

MINISTRY OF HEALTH OF THE REPUBLIC OF MACEDONIA

HEALTH SECTOR MANAGEMENT PROJECT

CONSULTANCY ON DEVELOPMENT OF A NEW PUBLIC HEALTH LAW

FINAL REPORT

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and

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Table of contents		page
1	Introduction	2
2	Workshop of 10 March 2009	2
3	Study tour	4
4	Workshop of 28 May 2009	4
5	Towards completion of the Public Health Law	6
6	Final remarks	8
	Annex A - Agenda of the workshop of 10 March 2009	10
	Annex B - Handout for the workshop of 10 March 2009	12
	Annex C - Presentation during the workshop on 10 March 2009	15
	Annex D - Background document of the study tour	17
	Annex E - Evaluation of the study tour	24
	Annex F - Draft of the Public Health Law of 13 April 2009	27
	Annex G - Agenda of the workshop of 28 May 2009	39
	Annex H - Presentation during the workshop on 28 May 2009	40
	Annex I - Handout for the workshop on 28 May 2009	41
	Annex J - Draft of the Public Health Law of 3 June 2009	43

1 INTRODUCTION

This report describes the developments in the development of the new Public Health Law since the submission of the consultants' progress report on 20 February 2009 until the end of the involvement of the international Public Health consultant on 11 June 2009.

The draft of the Public Health Law presented in the progress report was the main subject of discussion during the third workshop for the preparation of this law on 10 March 2009, see Chapter 2.

A study tour of Macedonian Public Health professionals to the Netherlands and Belgium took place from 31 March to 10 April 2009, with the purpose of studying the Public Health sectors in those countries, and their legal framework. This is described in Chapter 3.

The Working Group for the preparation of the new Public Health Law met several times in the period March-May 2009. A one-day long key meeting in which both consultants participated was held in a hotel in Ohrid, after a Public Health conference with Albanian and Macedonian participation. The last meeting of the Working Group with the two consultants was on 26 May 2009, just before the workshop of 28 May 2009.

The whole process of having a large group of members with particular interests moving systematically step-by-step towards the drafting of a new Public Health Law has proven to be difficult. Nonetheless, individual Working Group members contributed well to the development of the new law.

A new draft of the Public Health Law, now written in "legal language", was presented and discussed during the fourth workshop on 28 May 2009, see Chapter 4.

After the workshop of 28 May, the consultants prepared an (almost) final draft of the Public Health Law, the key element of this report, which is attached as Annex J. This draft is accompanied by comments by the consultants that are described in Chapter 5.

The (almost) final draft by the consultants has been discussed with the Ministry of Health and major stakeholders on 9 June 2009. The outcome of this discussion is presented in Chapter 6, "Final remarks". After the consultants have submitted their final draft to the Ministry of Health, the Ministry will prepare its own final draft for submission to Government and Parliament.

2 WORKSHOP OF 10 MARCH 2009

The third workshop for the preparation of the new Public Health Law took place on 10 March 2009 in Hotel Continental in Skopje. The main purpose was to present and discuss the draft of the new Public Health Law published in the consultants' progress report of 20 February 2009. The agenda of the workshop is attached as Annex A. A handout that was distributed during this workshop is attached as Annex B.

After the opening of the workshop by the deputy minister, the head of the legal sector of the Ministry of Health outlined the purposes of the new law. Difficult decisions are required on the 16 national programmes, on the funding of Public Health, and on inter-sectoral co-ordination.

The presentation by the Public Health consultant is attached as Annex C.

Once again, the 16 national programmes were discussed by the participants. There was agreement that the programmes must be split into medical and Public Health programmes, with appropriate government funding for the latter. However, the division is difficult, and the Ministry of Health and the Health Insurance Fund are still working on it, including on what to do with present exemptions from co-payments. Should there be in the future one general Public Health programme (including all existing Public Health programmes, plus the regular activities of the Institutes of Public Health), with the option to add a specific temporary programme if need arises? The Budget Law allows for adding programmes by a 15% reduction of existing programmes. The responsibility of primary care for prevention programmes must also be determined.

The scope of the International Health Regulations 2005 in the new law must be determined, and the relation between the new law and the Law on Infectious Diseases, the regular activities of the State Sanitary & Health Inspectorate and the Food Directorate, and the responsibilities of other ministries.

All participants agreed that a national Inter-sectoral Advisory Council on Public Health is needed. Most also agreed on the need for regional (inter-municipal) Public Health committees, but these will be more difficult (if not impossible) to establish. There was discussion on the status, tasks and composition of Council and committees, but no common conclusions.

The participants discussed crises and emergencies in general and public health emergencies in particular, both infectious and non-infectious. The new law should define these situations and clearly describe the responsibilities of the Ministry of Health and its institutions in relation with the Crisis Management Centre. Some amendments in the Law on Infectious Diseases may be required. As for the prevention and control of non-infectious emergencies, the roles of the Ministry of Health and the Ministry of Environment must be established.

The workshop discussed the need for a single Food Safety Law carried by both the Ministry of Health and the Ministry of Agriculture, without reaching a conclusion. A decision on this subject is important because it has consequences for the new Public Health Law. If there will be no new Food Safety Law, the new Public Health Law could have articles about food risk management and food risk communication which are insufficiently covered by the existing Veterinary Law and Food Safety Law. Food safety measures are carried out according to Macedonian and EU regulations, but the whole subject of food safety legislation in Macedonia needs to be considered at the highest level.

The opinion on the future of mother & child health care was divided among the participants, including the opinion on the possible integration of the Maternal and Child Health Institute into the National Institute of Public Health. There is general concern about maintaining the quality of mother & child services such as immunisation, child growth monitoring and patronage: the responsibility for those services must be clearly assigned. The future capacity of primary care providers (chosen doctors) for providing such services was doubted by some, whereas others disagreed with a role in mother & child health care for the (national and/or regional) Institutes of Public Health in this field.

Most participants seemed to support the idea of having a single basic Public Health programme implemented by the National and Regional Institutes of Public Health and paid from the government budget. Any specific temporary Public Health programme on top of the basic programme would have to be funded separately. The regional Institutes of Public Health rejected the proposal to limit commercial activities to a certain percentage until proper basic funding of the Institutes would be in place, although they accept that they are not-for-profit institutions. Official paid services will be provided against the existing tariffs. The diagnostic activities for referred patients will be paid by the Health Insurance Fund as a lump sum according to an average amount paid during the last three years.

3 STUDY TOUR

The background document for the study tour to the Netherlands and Belgium is attached as Annex D. This document was used both by the participants and by the receiving institutions to ensure a successful tour, and clearly explains the objectives and activities of the study tour.

All institutions mentioned in the background document were visited as planned. The Public Health consultant accompanied the Macedonian participants on all visits within the Netherlands.

The study tour was evaluated by the participants with a simple questionnaire. They were asked to indicate for each of the institutions that were visited if the visit was interesting and relevant. They were also asked for general comments, and for the three most important messages/ideas that were picked up during the study tour. The results are presented in Annex E.

It can be concluded that the study tour reached its objectives. The participants have certainly been able to analyse the Public Health systems of two EU countries, and to notice similarities and differences, both between the Netherlands and Belgium, and between Macedonia and the EU countries. They picked up a number of ideas that can be used in Public Health reform in Macedonia, especially about the role of local authorities, the way Public Health activities are financed, the emphasis on health promotion, and the complexity of the Public Health sector in other countries. It should be noted, however, that preparation of such a study tour is time-consuming, and that the cost of the tour is considerable.

4 WORKSHOP OF 28 MAY 2009

The main subject of the fourth and last workshop for the preparation of the new Public Health Law was the draft submitted by the consultants on 13 April 2009, attached as Annex F. The agenda for this workshop is attached as Annex G.

During the opening of the workshop, the chairwoman mentioned the welcome presence of representatives of other ministries. These representatives, however, collected information but did not participate in the discussions. The planned presentation by a representative of the Ministry of Health to give its opinion on the draft Public Health Law was cancelled and replaced by a discussion on food safety issues.

The presentation by the Public Health consultant is attached as Annex H, including the

benefits that passing the new Public Health Law can bring. A handout with questions about the draft law of 13 April 2009 is attached as Annex I.

The legal consultant presented his views on the annual general Public Health programme and the responsibility of the Government for its financing. There may also be separate specific Public Health programmes with separate financing, and other activities to be paid from other sources. The text of Article 36 on financing issues will need careful consideration. Article 15 of the draft law will be rewritten, taking into account the role of local authorities according to article 22 of the Law on Local Self-Government. It should be avoided to have a regional committee without clear mandate. Municipalities can express their own wishes for Public Health activities to be developed for their territories. Article 5 of the draft law will also be rewritten to make sure that the new Public Health Law has the final word in case there are inconsistencies with other laws, especially the Health Care Law.

The draft law does not yet contain one or more articles on risk management and risk communication in the area of food safety because discussions between the Ministries of Health and Agriculture are ongoing. It is hoped that agreement on one or more articles on these subjects can be reached in June.

It seems that there will be no new single Food Safety Law on behalf of both ministries. This is also not an EU requirement as long as the two ministries co-operate closely. It is envisaged to establish a coordinating body between the Veterinary Service and the Food Directorate. The legal basis for this coordinating body could be the new Public Health Law if agreement can be reached soon between the two ministries.

Description of the link between the Centres for Public Health and the Food Directorate (and the State Sanitary and Health Inspectorate) in the new Public Health Law is a wish by the Centres.

The participants presented and discussed the revised lists of tasks for the National Institute of Public Health and the regional Centres for Public Health (Articles 9 and 11 of the new law). In the existing Health Care Law, no distinction is made between these two levels. There appears to be general agreement on what these institutions should be responsible for. Also, one agreed on the merging of all standard Public Health activities (including the Public Health part of the so-called 16 national programmes) into a single general Public Health programme. As both the Institute and the Centres are established by the state, the Institute cannot supervise the Centres in the legal sense of the word, but it should monitor and support them. Some participants asked for modern terminology (health promotion etc.) to be used in the description of the tasks of the Public Health institutions.

The participants agreed that an article on quality assurance in Public Health institutions should be inserted into the new law. It should be clarified what “accreditation” means in the Macedonian Public Health institutions.

During the discussion on the financing of the Public Health Institutions, several models were presented, without reaching consensus. It is clear to most that the role of the Health Insurance Fund in financing the Public Health institutions will diminish in the future. Many participants seemed to like the idea of salaries to be covered by the state in one way or another, also because apparently they are not free to hire or fire staff according to their needs. The idea of a resource allocation formula (with a major role for capitation) to distribute funds among the institutions was not understood or accepted by all participants. Some Centres asked for special criteria in this formula to apply to special conditions in their territories.

It is clear that the National Institute of Public Health and the regional Centres for Public Health will not be financed in the same manner. The contribution of commercial activities in the survival of the institutions was also discussed. As the Centres do not all have the same equipment, they cannot operate “on the market” in the same way. Neither the Institute nor the Centres see commercial activities as their core business, although at the moment they depend on them for their survival. Sometimes the Institute and the Centres see each other even as rivals for commercial contracts. The participants were reminded of the work done by consultant Novotny. Any major changes in the financing of the Public Health institutions should be introduced gradually. In the end, all participants want a realistic package of services to be matched a stable source of government revenue that covers salaries, running cost and capital investment. The consultants promised to redraft Article 36, with added explanation.

5 TOWARDS COMPLETION OF THE PUBLIC HEALTH LAW

The prefinal draft of the new Public Health Law by the consultants is presented in Annex J. This draft again incorporates many suggestions by members of the Working Group and other stakeholders in Macedonia, but it remains the responsibility of the consultants. It is a short framework law that can stand up to international comparison.

Some explanation will help the reader to understand why certain articles are drafted as they are.

Article 4 (“Principles”) is based on a similar article in the new Serbian Public Health Law.

Article 5 (“Correlation with other laws”) co-ordinates between the new Public Health Law and existing specific Public Health laws. The relation with the existing Health Care Law is determined in Article 48 of the new law. It is proposed to amend and/or repeal some articles of the Health Care Law (see box).

Article 33

The second paragraph with 9 government programmes (of which 8 are public health programmes) should be aligned with the new Public Health Law.

Article 117

The first paragraph is fine, but the lists of activities in the next two paragraphs are somewhat strange: the first list presents the minimum activities to be carried out by an Institute/Centre of Public Health (IPH), and the second list seem to be additional activities. To avoid confusion, it is better to delete both lists and adopt the lists in the new Public Health Law (one for the National IPH and one for the regional IPHs).

Article 135

Activities 1-8 of Article 33 should *not* be paid by the HIF, but from the government budget.

Article 6 (“Essential Public Health Functions”) is based on the internationally recognised list established by the World Health Organisation, with slight modifications.

Articles 9 and 11 (“Competencies”) describe the tasks of the National Institute of Public Health and the regional Centres for Public Health, respectively, and they closely follow the recommendations by the Institute and Centres.

The “National annual programme for Public Health” that is mentioned in Article 9 and again

in Articles 11 and 12 can be seen as the “basic” or “essential” services that are provided to the Ministry of Health and the citizens of Macedonia by Institute and Centres. It consists of the tasks of Article 9 (minus item 13) and Article 11 (minus item 14), plus the Public Health parts of the 16 so-called national programmes. In fact, Articles 9 and 11 and the 16 national programmes are already overlapping. The Minister of Health may choose to include all Public Health activities of the 16 national programmes into the National annual programme for Public Health, or to keep some of these activities separate, with separate financing. The Minister can also add temporary specific Public Health programmes to the tasks of Institute and Centres, again with separate financing.

In Articles 9-11, we have used “Centres for Public Health” as the name of the regional Institutes of Public Health as instructed by the Ministry of Health. The minimum and maximum number of inhabitants covered by a Centre is to some extent arbitrary. Below a certain minimum there is insufficient critical mass to provide quality services to the population, and above a certain maximum one could consider splitting the Centre into two to provide services closer to the population. At present, none of the existing Centres drops below the threshold of 80,000. One Centre could become specialised in a specific Public Health activity (for example air quality measurement, or a sophisticated microbiological test, or indoor radon testing) and provide this service also to the territory and population of other Centres, so that not every Centre has to invest in such technology.

Article 18 regulates the establishment of “regional” Public Health Councils, to be appointed by the Minister of Health. As an alternative, one could consider joint appointment of the members by the Minister of Health and the Minister of Local Self-Government. In the future, it may become possible to establish formal partnerships between Centres for Public Health and groups of municipalities. For the moment, intermunicipal co-operation is considered as an option in Article 19.

Articles 20-22 deal with public health emergencies. Compatibility of these articles with Articles 173-177 of the Health Care Law should be checked.

Articles 23-33 deal with the International Health Regulations 2005. One should check if the existing Law on Infectious Diseases is still adequate in this respect, for example its Articles 28-32 and 56-58.

Article 42 may be the most complicated of the whole law. It proposes a lump sum financing for the execution of the National annual programme for Public Health by the Institute and the Centres. A similar approach is used for financing primary school education in Macedonia (Article 162 of the Primary Education Law). The Institute has a separate budget line based on an annual work plan; an alternative could be to allocate a certain percentage of the total lump sum to the Institute, as is done in Serbia (see below). The allocation of funds to the 10 regional Centres is done with a resource allocation formula that will be decided by the Ministry of Health in secondary legislation. To a large extent, allocation should be based on the number of inhabitants served by the Centre, but other factors (such as low population density or the presence of particular health problems or target groups) can play a role as well, although it is better not to make the formula too complicated. The Serbian formula for the allocation of resources to the Serbian regional Institutes of Public Health is based on the number of inhabitants on the territory of the IPH (70%), density of population (10%), number of health care facilities on its territory (5%), number of staff with university level (10%), and

contribution to medical faculties (5%). The allocation to the National IPH of Serbia has been set at 12% of the total government contribution; that means that the resource allocation formula is applied to the remaining 88% of Ministry of Health funds for Public Health. The financial allocation should cover all costs of implementing the National annual programme for Public Health, such as salaries, consumables, utilities, capital investment, and depreciation. The Centres will obtain other revenues from the Health Insurance Fund (for its clinical diagnostic activities and possibly other contracted tasks), from municipalities and public agencies (e.g. for the control of drinking water), and from private entities (e.g. food industry). The Institute and each Centre will have its internal business plan to match revenues and activities.

Some stakeholders may not accept all clauses of the draft in Annex J, others may miss some articles, or would like to see other articles drafted in another way. In the end, the Ministry of Health will decide how to handle this draft in order to prepare the text for the political discussion in Government and Parliament. One more meeting was organised on 9 June to enable stakeholders to discuss Annex J in a plenary session (see Chapter 6).

6 FINAL REMARKS

The plenary meeting to discuss Annex J was organised in the Holiday Inn in Skopje on 9 June 2009. The discussion focussed on three issues: financing of Public Health, the National Annual Programme for Public Health, and the involvement of local authorities in Public Health activities. Chapter 5 of this final report was provided as a handout to the participants.

The discussion on financing was fortunate to have an important input by two representatives of the Ministry of Finance. It appeared that the Ministries of Finance and Health can learn a lot from each other. What all participants really want is sufficient and stable financing of the Public Health network from the national budget. However, the draft law prescribes a *method* of financing, not a *level* of financing. We can agree that the present percentage of total public expenditures for health that is spent on Public Health (approx. 1%) is too low in international comparison. But it is not realistic to ask for a percentage for Public Health to be mentioned in the new law. In the end, no participant opposed the method described in Articles 38-44 (numbers used in Annex J) of the draft law and in Chapter 5 above. It will be necessary to introduce the new financing method gradually over a number of years. One interesting question that the Ministry of Health should consider is from which contingency funds any Public Health emergency activities should be paid.

In a follow-up meeting with representatives of the Ministry of Finance the next day, it became clear that they see many legal and administrative obstacles to the proposed lump sum (“block grant”) financing of Institute and Centres for implementing the National Annual Programme for Public Health. They of course also disagree with the present self-financing by Institute and Centres outside the Treasury system. The Ministry of Finance will react officially to the draft Public Health Law when it receives a request from the Minister of Health.

In another follow-up meeting on 11 June 2009, the representative of the Ministry of Local Self-Government was of the opinion that lump sum financing of a specific programme such as the National Annual Programme for Public Health is a valid option that should be prescribed in the new Public Health Law. The articles on the “regional” Public Health Councils and the optional inter-municipal co-operation in Public Health were correctly formulated.

Many participants needed more explanation on the meaning and content of the National Annual Programme for Public Health, as presented in Article 12 of the new law and Chapter 5 of this report. A rough calculation of the funds available for the National Annual Programme by splitting off the Public Health part of the 16 national programmes came to 120 million denar, which is woefully inadequate to form the basis of financing Institute and Centres for implementing the National Annual Programme. The good news is that the 16 national programmes are now indeed going to be separated into Public Health and insurance programmes, although this probably can only be implemented from 2011.

It would be nice if agreement could be reached with the Ministry of Local Self-Government on future elaboration of Article 22 paragraph 1 item 9 of the Law on Local Self-Government. The competencies of the municipalities in the field of Public Health could then be spelled out in an additional article of the new Public Health Law, but it appears that for the moment Article 19 is as far as we can go. There is consensus on the establishment of “regional” Public Health Councils, but the modalities still have to be worked out.

On 11 June, the two consultants sat together for the last time to agree on a number of last changes to be applied to the text presented in Annex J. They then produced a joint version with identical content in English and Macedonian that will be provided to the Ministry of Health as a separate file on 15 June 2009. In order to avoid confusion after that date, the consultants advise to not to translate the text of the new Public Health Law back and forth into English until the Ministry of Health has finalised its own version to be presented to Government and Parliament. The text and numbering of various articles will still change, and inconsistencies between Macedonian and English become unavoidable when repeated translations take place, with each time a delay of several days.

The new Public Health Law can only serve its purpose if political agreement can be reached on the content and financing of the National Annual Programme for Public Health. The level of financing should gradually become such that essential Public Health services of acceptable quality and intensity can be provided to the population without having to rely on commercial revenues. In actual terms, this means a government contribution between 400 and 600 million denars per year for Institute plus Centres, the exact amount depending on the intensity of the activities. If this amount cannot be made available, Institute and Centres will have to continue to focus on activities that are *not* Public Health, i.e. diagnostic tests for HIF patients and laboratory work for private clients. Decision-makers should understand and accept the consequences of their choice.

ANNEX A - AGENDA OF THE WORKSHOP OF 10 MARCH 2009

MINISTRY OF HEALTH OF THE REPUBLIC OF MACEDONIA

HEALTH SECTOR MANAGEMENT PROJECT

DEVELOPMENT OF A NEW PUBLIC HEALTH LAW

Third workshop on Tuesday 10 March 2009, 09.30 a.m. – 16.30 p.m.

Venue: Hotel Continental, Skopje

Background

The Government of the Republic of Macedonia wants to present a new public health law before the summer of 2009. Since December 2008, a Working Group appointed by the Ministry of Health and two external consultants are preparing this new public health law. Preliminary findings of the consultants have been presented and discussed at workshops on 18 December 2008 and 16 January 2009. The main results were:

- a) the new law should be an “umbrella” law for the field of public health that should refer to existing public health legislation;
- b) the new law should be based on the Essential Public Health Functions and an inter-sectoral approach;
- c) the new law should incorporate the International Health Regulations 2005 and should be “EU compatible”;
- d) agreement on a number of chapters and articles to be developed.

Since then, a first outline of the new public health law has been presented to the Ministry of Health and the Working Group on 20 February 2009. The Working Group gave its initial comments on this incomplete draft on 4 March 2009 and discussed it intensively with the consultants on 7 March 2009. Both the draft of 20 February and a summary of the discussion between the Working Group and the consultants are joined to this invitation as background materials. More information about the development of this new public health law can be obtained from the Project Co-ordination Unit (Dr Katerina Venovska).

Objective of the workshop

The aim of this third workshop is to discuss the first - still incomplete - draft of the new public health law and the comments by the Public Health Law Working Group. This discussion will be held between the representatives of various ministries involved in public health, other major stakeholders, and two external consultants. The results of this third workshop will be used to prepare a next, more complete, draft of the new law by the end of April 2009.

Invited to participate

- * Members of the Public Health Law Working Group
- * Ministry of Health, including State Sanitary and Health Inspectorate, Legal Sector and Department of European Integration, Food Directorate, and Health Sector Management Project
- * Representatives from the Ministries of Agriculture, Environment, Finance, Labour, and Local Self-Government
- * Representative from the Health Insurance Fund

- * Representatives from the national and regional Institutes of Public Health
- * Representative from the WHO Country Office
- * Representative from the Medical Chamber
- * Representative from the Institute of Occupational Health
- * External legal consultant and public health consultant

Agenda

- 09.00-09.30 Registration
- 09.30-09.45 Opening by the chairman, Prof. Vladimir Popovski
- 09.45-10.15 Developing a new public health law, by Angelina Bacanovic
- 10.15-11.00 Challenges for the development of the new public health law, by Kees Schaapveld, public health consultant
- 11.00-11.30 Tea/coffee
- 11.30-12.00 Discussion: What should be the future of the 16 “national (special) programmes”?
- 12.00-12.30 How should we integrate the IHR 2005 into the new law?
- 12.30-13.00 Should an intersectoral public health advisory (or co-ordination) council be established? Also at regional level?
- 13.00-14.00 Lunch
- 14.00-14.30 Are the prevention and control of public health emergencies sufficiently regulated by the Law on Infectious Diseases and the Crisis Law, or should the new public health law also play a role?
- 14.30-15.00 How to organise the safety of food and consumer products in Macedonia?
- 15.00-15.30 What should be the role of the national and regional Institutes of Public Health in the field of Mother & Child Health?
- 15.30-15.45 tea/coffee
- 15.45-16.15 How should the financing of public health activities be regulated in the new law?
- 16.15-16.30 Summary and conclusions by the chairman
- 16.30 Snacks and drinks

ANNEX B - HANDOUT FOR THE WORKSHOP OF 10 MARCH 2009

The draft of the new public health law of 11 February 2009 has been provided as background material to the participants of the workshop. This draft has been discussed intensively by the Public Health Law Working Group (“WG”) on 7 March 2009. This handout presents the main results of that discussion, without minor textual proposals. The comments by the WG and by the participants of the workshop of 10 March 2009 will be used to prepare the next version of the law in the coming weeks.

Article 1.3

It was decided to use the definition of public health that figures in the Health Strategy 2020.

The following new article will be added, borrowed from the draft Serbian law:

“The basic principles of public health are: emphasizing collective responsibility for health and the leading role of the state in preservation and improvement of the population health, focusing on the whole population, focusing on the social-economic determinants of health and most significant risk factors, multidisciplinary basis and introduction of both quantitative and qualitative methods of collection of information, as well as partnership with the population.”

Article 1.4

Some members of the WG would prefer to use a list of 11 Essential Public Health Functions that has been used in Macedonia for the past 3 years, instead of the WHO list used in the draft. A subcommittee of the WG will recommend a choice in the coming days.

Article 2.4

There appears to be consensus in the WG that the public health activities of the 16 national programmes should be considered as a single public health programme, part of the standard package of public health activities.

Article 3.2

The name of “National Institute of Public Health” should be changed into “Institute of Public Health of the Republic of Macedonia” (IPHRM).

The nature of the “supervision” of the regional Centres for Public Health by the IPHRM created confusion in the WG. It should be understood as “monitoring and support”, not as “inspection” or “accountability”. One of the purposes of articles 3.2 and 3.6 is to regulate the close relationship between IPHRM and Centres for Public Health.

The IPHRM wants to add control of pharmaceuticals as a core task.

Articles 3.4 and 3.7

The next version of the law will not mention departments but capacities or fields of expertise.

Article 3.5

There was no consensus in the WG about the proposal to define lower and upper limits for the number of inhabitants served by a Centre for Public Health.

Article 3.6

The representatives of the Centres for Public Health disagree with this new name proposed by the IPHRM. They prefer to remain “institutes”.

There is no consensus about the possible future responsibility of the Centres for Public Health for mother & child health, such as reproductive health, immunisation, child monitoring and “patronage”. Other options are the present situation (health houses) or chosen doctor offices.

Article 3.8

The State Sanitary and Health Inspectorate (SSHI) will formulate a text describing the relationship between the SSHI and the Centres for Public Health.

Article 3.9

Will be deleted.

Chapter 4

The term of “partnership” should be replaced by “co-operation and co-ordination”.

The tasks and responsibilities of the proposed Intersectoral Public Health Co-ordination Council should be clearly described in the new law.

The establishment of the proposed Public Health Advisory Committee at municipal/inter-municipal level appears to be highly problematic. The WG will wait for the results of the workshop of 10 March 2009.

Article 5.1

Article 5.1 will move to chapter 3 of the new law. Article 5.2 and Chapter 5 will be deleted.

Chapter 6

The differences between a crisis, a public health emergency and an epidemic, and the subsequent allocation of responsibilities for their prevention and control, proved to be a difficult subject that requires more thinking. There is also a link with the International Health Regulations 2005 (IHR).

Chapter 7

Many aspects of the public health information system are regulated by existing primary and secondary legislation. Chapter 7 will be replaced by a single article describing/regulating remaining aspects.

Chapter 8

The majority of the WG wants to keep articles 8.1 until 8.9 for the time being.

Responsibilities should be clearly allocated. As an alternative, this chapter could be replaced by a single article stating that Macedonia fully complies with the IHR, with operational procedures described in secondary legislation.

Chapter 9

The majority of the WG wants to keep a chapter of “special provisions” in the new law, including article 9.y.

The whole issue of food safety regulation in Macedonia seems to be under discussion at the moment. The WG awaits the discussion during the workshop of 10 March 2009.

Paragraph 3 of article 9.x generated many questions from the Centres for Public Health, although the idea seems accepted.

Chapter 10

Public health financing proved once again to be bottleneck of the system. Both the IPHRM and the Centres for Public Health want to continue with money-generating activities that are not their core business in order to keep their institutions afloat, until the government will provide sufficient revenues.

The IPHRM wants to reformulate paragraphs 3 and 4 of article 10.1 in a positive sense.

The IPHRM would like to have no direct contacts/contracts with clients that need tests (pharmaceuticals, food), but rather via intermediaries (Drug Bureau, Food Directorate). The resource allocation formula described in paragraph 2 of article 10.2 generated interest among the Centres for Public Health. The Serbian formula is based on number of inhabitants on the territory (70%), population density (10%), number of health care facilities on the territory (5%), number of staff with university level (10%), and contribution to medical faculties (5%).

(Note: the sentence in *italics* has been changed after the workshop)

ANNEX C - PRESENTATION DURING THE WORKSHOP OF 10 MARCH 2009

A NEW PUBLIC HEALTH LAW FOR THE REPUBLIC OF MACEDONIA
third workshop
Skopje, 10 March 2009
by consultant Kees Schaapveld

Challenges

1. Future of 16 national programmes
2. Integration of IHR 2005 into the new law
3. Inter-sectoral co-operation / co-ordination
4. Management of public health emergencies
5. Safety of food and consumer products
6. Mother & Child Health and Institutes of Public Health
7. Financing of public health activities

1. Future of 16 national programmes

- * Special programmes or normal activities?
- * Public health, medical care, and financial programmes
- * Should be split:
 - Public health activities
 - Basic benefit package
 - Possibly special insurance category
- * Financing accordingly

2. Integration of IHR 2005 into the new law

- * Are the responsibilities clear?
- * State Sanitary & Health Inspectorate
- * Institutes of Public Health
- * Focal Point
- * Customs, Transport
- * Relation with Law on Infectious Diseases?
- * Training and investment

3. Intersectoral cooperation/coordination

- * Is a National Intersectoral Public Health Council needed?
- * If so, what should its status and mission be?
- * Is it possible to have intersectoral advisory committees at regional level?

4. Management of public health emergencies

- * Definition of public health emergency
- * Crisis law:
 - Crisis Management Centre
 - Steering Committee
 - Assessment Group
- * Law on Infectious Diseases (epidemics, see articles 56-58)
- * New public health law?

5. Safety of food and consumer products

- * “from farm to fork”
- * Agriculture and Health
- * Risk assessment, risk management and risk communication
- * Food and non-food consumer products
- * Separate Authority?

6. Mother & child health and public health

- * Reproductive health
- * Child screening and monitoring
- * Immunisation
- * Health education
- * Role of primary care/family medicine
- * Role of “health houses” / prevention teams
- * Role of Institutes of Public Health?

7. Financing of public health activities

National Institute of Public Health:

- funded from the state budget
- no insurance or commercial activities
- participation in projects
- separate budget funding for investments

7. Financing (continued)

Centres for Public Health:

- funded from the state budget
- insurance payment for diagnostic tests
- contracts with public entities
- tariffs for legally required tests/certificates
- x% commercial activities
- separate budget funding for investments

Not on the agenda today:

Relation between national and regional Institutes of Public Health

- * Independent entities but ...
- * Clearly defined relationship
- * It takes two to tango
- * See Articles 3.2 and 3.6 in draft law

ANNEX D - BACKGROUND DOCUMENT FOR THE STUDY TOUR

Since a number of years, the Republic of Macedonia is reforming its health care system from a “Yugoslav” model to a more modern system that is oriented towards systems in the European Union. Macedonia has the status of a candidate country for membership of the European Union. The main project for health care reform is the Health Sector Management Project implemented by the Ministry of Health and supported by the World Bank. The website of the Ministry of Health is www.zdravstvo.gov.mk and the website of the Health Sector Management Project is www.moh-hsmp.gov.mk, both with pages in English. One of the tasks of the project is to support the reform of the Public Health sector. The Government of the Republic of Macedonia wants to submit a new public health law for the regulation of this sector to Parliament before the summer of 2009.

A delegation from the Republic of Macedonia wants to 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 different system of organising and financing public health activities.

Netherlands

In the Netherlands, the delegation will visit the following institutions:

- * the Ministry of Health, Welfare and Sport (VWS), directorates of PG, VGP and WJZ;
- * the National Institute of Public Health (RIVM);
- * Food and Consumer Product Safety Authority (VWA), head office and branch office/lab;
- * Regional Public Health Service (GGD) Zuid-Holland Zuid at Dordrecht;
- * Netherlands Institute for Health Promotion and Disease Prevention (NIGZ), Woerden;
- * Department of International Health, Maastricht University.

Belgium

In Belgium, the delegation will visit the following institutions:

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

* Provincial Institute of Hygiene, Antwerp (PIH)

Participants

- * Mr Bujar Osmani, Minister of Health (for part of the study tour);
- * Mr Vladimir Popovski, deputy Minister of Health and principal co-ordinator of the Health Sector Management Project (for part of the study tour);
- * Mr Azis Pollozhani, director of the National Institute of Public Health (RIHP) (for part of the study tour);
- * Ms Angelina Bacanovic, head of the legal sector of the Ministry of Health;
- * Mr Vladimir Kendrovski, head of sector for environmental health, food safety and nutrition of the National Institute of Public Health (RIHP);
- * Mr Vlado Trajkovski, director of the regional Centre for Public Health in Bitola;
- * Ms Valentina Simonovska, Centre for Public Health of the city of Skopje;
- * Ms Florentina Ristovska Surbevaska, director of the regional Centre for Public Health in Veles;
- * Ms Katerina Venovska, co-ordinator of the Health Sector Management Project;
- * Mr Shemsi Musa, Ministry of Health, director State Sanitary and Health Inspectorate;
- * Ms Olivera Stojkovska, Ministry of Health, State Sanitary and Health Inspectorate;
- * Ms Marina Popovska-Domazetovska, Ministry of Health, director of Food Directorate;
- * Ms Jovanka Kostovska, Ministry of Health, head of sector for preventive health care.

Most participants speak English, there will be no translation from and to Macedonian during the visits and meetings.

The study tour is being organised by Kees Schaapveld, consultant of the Macedonian Ministry of Health, e-mail: k.schaapveld@wxs.nl.

Suggestions for the discussion (based on actual interest in Macedonia):

At ministry level

- * Explanation about how the Ministries in the Netherlands and Belgium cover the field of public health.
- * To what extent should public health activities be centralised (national level) and to what extent decentralised (regional/community, provincial or municipal level)?
- * How was the new Dutch public health law prepared, who was involved, what were the difficulties encountered (if any), how does the new law relate to other legislation in the field of public health?
- * What are the main laws to regulate the Belgian public health sector, when were they adopted, how are they revised if necessary, how do these laws relate to other legislation in the field of public health?
- * How is EU public health legislation (regulations and directives) incorporated into Dutch and Belgian legislation?
- * How does intersectoral co-operation in the field of public health take place with other ministries (food safety, environment, traffic safety, safety and health at work, health promotion, etc.)?
- * How can intersectoral co-ordination in public health be regulated by law?
- * Which public health activities are directly financed by the Ministries and what are the budgets for these activities?

- * How are the relations with outside institutions regulated (RIVM, VWA, WIV/ISP, FAVV/AFSCA, advisory councils)?
- * How is the quality of public health activities being assured?

RIVM and WIV/ISP

- * An overview of the role and activities of RIVM and WIV/ISP in the field of public health and environmental control.
- * The revenues and expenditures of RIVM and WIV/ISP, including capital investments.
- * The legal basis and the legal position of RIVM and WIV/ISP, including links to more than one ministry.
- * What is the composition of the Boards of RIVM and WIV/ISP and what are their responsibilities?
- * The relationship between the national institute (RIVM and WIV/ISP) and peripheral public health services (in the Netherlands: GGD) in the areas of supervision, training, and data collection.
- * The role of RIVM and WIV/ISP in the International Health Regulations 2005.
- * Do RIVM and WIV/ISP manage any “national public health programmes” themselves?
- * How are RIVM and WIV/ISP involved in the assurance of the quality of its activities and the quality of activities of other public health institutions?
- * What is the relationship between RIVM and WIV/ISP on the one hand, and VWA and FAVV/AFSCA on the other?
- * What is the role of RIVM and WIV/ISP as a reference laboratory for other public health laboratories?
- * How is environmental monitoring and control shared between the RIVM and WIV/ISP, and provincial and municipal authorities?

VWA and FAVV/AFSCA

- * An overview of the role and activities of VWA and FAVV/AFSCA.
- * The legal basis and the legal position of VWA and FAVV/AFSCA, including links to more than one ministry.
- * The advantages and disadvantages of combining responsibility for the whole chain “from farm to fork” in a single agency.
- * The revenues and expenditures of VWA and FAVV/AFSCA, including for capital investment.
- * The legal powers of VWA and FAVV/AFSCA in enforcing the rules.
- * The role of VWA and FAVV/AFSCA in the International Health Regulations 2005.
- * The separation between food risk assessment and food risk management.
- * Implementation of control of imports (food and non-food).
- * How do VWA and FAVV/AFSCA assure of the quality of its activities?
- * If time allows: a visit to the laboratories.

GGD Zuid-Holland Zuid and its Board

- * An overview of the role and activities of the GGD.
- * Relationship between the GGD and the municipal authorities.
- * What do the municipal authorities expect from the GGD?
- * How to organise intermunicipal involvement/co-operation?
- * Revenues and expenditures of the GGD.

- * Specific activities of the GGD, e.g. policy advice, health promotion, youth health care, control of infectious diseases.
- * Relationship between the GGD and the RIVM.
- * Intersectoral co-operation in public health at municipal level.
- * How is environmental monitoring and control shared between the RIVM, provincial authorities and municipal authorities?

Provincial Institute of Hygiene (PIH), Antwerp

- * An overview of the role and activities of the PIH.
- * Relationship between the PIH and municipal, provincial, regional and federal authorities.
- * How is environmental monitoring and control shared between the PIH and other agencies?
- * Explanation of the organisation and financing of mass screening programmes (e.g. breast cancer).
- * A visit to the laboratories of the PIH.

Netherlands Institute for Health Promotion and Disease Prevention (NIGZ), Woerden

- * An overview of the role and activities of the NIGZ.
- * Position of the NIGZ as an independent centre of expertise; relations with customers.
- * Revenues and expenditures of the NIGZ.
- * Example(s) of health promotion campaigns in the Netherlands.
- * Experiences of the NIGZ in international projects.

Department of International Health, Maastricht University

- * Maastricht as a centre for European studies.
- * Projects of the Department of International Health
- * The network of public health in South Eastern Europe.
- * Overview of the public health system in Germany.
- * Evaluation of the study tour.

Programme of the study tour

Tuesday 31 March

Arrival at Schiphol airport at 21.45 p.m., transfer by train to Babylon hotel in The Hague

Wednesday 1 April

09.00-10.00	Ministry of Health, Welfare and Sport, Food, Health Protection and Prevention Directorate
10.00-11.30	Ministry of Health, Welfare and Sport, Public Health Directorate
10.00-10.30	Separate meeting of the Macedonian and Dutch Ministers of Health
11.30-13.00	Bus transfer from The Hague to Bilthoven
13.00-14.00	Lunch
14.00-17.00	National Institute of Public Health and Environment (RIVM), Bilthoven
17.00	Bus transfer from Bilthoven to The Hague

Thursday 2 April

08.23-09.08 Bus from The Hague to Woerden
09.30-11.30 Netherlands Institute for Health Promotion and Disease Prevention (NIGZ),
Woerden
12.00-12.30 Lunch
12.50-13.35 Bus from Woerden to The Hague
14.00-17.00 Food and Consumer Product Safety Authority (VWA), head office The Hague

Friday 3 April

07.51-08.31 Bus from The Hague to Dordrecht
09.00-12.30 Regional Public Health Service (GGD) Zuid-Holland Zuid, Dordrecht
12.30-13.15 Lunch
13.37-13.40 Bus from Dordrecht to Zwijndrecht (or on foot, 12 minutes)
13.45-16.30 VWA, regional office, Zwijndrecht

Saturday 4 April

Day off in the Netherlands

Sunday 5 April

Bus to Brussels, hotel Ibis

Monday 6 April

09.45-12.00 Federal Public Service Health, Food chain safety, and Environment, and Health
Insurance Institute: Belgian Public Health system
12.00-14.00 Lunch
14.00-16.00 Federal Public Service Health, Food chain safety, and Environment, Institute of
Public Health, and Ministry of the Flemish Community: International Health
Regulations

Tuesday 7 April

09.45-12.00 Federal Public Service Health, Food chain safety, and Environment, and
Federal Agency for the Safety of the Food Chain: food safety “from farm to
fork”, the Belgian response

Wednesday 8 April

08.36-09.25 Train from Brussels to Antwerp Central Station
10.00-13.00 Provincial Institute of Hygiene (PIH), Antwerp
Afternoon: Return to Brussels by train

Thursday 9 April

morning Bus from Brussels to Maastricht
10.30-11.15 Maastricht University and the Department of International Health
11.15-11.30 Coffee break

11.30-12.30 Projects of the Department of International Health
12.30-13.00 Overview of the Public Health system in Germany
13.00-14.00 Lunch
14.00-14.30 Public Health network in South Eastern Europe
14.30-15.30 Evaluation of the study tour

Afternoon/evening: Transfer to The Hague by bus

Friday 10 April

Return to Macedonia

Addresses and contacts

Netherlands

Ministerie van Volksgezondheid, Welzijn en Sport (Ministry of Health, Welfare and Sports, VWS), Parnassusplein 5, The Hague, www.minvws.nl.

Contact: Ms Jacqueline Roos, liaison officer International Affairs, tel. +31-70-3405027, rj.roos@minvws.nl.

Rijks Instituut voor Volksgezondheid en Milieu (National Institute of Public Health and Environment, RIVM), Antonie van Leeuwenhoeklaan 9, Bilthoven, www.rivm.nl.

Contact: Mr Jan Mos, head Corporate Affairs, tel. +31-30-2742199, jan.mos@rivm.nl.

Nederlands Instituut voor Gezondheidsbevordering en Ziektepreventie (Netherlands Institute of Health Promotion and Disease Prevention, NIGZ), De Bleek 13, Woerden, www.nigz.nl.

Contact: Mr Jan Jansen, tel. +31-348-439854, jjansen@nigz.nl.

Voedsel en Waren Autoriteit (Food and Consumer Product Safety Authority, VWA), CentreCourt, Prinses Beatrixlaan 2 (corner Juliana van Stolberglaan), tel. +31-70-4484848.

Contacts for 2 April: Mr Hans Jeuring and Frits van Vught (room 8A02, 8th floor)

GGD (Regional Public Health Service) Zuid-Holland Zuid, Korte Parallelweg 51, Dordrecht, www.ggdzhh.nl.

Contacts: Mr Koos Spanbroek, director, kspanbroek@ggdzhh.nl, tel. +31-78-6321830, and Ms Linda de Jongh, communication advisor, ljongh@ggdzhh.nl, mobile 06-51049325.

Voedsel en Waren Autoriteit (Food and Consumer Product Safety Authority, VWA), regional office, Westelijke Parallelweg 4, Zwijndrecht, tel. +31-78-6112100.

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Contact: Mr Stephan Vandenbroucke, tel. +31-43-3881589, s.vandenbroucke@inthealth.unimaas.nl

Belgium

Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen, en Leefmilieu (Federal Public Service Health, Food chain safety, and Environment), Eurostation II, Victor Hortaplein 40, Brussels, room 0D0011; <https://portal.health.fgov.be>.

Contacts: Ms Leen Meulenbergs, tel. +32-2-5249034, mobile +32-495-381305, leen.meulenbergs@health.fgov.be, and Ms Laurence Ballieux, laurence.ballieux@health.fgov.be.

Wetenschappelijk Instituut Volksgezondheid (Scientific Institute of Public Health) (WIV/ISP), Juliette Wytsmanstraat 14, Brussels; www.iph.fgov.be.

Contact: via Ms Leen Meulenbergs.

Federaal Agentschap voor de Veiligheid van de Voedselketen (Federal Agency for the Safety of the Food Chain), Kruidtuinlaan 55, Brussels, www.favv.be.

Contact: via Ms Leen Meulenbergs.

Vlaamse Overheid, Beleidsdomein Welzijn, Volksgezondheid en Gezin (Flemish Ministry for Welfare, Public Health and Family), <http://wvg.vlaanderen.be>, and Vlaams Agentschap Zorg en Gezondheid (Flemish Agency for Care and Health), www.zorg-en-gezondheid.be.

Contact: Ms Machteld Wauters, tel. +32-2-5533534, machteld.wauters@wvg.vlaanderen.be.

Provinciaal Instituut voor Hygiene, Kronenburgstraat 45, Antwerpen, tel. +32-3-2591200, www.provant.be/bestuur/departementen/leefmilieu/pih/.

Contact: Ms Vera Nelen, tel. +32-3-2591270, vera.nelen@pih.provant.be.

ANNEX E - EVALUATION OF THE STUDY TOUR

A relevant visit means that it can be related to the Macedonian situation and to planned legislation in Macedonia, either in a positive or negative sense. A visit can be interesting without being relevant, and the other way around.

1. Ministry of Health, The Hague

9 replies, 6 x very interesting, 2 x interesting, 1 x not interesting
9 replies, 5 x very relevant, 4 x relevant

2. National Institute of Public Health, Bilthoven

10 replies, 9 x very interesting, 1 x interesting
10 replies, 9 x very relevant, 1 x relevant

3. National Institute of Health Promotion, Woerden

10 replies, 5 x very interesting, 5 x interesting
10 replies, 6 x very relevant, 4 x relevant

Food & Consumer Product Safety Authority, head office The Hague

10 replies, 4 x very interesting, 5 x interesting, 1 x not at all interesting
10 replies, 8 x very relevant, 1 x relevant, 1 x not relevant

Regional Public Health Service, Dordrecht

10 replies, 6 x very interesting, 2 x interesting, 2 x moderately interesting
9 replies, 9 x very relevant

Food & Consumer Product Safety Authority, regional office Zwijndrecht

10 replies, 5 x very interesting, 3 x interesting, 2 x moderately interesting
10 replies, 6 x very relevant, 2 x relevant, 1 x moderately relevant, 1 x not relevant

Belgian health care system, Brussels (Monday morning)

12 replies, 7 x very interesting, 4 x interesting, 1 x moderately interesting
11 replies, 7 x very relevant, 3 x relevant, 1 x moderately relevant

International Health Regulations, Brussels (Monday afternoon)

12 replies, 8 x very interesting, 3 x interesting, 1 x moderately interesting
12 replies, 9 x very relevant, 3 x relevant

Food safety, Brussels (Tuesday morning)

12 replies, 6 x very interesting, 5 x interesting, 1 x moderately interesting
12 replies, 7 x very relevant, 5 x relevant

Provincial Institute of Hygiene, Antwerp

11 replies, 10 x very interesting, 1 x interesting
11 replies, 9 x very relevant, 2 x relevant

Department of International Health, Maastricht University

12 replies, 8 x very interesting, 4 x interesting
12 replies, 9 x very relevant, 3 x relevant

Comments from the members of the delegation for the organising institutions

1. A very useful and interesting way to learn about all those institutions, how they organise their work for public health.
2. All institutions were well organised and aware of the visit by the Macedonian delegation. They expressed willingness to respond to questions and to remain available for future co-operation.
3. Very interesting, and organised with great hospitality. I collected a lot of experience and knowledge.
4. Good organisation of the systems, clear, without overlapping.
5. To make organisations [illegible] for doing the right thing in the right way; to make a clear list of the responsibilities of each institution; to introduce responsibility and accountability for every institution and person.

What are the most important ideas/messages you picked up during the study tour?

1. I could compare how the system is working in these countries, how they are organised, what Public Health means in these countries, which issues are their priorities.
2. I noticed that health promotion is one of the main issues that is very important, and that it should be the priority in Public Health.
3. I noticed that Public Health activities should be financed from government resources in order to guarantee their sustainability.
4. The use of regional resources and capacities to implement Public Health policies and to improve the health of the population.
5. Co-ordination and division of responsibilities to Public Health and food safety between federal and regional authorities.
4. Strengthening of collaboration at regional level, especially in financing.
5. Well-equipped and connected laboratories with accreditation and scientific background.
6. Prevention should be more extensively included in the Public Health Law.
7. To make the Public Health network with collaborative organisational structure corresponding with the strategy in the Public Health Law.
8. To make a vision how Public Health services and institutions function (human resources, financing, activities, etc.).
9. To evaluate our activities after the Public Health Law will be implemented.
10. To support us in the whole process.
11. Public Health is well financed.
12. Food safety control is well integrated.
13. Clear competencies of the state bodies.
14. How to improve financial aspects and how the state could help in this issue.

15. Public Health is well organised and appropriately financed.
16. Better organisation of the International Health Regulations in my country.
17. Relations with the community and connection with regional authorities.
18. Different effective types of Public Health organisations.
19. Co-ordination of tasks and duties among intersectoral professionals.
20. Intersectoral co-operation in Public Health.
21. Organisation of Public Health system in these two countries.
22. Organisation of the food safety system.
23. How to improve the Public Health system in Macedonia.
24. Prioritisation during negotiations.
25. Putting Public Health high on the agenda.
26. Investing in capacity building.
27. We have to have clear-cut responsibilities for institutions.
28. To put in place rules of co-operation between institutions.

ANNEX F - DRAFT OF THE PUBLIC HEALTH LAW OF 13 APRIL 2009

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

Chapter 1 General provisions

Subject matter of the Law Article 1

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

Purpose of the law Article 2

The purpose of this Law shall be:

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

Definitions Article 3

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

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

constitute a public health risk to other states through the international spread of disease, and that potentially requires a co-ordinated international response

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

Principles

Article 4

Public health shall be rooted in the following principles:

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

Correlation with other laws

Article 5

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

Chapter II

Public health functions and tasks

Essential public health functions

Article 6

The essential public health functions are:

1. Surveillance and assessment of the population's health and well-being.
2. Identification, prediction, investigation and mitigation of health problems and health hazards in the community.
3. Health protection: technical assessment of needs and actions required to ensure health protection;
4. Disease prevention: applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Development and enforcement of laws and regulations that protect health and ensure safety.
7. Assuring a competent multidisciplinary public health workforce.
8. Initiation, support and carrying out of health-related research.
9. Initiation, development and planning of public health policy.
10. Preparedness and management of public health emergencies, including prevention, response and mitigation of consequences.
11. Ensuring intersectoral partnership and community participation to improve

health and reduce inequalities.

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

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

Essential tasks of public health

Article 7

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

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

Chapter III

Competent authorities for implementation of the Law

Competent ministries

Article 8

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

National Institute for Public Health
Article 9

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

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

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

Centers for Public Health
Article 10

Tasks of public health for the area of two or more municipalities shall be provided and coordinated by the Centers.

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

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

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

Article 11

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

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

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

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

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

Coordination and cooperation

Chapter IV

System of public health

Article 12

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

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

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

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

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

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

In addition to the Ministry of Health, other ministries engaged in areas of education, environmental protection, social care/ protection, science, sports, culture, traffic, agriculture,

economy, labor shall secure delivery of the public health functions pursuant to this and other laws.

Article 13

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

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

National Council for Coordination of Public Health

Article 14

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

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

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

The coordinative body shall be chaired by the Minister of Health.

The coordinative body of paragraph 1 of this article shall adopt Rules of Procedure.

Article 15

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

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

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

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

The Committee shall adopt rules of procedure for its operation.

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

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

The Committee shall be chaired by _____.

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

Public health emergencies Chapter V

Public health emergencies causes by infectious disease epidemics Article 16

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

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

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

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

Public health occurrence of international concern Article 17

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

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

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

Public health emergencies of a non- infectious nature Article 18

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

If the public health emergency of paragraph 1 of this article is of international concern

pursuant to the International Health Regulations, the Institute shall inform the Contact Center of the World Health Organization within 24 hours following the assessment of the public health information.

Application of the International Health Regulation Chapter VI

National Focal Point Article 19

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

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

The captain of an aeroplane in an international flight who wants to land at the airport, and who knows or seriously suspects that one or more passengers on board of the aircraft show signs of an infectious disease that may endanger public health, must inform the air traffic controller or the operator at the airport immediately after discovering and before landing. The air traffic controller must immediately inform the operator of the airport whereas the latter shall inform the responsible person of the medical team of the airport. The responsible person of the medical team of the airport shall immediately inform the State Sanitary and Health Inspectorate and the Institute of Public Health of Republic of Macedonia.

General declaration of the aircraft and other information Article 21

Pursuant to a request by the State Sanitary and Health Inspectorate, the captain of the airplane in charge of the international flight shall prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations. In addition to the Health Part of paragraph 1 of this Article the State Sanitary and Health Inspectorate can ask the captain for additional information about the airplane regarding the health situation of the passengers on board.

Entry point Article 22

The Minister for Transport following an opinion stated by the Minister of Health shall designate the airport(s) which is/are to be the entry point(s) to which the International Health Regulations apply. The airport(s) of paragraph 1 of this article is/are obliged to develop its/their capacities as prescribed by the International Health Regulation.

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

State Sanitary Inspectorate actions

Article 23

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

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

In cases of paragraphs 1 and 2 of this Article, the captain of the aeroplane will assure that after landing of aircraft, nobody is to enter or exit the aircraft, and no goods will be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained. The State Sanitary and Health Inspectorate, upon request, shall submit a list with the names, address, sex, age and destination of the passengers to the captain of the aircraft.

Article 24

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

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

Article 25

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

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

Road border crossings

Article 26

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

Active and passive immunization

Article 27

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

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

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

Airport Operators Costs
Article 28

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

Article 29

The Minister for Health shall publish the International Health Regulations.

Special provisions
Chapter 7

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

Article 30

An entrepreneur who is not a medical doctor and who performs activities that penetrate the skin of his clients needs a permit from the Ministry of Health.

Activities of paragraph 1 of this article include tattooing, piercing, permanent make-up and acupuncture.

Article 31

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

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

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

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

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

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

Article 32

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

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

Article 33

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

Article 34

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

Financing Chapter

Sources of financing

Article 35

Sources of financing for the Institute and Centers are:

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

Funds from the Budget of Republic of Macedonia

Article 36

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

The work programs of paragraph 1 of this article are adopted by the Institute or the Centers the latest of 31 December of the year in progress for the following year.

Consent for the programs of paragraph 1 and 2 of this article is provided by the Government of the Republic of Macedonia, following a previously submitted opinion by the Ministry of Health.

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

Own income resources

Article 37

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

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

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

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

Donation revenues

Article 38

Financial or material items can constitute a donation.
Donors could be domestic and international natural or legal entities.
The purpose and modality of use of donations are to be regulated with a contract between the donor and the Institute, or the Center.

Supervision **Chapter** **Article 39**

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

Penal provisions **Chapter** **Article 40**

Transitional and final provisions **Chapter_____**

Institute for mother and child care **Article 41**

On the day of entering into force of this Law, the Institute for Mother and Child Care as such shall cease to exist.
All employees, equipment and other assets of the Institute for Mother and Child Care are to be taken on by the Institute.

Enactment **Article 42**

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

ANNEX G - AGENDA OF THE WORKSHOP OF 28 MAY 2009

Fourth and last workshop on Thursday 28 May 2009, 09.30 a.m. – 14.00 p.m.

Venue: Hotel Bellevue near Skopje

Purpose

The purpose of the workshop is to discuss a pre-final draft of the new Public Health Law with the major stakeholders. An incomplete draft was already presented during the third workshop on 10 March 2009. The results of the discussion will be used by the consultants to produce a final draft that will be submitted to the Ministry of Health for further consideration and starting the political process of clearing the law with Government and Parliament.

Invited to participate

- * Members of the Public Health Law Working Group
- * Chair and/or members of the Parliamentary Health Committee
- * Ministry of Health, including State Sanitary and Health Inspectorate, Legal Sector, Department of European Integration, Food Directorate, and Health Sector Management Project
- * Representatives from the Ministries of Agriculture, Environment, Finance, Labour, and Local Self-Government
- * Representative from the Health Insurance Fund
- * Representatives from the national and regional Institutes of Public Health
- * Representative from the WHO Country Office
- * Representative from the Medical Chamber
- * Representative from the Institute of Occupational Health
- * External legal consultant and public health consultant

Agenda

09.00-09.30	Registration
09.30-09.45	Opening by the chairperson
09.45-10.15	Public health suggestions, by consultant Kees Schaapveld
10.15-10.45	Legal suggestions, by consultant Miroslav Trajanovski
10.45-11.15	Developments in Food Safety, by Marina Popovska-Domazetova
11.15-11.45	Tea/coffee break
11.45-13.45	Discussion on key issues of the pre-final draft by the participants
13.45-14.00	Summary and conclusions
14.00	Snacks and drinks

Issues for the discussion:

- a. Agreement on tasks of National and Regional Institutes of Public Health.
- b. One standard programme of Public Health activities, or separate programmes?
- c. Minimum and maximum number of inhabitants per Institute of Public Health.
- d. Can/should there be regional Public Health committees?
- e. Separate article on Quality Assurance in the Institutes of Public Health?
- f. Funding mechanism for standard Public Health programme.
- g. Investments according to investment plans?

ANNEX H - PRESENTATION DURING THE WORKSHOP ON 28 MAY 2009

A NEW PUBLIC HEALTH LAW FOR THE REPUBLIC OF MACEDONIA
fourth workshop
Skopje, 28 May 2009
by consultant Kees Schaapveld

Benefits of the new Public Health Law (1)

- * Providing a focus for Public Health
- * Explaining Public Health
- * Emphasis on inter-sectoral responsibility:
 - Inter-sectoral Public Health Council
 - (Cautious) involvement of local government
- * Legal basis for International Health Regulations 2005

Benefits of the new Public Health Law (2)

- * Clear description of tasks of
 - National Institute of Public Health
 - Regional Institutes of Public Health
- * Clear relationship between national and regional Institutes
- * Clear responsibilities for public health emergencies (infectious and non-infectious)

Remaining points for discussion (1)

- * Separate article on Quality Assurance
- * Distinction between General Public Health Programme and specific temporary activities (Art. 9)
- * More prominence for modern terminology (e.g. in names of departments, Art. 9 + 11)
- * Number of inhabitants covered by a regional Institute of Public Health (Art. 10)

Remaining points for discussion (2)

- * Explicit description of relationship between SSHI and Institutes of Public Health? (Art. 11)
- * Can there be a regional Public Health Committee? (Art. 15)
- * More explicit description of government funding (resource allocation) (Art. 36)
- * Explicit mention of investment plan (Art. 36)

Next steps

- * Next draft by the consultants by early June 2009, using latest comments
- * Further amendments before 30 June 2009?
- * Ministry of Health prepares its own draft version for discussion in government and Parliament
- * And what about food safety?

ANNEX I - HANDOUT FOR THE WORKSHOP ON 28 MAY 2009

Questions and remarks for the participants

- * Where does Article 4 come from? What does it add to Articles 6 and 7?
- * The Working Group has asked for references to other laws. Is Article 6 paragraph 2 sufficient for this purpose?
- * In the previous draft, there was a key Article 7c that should be called “Quality assurance in public health” (see box). This concept is totally missing in Macedonia (there is not even a Law on Quality Assurance in Health Care as in most other countries). I would prefer to keep Article 7c as it was, for example after the present Article 7.

Article 7c

1. Quality assurance activities in the Institute of Public Health of the Republic of Macedonia 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 Institute of Public Health of the Republic of Macedonia 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 Institute of Public Health of the Republic of Macedonia will monitor and support [or: oversee?] the activities of the Centres for Public Health according to a jointly developed protocol.
3. The Institute of Public Health of the Republic of Macedonia will provide reference laboratory services for the laboratories of the Centres for Public Health according to a jointly agreed schedule.
4. The Institute of Public Health of the Republic of Macedonia 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 Institute of Public Health of the Republic of Macedonia will assist the educational activities of the Centres for Public Health as required.
5. The laboratories of the Institute of Public Health of the Republic of Macedonia and the Centres for Public Health must be accredited according to [.....].

- * Article 9 item 1: Is the distinction between the standard general public health programme and any specific public health programmes not useful?
- * In Article 10: Should we have a lower and upper limit for the number of population covered by a Centre, or not?
- * In Article 11, I would like to add something similar to what is said at the end of Article 9, because the terminology used in the Centres for Public Health (social medicine, epidemiology, hygiene, microbiology) is of Soviet origin and outdated (as was clear again during the recent study tour). It is important to impose modern terminology. Therefore I propose the text presented in the following box:

Entries of paragraph 1 of this article shall be carried out by means of analysis, planning and assessment, health promotion, prevention and control of diseases (of specific communicable and non-communicable diseases; including emergency preparedness), environmental health, and microbiology and physicochemical analysis.

- * Article 11: Should the law describe the relation between the SSHI and a Centre?
- * Article 12: There seems to be some overlap between the first and last paragraphs.
- * Article 15: Is a regional public health committee feasible or not?
- * To what extent is Article 26 correct? At present, nothing is regulated in the Infectious Diseases Law, and the IHR are not only about infectious diseases.
- * What is the purpose of Article 29? The IHR have been published by the WHO in 2005.
- * Should Article(s) on food safety be inserted into the public health law?
- * In Article 36, I would like to mention “resource allocation formula” and/or “capitation” in order to prevent problems with funding in the future . Also, I would like to keep the words “investment plan”.
- * In Article 37, I would like to mention that NIPH services should be non-commercial.

ANNEX J - DRAFT OF THE PUBLIC HEALTH LAW OF 3 JUNE 2009

Chapter I General provisions

Subject matter of the Law Article 1

This Law shall regulate the essential public health functions and tasks, the public health emergencies, funding of public health programmes [listing of main chapters/ sections of the law.

Purpose of the law Article 2

The purpose of this Law shall be:

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

Definitions Article 3

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

1. „Public health” is the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society. Public health analyses and monitors the health status of the population, and tries to improve this health status by influencing the known determinants of health (also known as risk factors) such as environmental and microbiological causes, lifestyle and socio-economic factors
2. „Essential public health functions,, are a set of fundamental activities that address the determinants of health, protect a population’s health, and treat diseases of public health significance. They prevent and manage the major contributors to the burden of disease by using effective technical, legislative, administrative, and behaviour-modifying interventions or deterrents, and thereby provide an approach for intersectoral action for health.
3. „Public health emergency” is an occurrence or imminent threat of a situation that can cause wide-spread mortality or serious morbidity from a natural disaster, infectious agent, biological toxin, or chemical or nuclear release.
4. „Public health emergency of international concern” is an extraordinary event that may constitute a public health risk to other states through the international spread of disease, and that potentially requires a co-ordinated international response
5. An “epidemic” is the occurrence in the community or region of cases of an illness, specific

health-related behaviour, or other health-related events clearly in excess of normal expectancy.

6. “Prevention”: actions that prevent the occurrence of disease. Action aimed at eradicating, eliminating or minimising the impact of disease and disability.

7. “Health promotion” is the extent to which an individual or a group is able to realise aspirations and satisfy needs, and to change or cope with the environment. Health is a resource for everyday life, not the objective of living; it is a positive concept emphasising social and personal resources as well as physical capabilities.

8. “Communicable disease” is an illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.

9. A “reference laboratory” is a laboratory that carries out the control of the quality of services performed by other laboratories.

Principles Article 4

Public health shall be rooted in the following principles:

1. Collective responsibility for health and the leading role of the state in preservation and improvement of the health of the population;
2. Wide-ranging measures and activities focused on the entire population, and on the socio-economic determinants of health and the most significant risk factors;
3. Multidisciplinary basis and intersectoral cooperation;
4. Collection of information by means of qualitative and quantitative methods;
5. Partnership with population.

Correlation with other laws Article 5

In addition to the provisions of this law, the provisions in the laws regulating protection against communicable diseases, food safety, professional safety, environmental safety as well as other public health issues shall be applied (separate laws).

Chapter II Public health functions and tasks

Essential public health functions Article 6

The essential public health functions are:

1. Surveillance and assessment of the population’s health and well-being.
2. Identification, prediction, investigation and mitigation of health problems and health hazards in the community.

3. Health protection: technical assessment of needs and actions required to ensure health protection;
4. Disease prevention: applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Development and enforcement of laws and regulations that protect health and ensure safety.
7. Assuring a competent multidisciplinary public health workforce.
8. Initiation, support and carrying out of health-related research.
9. Initiation, development and planning of public health policy.
10. Preparedness and management of public health emergencies, including prevention, response and mitigation of consequences.
11. Ensuring intersectoral partnership and community participation to improve health and reduce inequalities.

These Essential Public Health Functions describe the framework in which all Public Health activities are carried out by all responsible bodies, institutions and other legal entities, in which the Ministry of Health has the leading role.

Tasks of public health

Article 7

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

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

Chapter III

Competent authorities for implementation of the Law

Competent ministries

Article 8

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

National Institute of Public Health

Article 9

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

1. Provide expert/professional assistance to the Ministry of Health in the preparation of medium-term and long-term public health plans, including the development and co-ordination - also intersectorally - of the annual general public health programme and separate interim 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, and monitoring and control of communicable and non-communicable diseases on the territory of the Republic of Macedonia;
2. Prepare annual national reports on relevant aspects of the population's health in agreement with the Ministry of Health;
3. Prepare standards for the scope of activities, and co-ordinate, inform and monitor the operation of the Centres for Public Health (hereinafter Centres);
4. Act as a reference laboratory for the Centres;
5. Develop and provide programmes for continuous professional development in the field of public health for its own staff, staff of the Centres, and other target groups, in co-operation with the Centres and other educational establishments in Macedonia;
6. Monitor the implementation and coordinate public health measures in case of epidemics and other emergencies on the territory of the Republic of Macedonia, together with other ministries and organisations pursuant to the Crisis Management Law;
7. Participate in international co-operation in the field of public health, shall provide health data to international organisations in accordance with law;
8. Organise and implement research in the field of public health;
9. Conduct testing of pharmaceuticals;
10. Monitor and assess ionizing radiation and non-ionizing radiation risk;
11. Assist the Ministry of Health and the other responsible ministries on issues stipulated in article 6 of this Law; and within the competencies of the Institute shall perform other tasks at the request of the Ministry of Health in the area of public health.

The activities of paragraph 1 of this Article shall be carried out through analysis, planning and assessment, health promotion, and prevention of diseases.

The subject of the scope of activities shall be in the areas of: science and research; expertise and consultancy; methodology and teaching in the field of public health; assessment of the health risks due to environmental factors, and risk factors related to the behaviour and lifestyle; research in the areas of public health, mother and child care, communicable and non-communicable diseases, including preparation for emergencies.

Centres for Public Health

Article 10

Public health tasks for the area of one (Skopje) or more municipalities shall be provided and coordinated by the Centres.

Centres are established in the area of a group of municipalities of combined number of inhabitants of at least 80,000 and the most 300,000.

Provisions of paragraph 2 of this Article shall not apply to the Centre of the city of Skopje which will cover all municipalities under the city of Skopje (urban and rural).

Article 11

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

1. Define, prepare, and implement annual, medium-term and long-term work plans for the implementation of public health activities, including health promotion, screening of the population, and monitoring and control of communicable and non-communicable diseases for the territory under the Centre. The basis for the annual work plan of each Centre is the National Annual Programme for Public Health developed by the Institute.
2. Prepare annual evaluation reports on the health of the population, and propose measures for overcoming public health problems for the territory under the Centre.
3. Collect, process and analyze records and data stipulated in laws.
4. Monitor, analyse, and evaluate the environmental health and sanitary conditions via risk assessment, as well as propose measures for overcoming public health problems.
5. Study and monitor the hygienic and other requirements as regards to the protection of air, foodstuffs and general usage items, drinking water, waste waters and solid waste materials, and participate in the preventive sanitary supervision over construction and other works.
6. Study the nutrition of the population, as well as the diseases and conditions which emerge as a consequence from improper diet, and propose measures for the elimination thereof.
7. Microbiological and physicochemical laboratory services, analysis and evaluation of laboratory data, and propose measures for overcoming the public health problems.
8. Monitor, analyse, evaluate and implement measures for active protection of the population against occurrence of communicable and other diseases, epidemics and other emergencies, and carry out active and passive immunisation.
9. Define and implement health education for target groups.
10. Implement preventive DDD measures of public health interest.
11. Draft operational plans for its territory in the framework of the National Strategy for Protection of the Population in case of emergencies.
12. Research in the field of public health.
13. Carry out other public health activities following a request by the Ministry of Health.

Entries of paragraph 1 of this Article shall be carried out by means of analysis, planning, and evaluation; health promotion; disease control and prevention (of specific communicable and non-communicable diseases; including emergency preparedness); environmental health; and microbiology and physicochemical analysis.

In addition to items in paragraph 1 of this Article, a Centre, on the basis of an approval obtained by the Ministry of Health, can carry out certain specialised activities in the fields mentioned in paragraph 2.

Pursuant to the case in paragraph 2 of this Article, this Centre for Public Health shall serve as the leading institution for the other Centres for these specialised activities.

In addition to the activities of paragraph 1 of this Article, the Centre for Public Health of the city Skopje shall perform the following:

1. carry out immunisation for tropical diseases and chemoprophylaxis;
2. issue internationally acknowledged certificates compliant to the International Health Regulations and the Law on Communicable Diseases.

National annual programme for public health

Article 12

Except for the provisions in Article 11, the Centres are responsible for the implementation of the National Annual Programme for Public Health (hereinafter: Programme).

The Program of paragraph 1 of this Article, following a proposal by the Ministry of Health shall be adopted by the Government of Republic of Macedonia.

The National Annual Programme for Public Health of paragraph 1 of this Article the Republic of Macedonia will contain a chapter for capital investments in the Institute and Centres based on a long term capital investment plan approved by the Ministry of Health.

In addition to the Programme of paragraph 1 of this Article, the Government of Republic of Macedonia, following a proposal by the Ministry of Health shall adopt separate, interim public health programmes

Article 13

Quality assurance

1. Quality assurance activities in the Institute and Centres will consist of developing and following agreed professional standards and guidelines, continuing professional development of staff, accreditation of laboratories, and peer review.
2. The Institute and the Centres 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 Institute will oversee the activities of the Centres according to a jointly developed protocol.
3. The Institute will provide reference laboratory services for the laboratories of the Centres according to a jointly agreed schedule.
4. The Institute and the Centres will provide sufficient opportunities for continuing professional development to their technical and academic staff to maintain the required level of expertise. The Institute will assist the educational activities of the Centres as required.
5. The laboratories of the Institute and the Centres must be accredited according to instructions given by the Ministry of Health.

Article 14

In response to the public health needs of public health interest and emergencies, the Centres for Public Health shall provide technical and expert assistance to the inspectors of the State Sanitary and Health Inspectorate, shall submit data and information to the Inspectorate, necessary for ordering measures by the Inspectorate to natural persons and legal entities, pursuant to this or another law.

For the delivery of certain measures stipulated in this or another law, teams comprised of representatives from the Centres for Public Health and the Inspectorate can be formed.

Coordination and cooperation

Chapter IV

System of public health

Article 15

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

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

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

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

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

In the course of implementing the public health functions of Article 6 of this Law, the following shall participate: citizens, families, employers and employees, educational and other institutions, humanitarian, religious, sport and other organisations, associations, public health and health care institutions, health insurance funds, as well as municipalities and the Government of the Republic of Macedonia, and other institutions as well as non-governmental organizations.

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

Article 16

The Institute and the Centres shall position the delivery of operations stipulated in Article 9 and Article 11 of this Law in the following principles:

1. Clearly defined public health purpose.

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

National Council for Coordination of Public Health

Article 17

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

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

The National Council shall be comprised of _____ representatives from the Ministry of Health, Ministry of Environment and Physical Planning, Ministry of Labour and Social Policy, Ministry of Education and Science, Ministry of Agriculture, the Ministry of Local Self-Government, the Institute and independent experts in the area of public health in the course of which one should consider an equal representation of the entire population in Republic of Macedonia.

The Council shall be chaired by the Minister of Health.

The mandate of the members of the National Council shall be 5 years.

The National Council, the coordinative body of paragraph 1 of this Article shall adopt Rules of Procedure.

Regional Councils for Public Health

Article 18

The Government of the Republic of Macedonia shall form a Regional Council for Public Health. Each Centre will establish an intersectoral Public Health advisory committee (hereinafter: Regional Council) for public health which shall advise the Centre for the municipalities on the territory of each Centre, upon their request and also at its own initiative, on all public health matters that involve other partners than the Centre.

The Regional Council of paragraph 1 of this Article shall comprise of at least 7 members, of which at least 3 shall represent the municipalities on whose territory the Centre is established, and other 2 independent public health experts.

The membership of the Regional Council shall elect the chairperson.

The mandate of the members of the Regional Council shall be 5 years.

The Regional Council shall adopt rules of procedure for its operation.

For the territory of Skopje, a Skopje Public Health Council shall be established. As regards to the composition and the operation of the Council of paragraph 5 of this Article, paragraphs 1 to 4 shall be respectively applied.

The role of the units of self-government in the delivery of public health
Article 19

The units of the local self government can deliver public health activities for their own territory for which purpose they have self-generated funds.

The units of the local self government within the inter-municipal cooperation can found a joint working body, committee, coordinative or other expert authority for the purpose of exchange of information, experiences and coordination of the public health cooperation for the territory of their municipality, in accordance with law.

Public health emergencies
Chapter V

Public health emergencies causes by infectious disease epidemics
Article 20

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

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

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

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

Public health occurrence of international concern
Article 21

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

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

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

Public health emergencies of a non- infectious nature
Article 22

In case of a public health emergency of a non-infectious nature, the Crisis Management Centre will be in charge of control of the emergency according to the Crisis Law, in co-

operation with the Ministry of Health, the Institute, and the Centres.

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

Application of the International Health Regulation Chapter VI

National Focal Point Article 23

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

Acting in instances of suspicion of a presence of an onboard infectious disease Article 24

The captain of an aeroplane in an international flight who wants to land at the airport, and who knows or seriously suspects that one or more passengers on board of the aircraft show signs of an infectious disease that may endanger public health, must inform the air traffic controller or the operator at the airport immediately after discovering and before landing. The air traffic controller must immediately inform the operator of the airport whereas the later shall inform the responsible person of the medical team of the airport. The responsible person of the medical team of the airport shall immediately inform the State Sanitary and Health Inspectorate and the Institute of Public Health of Republic of Macedonia.

General declaration of the aircraft and other information Article 25

Pursuant to a request by the State Sanitary and Health Inspectorate, the captain of the airplane in charge of the international flight shall prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations. In addition to the Health Part of paragraph 1 of this Article the State Sanitary and Health Inspectorate can ask the captain for additional information about the airplane regarding the health situation of the passengers on board.

Entry point Article 26

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

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

In case of accepting notification of Article 24, or if suspicion of a potential public health danger on board of an aeroplane has arisen otherwise, the Minister of Transport, after consultation with the Minister of Health, can determine at which airport the aeroplane should

land.

State Sanitary Inspectorate actions

Article 27

In case of article 24 of this law, the State Sanitary and Health Inspectorate shall submit a list of measures to be applied upon arrival of the airplane in the airport.

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

In cases of paragraphs 1 and 2 of this Article, the captain of the aeroplane will assure that after landing of aircraft, nobody is to enter or exit the aircraft, and no goods will be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained. The State Sanitary and Health Inspectorate, upon request, shall submit a list with the names, address, sex, age and destination of the passengers to the captain of the aircraft.

Article 28

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

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

Article 29

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

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

Road border crossings

Article 30

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

Active and passive immunisation and prophylaxis

Article 31

Active or passive immunisation of persons or the use of prophylaxis in order to obtain an internationally valid certificate as described in the International Health Regulations will be

provided according to the provisions of the Law on Infectious Diseases.
Shape and content of the certificates of paragraph 1 of this Article are prescribed by the International Health Regulations.
The Minister of Health will designate institutions that can provide immunisation against yellow fever and other types of immunisation only used for specific target groups.

Airport Operators Costs **Article 32**

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

Article 33

The Minister for Health shall publish the International Health Regulations.

Special provisions **Chapter VII**

[Regulation of food risk management; the Food Directorate will propose one or more articles before 3 June 2009. In that case, the numbers of the following articles will change. If the Food Directorate does not provide a text, we shall delete this paragraph.]

Article 34

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

Article 35

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

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

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

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

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

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

Article 36

The Minister of Health shall assess if the requirements of Article 35 of this Law have been

met, and shall adopt a decision for authorizing/ permitting work.

The work permit of paragraph 1 of this Article can be revoked if changes occur as a cause of which significant deviation according to article 35 of this law have been performed.

Article 37

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

Financing of public health activities Chapter VIII

Sources of financing

Article 38

Funds for public health funding shall be secured from the following sources:

- Budget of the Republic of Macedonia;
- self- generated income;
- Health Insurance Fund of the Republic of Macedonia under conditions stipulated in this law;
- donations and
- other sources of revenue regulated in another law.

Funds from the Budget of Republic of Macedonia

Article 39

Resources for funding the public health scope of activities shall be secured by the Budget of Republic of Macedonia in a manner stipulated according to the Law on Budgets of Republic of Macedonia and the Law on Execution of Budget of the Republic of Macedonia.

Allocation of resources from the Budget of Republic of Macedonia

Article 40

The Ministry of Finance shall adopt a financial plan and an annual statement for the operation of the Institute.

The funding of operations of the Centres shall be carried out according to a financial plan and an annual calculation adopted by the Ministry of Health as well as according to the programmes of Article 12 of this Law.

The Centres will be financed for their activities under the National Annual Public Health Programme of Article 12 of this law 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 financial plans of paragraph 1 and 2 of this Article will contain a chapter for capital investments based on a long-term capital investment plan approved by the Ministry of Health.

Control over the earmarked utilization of the resources from the Budget of the Republic of Macedonia

Article 41

The Ministry shall control the earmarked utilization of the funds allocated from the Budget of the Republic of Macedonia.

Mandatory insurance

Article 42

The Institute and the Centres shall sign up for an adequate damage liability insurance for which the founder- the Budget of the Republic of Macedonia shall secure funds.

Self- generated income

Article 43

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

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

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

The tariff book of paragraph 3 of this article shall be adopted by the Minister of Health.

Donation revenues

Article 44

Financial or material items can constitute a donation.

Donors could be domestic and international natural or legal entities.

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

Supervision

Chapter IX

Article 45

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

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

Penal provisions

Chapter X

Article 46

Fine in the amount of ____ to ____ EUR in MKD equivalent value shall be issued for a misdemeanour to an entrepreneur carrying out activities of article 30 of this law without a permit.

Final provisions

Chapter XI

Institute for mother and child care
Article 47

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

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

Article 48

On the day of entering into force of this Law, articles _____ of the Health Care Law shall cease to apply.

Enactment

Article 49

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

ANNEX K - CHANGES IN THE DRAFT OF 3 JUNE 2009