (appropriate) Macedonian legislation exists.

At first glance, only a few of the regulations and directives shown in Annex E will be directly relevant for the planned new public health law, but this must be confirmed after the thorough analysis of existing Macedonian public health legislation.

### **2.3 International Health Regulations 2005**

Governments are supposed to fully implement the (revised) International Health Regulations 2005 (IHR) as soon as possible after their adoption by the 58<sup>th</sup> World Health Assembly in 2005. The main aim of the IHR is to control the international spread of (mostly but not exclusively communicable) disease without interfering unnecessarily with international traffic and trade. Each country should designate a national IHR Focal Point; in Macedonia, this is the Republic Institute of Health Protection.

Each country should maintain or strengthen its surveillance, notification and control system at a level specified in Annex 1 of the IHR, within 5 years of the coming into force of the IHR in July 2007, that means by mid-2012. This will be verified by the WHO. The IHR control system consists of public health institutions and border and airport authorities, with their protocols, premises (including for quarantine), staff and equipment (especially laboratory equipment). The IHR are concerned not only with persons but also with animals, goods (including food), cars, trains and aeroplanes. They therefore require close co-operation between health, veterinary and border/airport authorities.

International public health risks should be communicated immediately to the designated WHO Contact Point. Practical implementation is described in further annexes to the IHR. WHO can undertake various types of action after receiving a communication from a member state, with help of several committees.

The IHR 2005 replaces a large number of earlier sanitary and other treaties, and will require amendments to existing Macedonian legislation. It would be easier if the planned new Public Health Law takes care of these changes, and also allows for future amendments to the IHR, although these fortunately do not come too often.

It would be helpful if all relevant Macedonian authorities and staff familiarise themselves with the text of the IHR which has been translated into Macedonian.

### **3 INITIAL REVIEW OF RELEVANT MACEDONIAN LEGISLATION**

According to the Constitution of Republic of Macedonia (Article 39), each resident shall have a guaranteed personal healthcare right. The resident shall have the right and bear commitment to maintain and advance personal health and other peoples' health. Pursuant to Article 42 of the Constitution of Republic of Macedonia, every person has the right to a healthy environment. Everyone is committed to improve and protect the environment and the Republic shall secure conditions for exercising the peoples' right to a healthy environment.

In addition to the Constitution of Republic of Macedonia, healthcare right, improvement of health and healthy environment right are regulated with a number of secondary legislation (legal acts and bylaws) addressing various aspects of healthcare of people.

Public health is an interdisciplinary approach to health and diseases and encompasses wide array of disciplines such as medical sciences, environmental sciences, social sciences, economic sciences, public service administration sciences etc.

The basic law attending to protection of health of individuals and the wider population is 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). This Law regulates the healthcare rights of the people as well as the system of healthcare organization.

According to this Law, healthcare is comprised of measures, activities and procedures for preserving peoples' health as well as preserving living and working environment, as well as of measures, activities and procedures undertaken by healthcare facilities for maintaining and improving peoples' health, preventing and suppressing diseases, injuries and other health deterioration, early detection of illnesses and health condition, timely and efficient treatment and rehabilitation by applying necessary expertise and technical measures, activities and procedures.

Article 32 of this Law stipulates the measures and activities intended for healthcare for the overall population which measures and activities are defined by various preventive programs adopted by the Government of Republic of Macedonia. The funds for delivery of the aforementioned programs are allocated by the Budget of Republic of Macedonia.

The organized system of healthcare facilities consists of healthcare facilities positioned on three levels: primary, secondary and tertiary healthcare. All types of healthcare facilities irrespective of whether they are public, private or mixed among other things, implement preventive measures and measures for health improvement. In addition, particular emphasis is placed on implementation of the measures for healthcare for specific (vulnerable) population groups such as women, pregnant women, infants, preschool and school children, youth and the elderly.

The Law on healthcare envisages the healthcare institutes and the National Healthcare Institute as separate types of healthcare facilities aimed towards delivery of specialized preventive healthcare.

Thus, the healthcare institutes according to the Law on Healthcare shall function as healthcare facilities that will carry out monitoring, research and study of the health condition of the population, the rational for emergence and spreading of communicable diseases of social and medical significance, as well as the impact of ecological factors over health, they propose and undertake measures for protecting and promoting peoples' health.

In addition to the healthcare institutes, according to the Law on Healthcare, the Occupational Medicine Institute along with the occupational medicine services also conducts specialized preventive healthcare, which pursuant to Law on professional health and safety (“Official Gazette of Republic of Macedonia” No. 92/07) are oriented towards preventive activities for professional health and safety of employees as well as provision of healthy working environment.

Numerous measures and activities addressed to protecting the health of the population such as promotion of health, control over the food safety, professional health and safety, control over communicable and non-communicable diseases, control of environmental health hazards are intersectoral, meaning the state participates by the means of different state authorities, state institutions and public services.

Consequently, there is a wide spectrum of legislation containing the provisions stating the general and specific measures for protecting the populations’ health, the competencies or the forms and areas of cooperation of the healthcare institutes, and especially of the National Healthcare Institute with other authorities such as the Ministry of Health, the State Sanitary and Health Inspectorate, Food Directorate, Veterinarian Directorate etc.

Healthy environment (water, air etc.) is regulated with a set of laws such as follows:

- Law on Environment ("Official Gazette of Republic of Macedonia" No. 53/2005, 81/2005 and 24/2007);
- Law on Ambient Air Quality (“Official Gazette of Republic of Macedonia” No.67/04 and 92/07);
- Law on Potable Water Supply and Urban Waste Waters Treatment (“Official Gazette of Republic of Macedonia” No.68/04, 28/2006 and No.103/08 );
- Law on Waters (“Official Gazette of Republic of Macedonia” No. 4/98,19/00, 42/05 and 46/06);
- Law on Environmental Protection Against Noise (“Official Gazette of Republic of Macedonia " No.79/07).

The significance of public health to population nutrition, and especially to food safety control, as well as the powers of the state authorities and the relevant institutions in this area are regulated in 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). This Law particularly envisages the conditions for provision of food safety and products and materials in contact with food, the production and marketing, the rights and responsibilities of natural persons and legal entities producing or marketing in order to protect peoples’ health, to protect consumers from deceits and to safeguard free trade in internal and external markets.

In the set of laws regulating the control over the food safety, the Law on Veterinary Public Health (“Official Gazette of Republic of Macedonia” No.114/07), should be mentioned which among other things regulates the food safety and animal origin products.

The public health addressing the communicable diseases and thus the dangerous diseases which might lead to epidemics, are regulated in the Law on Protection of Population against Communicable Diseases ("Official Gazette of Republic of Macedonia ” No. 66/04 and 139/08). In the course epidemics and other types of emergency conditions (natural disasters, earthquakes, floods, chemical hazards etc.) in line with the Law on Healthcare, Law on Safety

and Rescue (“Official Gazette of Republic of Macedonia ” No. 6p.36/04 49/04 ), Law on Protection of the Population against Communicable Diseases, as well as in line with the International Health Regulations 2005, the measures which are to be undertaken in such situations as well as the organization of services and emergency actions are clearly laid down, all in favour of protecting the health of the population.

Numerous aspects addressing the protection of the health of the population are regulated with other regulations in other areas (see Annex C).

## **4 WORK PLAN**

A Working Group for the preparation of the new Public Health Law has been established by the Ministry of Health. Study materials for the Working Group have been made available to the Project Co-ordination Unit (see Annex D).

The work plan and the findings of this inception report will be presented during a workshop on 16 January. During this workshop, a list of options for the new public health law will be presented that should ideally be discussed by the Macedonian stakeholders before the end of February.

The Minister of Health would like to receive a complete draft of the new Public Health Law by the end of March 2009. This is a very tight time schedule. In order to achieve the objective in time, the following work schedule is proposed.

It is proposed that the third visit (7-10 days) by the international consultant will take place somewhere during the end of February, e.g. 22-28 February, during which a progress report will be produced and discussed during a workshop. The progress report must contain:

- \* a thorough review of the existing relevant legislation in Macedonia;
- \* an outline of the new Public Health Law, focusing on the organisational, financial and human resources aspects of the public health sector;
- \* a report on the study tour (if it took place before the end of February, otherwise the report on the study tour will be in the draft final report).

There will be a study tour for members of the Working Group to one or two EU countries, to observe public health legislation and public health practice. This study tour will probably take place in February or March 2009. The Ministry of Health should select the countries to be visited not later than two months before the study tour.

It is proposed that the fourth and last visit (1.5-2 weeks) of the international consultant will take place between 22 March and 4 April 2009, during which the draft final report must be produced and discussed during a workshop. The core of this draft final report will be a complete draft of the new Public Health Law.

After the fourth visit, the final report will be produced with help of the comments received during the last workshop. The final report will be in Macedonian and English, so that some time is needed for translation.

## 5 CONCLUSIONS

The purpose of a new public health law is *not* to show the way forward to public health reform, with the activities that should take place, how and by whom. The new public health law is *not* a policy or strategy document. One should first have a vision and a strategy for the field of public health, with agreement on the content of the tasks and the organisation of their execution. The new law will then codify these tasks and responsibilities.

It is too early to propose an outline for the new Macedonian Public Health Law. However, on the basis of the analysis of existing legislation in Macedonia, legislation in other countries (including EU legislation), and with the International Health Regulations 2005 in mind, the following ideas for the new Macedonian Public Health Law are open for discussion:

- \* A shorter “framework” law seems preferable to a longer detailed law; however, some tasks and responsibilities may have to be spelled out in more detail.
- \* The new law should begin with its purpose, a definition of public health, and the terminology to be used in the law. For a comprehensive approach, one could use the Essential Public Health Functions (EPHF).
- \* EHPF 6, 7, 9 and 10 will probably be excluded explicitly if the new law will use the list of EPHF.
- \* We propose to include EHPF 8: the obligation to produce regular public health plans.
- \* The new law should refer to other Macedonian laws covering part of public health (see Annex C), including those based on EU directives, and including those in the pipeline. A table based on the EPHF and on a overview of practical public health activities can also be a useful tool (see Annex F).
- \* The new law should ideally include any EU public health directives not yet covered by existing Macedonian legislation.
- \* The new law should include the International Health Regulations 2005, including a provision for future amendments to the International Health Regulations.
- \* The establishment of an intersectoral public health advisory council can be considered.
- \* The inclusion of food risk management into the new law can be considered.
- \* The tasks, responsibilities and financing of the public health structures under the Ministry of Health should definitely be included into the new law: the Ministry itself, the national and regional Institutes of Public Health (with their new names), and the State Sanitary and Health Inspectorate. This may include a description of the minimal requirements in facilities, human resources, and equipment.
- \* The new law should include a large chapter on the control of communicable disease: immunisation, notification, quarantine, test orders, specific powers, etc.
- \* One should consider to include articles on so-called public health emergencies, including specific powers in case of emergency, if necessary.
- \* One should consider to include a chapter or articles on health promotion and the control of non-communicable disease (including screening programmes).
- \* One should consider to include a chapter on data collection including confidentiality.
- \* One option for the preparation of the new law would be to follow – or at least check - the US Model State Public Health Law, with some additions and deletions.
- \* It is important to discuss how the so-called “national programmes” should find their way into the new law.
- \* It is advisable to take the recommendations of the final report by Thomas Novotny into account.

## **ANNEX A - WORKSHOP PRESENTATION, 18 DECEMBER 2008**

A NEW PUBLIC HEALTH LAW FOR THE REPUBLIC OF MACEDONIA  
by Kees Schaapveld,  
consultant for the Ministry of Health  
Skopje, 18 December 2008

### **Essential Public Health Functions**

- 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 activities
- 4 Primary and secondary disease 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

### **Responsibilities for the Essential Public Health Functions**

- National and regional Public Health Institutes
- Other institutions of the Ministry of Health, e.g. Sanitary Inspectorate and Food Safety Agency
- Agencies for the environment
- Occupational health services
- Educational system
- etcetera

### **Public Health legislation**

- Planned general Public Health Law
- Existing public health laws, e.g. blood safety, food safety, drug abuse, infectious diseases
- Articles in other existing laws (e.g. Health Care Law)
- Other planned public health laws, e.g. occupational safety & health

### **To be considered (1):**

- Umbrella law (≈ 20 pages) versus detailed law (≈ 100 pages)
- International Health Regulations 2005 should be integrated into this law
- Relevant EU directives must be integrated in this law or in other laws

### **To be considered (2):**

- Which part of public health (i.e. the Essential Public Health Functions) should be covered by the new law?
- New law should refer to other (existing or planned) Public Health legislation
- Which existing laws and bylaws should be amended or cancelled?
- How should mother and child care be regulated?

### **International Health Regulations (IHR 2005)**

- \* Establishment of National IHR Focal Point
- \* Establishment of system of border/airport controls
- \* “Making the system work”: training, testing, equipment, etc.

### **To be decided (1):**

- \* Responsibilities of national and regional Institutes of Public Health
- \* Future of “national programmes”
- \* Roles of other agencies of the Ministry of Health, such as Sanitary Inspectorate and Food Safety Agency
- \* Mechanisms of co-operation and co-ordination with other ministries and their agencies

### **To be decided (2):**

- \* Management of Public Health Institutes (director, board)
- \* Requirements of Public Health Institutes (personnel, laboratories, other equipment)
- \* Financing of Public Health Institutes:
  - Ministry of Health
  - Health Insurance Fund
  - Other ministries
  - Local authorities
  - paid services (clinical, commercial)

### **Discussion**

What is YOUR opinion about the shape and content of the planned Public Health Law?

*Practicalities: working group, time schedule, study tour*

## **ANNEX B - SUMMARY OF THE FIRST WORKSHOP**

Deputy minister Vladimir Popovski opened the meeting with a short introduction. For the presentation by consultant Kees Schaapveld, see PowerPoint file in English and Macedonian.

Mr Popovski asked RIHP director Azis Pollozhani to comment on the presentation. Mr. Pollozhani made the following remarks:

- The new law is important for reforming and structuring of Public Health (PH).
- It is also needed for new developments such as control of pandemics (e.g. avian flu), bioterrorism, and the new International Health Regulations 2005 (IHR).
- However, we should not forget that there is a long tradition and an established infrastructure in PH in Macedonia.
- We need standardisation of PH activities and Institutes of Public Health (IPH), and improved horizontal and vertical co-operation.
- The new Law on Medical Record-keeping is relevant for the new PH Law.
- The options of an umbrella law or a detailed law are open for discussion.
- The articles on IHR in the new law should allow for future amendments in the IHR.
- IPHs face more and more competition in clinical diagnostic testing, with consequences for revenues and equipment.
- Intersectoral co-operation is important; we also need socio-economic indicators for PH planning and evaluation.
- Local authorities should contribute financially to PH, but how to organise this?
- Disaster preparedness is (also) a responsibility of local authorities. There is a new law on disaster preparedness.
- Importance of quality assurance and certification/accreditation in PH.

Mr Popovski mentioned the new names of the national and regional IPHs.

The head of the legal department of the Ministry of Health Ms Angelina Bacanovic gave the following comments:

- There is some confusion about the term of “PH” in Macedonian and related terminology.
- The new law should make reference to all related laws.
- There is no need to write anything about the boards and directors of the IPHs in the new law, because this is already regulated by the Health Care Law.
- It is important to clearly describe the relation between the national and regional IPHs.
- Many municipalities have insufficient institutional capacity to deal with PH issues (and also with issues of patients’ rights).

Ms Florentina Ristovska Shurbevaska, director of the Veles IPH, made the following comments:

- Various types of experts should be involved in drafting the new law, not only medical doctors but also lawyers and economists.
- The Health Insurance Fund (HIF) should pay (more) for prevention, this is also in their own interest; the Health Insurance Law should be adapted in this sense.
- Many municipalities have insufficient institutional capacity to deal with PH issues, so (further) decentralisation is risky.
- IPHs undertake additional activities (e.g. control of water and food), they should all have sufficient capacity to implement their tasks.
- IPHs collect many data manually, and their software is not standardised. This calls for an improved IT system (other participants agreed).
- She prefers a detailed law over a framework law because of poor quality of secondary

legislation in the past.

Mr Atanasko Michailov, director of the Ohrid IPH, made the following comments:

- Much useful information was already collected during the consultancy by Thomas Novotny, including a proposal how to fund the national programmes.
- The drafting of the new law requires intersectoral co-operation.
- There is poor linkage between the IPHs and the Sanitary Inspectorate. The new law should clearly delineate the responsibilities of the IPHs, Sanitary Inspectorate and Food Agency. In Bulgaria, the latter two integrated in the national IPH.
- The HIF should pay the IPHs for microbiology tests according to fee-for-service.
- Payment for PH activities by local authorities should be regulated by the new law.

Mr Popovski stated that the Food Agency must be truly intersectoral (Health and Agriculture).

Ms Jovanka Kostovska, PHC co-ordinator of the Ministry of Health made the following comments:

- The new law should clearly describe the relations between all PH stakeholders, also those from other ministries such as Environment, because at the moment these relations are insufficient.
- Macedonia should establish a national intersectoral PH committee, to be replicated at regional level.
- Important to correctly implement the new IHR.
- The national programmes are underfunded, they have no clear objectives, and the (modest) expenditures cannot be justified. This must improve.
- The IPHs depend too much on commercial activities at the moment.
- We should agree with the HIF for what they will pay apart from microbiology. in some countries, vaccines are paid by health insurance organisations.
- The national IPH should assume the responsibility for steering the regional IPHs.

Ms Brankica Mladenovic, head of the Maternal and Child Health Institute, stated that all regional IPHs should have a maternal and child health department, possibly within the health promotion department.

Ms Valentina Simonovska of the Skopje IPH wants the new law to prescribe a clear list of PH activities to be carried out by the various stakeholders, plus the expected results from these activities.

Mr Vlado Trajkovski, director of the Bitola IPH, wants the consultants to make a draft PH law that can then be commented upon by the Working Group (WG). However, Mr Popovski called this the old method of work, and wanted the WG to draft the law, with advice from the consultants. The WG group should provide suggestions to the consultants in January 2009.

It was agreed that the international consultant will return to Macedonia 13-22 January 2009.

He will make background information available to the WG and other stakeholders.

The composition of the WG was discussed, but not yet firmly established.

## ANNEX C - LIST OF RELEVANT MACEDONIAN LEGISLATION

1. Закон за здравствената заштита ("Сл. весник на Р. Македонија" бр. 38/91, 46/93, 55/95, 10/04, 84/05, 111/05, 65/06, 5/07 и 77/08);
2. Закон за здравственото осигурување ("Сл. весник на Р. Македонија" бр. 25/2000, 34/2000, 96/2000, 50/2001, 11/2002, 31/2002, 84/2005, 37/2006, 18/2007 и 36/2007 и 82/08);
3. Закон за заштита на населението од заразни болести ("Сл. весник на Р.Македонија " бр. 66/2004 и 139/2008);
4. Закон за заштита на правата на пациентите („Сл весник на Р. Македонија,,бр. 82/08);
5. Закон за условите за земање, разменување, пренесување и пресадување на делови од човековото тело заради лекување ( "Сл. весник на Р. Македонија бр. 30/95);
6. Закон за безбедност во снабдувањето со крв ("Сл. весник на Р. Македонија" бр.110/07);
7. Закон за лековите, помошните лековити средства и медицинските помагала („Сл. весник на Р.Македонија,, бр. 21/98);
8. Закон за санитарната и здравствената инспекција („Сл. весник на Р.Македонија,, бр. 71/2006 и 139/2008);
9. Закон за установите („Сл. весник на Р. Македонија,, бр. 32/05 и 120/05);
10. Закон за безбедност на храната и производите и материјалите што доаѓаат во контакт со храната ("Сл. весник на Р Македонија" бр.54/2002 и 84 /2007);
11. Закон за ветеринарно јавно здравство („Сл. весник на Р. Македонија,, бр.114/07);
12. Закон за ветеринарно здравство („Сл. весник на Р. Македонија,, бр.113/07);
- Закон за заштита на потрошувачите("Сл. весник на Р. Македонија" бр. 38/04,77/07и 103/08);
14. Закон за безбедност на производите ("Сл.весник на Р. Македонија", бр.33/06 и 63/07);
15. Закон за заштита на растенијата ("Сл. весник на Р. Македонија" бр. 110/07);
16. Закон за идентификација и регистрација на животните ("Сл. весник на Р. Македонија" бр69/04 и 81/07);
17. Закон за нуспроизводи од животинско потекло("Сл. весник на Р. Македонија" бр. 113/07);
18. Закон за органско земјоделско производство ("Сл. весник на Р. Македонија" бр. 16/04 и 89/08);
19. Закон за безбедност на козметичките производи ("Сл. весник на Р.Македонија" бр. 55/07);
20. Закон за тутун и тутунски производи ( "Сл. весник на Р. Македонија" бр. 24/06);
21. Закон за контрола на опојни дроги и психотропни супстанции ("Сл. весник на Р. Македонија" бр. );
22. Закон за прекурзори ( "Сл. весник на Р. Македонија" бр. 37/04 и 40/07);
23. Закон за генетски модифицирани организми ( "Сл. весник на Р. Македонија" бр. 35/08);

24. Закон за хемикалии ( "Сл. весник на Р. Македонија" бр.113/07);
25. Закон за ѓубриња ("Сл. весник на Р. Македонија" бр. 110/07);
26. Закон за градежните производи ( "Сл. весник на Р. Македонија" бр. 39/06);
27. Закон за животна средина ("Сл. весник на Р. Македонија" бр. 53/2005, 81/2005 и 24/2007);
28. Закон за заштита на природата ("Сл. весник на Р. Македонија" бр. 67/04, 14/04 и 84/07);
29. Закон за квалитетот на амбијенталниот воздух ("Сл. весник на Р. Македонија" бр.67/04 и 92/07 );
30. Закон за снабдување со вода за пиење и одведување на урбани отпадни води (Сл. весник на Р.Македонија" бр.68/04, 28/2006 и бр.103/08 );
31. Закон за водите ("Сл. весник на Р. Македонија" бр 4/98,19/00, 42/05 и 46/06);
32. Закон за енергетика("Сл. весник на Р. Македонија" бр. 63/06, 36/07 и 106/08);
33. Закон за комунални дејности ("Сл. весник на Р. Македонија" бр. 45/97,23/99 и 16/04);
34. Закон за управување со отпад ("Сл. весник на Р. Македонија" бр. 68/04,71/04,107/07, 102/08 и 143/08);
35. Закон за јавна чистота ("Сл. весник на Р. Македонија" бр. 111/08);
36. Закон за гробиштата и погребалните услуги ("Сл. весник на Р. Македонија" бр 86/08);
37. Закон за заштита од јонизирачко зрачење и радијациона сигурност ("Сл. весник на Р. Македонија" бр.48/02 и 135/07);
38. Закон за заштита од бучавата во животна средина ("Сл. весник на Р. Македонија" бр.79/07);
39. Закон за заштита од пушењето ("Сл. весник на Р. Македонија" бр. 36/1995, 70/2003, 29/2004, 37/2005, 103 /2008 и 40/08);
40. Закон за заштита и спасување ("Сл. весник на Р.Македонија" бр.36/04 и 49/04 );
41. Закон за пожарникарство ("Сл. весник на Р. Македонија" бр. 67/04 и 81/07)
42. Закон за промет со експлозивни материи("Сл. весник на Р. Македонија" бр.30/85,6/89, 53/91 и 66/07);
43. Закон за заштита од експлозивни материи ("Сл. весник на Р.Македонија,, бр. 4/78, 10/78,, 36/90, 12/93 и 66/07);
44. Закон за оружјето ("Сл. весник на Р. Македонија" бр. 7/05);  
Закон за складирање и заштита од запаливи течности и гасови ("Сл. весник на Р. Македонија" бр. 15/76, 51/88, 19/90,12/93, 66/07 и 130/08);
46. Закон за работните односи("Сл. весник на Р. Македонија" бр 62/05 и 106/08)
47. Закон за безбедност и здравје на работа ("Сл. весник на Р. Македонија" бр.92/07);
48. Закон за инспекција на трудот ("Сл. весник на Р. Македонија" бр.35/97 и 29/02)
49. Закон за градење ("Сл. весник на Р. Македонија" бр 51/05 и 82/08)
50. Закон за просторно и урбанистичко планирање ("Сл. весник на

- Р. Македонија" бр 24/08);
51. Закон за семејство ("Сл. весник на Р. Македонија" бр.
  52. Закон за домување ("Сл. весник на Р. Македонија" бр. 39/03, 96/04, 120/05 и 13/07);
  53. Закон за јавните патишта ("Сл. весник на Р. Македонија" бр. 84/08);
  54. Закон за превоз во патниот сообраќај ("Сл. весник на Р. Македонија" бр. 68/04 и 127/2006);
  55. Закон за безбедност на сообраќајот на патиштата ("Сл. весник на Р. Македонија" бр.14/98, 38/02, 38/04, 19/07 и 54/2007);
  56. Закон за безбедност во железничкиот сообраќај("Сл. весник на Р. Македонија" бр.40/07);
  57. Закон за основно образование("Сл. весник на Р. Македонија" бр.103/08);
  58. Закон за средно образование("Сл. весник на Р. Македонија" бр.44/95, 24/96, 34/96,82/99, 40/03, 42/03, 67/04, 55/05, 113/05, 35/06, 30/07, 49/07, 81/07, 92/08);
  59. Закон за спортот ("Сл. весник на Р. Македонија" бр. 29/02 и 64/04);
  60. Закон за трговија ("Сл. весник на Р. Македонија" бр. 16/04,128/06, 63/07 и 88/08);
  61. Закон за угостителска дејност ("Сл. весник на Р. Македонија" бр. 62/04);
  62. Закон за пазарна инспекција ("Сл. весник на Р. Македонија" бр. 35/97, 23/99, 07/02 и 20/02);
  63. Закон за хидрометеоролошка дејност ("Сл. весник на Р. Македонија" бр. 103/08);
  64. Закон за шумите ("Сл. весник на Р. Македонија" бр. 47/97, 7/00, 89/04, 54/07 и 103/08);
  65. Закон за пасишта ("Сл. весник на Р. Македонија" бр. 3/98,101/2000 и 89/08);
  66. Закон за сточарството ("Сл. весник на Р. Македонија" бр 7/08);
  67. Закон за рибарство и аквакултура ("Сл. весник на Р. Македонија", бр 7/08);
  68. Закон за локалната самоуправа ("Сл. весник на Р. Македонија" бр.5/02);
  69. Закон за финансирање на единиците на локалната самоуправа ("Сл. весник на Р. Македонија" бр. 61/04, 96/04 и 67/07).
  70. Закон за концесии и други видови јавно приватно партнерство ("Сл. весник на Р. Македонија" бр 7/08 и139/08);

## **ANNEX D - BACKGROUND MATERIALS FOR THE WORKING GROUP**

- \* Public Health Act, Malta, 2007
- \* Summary of new Public Health Law, Netherlands, 2008 (this law can be translated in full if so desired)
- \* Summary of the proposed Public Health Bill, New Zealand, 2007 (full text available if desired)
- \* Public Health Act, Québec, 2008
- \* Proposed Public Health etc. (Scotland) Bill, 2008
- \* Proposed Public Health Law, Serbia, 2005 (in Serbian)
- \* Public Health Statute Modernization National Excellence Collaborative, Model State Public Health Act, United States, 2003
- \* Draft Public Health Bill, Western Australia, 2008
- \* World Health Organisation, International Health Regulations 2005
- \* K. Schaapveld, Essential Public Health Functions (draft), 2007

(Other materials mentioned in this inception report can be made available if desired.)

## **ANNEX E – OVERVIEW OF EUROPEAN PUBLIC HEALTH LEGISLATION IN FORCE**

Search in EUR-LEX with term of “public health” and excluding typical agricultural and environmental issues.

### EU REGULATIONS

1291/2008 on salmonella and avian influenza  
1251/2008 on import of fishery products  
1250/2008 on import of fishery products  
1234/2008 on marketing of medicinal products  
1021/2008 on control of food of animal origin  
1020/2008 on hygiene of food of animal origin  
1019/2008 on hygiene of foodstuffs  
798/2008 on import of poultry products  
689/2008 on import/export of dangerous chemicals  
746/2008 on spongiform encephalopathies  
709/2008 on tobacco regulation  
629/2008 on contaminants in foodstuffs  
584/2008 on salmonella  
565/2008 on food contaminants  
553/2008 on spongiform encephalopathies  
523/2008 on import of blood products  
1523/2007 on banning of cat and dog fur  
1394/2007 on advanced therapy medicinal products  
1275/2007 on spongiform encephalopathies  
1244/2007 on food of animal origin  
1237/2007 on salmonella  
1126/2007 on food contaminants  
863/2007 on rapid border intervention teams  
646/2007 on salmonella  
333/2007 on levels of lead etc. in food  
2007/2006 on medical devices and diagnostics  
1925/2006 on food additives  
1924/2006 on nutrition and health claims of food  
1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction  
1901/2006 on medicinal products for paediatric use  
1881/2006 on food contaminants  
1664/2006 on food of animal origin  
1663/2006 on food of animal origin  
1177/2006 on salmonella  
1168/2006 on salmonella  
816/2006 on export of pharmaceutical products  
507/2006 on marketing of medicinal products  
2075/2005 on trichinella  
2073/2005 on microbiological criteria for food  
1048/2005 on biocidal products  
1003/2005 on salmonella  
396/2005 on pesticides in food

1935/2004 on food packaging  
1851/2004 on residues of veterinary medicinal products in food  
851/2004 on establishment of the European Centre for Disease Prevention and Control  
726/2004 on establishment of the European Medicines Agency  
2160/2003 on salmonella  
1873/2003 on residues of veterinary medicinal products in food  
1234/2003 on spongiform encephalopathies  
1084/2003 on marketing of medicinal products  
665/2003 on residues of veterinary medicinal products in food  
304/2003 on import/export of dangerous chemicals  
2182/2002 on tobacco control  
270/2002 on spongiform encephalopathies  
178/2002 on food safety and the European Authority  
2584/2001 on residues of veterinary medicinal products in food  
1326/2001 on spongiform encephalopathies  
999/2001 on spongiform encephalopathies  
1896/2000 on biocidal products  
141/2000 on orphan medicinal products  
2821/1998 on antibiotics in animal feeds  
258/1997 on novel foods  
2232/1996 on flavouring in food  
297/1995 on fees for European Agency for Evaluation of Medicinal Products  
315/1993 on food contaminants  
1768/1992 on certificates for medicinal products  
2377/1990 on residues of veterinary medicinal products in food  
2219/1989 on food in nuclear accidents/emergencies  
566/1976 on fat content of milk

## DIRECTIVES

2006/141/EC on infant formula  
2006/125/EC on baby food  
2006/7/EC on bathing water quality  
2005/94/EC on avian influenza  
2005/90/EC on dangerous substances  
2005/36/EC on professional qualifications  
2004/27/EC on medicinal products for human use  
2004/24/EC on traditional herbal medicinal products  
2004/23/EC on human tissues and cells  
2004/9/EC on good laboratory practice  
2003/114/EC on food additives  
2003/99/EC on zoonoses  
2003/63/EC on medicinal products for human use  
2003/40/EC on mineral water  
2003/36/EC on dangerous substances  
2003/34/EC on dangerous substances  
2003/33/EC on tobacco advertising  
2003/32/EC on medical devices of animal origin  
2003/15/EC on cosmetic products

2002/98/EC on blood safety  
2002/72/EC on plastic in contact with food  
2002/46/EC on food supplements  
2001/104/EC on medical devices  
2001/101/EC on labelling of foodstuffs  
2001/83/EC on medical products for human use  
2001/57/EC on pesticides in food  
2001/41/EC on dangerous substances  
2001/37/EC on tobacco products  
2001/20/EC on good clinical practice in trials  
2001/15/EC on food additives  
2001/5/EC on food additives  
2000/70/EC on medical devices and blood  
2000/41/EC on animal tests for cosmetics  
2000/13/EC on advertising for food  
1999/43/EC on dangerous substances  
1999/41/EC on specific foodstuffs  
1999/3/EC on food treated with radiation  
98/83/EC on drinking water  
98/79/EC on in vitro diagnostic devices  
98/72/EC on food additives  
98/36/EC on baby food  
98/28/EC on hygiene in sugar  
98/24/EC on health and safety of workers  
98/8/EC on biocidal products  
97/41/EC on pesticides in food  
96/90/EC on animal health and public health in trade and imports  
96/83/EC on sweeteners in food  
96/70/EC on mineral water  
96/54/EC on dangerous substances  
96/33/EC on pesticides in food  
96/8/EC on diets for weight reduction  
96/3/EC on hygiene of oil and fat  
95/39/EC on pesticides in food  
95/34/EC on cosmetic products  
95/17/EC on cosmetic products  
94/65/EC on meat packaging  
94/32/EC on cosmetic products  
94/29/EC on pesticides in food  
93/57/EC on pesticides in food  
93/47/EC on cosmetic products  
93/5/EC on scientific questions on food  
92/118/EC on animal health and public health in trade and imports  
92/116/EC on poultry meat  
92/69/EC on dangerous substances  
92/86/EC on cosmetic products  
92/48/EC on hygiene of fishery products  
92/46/EC on milk  
92/45/EC on wild-game meat  
92/32/EC on dangerous substances

92/5/EC on trade in meat  
92/4/EC on food additives  
91/497/EC on health problems from meat  
91/495/EC on wild-game meat  
91/493/EC on fishery products  
91/492/EC on molluscs  
91/184/EC on cosmetic products  
90/612/EC on food additives  
90/496/EC on labelling of foodstuffs  
90/385/EC on implantable medical devices  
90/219/EC on genetically modified organisms  
90/121/EC on cosmetic products  
89/686/EC on personal protective equipment  
89/618/Euratom on radiological emergencies  
89/398/EEC on particular foodstuffs  
89/227/EEC on meat imports  
89/174/EEC on cosmetic products  
89/107/EEC on food additives  
89/105/EEC on the price of medical products  
88/388/EEC on food flavourings  
88/344/EEC on solvents in food  
88/298/EEC on pesticides in food  
88/233/EEC on cosmetic products  
87/137/EEC on cosmetic products  
86/199/EEC on cosmetic products  
86/179/EEC on cosmetic products  
85/467/EEC on dangerous substances  
85/391/EEC on cosmetic products  
84/449/EEC on dangerous substances  
84/415/EEC on cosmetic products  
83/417/EEC on lactoproteins  
83/191/EEC on cosmetic products  
83/91/EEC on meat import  
82/368/EEC on cosmetic products  
81/464/EEC on colouring in medicines  
80/777/EEC on mineral water  
78/25/EEC on colouring in medicines  
77/99/EEC on trade in meat  
77/96/EEC on trichinella  
76/768/EEC on cosmetic products  
76/621/EEC on erucic acid in food  
76/399/EEC on colouring in food  
76/160/EEC on bathing water quality  
65/469/EEC on colouring in food

**ANNEX F. FORMAT FOR AN OVERVIEW OF PUBLIC HEALTH ACTIVITIES AND THEIR LEGAL BASIS.** [incomplete, last three columns to be filled in later]

<i>Essential Public Health Function</i>	<i>public health activity</i>	<i>present and planned legal basis</i>	<i>executed by</i>	<i>financed by</i>
1. assessment of health status	data collection		IPHs	
	data analysis		IPHs	
2. investigation of health problems and hazards	notification and follow-up of communicable diseases		IPHs	
	controls at points of entry (IHR 2005)			
3. health protection	environmental control (air, water, soil, various types of waste, sewage, noise)			
	drinking water control			
	food safety measures	Food Safety Law	Food Directorate of MoH; Ministry of Agriculture	
	safety of consumer products			
	hygiene public places		IPHs, (State Sanitary Inspectorate?)	
	pest control (rats, rabies, etc.)			
	occupational safety & health	.....; planned Occupational Safety & Health Law	employers, occupational health services	
	other safety measures (fire, buildings, traffic, etc.)		local authorities, ....	
	blood safety			
4. disease prevention	mother & child services		primary care, patronage services, .....	
	immunisation programmes			
	screening programmes (PKU, cancer, etc.)			
	tuberculosis programme			
	addiction care			
	oral health care			
	international travel			

	advice and vaccination			
5. health promotion	health education activities		IPHs, NGOs, schools, ....	
6. quality assurance in health care	various quality assurance measures (licensing, accreditation, patients' rights, clinical guidelines, audits, etc.)		providers, professional associations, MoH, ....	
7. scientific research in public health	various forms: epidemiology, health services research, economics, microbiology (incl. reference laboratories), forensic medicine		RIHP, Medical Faculty, ....	
8. public health planning	producing multi-annual plans	new PH Law	MoH, IPHs	
9. disaster preparedness	emergency health services			
10. development of human resources	undergraduate and postgraduate education of health professionals		Ministry of Education, educational institutions	
	continuous professional development		professional associations, RIHP	