



# **DIRECTORATE-GENERAL FOR INTERNAL POLICIES**

# POLICY DEPARTMENT A ECONOMIC AND SCIENTIFIC POLICY



Food Safety and Public Health Situation in Serbi

**Economic and Monetary Affairs** 

**Employment and Social Affairs** 

**Environment, Public Health** and Food Safety

**Industry, Research and Energy** 

**Internal Market and Consumer Protection** 



NOTE

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# **DIRECTORATE GENERAL FOR INTERNAL POLICIES**

# POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

# FOOD SAFETY AND PUBLIC HEALTH SITUATION IN SERBIA

# NOTE

# Abstract

This note is composed of two parts.

Part one reviews the Serbian food and drink industry, the organisations and controls involved in food safety, food safety concerns, the risk management and risk communication of animal diseases and finally the status of preparation of Serbia against the acquis in the area of food safety.

Part two provides an overview of the public health situation in Serbia. It presents the health status of the population and its determinants, and describes the Serbian health care system. It also provides information on the status of, and challenges with regard to, the implementation of the EU acquis.

This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI)

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# **FOOD SAFETY SITUATION IN SERBIA**

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# **LIST OF ABBREVIATIONS**

AI	Avian influenza
ВСР	Border crossing point
BIP	Border inspection post
BSE	Bovine spongiform encephalopathy
CA	Competent authority
CSF	Classical swine fever
DNRL	Directorate for the National Reference Laboratories
EC	European Commission
EU	European Union
FVO	Food and Veterinary Office
GDP	Gross domestic product
GMO	Genetically Modified Organism
HACCP	Hazard analysis and critical control point
IPA	Instrument for pre-accession assistance
MAFWM	Ministry of Agriculture, Forestry and Water Management
МоН	Ministry of Health
MoTT	Ministry of Internal and External Trade and Telecommunications
NPAA	National plan for the adoption of the acquis
PPP	Plant protection products
RASFF	Rapid alert system for food and feed
SEIO	Republic of Serbia European Integration Office
SMEs	Small and medium sized enterprises
<b>TAIEX</b>	Technical assistance and information exchange

# **EXECUTIVE SUMMARY**

This briefing on food safety in Serbia has been prepared for the Environment, Public Health and Food Safety Committee (ENVI) Delegation to Serbia from 28 -31 October 2013. It provides a summary of Serbia's food and drink industry, an overview of the food safety and control system in Serbia, the risk management and risk communication of animal diseases and the status of preparation of Serbia against the *acquis* in the area of food safety.

The Republic of Serbia was granted the status of candidate country of the European Union on 1 March 2012.

Historically the food industry of Serbia was made up of small-scale farms and small, domestically orientated processing plants. Today, despite the presence of larger multinational organisations and support from the government and international agencies to encourage development, the food industry is still dominated by small and medium sized enterprises. Increasing competiveness, the finding of new markets, adapting to the rules and standards of the EU and WTO, adopting new technologies and methods to meet local and international requirements are all challenges facing the Serbian agri-food industry. These will also affect the existing structure of agriculture and of food production.

Serbia is a net exporter of food the main export being grain and grain products and fruit (especially plums and raspberries). Food and drink represent approximately 30% of total exports. The production of food products and beverages accounts for 24% of industrial production. Cereal (wheat, corn) production is important and is approximately three times that of the European countries (34% in Serbia compared to 11% in the EU). Milk production however has decreased. Similarly the number of all animal herds has declined-most noticeably that of cattle. Pig production represents the largest (3.3 million head) but is 8% lower than in 2001. Pigmeat production at 59% (2011) of total meat production is higher than the EU average (52%).

Two principal organisations are involved in food safety: The Ministry of Agriculture, Forestry and Water Management (MAFWM) and the Ministry of Health (MoH) including the Secretariat for Health in the autonomous Province of Vojvodina. Within MAFWM there are four responsible directorates: Veterinary; Plant Protection; General and the Directorate for National Reference Laboratories (DNRL). Analytical studies and compliance monitoring are conducted by a range of official and authorised private laboratories and institutes, accredited to ISO 17025. Such accreditation enhances the credibility, and hence acceptance, of results obtained and is important in facilitating trade. The Accreditation Body of Serbia (ATS) therefore is responsible for the accreditation of certifying bodies and Serbia also co-operates with other international quality assurance organisations.

Both MAFWM and MoH are responsible for the development of food safety legislation of which The Law on Food Safety (Official Gazette RS no.41/09), which reflects the requirements of the EU General Food Law Regulation 178/2002, is the most important. The Law on Food Safety also puts in place the delegation of responsibilities, management and organisation of official controls which are conducted based on risk assessment. Official controls are developed and managed centrally but are delegated and undertaken at regional and local level and at the border.

The European Commission Serbia 2012 Progress report and recent FVO mission reports have all confirmed that the Serbian competent authorities have a clear structure and that organised official controls are carried out.

Serbia is bordered by a number of countries and has a number of border inspection posts (BIPs). Funding has been received via IPA to enhance the BIP facilities and IT systems.

Although certain animal diseases are endemic in Serbia the animal health situation is said by the competent authority to be favourable. Serbia is a member of the World Organisation for Animal Health (OIE) and fufils its obligations for the notification of animal diseases. It also undertakes notifications to the European Animal Disease Notification System (ADNS). Notifiable diseases are those identified by OIE and within Serbia rulebooks lay down the surveillance requirements and the actions to be taken in the case of the identification of a notifiable disease. Inspections and enforcement actions are taken by the Veterinary Inspectors. Pigs are the largest animal herds and particular support has been received in relation to the control and eradication of Classical swine fever as this would enable Serbia to export pig meat to the EU.

A number of establishments are now approved to export products of animal origin to the EU.

Serbia is developing systems to establish the Rapid Alert System on food and feed (RASFF) and to contribute to the European system. Products from Serbia have been the subject of a number of notifications under the European RASFF system. The most recent incidents have involved plant products, specifically norovirus in frozen raspberries and aflatoxins in maize.

Serbia has developed a national plan (NPAA) for the further transposition, implementation and enforcement of the *acquis* from 2013 – 2016. This details the legislation to be transposed, the resources available and those which are still required including additional staff, facilities and capability to conduct official analyses. Similarly the EC Progress report 2012 identified the need for further strengthening of the administrative capacity (to address the lack of resources in terms of personnel, training, equipment and IT) of those institutions involved in monitoring food chain safety, in particular the veterinary, phytosanitary and national reference laboratories.

# 1. INTRODUCTION

This briefing on food safety in Serbia has been prepared for the Environment, Public Health and Food Safety Committee (ENVI) Delegation to Serbia from 28 - 30 October 2013.

# 1.1. Aim

This report provides a summary of Serbia's food and drink industry and an overview of the food safety and control system in Serbia, the risk management and risk communication of animal diseases and the status of preparation of Serbia against the *acquis* in the area of food safety.

# 1.2. Method

#### 1.2.1. Sources of information:

The websites and official publications of the relevant regulatory and other authorities in Serbia were examined. Serbia has been subject to a number of FVO audits during the last five years (2008 – 2012) the most recent reports of which have also been considered.

Relevant scientific literature was also searched.

# 1.3. Map of Serbia

Map 1: Map of Serbia



Source: UN Cartographic section - Map of Serbia

# 2. FOOD PRODUCTION AND EXPORTS

#### **KEY FINDINGS**

- Serbia produces a variety of agricultural products including cereals (maize and wheat), fruit and vegetables (plums, raspberries, grapes, sugarbeet, potatoes) and livestock
- There are still many small farms and enterprises. Agriculture employs 20% of the workforce and represents 17% of the GDP
- · Serbia is a net exporter of food
- The EU is the main trading partner of Serbia
- Food and drink account for 24% of industrial production and 30% of total exports
- The food, agriculture and beverage sector attracted a large proportion of the foreign direct investment with a number of large international companies having a presence in Serbia

This chapter provides general information on Serbia and the Serbian food industry.

The Republic of Serbia was granted the status of candidate country of the European Union (EU) on 1 March 2012. It is the second most populous of the enlargement¹ countries having a population of 7.2 million in 2011. Administratively Serbia is divided into provinces (The two autonomies – Vojvodina and Kosova-Metohija²); five regions (Belgrade, Vojvodina, Sumadija and western Serbia, eastern and southern Serbia and Kosova-Metohija), the City of Belgrade as a separate territorial unit; 29 administrative areas (districts); 23 cities; 150 municipalities; 6,158 villages and 195 urban settlements. The 29 districts are regional centres of state authority.

Historically small farms and domestically orientated processing plants predominated. The farm structure in Serbia is reported to be changing with the gradual emergence of a commercial farm sector employing modern agricultural technology in response to the challenge of the modern market. Many small farms continue to produce in the traditional ways and market through informal channels. However when supplying processors they do not have a strong negotiating position and the economic options for small farmers remain limited (World Bank Group, 2013). The Serbian government provides support for export to industry development projects (including food) by attracting foreign investments. In particular support is provided for those that adopt advanced technologies, have a trained workforce, are of potential high value, involve small and medium enterprises or involve an increase in employment (NPAA).

Approximately 20% (5% EU average) of the workforce is employed in the agriculture sector and 52% (70% EU average) in the services sector (Eurostat, 2013).

The most important agricultural products in Serbia are: maize, wheat, sunflower, sugar beet, soya bean, potato, apple, plums, grapes, pork meat, beef, poultry meat and dairy (Serbian Chamber of Commerce)

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<sup>&</sup>lt;sup>1</sup> Enlargement countries include Albania, Bosnia and Herzegovina, Iceland, Kosovo, Montenegro, the Former Republic of Macedonia, Serbia and Turkey (at approximately 74 million in 2011 Turkey has the largest population of the enlargement countries)

This designation is without prejudice to the positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

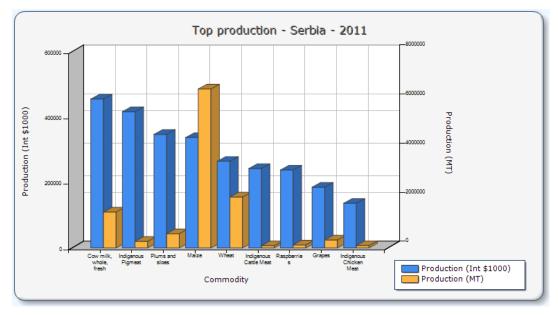


Figure 1: Commodity production 2011

Source: FAOstat

The utilised agricultural area, over half of which is arable, has remained stable during 2001 – 2011. Representing 65% of the total land area this is the highest proportion for all enlargement countries. Cereals production has increased slightly between 2001 – 2011 and that of sugarbeet has increased particularly. Cereal (wheat, corn) production is important to Serbia and the share of cereals in the total production value in Serbia is approximately three times that of the European countries (34% in Serbia compared to 11% in the EU) (World Bank Group, 2013). Milk production however has decreased. Similarly the number of all animal herds has declined - most noticeably that of cattle. Pig production represents the largest (3.3 million head) but this is 8% lower than in 2001. Pig meat production at 59% (2011) of total meat production is higher than the EU average (52%) (Eurostat 2013).

Although the proportion of primary agriculture in Serbia's GDP has been steadily decreasing over the last 10 years (13.1 - 10.0%), Serbia is still a net exporter of food. The share of agricultural products in Serbia's total exports increased from 7.9% in 2011 to 8.5% in 2012 (World Bank Group, 2013).

The EU is the main trading partner of Serbia accounting for 57.7% of total exports. The value of Serbia's exports has more than doubled over recent years whilst the value of imports has increased less than that of the EU average (62% vs 75%). Due to the difference in value however Serbia has a net trade deficit with the EU (Eurostat 2013).

The production of food products and beverages accounts for 24% of industrial production. Increasing competiveness, finding new markets, adapting to the rules and standards of the EU and WTO, adopting new technologies and methods to meet local and international requirements are all challenges facing agriculture and of food production (Serbian Chamber of Commerce 2013; Cvijanovic, D et al 2012).

Food and drink represent approximately 30% of total exports. The export structure (total) for agricultural products is shown in Figure 2.

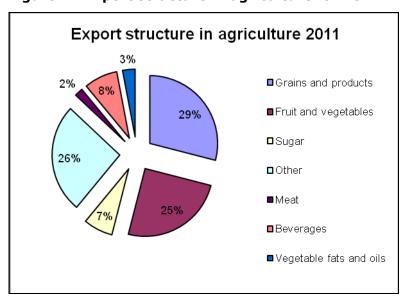


Figure 2: Export structure in agriculture for 2011

Source: Chamber of Commerce and Industry of Serbia

Serbia is integrated with the global markets and felt the effects of the global market crisis and, after a slight recovery, the economy is back in recession (Eurostat, 2013).

The World Bank attributes high volatility in the prices of many agriculture and food products to a lack of competition and efficiency in the marketing chains. Various projects<sup>3</sup> have been supported by the International Finance Corporation (IFC) aimed at the development of the private sector and revitalising agribusiness.

Small and medium enterprises (SMEs) represented 99.8% of all enterprises in Serbia in 2011 and are reported to be dominated by micro- and small enterprises (NPAA 2013-2016). The Serbia Investment and Export Promotion Agency (SIEPA) assists SMEs to internationalise their business and links them to multinational companies to encourage their integration with the supply chain (SIEPA 2013; SEIO 2013, henceforth referred to as NPAA). The food, agriculture and beverage sector attracted a large proportion of the foreign direct investment during the period 2001 – 2011 whether in terms of value (approximately 15%) or of the number of projects with a number of prominent international companies having a presence in Serbia (Ministry of Foreign and Internal Trade, SIEPA).

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<sup>&</sup>lt;sup>3</sup> Examples include:

Vino Zupa – A producer of both alcoholic beverages and fruit juices and other products made from fruit and vegetables. It was privatised in 2002. Investment for a number of aspects of the business including adding capacity (increasing production from 2 million to over 90 million litres); improve efficiencies, remove bottlenecks.

<sup>•</sup> Victoria group – Process soybean and sunflower oilseeds and grain trading. Investment was to restructure the group, strengthen the support given to farmers, address food security concerns and increase sustainability of the group's operations.

MK Group – Privately owned. Market leader in its areas of crop production, sugar production, storage, transport
and trading of agricultural commodities. Loan to expand further into meat and livestock production (via the
acquisition of Carnex AD), and the expansion of the modernisation and expansion of the Group's primary
agriculture operations. The loan supports the development of the private sector in Serbia.

# 3. STRUCTURE OF THE FOOD SAFETY AND CONTROL SYSTEM

#### **KEY FINDINGS:**

- Two principal organisations are involved in food safety: The Ministry of Agriculture, Forestry and Water Management (MAFWM) and the Ministry of Health (MoH) including the Secretariat for Health of the autonomous Province of Vojvodina
- Within MAFWM there are four responsible directorates: Veterinary; Plant Protection; General Inspectorate and the Directorate for National Reference Laboratories (DNRL)
- The Law on Food Safety reflects the requirements of the EU General Food Law Regulation 178/2002
- Analytical studies and compliance monitoring are conducted by a range of official and authorised private laboratories and institutes which are accredited to ISO 17025
- Serbia is bordered by a number of countries and has a number of border inspection posts (BIPs)

This chapter provides an overview of the structure of the food safety and control system in Serbia.

A National Plan for the adoption of the Acquis 2013 - 2016 (NPAA) was adopted by the Serbian government on 28 February 2013. This details the plan for legislative alignment with the corresponding budgetary resources (European Commission, 2013). The Serbian government provides update reports of progress against the NPAA.

# 3.1. Principal Organisations

The principal organisations involved in food safety are:

Ministry of Agriculture, Forestry and Water Management (MAFWM)

MAFWM is the competent authority (CA) responsible for veterinary, phytosanitary and food safety policies (safety of food of animal origin, composite food, food of plant origin and feed). It consists of four directorates / inspectorates namely:

- Veterinary;
- Plant Protection;
- General Inspectorate;
- o Directorate for National Reference Laboratories.

Table 1 indicates their areas of responsibility.

Veterinary, phytosanitary and agricultural inspections are carried out in both domestic and foreign (border inspection) trade. Official controls are managed centrally but are delegated and undertaken by inspectors at the regional and local level and at the border.

The National Reference Laboratories Directorate (DNRL) was established in 2009. A draft proposal amending the Law on Food Safety to determine the legal status of the National Reference Laboratories (NRLs) has been prepared. The Law on Food Safety states that the DNRL, and laboratories undertaking testing and participating in the monitoring programme, must be accredited according to international standards<sup>4</sup>.

<sup>&</sup>lt;sup>4</sup> EN ISO 17025; General requirements for the competence of testing and calibration laboratories; EN 45002 General criteria for the assessment of testing laboratories, EN 45003 Calibration and testing accreditation systems: General requirements for operation and supervision.

**Table 1: Organisation of responsibilities** 

Ministry	organisation of respons	Ministry of Agriculture, Forestry a	nd Water Management (MAFWM	)	Ministry of Health (MoH) and Secretariat for Health of the Province of Voivodina (SH)
Directorate	Veterinary	Plant Protection	General inspection	National Reference Laboratories	Sanitary inspection of the MoH and SH
Area of responsibility	<ul> <li>Veterinary inspection</li> <li>Foods of animal origin</li> <li>Animal health</li> <li>Animal welfare</li> <li>Composite food</li> <li>Residues of veterinary drugs and pesticides</li> <li>GMOs</li> <li>Enzyme preparations of animal origin</li> <li>Feed</li> </ul>	<ul> <li>Plant origin (Plant health)</li> <li>Harmful organisms</li> <li>Plant protection products</li> <li>Plant nutrition product</li> <li>Establishing MRLs of pesticides in food and feed</li> <li>Seeds and planting material</li> <li>Registration of plant varieties</li> <li>Plant variety protection</li> <li>GMOs (Biosecurity)</li> </ul>	Phytosanitary inspection Agricultural inspection Food and feed of plant origin Wine, spirits and alcohol  Plant health / Quarantine Quality of PPPs, PNPs Primary and simple processed products Seeds and planting material GMOs Feed Processed food — processing and wholesale Residues of pesticides Composite foods (sweets, bakery products, soup) Non-alcoholic drinks and beverages Spirits Wines	National Reference laboratories  Residues Phytosanitary Planting material and seed Food  Official Laboratories  Agricultural services Faculties Institutes Private	Novel food Infant formula Dietary supplements Additives, flavourings, enzyme preparations and supplementary agents of non-animal origin Salt (human consumption) Water (public water supply)
Services	Veterinary services Authorised veterinary stations Veterinary institutes Residue and BSE laboratories	Agricultural services Agricultural stations			Institutes and offices for public health
Food chain responsibility	Primary production of animal products – Farms  Food business operators – food of animal origin  Retail	Primary production of plant products	Food business operators – foods of plant origin		Food business operators

**Source:** Pre-accession questionnaire SEIO, 2011

In addition to the NRLs there are also a number of state laboratories, contracted laboratories, official testing stations and institutes and private laboratories authorised to conduct particular tests.

- Ministry of Health (MoH)
   MoH, along with MAFWM is responsible for the drafting of food safety legislation.
   In the autonomous province of Vojvodina those tasks related to food safety which fall under the competency of the Ministry of Health have been conferred to the Secretariat for Health of the Province of Vojvodina; control over the deferred tasks is carried out by the Ministry of Health.
- Ministry of Internal and External Trade and Telecommunication (MoTT)
   The Market Inspection department is responsible for inspecting food quality at the retail level.

# 3.2. Border controls

Serbia is bordered by a number of countries, four of which are EU member countries (Bulgaria, Croatia, Hungary and Romania), two are candidate countries (the former Yugoslav Republic of Macedonia and Montenegro) whilst Albania, Bosnia and Herzegovinia and Kosovo<sup>5</sup> are all potential candidate countries.

There are 71 border crossings on the territory of the Republic of Serbia, although not all interchange with the EU:

Table 2:	Border crossing	points in the	<b>Republic of Serbia</b>
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Category of traffic	Number of BCPs	Type of traffic				
category of traffic	Number of Bers	Road	Railway	River	Air	Ferry
International	60	36	11	10	3	0
Inter-state	2					
Local cross-border	8					
Exceptional	1					

**Source**: Serbian Government - Integrated border management strategy in the Republic of Serbia

Four services in three main ministries are involved in border management although additional Ministries may be involved in relation to some specific aspects.

- Ministry of Internal Affairs Border Police
- Ministry of Finance Customs
- Ministry of Agriculture, Forestry and Water Management
  - Veterinary Inspection
  - o Phyto-sanitary Inspection

The Republic of Serbia is implementing a strategy for integrated border management. This establishes the national goal, the roles and responsibilities of the border services, the responsibilities of individual sectors and the requirement for these to collaborate and coordinate in the implementation of common functions (training, telecommunications and information technology systems, infrastructure and equipment).

This designation is without prejudice to the positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

All border services are also required to co-operate with other state bodies, institutions and international organisations (Serbian Government).

Those border posts where veterinary and / or phytosanitary inspection posts exist are given in Table 3.

Table 3: Border crossings operating veterinary and / or phytosanitary inspection<sup>6</sup>

Border	Type of	Category of	Border	Customs	Veterinary	Phytosanitary	Port
Crossing Point	traffic	Traffic	Police		Inspection	Inspection	Authority
Kotroman	Road	International	*	*		*	
Mali Zvornik	Road	B&H	*	*	*	*	
Sremska Raca	Road	B&H	*	*	*	*	
Batrovci	Road	Croatia	*	*	*	*	
Bogojevo	Road	International	*	*		*	
Horgoš	Road	Hungary	*	*	*	*	
Vatin	Road	Romania	*	*	*	*	
Gradina	Road	Bulgaria	*	*	*	*	
Preševo	Road Railway	Macedonia	*	*	*	*	
Šid	Railway	Croatia	*	*	*	*	
Subotica	Railway	Hungary	*	*	*	*	
Vršac	Railway	Romania	*	*	*	*	
Kikinda	Railway	International	*	*		*	
Dimitrovgrad	Railway	Bulgaria	*	*	*	*	
Bezdan	River	Hungary	*	*	*	*	*
Veliko Gradište	River	Romania	*	*	*	*	*
Surcin- Belgrade	Air	International	*	*	*	*	
Prijepolje	Railway	Montenegro			*		
Gostun	Road	Montenegro			*		
Merdare	Road	Kosovo & Metohija			*		
Rudnica	Road	Kosovo & Metohija			*		
Tabanovei	Road	Kosovo & Metohija			*		
Konculj	Road	Kosovo & Metohija			*		

Source: Integrated Border Management Strategy in the Republic of Serbia and Pre-assessment questionnaire

Serbia has continued to improve the infrastructure and equipment at border crossing points and participates in the West Balkans Risk Analysis Network. The European Commission 2012 Progress report states however that operational coordination between border police, customs and phytosanitary services remains to be improved.

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<sup>&</sup>lt;sup>6</sup> An agreement on integrated border / boundary management was agreed with Kosovo in February 2012, revised in September but is yet to be signed by Serbia. There is reported to be considerable traffic using unregulated crossing points into and from Serbia (European Commission, 2012).

Further modernisation and upgrading of equipment and infrastructure was also identified as being required both at crossing points and for surveillance purposes and that not all meet the required standards. The BIP at Horgos was constructed and equipped as part of the project to refurbish BIPs supported by the EU and does meet the required standard. In addition funding was received following an agreement in 2011 for the building and reconstruction of border crossings at Preševo and Batrovci.

Harmonised regulations with regard to international trade, certification and veterinary border control have been adopted and are being implemented. IT systems were also identified as requiring improvement including a central database to connect all border crossings with the Veterinary Directorate and laboratories to enable exchange of results. Similarly connection to all warehouses and production facilities storing imported consignments is required to achieve traceability. Freight companies also need limited access to be able to pre-register consignments. The system should also be integrated with that of Customs.

# 3.3. Legislation

The National Assembly of Republic of Serbia is responsible for enacting laws proposed by the Serbian Government. Ministries and special organisations adopt rulebooks, orders and guidelines for the enforcement of laws and other regulations.

A number of new laws have been introduced in recent years in the area of agriculture, food and feed.

The main item of legislation is the Law on Food Safety (Official Gazette RS no.41/09) which is harmonised with Directive 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and complying with the agreement on the Application of Sanitary and Phytosanitary measures of the World Trade Organisation (WTO). Thus the Law governs the general conditions for the safety of food and feed, duties and responsibilities of food and feed business operators, the establishment of the rapid alert system, emergency measures and crisis management, food and feed hygiene and quality.

The Law on Food Safety also puts in place the delegation of responsibilities, management and organisation of official controls (as discussed in section 3.1) so that there is no overlap or uncertainty of competency, as occurred previously. Controls are conducted in accordance with a risk assessment (GAIN 2012).

Along with the Law on Food Safety the Law on Veterinary Matters (Official Gazette 91/2005, 30/2010 and 93/2012) and on Animal Welfare (Official Gazette 41/2009) create the legal basis for the transposition of veterinary regulations covering feed and animal byproducts, animal health protection and animal welfare, international trade, certification and veterinary control. Regulations are accompanied by guidelines and instruction documents to facilitate their implementation.

The Law on Plant Protection Products (PPPs) (Official Gazette of RS 41/2010) was introduced and harmonised with Directive 91/414/EEC. However following the adoption in 2009 at the EU level of a new legislative framework concerning pesticides which introduces new rules for the authorisation of active substances and PPPs as from June 2011 the current control and authorisation of PPPs in Serbia is complex. The Law on Plant Protection Products is not fully implemented. The Serbia 2012 progress report stated that the registration system for new PPPs is not harmonised with the EU *acquis* and that an official monitoring programme for pesticide residues that meets EU requirements is yet to be established. The NPAA contains details of the planned legislative activities in this area and

An FVO audit in September 2012 evaluated the controls of pesticides in food of plant origin (FVO, 2012). This report concluded that the controls in place provided sufficient guarantees that fruit and vegetables exported to the EU meet EU requirements. Since 2009 there has only been one notification via the RASFF system concerning pesticide residues which related to nicotine in mushrooms from Serbia.

The audit report found however that there were a number of shortcomings including:

- The implementation of training of distributors and users of PPPs, controls on the use of PPPs and national control programme for pesticide residues
- The analytical scope of the control laboratory was very limited

Although the competent authority was aware of these findings and had developed plans to address them it was reported that lack of financial resources was preventing their implementation.

# 3.3.1. Other relevant legislation

amendments to the Law.

A number of individual laws have been introduced and contribute to establishing the legal framework for the adoption of regulations to conform with the EU *acquis* including: The Laws on Food Safety, Veterinary Medicine, Animal Welfare, Plant Health, Plant Protection Products.

In addition laws on other areas are also in progress including:

- Food labelling
  - A working group for developing a draft rulebook on food labelling, presentation and advertising has been formed, in co-operation with the MAHRW and the MoH. Legislation will be harmonised with Directive EC 2000/13 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. A guide to accompany the Rulebook is also being prepared to assist food business operators and inspectorates.
- Genetically Modified Organisms (GMOs) The Law on Genetically Modified Organisms (Official Gazette 41/2010) and the Law on Food safety govern the use of GMOs. It has been proposed however that reference to GM is removed from the Law on Food Safety. The Law on Genetically Modified Organisms bans the commercial growing of GMOs and the placement on the market of GMOs and GM products. This is not consistent with the WTO Free Trade Agreement or with EU Legislation in this area and the law therefore requires amendment to bring it line with WTO and EU requirements. Comments have been submitted to the Expert Council on Biosafety which will then deliver its opinion and a proposal to MAFWM on
- Other areas
   Rulebooks to transpose the regulations for food additives, materials and articles in contact with food and nutrition labelling and health claims are also in progress.

# 3.4. Other Organisations

#### 3.4.1. Accreditation and Standardisation

In Serbia accreditation<sup>7</sup> is granted by the Accreditation Body of Serbia (ATS) which is responsible for accrediting bodies who then certify the implementation of quality management systems such as ISO 22000 Food Safety Management and HACCP systems. ATS is itself a member of European and international accreditation bodies. A number of European accreditation bodies also have offices in Serbia.

The adoption of a quality infrastructure, and the membership of and recognition by European and international institutions for compliance assessment, is seen to be important in facilitating the trade of Serbian goods by enabling the mutual recognition of product testing results and certificates issued by Serbian authorities.

The Institute for Standardisation for Serbia (ISS) has adopted a majority of required European standards.

#### 3.4.2. Trade and Academic institutions

A number of academic institutions have departments (eg University of Belgrade - Veterinary and Agriculture faculties) which undertake research contributing to the food industry and the area of food safety. These laboratories may also form part of the laboratory network contracted to undertake laboratory analysis in relation to official controls.

There are a number of institutes which either undertake research or provide services, assistance, guidance and information to their members including Institute of Meat Hygiene and Meat Technology and the Institute for Science Application in Agriculture.

#### 3.4.3. Other government departments

The Chamber of Commerce promotes Serbian business and the Statistical Office records key statistical information. Within the Chamber of Commerce the Association of Agriculture, food industry, tobacco industry and water management focuses on agriculture and the food industry.

# 3.4.4. European and International collaboration

Serbia is not currently a member of the World Trade Organisation (WTO) but, as discussed above, is harmonising its legislation in order to progress the accession process.

Serbia is a member of Codex Alimentarius, the European Plant Protection Organisation (EPPO), the Convention on Biodiversity (CBD), the Union of Protection of New Varieties of Plants (UPOV), the World Intellectual Property Organisation (WIPO), the European Cooperative Program for Crop Genetic Resources Networks (ECP/GR) and is a signatory of the Aarhus Convention and the International Plant Protection Convention (IPPC).

Accreditation is a process conducted by a national accreditation body upon which it determines and verifies that a specific organisation meets the requirements necessary to perform certain conformity assessment activities laid down in relevant international standards and that it is competent to perform the said activities.

# 4. RISK MANAGEMENT AND RISK COMMUNICATION OF CERTAIN ANIMAL DISEASES

#### **KEY FINDINGS**

- In general FVO reports comment that animal health conditions are favourable although recommendations were made to the CA in a number of areas
- Serbia has joined the system for tracking the movement of animals and products of animal origin (TRACES) which is functioning for bovine animals but that of pigs, sheep and goats has yet to start (due 2013).
- A number of establishments are now approved to export products of animal origin to the EU. A national programme to upgrade establishments producing food and a management strategy for animal by-products is underway.
- Salmonellosis, Campylobacteriosis and Trichinellosis are the most common zoonoses. Incidences of the latter have more than doubled in recent years.
- Products from Serbia which have been the subject of notifications in the RASFF system particularly relate to fruit and vegetables and most recently (2013) norovirus contamination of frozen raspberries and aflatoxin contamination of maize

This chapter reviews the current situation relating to the system of risk management and risk communication of animal diseases, the prevalence of animal diseases (in particular classical swine fever) and also the occurrence of zoonoses. The animal products which Serbia mainly exports to the EU are honey, dairy products and bovine meat.

# 4.1. Risk management and risk communication

The Law on Food Safety delegates responsibility on food safety between and within the MAFWM and the MoH (as discussed in Chapter 3). It also defines the principles of risk analysis, assessment and management. Planned and targeted official controls of establishments are performed by inspection, in accordance with the Law on Food Safety and are based on risk assessment.

The Law on Food Safety provides for the establishment of the Expert Council for Risk Assessment in the Field of Food Safety. The Expert Council is to continually monitor and carry out risk assessment relating to food and feed safety, propose decisions on professional decisions and render scientific and expert assistance in decision making and preparing food and feed regulations. Until this is established risk assessment and risk management is carried out by each ministry according to their competencies (Serbia – Preaccession questionnaire responses).

A Food Safety Council also needs to be established in order to take an active part in the preparation of technical and scientific opinions for ministries and other interested parties, in the collection and analysis of scientific and technical data regarding food and feed safety risks and production of guideline documents on various topics including good agricultural and hygiene practices (NPAA).

The Law on Food Safety obliges producers (food business operators) to be responsible for their products and to implement self-control systems based on HACCP principles. The requirement for production according to HACCP principles and the voluntary accreditation to quality management and food assurance systems is also driven by the larger multinational producers or retailers who also set their own standards (Djekic et al 2011; Toamasevic, 2013).

The notification of animal diseases is the responsibility of all in the food chain.

# 4.1.1. Implementation of RASFF

MAFWM, MoH, Expert Council on Food Safety, DNRL as well as laboratories authorised for food safety are the organisations identified as those to be involved in the RASFF system which was also to have a defined national contact point, organisational structure and communication procedure established (Pre-accession questionnaire).

The Rulebook on the establishment and organisation of the rapid alert system for food and feed has been published (Official Gazette 62/13). By the time of the delegation visit this should have been implemented and the RASFF system incorporated into the European Union international level systems (NPAA 2013-2016).

#### 4.1.2. Market surveillance

The Market Surveillance Strategy (Official Gazette No 68/10) was adopted in September 2010. This strategy requires the relevant surveillance and enforcement authorities to cooperate and hence develop a co-ordinated unified approach and also to adopt the application of risk based methods of assessment.

An IPA project (IPA, 2010) began in July 2012 and runs until July 2014 aimed at strengthening the Serbian system for the surveillance of both non-food and food products. As well as establishing the Council for Product Safety this project will assist with the transposition of the relevant legislation, the development of the information systems required and the education of inspectors.

# 4.2. Overview of Animal Diseases

Serbia is a member of the World Organisation for Animal Health – Office for International Epizoonoses (OIE) and fulfils its obligations to report incidences of animal disease. FVO audits conducted in 2011 (FVO 2011a,b) made a number of recommendations but concluded there was a robust and comprehensive system in place of animal health controls and that the animal health situation appeared to be favourable according to information provided by the competent authority.

The Law on Veterinary Matters (Official Gazette of RS 91/2005, 30/2010 and 93/2012), the Law on Food Safety (Official Gazette 41/2009) and the Law on Animal Welfare (Official Gazette 41/2009) have created the legal basis for the transposition of veterinary regulations covering feed and animal by-products, animal health protection and animal welfare, international trade, certification and veterinary control. The regulations are accompanied by guidelines and instructions. Surveillance measures for contagious animal diseases are given by the Law on Veterinary matters and the Rulebook on the list of particularly contagious animal diseases and the list of compulsory notifiable animal diseases as well as the notification procedure. Compulsory notifiable diseases are those identified by OIE.

Official controls are carried out by veterinary inspectors in production, internal and export trade in accordance with the laws and adopted plans and programmes of control. The inspectors receive education and training accordingly.

FVO missions in 2011 (FVO, 2011a,b,c) were conducted at the request of the Serbian authority to approve Serbia for the export of certain live animals (cattle and poultry) to the EU. At that time however the CA was not in a position to provide adequate guarantees for live cattle to be exported to the EU. Herds had not been granted the status of being officially free from tuberculosis, bovine brucellosis and enzootic bovine leukosis, diseases which the CA acknowledged were endemic but occur at relatively low levels. Measures are in place for the surveillance and control of these diseases.

Similarly an audit was undertaken of the animal health controls of live poultry. Of the main diseases associated with poultry, Avian influenza (AI) has not been reported since 2006 and Newcastle disease (ND) since 2007 (OIE). At the time of the audits there was no monitoring programme in place for AI although a new programme was being drafted. ND vaccination was applied to all poultry whilst a programme existed for the monitoring of Salmonella in live flocks it had not then been submitted for approval.

## 4.2.1. Classical swine fever<sup>8</sup>

Classical swine fever (CSF), also known as hog cholera, is a contagious viral disease of domestic and wild swine. Humans are not affected by the virus. Pigherds represent the largest animal population. Animal diseases obviously affect the health of the animal and prevent the efficient production and trade of food of animal origin. Serbia was an exporter of pork meat to the EU. Once the CSF situation has improved Serbia will request permission once again to export pigmeat to the EU.

Support has been received under the IPA project Support for the control / eradication of Classical Swine Fever and Rabies in Serbia since 2008 and latterly under the IPA 2012 project Capacity building in the field of zoonoses and foodborne diseases and continued support for the control / eradication of Classical swine fever and rabies which is near completion. The aim of this project was to prevent the development and spread of animal diseases and their transmission to humans, to control and reduce antimicrobial resistance in food, food animals and humans.

Suppression and eradication measures for CSF are given in the Rulebook on Defining the measures for the early identification, diagnosis, prevention and eradication of the contagious disease CSF (Official Gazette 102/2009). The Ministry is to be informed of every occurrence and suspected occurrence of CSF. CSF was last reported in Serbia in March 2013 (OIEa).

Instructions were adopted for risk analysis at pig farms based on bio-safety questionnaires.

#### 4.2.2. Other animal diseases

Specific rules also exist for the control of Foot and Mouth Disease, African swine fever, Avian influenza, Newcastle disease, Fish and mollusc diseases, Bluetongue disease, Transmissable spongiform encephalopathies (TSE) and zoonoses. No cases of TSE have been reported in Serbia.

# 4.2.3. Veterinary medicinal residues

Animal diseases may be treated by the use of veterinary medicines. Products that can be used and the level of residues and contaminants in live animals and animal products is controlled by legislation in the EU. A recent FVO mission reported (FVO, 2013a) that Serbia has a National Residue Monitoring plan in place which is in line with EU requirements and that sampling is carried out in a timely manner, is co-ordinated and comprehensive. However testing was found to be limited in scope, the sampling strategy inadequate and shortcomings in follow-up procedures were identified in some areas. Deficiencies in method

<sup>&</sup>lt;sup>8</sup> CSF is a notifiable disease. Treatment is not attempted. Acutely infected animals die within 1 -2 weeks. Chronically infected animals may show no clinical symptoms but can shed the virus in their faeces. Offspring of infected sows can become infected in the uterus and also shed the virus. In areas where the disease is endemic, vaccination can prevent its spread. In disease-free areas, a stamping out policy is applied consisting of early detection, movement control, proper disposal of carcasses, and cleaning and disinfection. CSF virus can survive in pork and processed pork products for months when meat is refrigerated and for years when it is frozen. Pigs can become infected by direct contact between healthy and infected animals and by eating CSF-infected pork meat or products. The wild boar population has also been shown to play a part in the epidemiology of the disease (OIEb).

# 4.2.4. Traceability

In January 2012 Serbia joined a system for tracking the movement of animals and products of animal origin (TRACES) and training of staff is underway.

The identification, registration and movement of bovine animals is fully functional and integrated in the Laboratory Information System (LIMS). The registration of pigs, sheep and goats and their movements has yet to be completed (Progress report 2012) and is now currently scheduled for activation in the second quarter of 2013 (NPAA).

All regulations in the field of animal marking and traceability are harmonised with those of the EU.

# 4.2.5. Approval of establishments

During the transposition of regulations relating to the 'Hygiene Package' the application of hygiene standards, the awareness among the food business operators and the animal byproduct management were found to be inadequate. Deficiencies were identified in the structure, layout-out, equipment and maintenance of establishments; incomplete documentation and records; the absence of or inadequate HACCP plans; traceability of raw material and products; own checks and animal welfare (FVO, 2006).

A national programme for upgrading the establishments producing food and a management strategy for animal by-products is underway. Funding has been obtained via the IPA 2012 (NPAA) and the project is expected to start in the second half of 2013.

A number of establishments are now authorised to export products of animal origin to the EU. This approval depends upon the implementation of all adopted regulations by all responsible services, institutions, businesses handling food and other interested parties. Employees of the Veterinary Directorate, food business operators, veterinary inspectors, representatives of laboratories and universities have attended seminars on animal health protection and animal welfare, food safety, feed and animal by-products, international trade and certification.

Establishments authorised to export to the EU include: 5 exporting beef; 1 exporting poultry; 1 exporting meat preparations and MSM products; 6 exporting meat products; 3 exporting milk and dairy products; 18 exporting products from establishments that collect and handle animal by-products and 24 processing animal by-products.

### 4.3. Zoonoses in Humans

A zoonoses is any disease or infection that is naturally transmissible from vertebrate animals to humans. Animals thus play a part in maintaining zoonotic infections in nature. Zoonoses may be bacterial, viral or parasitic or may involve unconventional agents. As well as being a public health problem, many of the major zoonotic diseases prevent the efficient production of food of animal origin and create obstacles to international trade in animal products (WHO, Health Topics, Zoonoses).

According to information from OIE the most common instances of infection with zoonoses in Serbia are Salmonellosis, Campylobacteriosis and Trichinellosis. Cases of Salmonellosis (2046, 1722, 1904) and Campylobacteriosis (396, 357, 298) have varied slightly but have remained of the same order during 2009 – 2011 whilst those of Trichinellosis<sup>9</sup> have more than doubled from 50 to 127 during this time.

Trichinellosis, also called trichinosis, is a disease that people can get by eating raw or undercooked meat from animals infected with the microscopic parasite *Trichinella* typically raw or undercooked pork or game.

One of the planned measures for 2014 – 2016 is a Rulebook on methods for the control of Trichinella in meat (in line with Regulation (EC) 2075/2005 laying down specific rules on official controls on Trichinella in meat) including the aims to develop a reference method for laboratory testing and the possibility of obtaining Trinchinella-free status for some farms.

Similar rulebooks are in place for measures to suppress and eradicate Salmonella serotypes in poultry.

# 4.4. Rapid Alert System for food and feed (RASFF)

Products originating from Serbia have been the subject of 48 notifications from 2008 – 2013 (RASFF portal database) with the three categories most often responsible for these notifications being Confectionary (5), fruit and vegetables (21) and nuts, nut products and seeds (6) including:

- 4 instances of hepatitis A contamination in frozen berry mix May Aug 2013
- 4 instances of Salmonella infantis contamination in "munchmallows" Jan/Feb 2012
- 11 instances of Norovirus contamination in frozen raspberries and blackberries
   Oct 2009 Oct 2011
- 5 instances aflatoxin presence in peanuts processed in Serbia (originating from China and Argentina) March 2008

The number of notifications from products from Serbia increased from 4 in 2009 to 12 and 11 in 2010 and 2011 respectively before reducing to 4 again in 2012.

# 4.4.1. Particular incidents in the RASFF system

# Norovirus contamination of raspberries

Raspberries represent one of the main products exported from Serbia to the EU.

The number of notifications related to norovirus<sup>10</sup> contamination of raspberries from Serbia and the volume of exports of this commodity (67,626 tonnes of frozen raspberries in 2011) formed the background to a recent FVO audit carried out in Serbia during May 2013 (FVO, 2013b), as summarised below. A Norovirus foodborne outbreak is usually as a result of eating contaminated foodstuff. Raspberries from Serbia were linked to Norovirus outbreaks in some member states (MSs). In 2011 raspberries from Serbia were related to a food outbreak involving 237 cases which were all reported from Denmark.

Frozen raspberries are exported to the EU via road transport, the main importing MSs being Germany, France, United Kingdom and Belgium.

There are 25,000 raspberry growers in Serbia with the majority being small-scale farmers. The main growing areas are located in Zlayibor, Morava, Macva, Jablanica and Kolubara districts. Most raspberries are frozen and stored in cold stores prior to export. 370 cold stores hold soft fruit of which 212 carry out processing (deep freezing) and of these 130 are export orientated. The processing of raspberries is usually conducted near to the area of production.

Noroviruses are a group of highly contagious viruses that are the most common cause of stomach bugs (Gastroenteritis). They typically cause vomiting and diarrhoea lasting 2-3 days. More serious cases can result in hospitilisation and sometimes death.

The FVO audit report concluded that official controls on the production and processing of raspberries are in place and based on an adequate legal framework. The control system includes documented procedures, voluntary norovirus certification, an obligation for the FBO to register and to implement good hygiene practice and HACCP principles. Failings in the system were identified to be:

- Limited monitoring of norovirus contamination
- The officially designated laboratories for norovirus analyses do not provide adequate guarantees for the validity of the results. The laboratories are accredited to ISO 17025. The methods used for norovirus detection however are not accredited nor validated and there were no performance criteria in place for the analytical methods.
- No adequate system to transmit RASFF notifications to the CAs although there is adequate response if they are received by the CA.

The competent authorities have responded that action will be taken to address the initial points during 2014 including the requirement for mandatory norovirus risk analysis by FBOs, guide for the application of the general principles of food hygiene, procedures for the official control of primary producers of raspberries and FBOs, validation of laboratory methods and staff training.

The development of the rapid alert system is in progress as discussed in section 4.1.1.

#### Aflatoxin contamination of maize

In December 2012 a Swiss surveying company detected aflatoxin contamination in Serbian maize. Their findings were initially rejected by the Serbian Department of Agriculture (AllAbout Feed, 2013a; 2013b).

In early 2013 maize from Serbia, Romania and Bulgaria was the subject of three notifications via the RASFF system, reported by Germany, due to high levels of aflatoxins.

45,000 metric tonnes of maize contaminated with aflatoxin from Serbia were imported into northwest Germany early in 2013 and a batch delivered to more than 3,000 farms for animal feed and also shipped to the Netherlands. The maximum permitted level of aflatoxin in the EU is 0.02 milligrams per kilogram, however the maize from Serbia registered amounts of up to 0.204 mg/kg.

MAFWM has established a commission to review the state of maize production and monitor the content of mycotoxins in maize (MAFWM, Plant Protection Directorate).

# 5. STATUS OF THE PREPARATION OF SERBIA (BASED ON THE ACQUIS COMMUNITAIRE IN THE AREA OF FOOD SAFETY AND FORTHCOMING CHALLENGES

#### **KEY FINDINGS:**

- Serbia has prepared a detailed strategy for the transposition, implementation and enforcement of the *acquis*
- The report of the European Commission and the audit reports of the FVO note progress in a number of areas including the introduction of legislation and the organisation of the system for official controls
- Shortcomings relate to the budgetary requirements to implement the changes and to provide the level of resource (personnel, training, equipment and IT) required

This chapter reviews the progress made by Serbia in adoption of the *acquis* in the area of food safety.

The European Commission progress report 2012 reported little progress with regard to general food safety principles. The report comments that the Food Safety Law includes most of the principles required in the *acquis* and that certain features such as the principle of risk analysis and the implementation of HACCP are being applied, however further strengthening of the administrative capacity of the institutions involved in the monitoring of the food chain safety, in particular the veterinary, phytosanitary and national reference laboratories is needed. Additional efforts were also identified as being required to upgrade food and feed establishments, the management of animal by-products and genetically modified organisms.

It concluded that some progress has been made but that overall preparations in the area of food safety, veterinary and phytosaniatary policy are moderately advance.

The main points of these shortcomings and areas for improvement in the present system identified by the National Plan for the Adoption of the Acquis (NPAA) of the government of the Republic of Serbia and update reports, annual reports of the European Commission and reports of audit visits by the Food and Veterinary Office (FVO) including the responses of the competent authorities are summarised below:

# 5.1. Legislation

Serbia has prepared a National programme for the adoption of the *acquis* 2013 – 2016 which identifies the priorities for harmonisation, details the strategy for the transposition, implementation and enforcement of the *acquis* and identifies areas where there are problems. In addition the Veterinary Inspectorate of MAFWM plans to prepare a multi-annual and annual plans of official controls, monitoring plans for food safety, food safety on the borders and for zoonoses and foodborne diseases.

European legislation however continues to develop (as discussed in section 3.3) and it is therefore a challenge for the Government of Serbia to ensure that the transposition is conducted accordingly. The area of Phytosanitary legislation including the use of plant protection products is one where there has been little progress.

# 5.2. Resources

The NPAA comments on the trend towards reducing the number of staff involved and budget cuts (NPAA 2013 – 2016). The size of the expenditure for the agriculture and food sector as a share of total public expenditure increased in 2013 to 4% however the World Bank reports that this is still not enough to meet all the tasks of the Government adequately (World Bank, 2013).

# **5.2.1. Plant Protection Directorate**

According to the NPAA the number of employees at the Plant Protection Directorate (PPD) and their educational profiles are insufficient to support the transposition of the EU regulations in the national legislation or their implementation. Similarly the number of phytosanitary inspectors is reported to be insufficient to support law implementation however there are no plans to hire new employees (NPAA). There is also a lack of suitably qualified staff and the responsibilities of the expansion and advisory services are ill defined and overlap in certain areas (seed and plant propagation material, plant identification).

It is planned to overcome the lack of staff by hiring external assistance from institutes and universities, under temporary contracts, following a public tendering process. This was to be completed by the end of January 2013. IPA and TAIEX funding has been provided in this area.

The legislation relating to plant health in the EU is under revision and is being monitored and activities planned accordingly.

# **5.2.2. Veterinary Directorate**

Similarly implementation of the proposed veterinary requirements is reported to require a 50% increase in the number of employees in the period 2014 – 2016.

#### **5.2.3. National Reference Laboratories**

The DNRL has also been reported to be understaffed and unable to perform the duties assigned to it under the Food Safety Law. A number of projects (Twinning Project 2011, IPA) have been undertaken to renovate, build the capacity of (end 2013) and equip (Feb 2013) the NRLs. Additional equipment however is still required (NPAA 2013).

FVO reports have also commented on the limited scope of the analytes offered by certain laboratories and the accreditation and validation of methods as recommendations for improvement.

# 5.2.4. Information sources, database construction and IT

The European Commission Progress report for 2012 reported that the enforcement of the Food Safety Law needed to be improved along with the implementation of risk analysis and HACCP. Accordingly the associated IT systems needed to be upgraded and the skill base and equipment of the authorities responsible for official controls and policy making improved further.

The Agricultural Inspection Division has established a central registry of the Ministry of Agriculture where all Serbian supervisory services under the jurisdiction of the Ministry are listed. All organisational units of the Ministry can access the central resister. The establishments registered and approved by the Veterinary Directorate will be an integral part of the central register.

In 2008 there was an initiative to create an information system to support the Internal Trade Control of the Agricultural Inspection Division. Although a number of activities have been carried out however the envisaged database has not yet been established and is due to be completed in 2016.

# 5.3. Adoption by the food industry

A recent study of the Serbian meat industry reported that 93.5% of the producers surveyed claimed that they had a fully operational and certified HACCP system in place whilst the remaining 6.5% had a HACCP system in place but this was not certified (Tomasievic, 2013). The smaller enterprises however are reported to experience problems in introducing such HACCP based systems with factors such as awareness of the legislation and requirements, cost of implementation, availability of systems and training being reported as contributory factors (Djekic et al 2011; Toamasevic, 2013).

Headage payments and milk subsidies to the livestock sector are linked to compliance by producers with legislation on animal identification, registration and movement control and participation in national animal health measures (EC Progress Report 2012). These however will need to be aligned with EU requirements for subsidies.

# 5.4. Challenges identified

The European Commission 2012 Progress report identified the following additional areas as shortcomings:

General food safety principles

The Law on Food Safety includes most of the principles required by the *acquis* and some are being applied

Risk analysis and the implementation of HACCP have started to be applied but need to be improved

The associated IT systems need to be upgraded

Veterinary policy

There has been some progress in the alignment and implementation of the *acquis* Implementing legislation, and instructions for applying it, has been introduced Veterinary IT systems are being upgraded

Participation in the EU Trade Control and Expert System (TRACES) started in January 2012

Animal by-products

Some progress has been made in the area of placing on the market food and feed of animal by-products

New hygiene rules for food and feed establishments have been adopted and implemented

The national upgrading programme for establishments needs to be prepared

The national system for the management of animal by-products needs to be upgraded

Phytosanitary policy

Some progress has been made

A plant passport system has been introduced

The Phytosanitary inspection procedures are outdated and need to be improved.

The procedure for registering new PPPs is not yet aligned with the acquis

Legislation for placing PPPs on the market needs to be further aligned with the *acquis* 

A pesticide residues monitoring programme is not yet in place

The capacity of the NRL and of the regional laboratories needs to be strengthened to meet EU requirements.

Preparations in the area of Phytosanitary policy were considered weak.

# 5.5. Conclusion

Advances in the adoption of the *acquis* have been made although to differing extents in differing areas. Implementation in the area of Phytosanitary policy was considered weak.

Challenges identified have related to the continued introduction and implementation of the adoption of the acquis to meet all the requirements and the provision of resource to enable its effective implementation.

# 6. POSSIBLE ISSUES FOR DEBATE WITH THE SERBIAN AUTHORITIES

#### **National Control Plan**

The national plan for the adoption of the *acquis* 2013 – 2016 sets out the plans for its implementation but also highlights a number of areas that may impact on its implementation such as lack of staff, training, equipment, facilities, IT.

- What plans are in place to address these areas?
- What additional budgetary resource is in place?

#### **Animal diseases**

- How effective is the programme on the eradication of Classical swine fever?
- When will the status of being classed as officially free of tuberculosis, bovine brucellosis
  and enzootic bovine leukosis be achieved and what steps are being taken to achieve
  this?

# **Border Inspection Posts**

When will all border inspection posts be fully operational?

#### **RASFF**

- Is the RASFF system now operational?
- If not what is the planned implementation date?

#### **Food incidents**

The most recently reported incidents via the RASFF system have involved two of Serbia's main exports ie raspberries and maize

- How were these incidents investigated?
- What steps have been put in place to prevent a re-occurrence?
- Original results on the aflatoxins were disputed. What procedures are in place to check that such results are drawn to the attention of the authorities?

### Support for SMEs

- What support is in place to support SMEs (in particular) to be made aware of changes in the legislation and assistance with complying and implementing appropriate systems?
- What support is available for SMEs (in particular) to adapt to the changing market place?

#### Zoonoses

- What steps have been taken to investigate the increase in the number of incidents of Trichinellosis?
- The levels of incidences of Salmonellosis and Campylobacteriosis appear to be remaining constant. Is this considered to be a problem? Is it being investigated and, if so, what steps are being taken to bring about a reduction in the level of incidence?

# 7. REFERENCES

- Accreditation Body of Serbia (ATS) <a href="http://www.ats.rs/en/pages/about-us">http://www.ats.rs/en/pages/about-us</a>
- AllAboutFeed (2013a) Contaminated corn delivered to German farmers 6 March 2013
- AllAboutFeed (2013b) EU feed contaminated with aflatoxin 11 March 2013
- Chamber of Commerce and Industry of Serbia Serbia your business partner 2013 http://www.pks.rs/SADRZAJ/Files/CMIP/Brosura%20PKS%20en.pdf
- Cvijanovic D, Mihajlovic B, Cvijanovic G (2012) General trends on agriculture Food products market in Serbia Third International Symposium Agrosym Jahorina 2012
- Djekic I, Tomasevic I, Radovanovic R (2011) Quality and food safety issues revealed in certified food companies in three Western Balkan countries, Food Control 22, pp1736 – 1741
- Eurostat (2013) Pocket book Key figures on the enlargement countries 2013 edition. ISSN 1977-9194
   <a href="http://epp.eurostat.ec.europa.eu/cache/ITY">http://epp.eurostat.ec.europa.eu/cache/ITY</a> OFFPUB/KS-GO-13-001/EN/KS-GO-13-001-EN.PDF
- European Commission, (2013) Joint report to the European Parliament and the Council
  on Serbia's progress in achieving the necessary degree of compliance with the
  membership criteria and notably the key priority of taking steps towards a visible and
  sustainable improvement of relations with Kosovo<sup>11</sup> JOIN(2013) 7 Final
- European Commission, (2012a) Communication from the Commission to the European Parliament and the Council Enlargement strategy and the main challenges 2012 – 2013 COM(2012) 600 final <a href="http://ec.europa.eu/enlargement/pdf/key">http://ec.europa.eu/enlargement/pdf/key</a> documents/2012/package/sr rapport 2012 en.pdf
- European Commission, (2012b) Commission staff working document: Serbia 2012 progress report SWD(2012) 333
   <a href="http://ec.europa.eu/enlargement/pdf/key">http://ec.europa.eu/enlargement/pdf/key</a> documents/2012/package/sr rapport 2012 e n.pdf
- FAOSTAT <a href="http://faostat.fao.org/">http://faostat.fao.org/</a>
- Food and Veterinary Office (FVO), (2013a) Final report of an audit carried out in Serbia from 08 to 17 May 2013 in order to assess the control systems in place to control microbiological contamination in raspberries intended for export to the European Union DG(SANCO) 2013-66660 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3131">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3131</a>
- Food and Veterinary Office (FVO), (2013b) Final report of an audit carried out in Serbia from 15 to 19 April 2013 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products DG(SANCO) 2013-6763 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3145">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3145</a>

<sup>&</sup>lt;sup>11</sup> This designation is without prejudice to the positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

- Food and Veterinary Office (FVO), (2012) Final report of an audit carried out in Serbia from 11 to 18 September 2012 in order to evaluate controls of pesticides in food of plant origin intended for export to the European Union DG(SANCO) 2012-6299 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3017">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=3017</a>
- Food and Veterinary Office (FVO) (2011a) Final report of a mission carried out to Serbia from 10 to 20 May 2011 in order to evaluate animal health controls over live cattle DG(SANCO) 2011-6225 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2740">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2740</a>
- Food and Veterinary Office (FVO) (2011b) Final report of a mission carried out to Serbia from 10 to 20 May 2011 in order to evaluate animal health controls over live poultry DG(SANCO) 2011-6224 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2739">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2739</a>
- Food and Veterinary Office (FVO) (2011c) Final report of an audit carried out to Serbia from 10 to 12 May 2011 in order to evaluate the food safety control systems in place governing the production of poultry meat and poultry meat products intended for export to the European Union DG(SANCO) 2011-8847 MR FINAL <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2747">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=2747</a>
- Food and Veterinary Office (FVO) (2006) Final report of a mission carried out to Serbia from 31 January to 10 February 2006 concerning the general assessment of the animal health and food safety situation in the context of the possible export of live horses and certain products of animal origin intended for human consumption from Serbia to the EU DG(SANCO)/8298/2006 MR Final <a href="http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=1506">http://ec.europa.eu/food/fvo/rep\_details\_en.cfm?rep\_id=1506</a>
- Global Agricultural Information Network (GAIN) Report 2012 FAIRS Country report: Serbia – Food and agricultural import regulations and standards Report number RB1220 December 2012 <a href="http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative Belgrade Serbia 12-28-2012.pdf">http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative Belgrade Serbia 12-28-2012.pdf</a>
- International Standards Organisation (ISO) (2005) ISO 17025 General requirements for the competence of testing and calibration laboratories <a href="https://www.iso.org">www.iso.org</a>
- IPA, (2010) Strengthening of the Serbian system of market surveillance for non-food and food products <a href="http://ec.europa.eu/enlargement/pdf/serbia/ipa/2010/19">http://ec.europa.eu/enlargement/pdf/serbia/ipa/2010/19</a> intmkt ipa10.pdf
- Ministry of Foreign and Internal Trade and Telecommunications Sector for Market Inspection mtt.gov.rs/en/sectors-of-the-ministry/sector-for-market-inspection/
- Ministry of Foreign and Internal Trade and Telecommunications (2012) Serbia an attractive investment destination <a href="http://mtt.gov.rs/wp-content/themes/mtt/images/baneri/brosura\_engleski\_33.pdf">http://mtt.gov.rs/wp-content/themes/mtt/images/baneri/brosura\_engleski\_33.pdf</a>
- Ministry of Agriculture, Forestry and Water Management (MAFWM) <u>www.mpt.gov.rs</u>
- Ministry of Agriculture, Forestry and Water Management, Plant Protection Directorate Preventative measures against contamination of maize: Mycotoxins <a href="https://www.mpt.gov.rs">www.mpt.gov.rs</a>

- National plan for the adoption of the acquis 2013 2016 (NPAA), Serbia European Integration Office (SEIO) February 2013 <a href="http://www.seio.gov.rs/upload/documents/nacionalna\_dokumenta/npaa13\_16.pdf">http://www.seio.gov.rs/upload/documents/nacionalna\_dokumenta/npaa13\_16.pdf</a>
- OIEa World organisation for animal health www.oie.int
- OIEb General disease information sheet Classical swine fever <a href="http://www.oie.int/fileadmin/Home/eng/Media\_Center/docs/pdf/Disease\_cards/CSF-EN.pdf">http://www.oie.int/fileadmin/Home/eng/Media\_Center/docs/pdf/Disease\_cards/CSF-EN.pdf</a>
- Republic of Serbia Third Report on Implementation of the Action plan for fulfilment of The European Commission recommendations under the Serbia 2012 Progress Report in the European integration process <a href="http://www.seio.gov.rs/upload/documents/akcioniplan/ap\_repord\_third.pdf">http://www.seio.gov.rs/upload/documents/akcioniplan/ap\_repord\_third.pdf</a>
- Serbia European Integration Office (SEIO) February 2013 National plan for the adoption of the acquis 2013 – 2016 (NPAA), <a href="http://www.seio.gov.rs/upload/documents/nacionalna\_dokumenta/npaa13\_16.pdf">http://www.seio.gov.rs/upload/documents/nacionalna\_dokumenta/npaa13\_16.pdf</a>
- Serbia European Integration Office (SEIO) (2011) Answers to the European Commission's Questionnaire on Serbia's candidacy for membership in the European Union 2011 <a href="http://www.seio.gov.rs/documents/national-documents.222.html">http://www.seio.gov.rs/documents/national-documents.222.html</a>
- Serbian Government Integrated border management strategy in the Republic of Serbia www.srbija.gov.rs/uploads/documents/strategy\_border.pdf
- Serbian Investment and Export Promotion Agency (SIEPA) (2013) Serbia food industry <a href="http://siepa.gov.rs/en/files/pdf2010/FOOD\_SEKTOR.pdf">http://siepa.gov.rs/en/files/pdf2010/FOOD\_SEKTOR.pdf</a>
- Serbian Investment and Export Promotion Agency (SIEPA) Food Industry <a href="http://siepa.gov.rs/en/index-en/key-industries/food.html">http://siepa.gov.rs/en/index-en/key-industries/food.html</a> and Success stories Food and beverages <a href="http://siepa.gov.rs/en/index-en/success-stories/food-and-beverages/">http://siepa.gov.rs/en/index-en/success-stories/food-and-beverages/</a>
- Tomašević I, Šmigić N, Dekić I, Zarić V, Tomić N, Rajković A (2013) Serbian meat industry: A survey on food safety management systems implementation Food Control 32 pp25-30
- United Nations Cartographic section <a href="http://www.un.org/Depts/Cartographic/english/htmain.htm">http://www.un.org/Depts/Cartographic/english/htmain.htm</a>
- World Bank Group, 2013 World Bank Group Serbia Partnership program snapshot April 2013

http://www.worldbank.org/content/dam/Worldbank/document/Serbia-Snapshot.pdf

(All websites accessed during August or September 2013)

# **PUBLIC HEALTH SITUATION IN SERBIA**

## **LIST OF ABBREVIATIONS**

AP	Autonomous Province
DILS	Delivery of Improved Local Services
ECDC	European Centre for Disease Prevention and Control
ENVI	Environment, Public Health and Food Safety Committee
EU	European Union
GDP	Gross Domestic Product
HDI	Human Development Index
ICJ	International Court of Justice
IPH	Institute of Public Health
IPHS	Institute of Public Health of Serbia ("Dr Milan Jovanović Batut")
MDGs/SDGs	Millennium Development Goals/Sustainable Development Goals
MICS	Multiple Indicator Cluster Survey
NGO	Non-governmental organization
OECD	Organization for Economic Co-operation and Development
PHC	Primary Health Care
RFHI	Republic Fund of Health Insurance
SEIO	Serbian European Integration Office
SORS	Statistical Office of the Republic of Serbia
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNSC	United Nations Security Council
WHO/EURO	World Health Organization/Regional Office for Europe
WHO GHO	World Health Organization Global Health Observatory Data Repository
WHO HFA	World Health Organization "Health for All" database

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#### **EXECUTIVE SUMMARY**

This briefing responds to a request of the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament. It aims to provide Members of European Parliament with an overview of the public health situation in Serbia, in preparation for the visit of the ENVI delegation to Serbia set for 28 to 30 October 2013.

Serbia is situated in the central part of the Balkan Peninsula and covers an area of 88,509 square kilometres. The country has a total population of 7.151 million. The Serbian economy was badly affected by the recent economic crises, which resulted in a significant rise in social costs.

Life expectancy for both sexes is slowly increasing and at the end of the last decade stood at 71.5 for men and 76.8 for women respectively. However, this is still approximately five years lower than the European Union (EU)-27 average. Rapid aging of the population combined with decreased fertility rates and an overall negative population growth rate have been identified as one of the major issues in Serbia. Cardiovascular diseases and malignant diseases dominate the mortality structure of Serbia. On the other hand, communicable diseases play a comparatively minor role. Although infant mortality is still above the EU-27 average, Serbia is likely to reach the Millennium Development Goals (MDG) directly related to health by 2015.

Serbia shares many of the risk factors of other EU Member States. They include physical inactivity, hypertension, obesity and smoking, although the rate of the latter has been reduced considerably in the last few years. While Serbia has recorded satisfactory progress at the national level in many areas, data reveals significant regional variations, particularly relating to perinatal mortality. Also, health inequalities are significant within the Roma population.

The basic infrastructure and organization of the health care system is inherited from the former Yugoslavia. It is characterized by a comprehensive coverage, contributions as the major source of financing, a well-developed network of health institutions, and predominantly state owned health care facilities and equipment. In the recent years, general health reforms have been put in place, attempting to tackle the decline and stagnation of the health care system. National legislation allows private health care providers to operate, but their services are covered through out-of pocket payments.

In Serbia, 94% of the population is covered through a mandatory health insurance scheme, of which the State pays for contributions of approximately one in five. The expenditure on health amounts to 10.4% of the Serbian Gross Domestic Product (GDP). In absolute terms it amounts to about half of the EU average.

The new Health Care Law introduced certain reforms in the health care system. It emphasizes: the concept of the "chosen doctor"; introduces devolution of ownership, management and capital investment in Primary Health Care (PHC) to the municipality level; and promotes a culture of continuous quality improvement at all health care levels. The hospital infrastructure in Serbia is extensive and complex comprising a wide range of hospital types. In 2011, total beds in Serbia numbered 41,269 i.e. 5.7 beds per 1,000 inhabitants, somewhat less than the EU-27 average. Serbia appears to have a high number of doctors (21,030), but about one third of those are concentrated in Belgrade. Furthermore, due to the economic crisis, public health expenditure is decreasing while private expenditure for health is increasing.

Serbia, like many EU Member States and candidate countries, has insufficient institutional and professional capacities for public health with a slow on-going reform process. The financial resources are distributed inequitably between regions. In general, the public health services are considered to be underfinanced.

The Serbian government is committed to Serbia's accession to EU. The transposition of the *aquis communautaire* is on-going. However, full and proper implementation and application of the *acquis* will remain a challenge in the years to come. To facilitate the process of Serbia's accession to the EU, decentralisation and support for an effective national decision making process in the health sector is expected to continue.

## **GENERAL INFORMATION**

#### Aim

This briefing has been requested by the ENVI of the European Parliament, following an agreement by the Coordinators of the political groups represented in ENVI. The briefing aims to provide Members with an overview of the situation in the field of public health in Serbia in the light of the accession process. The delegation will travel to Serbia from 28 to 30 October 2013. The briefing covers the following topics:

- An overview of public health system in Serbia and its main trends;
- A comparison in selected areas between the situation in Serbia and that of the EU;
- The status of preparation of Serbia (based on the *acquis communautaire*) in the area of public health; and
- Likely scenarios for the health sector in Serbia in the coming years.

#### **General information on Serbia**

Serbia<sup>12</sup> is situated in the central part of the Balkan peninsula. The total population of Serbia comprises 7,151,000 in an area of 77,570 (with Kosovo and Metohija 88,509) km<sup>2</sup> (1). The country entered the 1990s with an overall population profile of a developed country. The events that took place in 1990s and 2000s, as well as the economic crisis, led to a smaller number of births, increased emigration of young people and immigration of elderly ones (refugees from wars in the territory of the former Yugoslavia).

Serbia is an EU candidate country. It consists of five regions (Belgrade; Vojvodina; Šumadija and western region; eastern and southern region; and Kosovo-Metohija), two of them being territorial autonomies: AP Vojvodina and AP Kosovo-Metohija (2). According to the 2002 census, there are 1,198,712 members of national minorities in Serbia (16.7%), excluding Kosovo-Metohija. According to the same census, a Roma population numbers 147,604 or 2.1% (1) of the overall population.

Refers to the territory without Kosovo, which is not included in this briefing note. This designation is without prejudice to positions of status, and is in line with UNSCR 1244/99 and the ICJ opinion on the Kosovo declaration of independence.

Map 1: Map of Serbia



**Source:** The Cartographic Section of the United Nations (CSUN): <a href="http://www.un.org/Depts/Cartographic/map/profile/serbia.pdf">http://www.un.org/Depts/Cartographic/map/profile/serbia.pdf</a> (accessed August 20, 2013)

The 2006 Constitution (2) defines Serbia as a parliamentary democracy with a separation of powers between the legislative, executive and judicial branches of government. Serbia is predominantly a centralized country with a decentralisation process currently underway. The basic infrastructure and organization of the health care system in Serbia is inherited from the former Yugoslavia. It is characterized by a comprehensive coverage, contributions as the major source of financing, a well-developed network of health institutions, and predominantly state owned health care facilities and equipment (Figure 0.2).

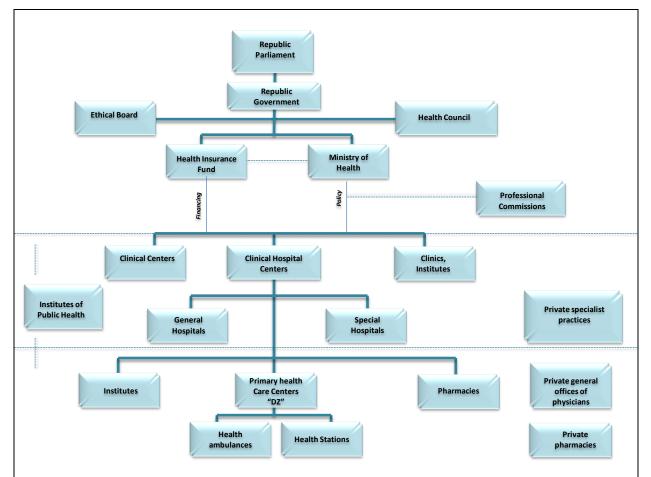


Figure 1: Organizational structure of the health care system in Serbia

Source: Compiled from the Health Care Law (21)

In the period 2001 – 2008, the economy of Serbia reached an average growth rate of 4.9% (3) with the growth of macroeconomic imbalances that at the end of 2008 slipped Serbia into recession. After a weak recovery in 2010/11 expansive public expenditure in 2012 resulted in growth of inflation (11.0 in 2013) and high unemployment (25.0%) with a current account deficit of 10.6% of GDP (Table 0.1).

Table 1: Economic indicators of Serbia 2010 – 2015 (\*estimated)

Indicator	2010	2011	2012	2013*	2014*	2015*
GDP (EUR, millions)	28,006	31,140	29,503	33,002	34,728	36,555
GDP growth (%)	1.0	1.6	-2.0	2.5	3.0	3.0
Inflation (CPI, average %)	6.5	11.0	7.3	11.0	4.0	4.0
Unemployment (%)	19.2	23.0	25.0	25.0	24.0	23.0
Foreign trade deficit (% GDP)	-16.4	-17.1	-18.2	-14.5	-12.6	1
Current account deficit (% GDP)	-6.7	-8.9	-10.6	-7.9	-6.0	/

**Source:** The European Integration Office: National Plan for the Adoption of the Aquis 2013-2016. Belgrade, February 2013

The Human Development Index summarises the country's situation considering 3 key dimensions: life expectancy, education (measured as schooling rates), and the Gross National Income per capita. In 2012 Serbia ranked with a value of 0.769 in the high human development category at position 64 out of 187 countries analysed (4).

#### 1. HEALTH STATUS AND DETERMINANTS OF HEALTH

#### **KEY FINDINGS**

- Life expectancy for both sexes is slowly increasing, but is still five years lower than the EU average. The aging of the population, decreased fertility rates and overall negative growth rate are identified as important issues.
- The main causes of deaths are cardiovascular and malignant diseases. The death rates, due to breast cancer as well as for cervical cancer, are higher than the EU average.
- Although infant mortality is still above the EU–27 average, Serbia is likely to reach the MDGs directly related to health by 2015.
- A reduction in the rate of smoking has been observed.
- Progress in health improvement is uneven; the southern regions are not faring as well as other parts of Serbia. Also, differences in health status between Roma and the majority of Serbian children have been identified.

## 1.1. Demographic Developments and Trends in Life Expectancy

The most comprehensive indicator of public health, total life expectancy, reached an average for the years 2008-2010 of 71.5 for males and 76.8 for females (EU-27 average 75.3 and 81.7 respectively) (5). This contributed to a combined overall increase from 72.4 years in 2001/03 to 74.0 in 2010 (6). Accordingly the proportion of the population older than 65 years increased to 17.4% (2011), corresponding to rapid aging. On the other hand the crude birth rate fell from 27.4 in 1950 to 9.8 in 2000 and 9.0 in 2011. In 2010, the number of reported abortions was 23,000 per year (estimated 150,000) or 323 per 1,000 live births (7) one of the highest in Europe. For these and other reasons, the population decreased from 7,806,000 in 1990 to 7,151,000 in 2012 (see also table 1.1).

Table 2: Trends in population/demographic indicators, selected years 1950-2012

Parameter	1950	1960	1970	1980	1990	2000	2010	2011	2012
Average population (x 1,000)	5,970	6,635	7,171	7,688	7,806	7,516	7,291	7,187	7,151
Live births (x 1,000)	163	119	102	110	91	74	68	66	67
Deaths (x 1,000)	77	62	67	76	86	104	103	103	102
Natural change (x 1,000)	86	57	35	33	5	-30	-35	-37	-35
Crude birth rate (per 1,000)	27.4	18.0	14.3	14.3	11.6	9.8	9.4	9.1	9.3
Crude death rate (per 1,000)	12.9	9.3	9.4	9.9	11.0	13.8	14.2	14.3	14.2

Parameter	1950	1960	1970	1980	1990	2000	2010	2011	2012
Natural change (per 1,000)	14.5	8.7	4.9	4.3	0.6	-4.0	-4.8	-5.2	-4.9
Total fertility rate	3.51	2.56	2.40	2.26	2.11	1.48	1.39	1.40	/

**Source:** SORS. Statistical yearbook of the Republic of Serbia. Belgrade<sup>13</sup>

#### 1.2. Burden of disease

Similar to other countries, cardiovascular diseases, together with malignant diseases, dominate the mortality structure (53.9% and 20.4% respectively). Communicable diseases play a comparatively minor role. Nevertheless, a rising incidence rate of communicable diseases was observed during the last decade (from 1,289 per 100,000 inhabitants in 2000 to 4,364 in 2007 (8)) which may be attributed to underreporting in the earlier years. In the same period, the mortality from communicable diseases rose at a low level from 1.5 to 3.1 per 100,000 inhabitants. Cases of HIV/AIDS do not contribute to morbidity and mortality to a relevant degree with the number of cases well below 100. Immunization rates are high (e.g. DPT 97% and Measles 95% of 1-year old children in 2010<sup>14</sup>), which reliably prevents outbreaks of epidemics like diphtheria.

Table 3: Main causes of death in Serbia, selected years, x 1,000 (rounded)

Disease	2002	2004	2006	2008	2010	2011
Cardiovascular diseases	57	57	59	57	56	56
Malignant diseases	19	19	20	21	21	21
Injuries and poisoning	4	4	4	4	3	3
Diabetes	3	3	3	3	3	3
Chronic obstructive lung diseases	2	3	2	3	3	3
All communicable diseases				21	25	33

**Source:** Institute of Public Health of Serbia: Health Statistics Yearbook of the Republic of Serbia. Belgrade: IPHS 2012.

Maternal and infant mortality are generally regarded as basic indicators of population health. Maternal mortality saw an increase in the period between 2004 and 2010 (13.9 and 17.6 per 100,000 live births respectively) as compared to the EU-27 averages of 7.2 and 6.1. On the other hand, child mortality is steadily decreasing, e.g. infant mortality from 10.6 per 1,000 (year 2000) to 6.7 (2010) and 6.3 (2011) (Figure 1.1) as compared to the EU-27 average of 4.1 (last figures from 2010)<sup>15</sup>. Serbia is close to achieving the MDG goals concerning reduction of mortality for infants and children under 5 years of age (8,10).

<sup>&</sup>lt;sup>13</sup> Excluding Kosovo; <a href="http://www.ined.fr/fr/pop chiffres/pays developpes/base pays developpes/">http://www.ined.fr/fr/pop chiffres/pays developpes/base pays developpes/</a> (accessed September 08, 2013)

<sup>&</sup>lt;sup>14</sup> United Nations Development Program (UNDP). Human Development Report. Annex on Health New York: UNDP 2013. (p. 166 ff.)

ECHI (European Community Health Indicators). Infant Mortality. http://ec.europa.eu/health/indicators/echi/list/index\_en.htm#id3 (accessed September 21, 2013)

14 12,7 11,2 12 10,6 10 9,3 9,2 8,8 8.0 7,7 8 6,5 6,3 5.8 6 4,7 4,5 4 2 0 Infant mortality Perinatal mortality Neonatal mortality Mortality of children under 5 ■ 2000 2005 2011 ■ MDG: 2015

Figure 2: Child mortality rates in Serbia, desired Millennium Development Goal by 2015

**Source:** Statistical Office of the Republic of Serbia – Vital Statistics 2011. <a href="http://webrzs.stat.gov.rs/WebSite/Default.aspx">http://webrzs.stat.gov.rs/WebSite/Default.aspx</a> (accessed January 30, 2013); Institute of Public Health of Serbia "Dr Milan Jovanović Batut". Health Statistical Yearbook of Republic of Serbia 2011. Belgrade: IPHS 2012.

#### 1.3. Determinants of health

An overview of the burden of disease caused by the ensemble of risk factors is shown in table 1.3. Changes since 2000 are likely to be minor.

Table 4: The Burden of Disease in terms of Disability Adjusted Life Years attributable to selected risk factors according to information from 2000

Selected risk factor	Males	Females
Smoking	35,2	12,5
Alcohol benefit	4,6	7,5
Alcohol harm	5,7	1,5
Physical inactivity	19,5	16,3
Low fruit & vegetable intake	3,3	1,6
Hypertension	21,7	17,5
Obesity	15,0	12,2
Cholesterol	3,0	1,7

**Source:** The Burden of Disease and Injury in Serbia. Belgrade: Ministry of Health of the Republic of Serbia 2003; standardized according to WHO World population (9).

Key sources of reduced quality of living and premature death (11) are discussed below.

Smoking: According to survey information from 2006, smoking among adults was reduced by 6.9% in comparison with the year 2000, from 40.5 to 33.6% (12). Exposure to tobacco smoke for adults at home was 61.7% and 44.9% at the workplace. 16.3% of schoolchildren were regular smokers.

Alcohol: The daily average alcohol consumption per person in the period 2004-2007 increased from 56.3 ml to 71.4 ml (13), approaching the highest level recorded in 2003 (79.2 ml). In 2006 3.4% of the population used alcohol every day - most commonly hard liquor followed by beer and wine. The percentage is higher among the poorest group (5.3%) and those with only elementary or lower education (5.1%).

Nutritional status: Between 2000 and 2006, malnutrition (<18.5 kg/m $^2$ ) decreased from 7.4 to 2.3%, whereas obesity (>= 30.0 kg/m $^2$ ) increased slightly from 17.3 to 18.3%. In children and adolescents, aged 7-19, the prevalence of malnutrition decreased from 8.4 to 6.2% while obesity increased from 4.4 to 6.4%. Malnutrition and obesity in later life are to some degree determined during infancy and are related to breastfeeding. It is unlikely that Serbia will reach the MDGs by 2015 concerning this.

#### 1.4. Health inequalities

Health inequalities are marked at both regional level and concerning the Roma population.

While Serbia has recorded satisfactory progress regarding social equality at the national level, data derived from an updated registration and reporting systems (DevInfo database), reveal marked regional variations in Serbia (Figure 1.2), particularly relating to perinatal mortality. For example, the districts of Pirot, Jablanica and Toplica have significantly higher perinatal mortality than the districts of Srem, Morava or Braničevo.

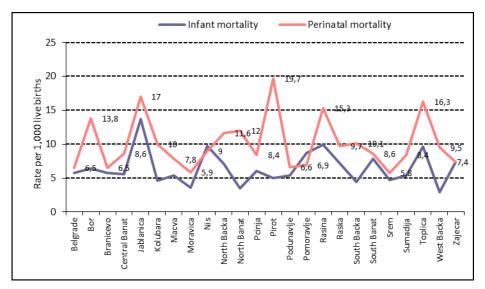


Figure 3: Regional variations in perinatal and infant mortality in 2011

**Source:** Statistical Office of the Republic of Serbia – Vital Statistics 2011. http://webrzs.stat.gov.rs/WebSite/Default.aspx (accessed July 15, 2013)

Studies conducted by UNICEF (14) revealed disturbing differences in health status between Roma and the majority of Serbian children (Figure 1.3) (15, 16).

However, due to the increased efforts of the Serbian government, mortality among Roma children, although high, has almost halved over the last five years bringing the number closer to the national Millennium Goal of reducing Roma under-5 child mortality to 14 and infant mortality to 12 (17). However, the current mortality rate of Roma children is still three times as high as the Millennium Goal set at the national level for Serbia (Figure 1.1).

2005:Roma children Rate per 1,000 35 live births ■ 2010: Roma children 29 2015: MDG for Roma children 30 25,9 ■ 2005: Average for Serbia 25 2010: Average for Serbia 2015: MDG for Serbia 20 Roma settlements Roma settlements 15 14 14 15 12 Serbia Serbia 9,2 10 8 7,9 6.7 5 4,5 5 0 Infant mortality Mortality of children under 5

Figure 4: Differences in mortality rates between average population of children and Roma children in 2005 and 2010 in Serbia

**Source:** UNICEF. Monitoring the situation of children and women. Multiple Indicator Cluster Survey (MICS 2005 i MICS 2010). Belgrade: UNICEF Belgrade 2007. and 2011. and Institute of Public Health of Serbia "Dr Milan Jovanović Batut". Health Statistical Yearbook of Republic of Serbia 2011. Belgrade: IPHS 2012.

#### 2. THE HEALTH SYSTEM

#### **KEY FINDINGS**

- The health care system in Serbia is characterised by a well-developed network of health institutions, with predominantly state-owned health care facilities and equipment, broad public coverage, contributions to the Republic Fund of Health Insurance (RFHI) as the major source of funding.
- Health care services are provided through a total of 344 health institutions with 113,384 employees (2011).
- Serbia allocated roughly the same percentage of its GDP to health care as the EU average (10.4% Serbia; 9.5% EU average in 2010). However, in terms of total money allocated Serbia allocates less than half of the EU average. Due to the economic crisis, public health expenditure is decreasing while private expenditure for health increases.

#### 2.1. Overview of the Health Care System

In the recent years, general health reforms have been put in place, attempting to tackle the decline and stagnation of the health care system (8, 18).

#### 2.1.1. Public and private health care system organisation and infrastructure

Public health care services are provided through a wide network of public health care institutions, organized at the primary, secondary and tertiary level and overseen by the Ministry of Health. As of late 2011 this network was comprised of 344 health institutions with a total of 113,384 employees in the public sector. (19).

The primary health care includes preventive care, urgent care, general medicine, health care for women and children, health visitor service, as well as laboratory and other diagnostics, dental care, occupational medicine and physical medicine and rehabilitation. The primary health care physicians also act as the first point of access for providing mental health care. If necessary they can refer these patients to suitable secondary and tertiary clinics. Health care at the primary level is provided by 157 state-owned primary health centres, with a well-developed network of outpatient facilities and offices, covering the territory of one or more municipalities or towns, in accordance with the Health Institutions Network Plan (20). Apart from primary health centres, certain institutes deliver primary health services to specific groups, such as students, patients with skin diseases, sexually transmitted infections etc. Primary health care is performed by a chosen doctor who is either a general practitioner or a specialist in general medicine, in occupational medicine, paediatrics, gynaecology or dentistry (21). The entire primary health care network is now equipped with computers, printers, bar-code readers and card readers (Serbia Health Project – Additional Financing) (22).

Secondary and tertiary health care services are provided by hospitals, continuing the diagnostics, treatment and rehabilitation initiated at the primary level, or when specialized care is required.

There are 40 general hospitals, 37 special hospitals for acute and chronic conditions and rehabilitation, 6 teaching hospitals, 16 institutes, 4 clinical-hospital centres, 4 clinical centres and 23 institutes of public health (different from the PHC, i.e. not offering health care). While the network of healthcare institutions is well developed, the economic recession is impacting system development and even sustainability (23).

National legislation allows private health care services to operate, but their operation is poorly regulated. Private health care services are covered through out-of pocket payments, while at the same time a system of additional private health insurance is missing. This inevitably leads to a power imbalance, where private health providers are negotiating prices directly with individual users (patients), instead of institutions with more leverage. Provision of private health care services is still limited but is increasing, especially as regards dental services. Private health care providers mainly employ medical professionals from the public sector who work on a temporary, consultancy basis. The private sector includes 1,220 out-patient medical offices and clinics, 1,663 dental clinics, 1,835 pharmacies and 149 laboratories. There are also 81 private hospitals and 58 policlinics providing secondary level health service as of 2010 (24). However, the volume of services provided by the private sector remains small, and it rarely surpasses 5% of services provided by the public sector because the facilities mentioned are much smaller than those in the public sector.

#### 2.1.2. Physical and human resources for health

Total beds in Serbia in 2010 numbered 41,269 i.e. 5.0 beds per 1,000 inhabitants, which is slightly less than the EU-27 average of 5.3 beds per 1,000 inhabitants. This number includes day hospital beds, but they are not very well defined and standardized (1,473 or 3.6%). Hospital beds are not separated in short term and long-term health care beds. The number of hospital beds saw a slight decrease during the last decade (in 2000 there were 6.1 beds per 1,000 inhabitants).

In recent years, the medical devices market in Serbia has grown considerably. As a result, Health Technology Assessment (HTA) is slowly gaining momentum (25). According to recent World Health Organization (WHO) data base (26) and the national inventory for medical equipment, the biggest share of medical devices belongs to CT scanners (130 units), followed by mammographs (105 units) and MRI units (59 units). Approximately one third is owned by the private sector.

Looking at human resources for health in 2010, there were 2.8 practicing physicians per 1,000 inhabitants in Serbia, while the average for EU-27 was 3.4. Out of 113,384 employees in the health public sector, 27,059 had a university education. Of those with university education, 21,030 (77.7%) were doctors, 2,227 (8.2%) dentists, 2,130 (7.9%) pharmacists, and 1,672 (6.2%) are other professionals. In total there were 15,361 (73%) specialists. Despite the good provision of staff within primary healthcare, their geographical distribution is not even. Close to one-third of health professionals are concentrated in the capital city Belgrade (397 per 100,000 inhabitants) while the district of Sremski shows the lowest density of 178 per 100,000 inhabitants. It is expected that over the next 10 years, 10,000 medical doctors will graduate while only 2,000 medical posts will become available (27)..

## 2.2. Health care financing

The health care system in Serbia is funded through the RFHI, with mandatory employee contributions as the major source of financing. The Fund is overseen by the State.

#### 2.2.1. Health expenditure

The health care system is characterized by the comprehensive coverage of 94.2% of the population. Out of the insured population 1.2 million do not generate any income, a deficit which has to be covered by the state. The high number of non-income insured persons is due to the fact that registered unemployed individuals, as well as children, pregnant women and mothers on maternity leave, single parents with children under 7 years of age and the population older than 65 are also entitled to access the health care system.

Total expenditure on health, as a percentage of GDP, was estimated at 10.4% in 2010, with a slight rise in the past years (see Table 2.1). It was higher than in any other country in South Eastern Europe, except Bosnia and Herzegovina. However, expenditure per capita, because of Serbia's low GDP, is comparatively low and is half of the EU average. The share of public health expenditure in total health expenditure was 61.9%. Almost all private health expenditure is out of pocket payments (including under the table payments) of citizens for health services and medicines (95.5%). However, it makes up a large share of total health expenditure (4% of GDP, EU-27 2.3%) in spite of the small volume of private medical services.

Table 5: Selected indicators of health expenditure in Serbia

Parameter	2005	2007	2009	2010
Share of total expenditures for health care in GDP (%)	9.0	10.4	10.5	10.4
Share of public expenditures for health care in GDP (%)	6.0	6.4	6.5	6.4
Share of expenditures for health care by the Republic Fund of Health Insurance in GDP (%)	5.5	6.0	6.1	6.0
Share of private expenditures for health care in GDP (%)	3.0	4.0	4.0	4.0
Total health care expenditure per capita in EUR	212.0	400.0	415.0	412.0
Public expenditures for health care per capita in EUR		245.0	257.0	255.0
Expenditures of the RFHI for healthcare per capita in EUR		229.0	240.0	240.0

**Source:** Institute of Public Health of Serbia "Dr Milan Jovanović Batut. Republic of Serbia. Selected Health Indicators for 2011. Belgrade: Institute of Public Health of Serbia 2012. Health expenditure series, World Health Organization, Geneva, (latest updates are available on <a href="http://apps.who.int/nha/database/DataExplorerRegime.aspx">http://apps.who.int/nha/database/DataExplorerRegime.aspx</a>) (accessed January 30, 2013)

#### 2.2.2. Source of funds and payment mechanisms

In 2011, the RFHI raised most of its funds through health insurance contributions from individual salaries (12.3% of gross salary), shared equally between employer and employee. Contributions are received from employees, farmers, self-employed persons and from state budget i.e. the funding for pensioners, unemployed and other disadvantaged groups as indicated in the section 2.2.1. Collection of contributions proved to be a problem since at the end of 2012 the accumulated deficit amounted to more than 1 billion EUR (28).

The capacity of the mandatory health insurance system to provide adequate funding has come under considerable strain as a result of the economic recession. In response to this situation, a number of steps have been taken to increase the efficiency of health care financing. Under the new regulation that came into force in October 2012 (29), chosen physicians are paid based on their performance, instead of fixed salaries (as a transitional phase before capitation). Changes in payment of services provided in hospital care on the basis of Diagnosis Related Groups (DRGs) have also been prepared, in combination with a system of payment based on fee for service. It is expected that the new system will be more cost-effective (30). Efficiency has been further improved through a reduction of non-medical staff, more efficient use of hospital beds and better monitoring of expenditure for medical services. There are also plans to further improve the collection of contributions for health insurance.

## 2.3. Provision of public health and healthcare services

#### 2.3.1. Primary health care and inpatient care

The new Health Care Law (21) introduced certain reforms in the health care system. It emphasizes the concept of the "chosen doctor", introduces devolution of ownership, management and capital investment in Primary Health Care (PHC) and promotes a culture of continuous quality improvement at all health care levels.

Primary healthcare is provided by teams of chosen physicians (Paediatrician, Gynaecologist, and General Practitioner) in primary healthcare centres with specified lists of activities and performance measures (31). At the national level overall availability is good and still above the level stipulated for services, particularly those for healthcare of preschool and school children, as well as of women (Table 2.2).

Table 6: Availability and annual performance of primary healthcare in Serbia

Health care service	Population po care	er chosen p physician	orimary	Average number of visits per chosen physician			
Service	Regulation*	2000.	2011.	Regulation*	2000.	2011.	
Preschool children (under 6 yrs)	850	769	649	6,300	4,944	5,116	
School children (under 19)	1,500	1,950	1,351	6,300	5,690	5,060	
Women (15 yrs and above)	6,500	5,389	5,459	6,300	3,180	2,621	

Health care service	Population po care	er chosen p physician	rimary	Average number of visits per chosen physician			
sei vice	Regulation*	2000.	2011.	Regulation*	2000.	2011.	
Adults (19 yrs and above, general practice)	1,600	2,049	1,468	7,350	6,356	6,610	

**Regulation:** Book of rules about conditions to perform health care in health organizations and other forms of health services. Official gazette of RS 43/2006; 112/2009;

**Source:** Institute of Public Health of Serbia "Dr Milan Jovanović Batut". Health Statistical Yearbook of Republic of Serbia 2011. Belgrade: Institute of Public Health of Serbia 2012. 106-107.

Within inpatient health care, the rate of hospitalization is 179.2 per 1,000 inhabitants, the number of hospital days is 1,588 per 1,000 inhabitants, the average hospital length of stay is 8.4 days while the average hospital bed occupancy rate is 72% (19). The average hospital length of stay has recorded a downward trend (EU-27 average is 6.9 days in 2010) (32), which contribute to higher hospital efficiency, while the average daily bed occupancy has increased. However, significant variations among hospitals exist in terms of length of stay and bed occupancy, for the same illnesses and conditions, which indicates differences in efficiency and work productivity and inadequate bed distribution in relation to the existing needs.

Mentally ill patients are treated in specialized psychiatric hospitals and psychiatric wards in general hospitals. The capacity to provide palliative and terminal stage care for patients is very limited. The Strategy for Palliative Care integrates palliative care and treatment in the existing health care system. At the primary health care level, palliative care is provided through home care services for which training was carried out. At the secondary level, in general hospitals, special palliative care units are foreseen within extended treatment and care wards. It is envisaged that palliative care units with a total of 140 beds will be established in 13 health care institutions in the future (33).

The system for monitoring indicators of health care quality has been significantly improved over the past years. This system allows better insight into the activities of health care services in the areas of primary, secondary and tertiary health care. The monitoring of quality indicators in primary health care was updated in 2010 (34).

#### 2.3.2. Maternal and child health care

At the national level, the overall availability of PHC for children and women can be considered good and in compliance with the levels stipulated in the relevant legislation (see table 2.2). The accessibility of additional counselling services, however, is not adequate and does not meet the requirements of a child friendly and adolescent friendly system (35). Secondary specialized healthcare for children and women is provided within the paediatric (0.18 beds per 1,000 children), gynaecological/obstetric (0.40 beds per 1,000 women in reproductive age) and other departments of general hospitals. Highly specialized services are provided by tertiary level institutions only in Belgrade<sup>16</sup>.

<sup>&</sup>lt;sup>16</sup> University Hospital for Neurology and Psychiatry of Children and Adolescents (45 beds), Institute for Mother and Child Health care of Serbia "Dr Vukan Čupić" (400 beds), University Children's Hospital (292 beds), Institute of Neonatology (160 beds), University Hospital for Gynaecology and Obstetrics (330 beds).

The availability, accessibility, quality and efficiency of health care service for children at the national level have been significantly improved over the last decade, although there are still significant regional differences. Research and surveys also suggest that there are significant differences in the accessibility of healthcare among children and women in vulnerable groups (36, 37). Furthermore, data indicate a low level of referrals to specialists and not all paediatricians record nutritional advice for obese children. Another indicator of the quality of paediatric health care is the relatively high frequency of unnecessary prescriptions of antibiotics at the first visit of a child with acute infection of the upper airways. The Ministry of Health therefore has initiated the development and adoption of guidelines for good clinical practice (38, 39).

The share of women in the first trimester of pregnancy benefiting from modern health care services has increased from 54.3% in 2000 to 70.6% in 2010 (MDG goal for Serbia is 85%). The situation is much worse with regard to community nurse home visits with the number of visits falling from 2.9 in 2000 to under one in 2010 (MDG goal for Serbia is 5 visits). Multiple Indicator Cluster Surveys (15, 16) also reveal that there are significant disparities, not only in the coverage, but also in the content of antenatal and post-neonatal healthcare available to women belonging to marginalized groups.

Various government documents call for strengthening and coordinating activities to promote higher birth rates. These range from encouraging families to have more children to assistance to couples requiring in vitro fertilization, assistance to women during pregnancy and after birth, improved child care in the society in general, and the introduction of a tax refund to poor families for the purchases of baby care products (23).

#### 2.3.3. Health care for specific populations

The health care sector has formulated a number of strategies and projects to improve the accessibility of health care and the overall health status of vulnerable groups, especially the Roma population. A particularly successful initiative has involved the hiring of Roma health mediators assigned to multidisciplinary teams of primary health care centres which conduct home visits in 59 towns and municipalities in Serbia. All of the 75 mediators so far are female, live in Roma settlements, have children of their own, and have finished at least elementary school. Their task is to be a link between the Roma community and health institutions, but they also provide assistance and advice in other areas relating to education and social protection in order to cope with the numerous difficulties especially for Roma children (40). Significant progress in access to health and healthcare has been recorded for Roma children in qualitative studies conducted by Non-governmental organizations (NGOs) (41).

#### 2.3.4. Public health services

The Government of the Republic of Serbia is responsible for public health at all levels. The structural characteristics and the functioning of the IPHs in Serbia are regulated by a separate Law on Public Health adopted in 2009 (42) and by the basic laws and their amendments (the Health Care Law and the Health Insurance Law) and also by a set of about 32 legislative acts primarily relating to other areas. The IPHs are financed from the governmental budget and by the RHIF.

The system of services for public health comprises of networks of different institutions and services. In Serbia, the most important institutions of public health are the Institutes of Public Health (IPH), with a long tradition in the former Yugoslavia. The 23 IPH (including the National Institute of Public Health of Serbia "Dr Milan Jovanović-Batut") are organized at the republic, regional and city level. Their work is financed from the budget of the government and the RHIF.

Other responsible institutions are primary health care centres, as discussed above, and inspection services. Furthermore, the role of institutions for education – especially faculties, colleges and secondary schools for the health professions and other relevant profiles, is very important.

# 3. POLICY AND LEGAL CONTEXT: PROGRESS IN THE ADOPTION AND IMPLEMENTATION OF THE EU ACQUIS

#### **KEY FINDINGS**

- The regulatory mechanisms are characterised by a large number of laws, by-laws, statutes, and strategies etc., which are not always harmonised. The planned decentralisation process is progressing slowly.
- The current, as well as the previous, Serbian governments are committed to the accession of Serbia to the European Union.
- The transposition of the public health acquis is on-going.

## 3.1. Legal aspects of the health system

The health care system is defined and regulated by relevant policy and legal instruments. The right to health and health care is defined in article 68 of the Constitution of the Republic of Serbia, which also provides for a health care system based on mandatory health insurance (2). Legal framework is further complemented by a large number of laws and bylaws.

Furthermore, many international and EU documents, instruments, health policies and strategies have an impact on the developments in the health care system in Serbia. The most important include the International Covenant on Economic, Social and Cultural Rights, the UN Declaration on MDG with post 2015 agenda (Sustainable Development Goals), EU public health policies (Europe 2020; EU Health Programme "Together for Health") and EU legal instruments.

#### 3.1.1. Overview of relevant legal acts

The reform of the health care system was initiated in 2005 with the adaption of the Health Care Law, the Health Insurance Law and the Law on Health Professional Chambers. These three laws, in addition to the Law on Drugs and Medical Products adopted in 2004, make up the basic framework for transition of the relevant EU legislation. The Health Care Law, *inter alia*, sets out the values of the health system, as well as the rights of patients, emphasizes the concept of the chosen doctor in primary health care and introduces decentralisation of management. The Health Insurance Law contains further provisions on the compulsory health insurance mode, aiming to guaranty equity and solidarity in health financing and provision of health care for the whole population, with priority given to vulnerable groups.

In 2009 and 2010 additional laws governing important areas of health and health care were adopted. These include the Law on Public Health, the Law on Organ Transplantation, the Law on Cell and Tissue Transplantation, the Law on Blood Transfusion, the Law on Infertility Treatment by Applying In Vitro Fertilization Procedures, the Law on Protection of the Population from Exposure to Tobacco Smoke, the Law on Psychoactive Controlled Substances, the Law on Ratifying the Convention for the Protection of Human Rights and Dignity of the Human Rights and Biomedicine, the Law on Food Safety. In addition, in 2013 the Law on Patients' Rights and the Law on the Protection of Persons with Mental Health Disorders were adopted. All in all, there are over 170 legal instruments in force dealing directly or indirectly with the health care system.

#### 3.1.2. Overview of key players

The primary competent authorities in Serbia are the Government, and within it the Ministry of Health, as well as the RFHI. In addition some relevant health care functions are entrusted to lower government levels (2, 43, 44). The Ministry of Health is the central authority and has operational units for health service organisation, health insurance, public health and programmed healthcare, European integration and international cooperation, inspection operations, budgetary funding, legal operations, biomedicine, and the internal audit group (45). The Republic Fund of Health Insurance is a national, public and non-profit organization through which Serbian citizens exercise their health insurance rights (46). The activities of the Republic Fund of Health Insurance are conducted in its organizational units: Directorate of the Institute, Provincial Health Insurance Agency, the Fund's branch and subbranch offices. The Agency for Accreditation of Health Care Institutions of Serbia was founded in 2008 (47) with the EU support. Its role is to perform professional, regulatory and development activities in the process of accreditation of healthcare institutions. However since its establishment, the Agency has also taken role in the international relations (e.g. since 2012, the Agency is the Regional Health Development Centre for the South Eastern Europe).

## 3.2. Policy background

Following the political changes in 2000, the government identified the reform of the health sector as one of its national priorities. The government committed itself to carry out health reforms within the wider context of EU integration and public sector reform. Several steps have been taken so far. Amongst the efforts to establish order in the domain of health care, the most important was the adoption of the Health Policy Document (48) by the Serbian Government with an aim of bringing health in Serbia closer to the relevant policy of the EU.

The majority of the required strategic documents are written but their implementation is delayed due to dependence upon the financial and expert support of international agencies and donors. Also, the Government of Serbia adopted the Healthcare Development Plan (49) which sets a number of specific goals to be met by 2015. The plan's main goals include structural and functional changes to the existing model of primary health care, a strengthened gate-keeping function, improved accessibility of primary health care services and a focus on the quality of services as well as the systematic management of non-communicable diseases. Also with reference to a Strategy for Development of Information Society in the Republic of Serbia, the Ministry has adopted the Program of Operation, Development and Organization of Integrated Health Information System - e-Health (43). Until now out of 97 strategies adopted, 19 are related to employment, social affairs, and health.

#### 3.2.1. Policy reforms and decentralisation

The dominating factor in policy reform is decentralisation. With decentralisation, the primary health centres became the responsibility of local governments. The local government is now obliged to prepare a local health care plan and to formulate specific programmes tailored to the needs of the local population<sup>17</sup> and is responsible for governing of the primary health centres. However, lack of financial resources and economic crisis has slowed down these processes.

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<sup>17 &</sup>lt;a href="http://www.inkluzija.gov.rs/?page">http://www.inkluzija.gov.rs/?page</a> id=2347&lang=en

Those health care facilities that are state funded are done so in accordance with a so-called Plan of the Network of Health Care Facilities, adopted by the State Government.

The Ministry of Health is continuously investing efforts in improving quality of health care with various strategies and guidelines, such as the guidelines for good clinical practice in many areas of health care (50). In recent years, the system for monitoring health care indicators has been significantly improved, which allows better insight into the work of health services (51). The national survey on patient satisfaction has been on-going since 2004. The survey showed that the satisfaction of patients increased over time which seems to indicate that reforms are yielding results.

# 3.3. Current status of the implementation of the *acquis* in the area of public health

Serbia is an EU candidate country. To facilitate the process of legal approximation, the Serbian Parliament adopted the National Plan for the Adoption of the *acquis* 2013-2016 (NPAA) (3). Of the NPAA activities set for 2013, 85% were implemented (111 legal instruments out of 131 were adopted) (52). The competent authority for the implementation of the public health *acquis* is the Ministry of Health. Its Sector for European Integration, together with other relevant institutions, is directly working on monitoring harmonization in the field of health.

The 2012 Commission's Progress Report on Serbia (52) noted the lack of progress in the area of public health in the period October 2011 September 2012. It further pointed to the poor financial situation of the Serbian health insurance fund. The Report continued to call for further implementation of the existing legislative framework (presented in Chapter 3 of this note) and further alignment of the relevant Serbian legislation with the *acquis*.

The adoption of the new Law on Protection of Population from **Communicable Diseases** is expected in late 2013. This Law should incorporate, *inter alia*, relevant definitions identified in the 2012 Progress Report. The national registry of communicable diseases is run by the Institute of Public Health of Serbia in cooperation with the network of 23 IPHs<sup>18</sup>. The National Health Survey, providing input for updated reporting on several current indicators of health determinants and health status including communicable diseases, is ongoing and will be completed at the end of 2013 (53). A national Communication Centre for surveillance is established, based on the European Center for Disease Prevention and Control (ECDC) methodology, and capable to provide on-line communication in the case of pandemics in order to coordinate the national IPH-network and be in contact with ECDC (in line with Regulation (EC) No 851/2004). The national strategy related to HIV/AIDS is regularly updated.

Following the National Strategy for Control and Prevention of chronic Non-Communicable Diseases adopted in 2009 (54) and respective programmes, the National **Cancer Screening** Office has been established within the above mentioned Institute of Public Health of Serbia in 2013. The Office is supervising screening for breast cancer, cervical cancer, and colorectal cancer. Additional efforts are needed to implement the EU guidelines in this field (53).

<sup>&</sup>lt;sup>18</sup> Institute of Public Health of Serbia "Dr Milan Jovanović Batut". <a href="https://www.batut.org.rs">www.batut.org.rs</a> (accessed September 08, 2013)

The Directorate for Biomedicine in the Ministry of Health was established as competent authority to deal with monitoring of **organ donation**, **cell and tissue transplantation**, **and blood transfusion**. However, its administrative and technical capacity is limited. Based on its data for 2012, there were 28 donors, 47 kidney transplantations, and 7 transplantation of liver. The 2009 Law on Organ Transplantation (55) also regulates organ donation. The donations are carried out on the basis of donor cards representing a donor's consent. In 2012, six by-laws regulating organ donations (Directive 2010/53/EU) were adopted on the basis of the Law on Organ Transplantation (56). However, Serbia is still not a member to the Eurotransplant. The Law on Infertility Treatment regulates In Vitro Fertilization Procedures (57). The 2012 saw adoption of by-laws concerning standards, organization, staff, equipment for blood transfusion and safety of blood donations. These by-laws are harmonised with the EU *acquis*, notably directives 2004/23/EC, 2006/17/EC, 2006/86/EC, 2010/45/EU and 2012/39/EU. In 2013 these activities continued with the adoption of further eight by-laws (58).

The transposition of the *aquis* in the area of **recognition of foreign diploma and professional qualifications** is on-going. Amendments to existing legislation and policy instruments (59, 60) are foreseen to take place in the third quarter of 2013. In regards to regulated professions, further harmonization of the Serbian legislation with the *acquis*, namely the Directive 2005/36/EC, is made in the field of medicine and public health

Currently **bilateral agreements in the field of health insurance** already exist with 19 countries (62). This number, as well as their implementation, is expected to improve with the adoption of the Law on Conclusion and Implementation of International Agreements in 2013 (61).

The introduction of the European Health Insurance Card is closely linked to the introduction of the new health insurance card, to be issued to all by the end of 2014 (63).

Concerning **mental health**, the Law on the Protection of Persons with Mental Health Disorders was adopted in 2013, with several by-laws remaining to be adopted in the near future. Issues of tobacco and alcohol use have been discussed in section 1.3 of the document.

## 3.4. Challenges in relation to the accession

The main challenge for Serbia in the years to come will not be only the transposition of the *aquis* but also its full implementation and application. Serbia must implement and apply a tremendous volume of public health sector law in the coming years. Other challenges, some of them stemming from the NPAA (3), are discussed further below,

The opening of the EU market to medical professionals from Serbia may lead to a brain drain which is especially harmful considering the resources used for their education. An agreement on cooperation with Eurotransplant remains to be concluded. Implementing effective breast screening, colorectal and cervical cancer programmes, as well as strengthening the national office for screening in the Institute of Public Health will remain some of the biggest future challenges.

Implementing improvements in mental health care in line with the 2007 Strategy on mental health protection and the 2013 Law on the Protection of Persons with Mental Health Disorders is also demanding. Instead of referring most patients to the secondary or tertiary level of care, the community health care and accompanying outpatient services have to be improved. However, at the moment, the standards of most of these facilities are below acceptable level. Intensive monitoring is required to successfully implement the above mentioned Law.

## 4. THE FUTURE OF THE HEALTH SECTOR IN SERBIA

#### **KEY FINDINGS**

- The process of decentralisation and the strengthening of an effective national decision making body (Health Council of Serbia), consisting of all the relevant stakeholders including health NGOs, is on-going.
- The Health Council of Serbia could play an important role, together with the Ministry of Health, in fostering implementation of the acquis.
- Reducing the well-known implementation gap and agreeing on a binding time frame for reforms should be further encouraged.
- Establishing obligatory schemes for education and training of public health professionals and managers and supporting sustainability of the state's institutional capacity to teach, train and advise on a scientific basis, should be encouraged.

The following four key challenges for the future development of the health care system in Serbia have been identified:

#### 1) Providing sufficient funding for a comprehensive health service

Serbia maintained a relatively high standard of health care but, as indicated in the 2012 Progress Report, funding is becoming more and more challenging. A more rational use of available funding and a more effective leverage of contributions are essential. Also expenditure is unequally distributed between regions which may become a key factor for social unrest and dissatisfaction among the population. Due to the lower health status of some population groups, such as Roma, additional funding, in this regard, is needed.

For the first challenge four possible scenarios can be anticipated:

- To reduce the package of covered services or the corresponding remuneration by a
  considerable amount, approximately by at least one third, in order to cover the
  growing deficit of the RFHI. This would understandably meet serious social
  resistance and require careful scientific evaluation of the evidence-base of certain
  medical treatment schemes and technologies.
- To enforce delayed contributions which are estimated to amount to more than one billion EUR at the end of 2012, of which about 490 million are considered as lost (due to bankruptcy of companies or silently accepted evasion).
- To introduce additional financial sources, such as (proportional) co-payment, coinsurance (cappuccino principle) or to increase the amount of the so-called "tobacco dinar". Previous experience shows that these measures can, at most, only alleviate the financial deficit. This is also due to the fact that administrative requirements eat up a large part of the returns.
- To support actively the opening of the market for private insurance, including a core
  package of minimum services, and to allow for competition between the RHIF and
  registered private insurance schemes.

The merits of each scenario depend on the progress or delay of three political strategies:

- The progression of the devolution transferring budget planning especially with regard to staffing the local health facilities to a fully independent RFHI and municipal governments.
- The full participation of all relevant stakeholders including health NGOs and private health insurances in the decision making in terms of a Health Council, chaired by the Ministry of Health replacing the present centralist planning model.
- The adoption of a strategy for the effective transposition of the *acquis* and an implementation plan with binding deadlines.
- 2) Improving the efficiency of the health care system

In spite of the improvement in the efficiency of the health care system, visible from the improved performance concerning hospital length of stay and bed occupancy rates, costs of the system remain high with considerable discrepancies between institutions and regions. Remuneration payments are still not effectively regulated. Likewise the re-organisation of long-term including mental and palliative care has not been finished.

For this challenge three possible scenarios can be anticipated:

- To continue to enhance the downward trend of the length of hospital stay together with an increased bed occupancy rate, supported by the country-wide introduction of an output-based system.
- To free the clinical hospital services from long-term care for chronically, especially mentally ill, patients.
- To facilitate the out-sourcing of services which are not primary activities of the health care system (e.g. food preparation, laundry, cleaning etc.).

The merits of each scenario depend on the progress or delay of three political strategies:

- Progressing from in performance based payment of providers to a full countrywide introduction of capitation schemes and DRG against the resistance of lobby groups.
- The progressive establishment of community-based mental health centres which allows the patients to live in an open social environment
- The progressive establishment of decentralised palliative care capacity in cooperation with the church and specialised NGOs.
- 3) Reduction and better utilisation of resources spent on education of medical professionals in terms of their numbers and composition

A gross overproduction of medical professionals, especially physicians and nurses, was observed. This has resulted in unemployment and emigration. At the same time, there is a lack of qualified/trained healthcare managers.

For this challenge, four possible scenarios can be anticipated:

- Restriction of available slots for professional education (based on objective criteria for admission).
- Requiring trained professionals to work for a certain time period for public health care system.
- To delegate admission policies to the training institutions/medical faculties including the possibility to increase fee rates. This would require a social scholarship programme supported by the state. 3.4 To enhance the education for public health services (network of institutes of public health). This would strengthen the population's health at limited cost.

The merits of each scenario depend on the progress or delay of three political strategies:

- Continuation of the liberalization of the educational market allowing for unrestricted competition between state and private training institutions.
- Encouraging the state-based institutions to increase their engagement in qualified Continued Medical Education with unrestricted and not-taxed financial surplus.
- Re-defining the status of the institutes of public health and related organizations as state-based but autonomous institutions with reduced but better trained staff and devolution of accountability.
- 4) Encouraging improvement of the living conditions and embracement of the healthier life style

Although the Human Development Index (HDI) and the Inequity adjusted HDI improved over time there is a considerable degree of inequality between regions and population groups as regards standards of living and adoption of healthier life styles especially related to tobacco and alcohol consumption. Vulnerable groups have higher levels of unemployment, lower education and less access to health information.

For this challenge three possible scenarios can be anticipated:

- Embracing the current slow but permanent progress of average health indicators as e.g. life expectancy. However this approach disregards issues such as regional differences, lower health status of certain groups, such as Roma.
- To concentrate on vulnerable groups and to develop special support schemes.
- To invest in lifestyle campaigns following the successful model of smoking reduction in the areas of excessive alcohol and drug consumption and healthier nutrition (including subsidizing healthier food). A special effort should be made to reduce the persistence of traditional patriarchal stereotypes and acceptance of violence in conflict solution.

The merits of each scenario depend on the progress or delay of two political strategies:

- To acknowledge permanent regional differences in health as unacceptable and ask especially the EU for support for disadvantaged population groups and regions, especially in southern Serbia.
- To transfer the responsibility for healthier living of the population to the level of districts and municipalities with the obligation to report to an annual Health Conference at regional or national level.

#### REFERENCES

- SORS. Statistical Pocketbook of the Republic of Serbia 2013. Belgrade: Statistical Office of the Republic of Serbia 2013.
- Constitution of the Republic of Serbia. Belgrade ("O.G. of RS", No 98/2006) (see also: Serbian Government. <a href="http://www.srbija.gov.rs">http://www.srbija.gov.rs</a> (accessed 8 September 2013).
- The European Integration Office: National Plan for the Adoption of the Aquis 2013-2016. Belgrade: SEIO 2013 <a href="http://seio.gov.rs/home.50.html">http://seio.gov.rs/home.50.html</a> (accessed 12 September 2013).
- United Nations Development Program (UNDP). Human Development Report. New York: UNDP 2013.
- OECD. Health at a Glance: Europe 2012. Paris: OECD Publishing 2013. http://www.dx.doi.org/10.1787/9789264183896-en (accessed 8 September 2013).
- Government of the Republic of Serbia. Social Inclusion and Poverty Reduction Unit and Republic Statistical Office: Monitoring Social Inclusion in Serbia; Overview and Current Status of Social Inclusion in Serbia, based on Monitoring European and National Indicators. 2006 – 2012, Second amended edition. Belgrade: Social Inclusion and Poverty Reduction Unit and Republic Statistical Office 2012.
- http://trekfortruth.com/daily-life/fertility-crisis-in-serbia (accessed September 8, 2013); and: OECD. Health at a Glance: Europe 2012. Paris: OECD Publishing 2013. http://www.dx.doi.org/10.1787/9789264183896-en (accessed 8 September 2013).
- Institute of Public Health of Serbia. Health of Population of Serbia, Analytical Study 1997-2007. Belgrade: IPHS 2009.
- The Burden of Disease and Injury in Serbia. Belgrade: Ministry of Health of the Republic of Serbia 2003.
- Institute of Public Health of Serbia. Selected Health Indicators for 2011. Belgrade: IPHS 2012.
- WHO-EURO. The European health report 2012. Copenhagen: WHO 2013.
- Ministry of Health of Republic of Serbia. National health survey Serbia, 2006. Key findings. Belgrade: IPHS 2007. <a href="http://www.batut.org.rs/index.php?lang=2">http://www.batut.org.rs/index.php?lang=2</a>. (accessed 8 September 2013).
- SORS. Household survey on food consumption, 2003–2007. Belgrade: Statistical Office of the Republic of Serbia 2013.
- UNICEF. Breaking the cycle of exclusion. Roma children in South East Europe. Belgrade: UNICEF Belgrade 2007.
- UNICEF. Multiple Indicator Cluster Survey 2005. Monitoring the situation of children and women. Belgrade: UNICEF Belgrade 2007.
- UNICEF. Multiple Indicator Cluster Survey 2010. Monitoring the situation of children and women. Belgrade: UNICEF Belgrade 2012.

- Government of the Republic of Serbia. Millennium Development Goals in the Republic of Serbia. Monitoring Framework. Belgrade: Government of the Republic of Serbia 2006.
- Simic S, Marinkovic J, Boulton G. Primary Health care Reform in Serbia: Driven by whom? In: Bartlett J, Bozikov J, Rechel B. Health reforms in south-east Europe. New York: Palgrave Macmillan 2012. 105-129.
- Institute of Public Health of Serbia. Health Statistical Yearbook of Republic of Serbia 2011. Belgrade: Institute of Public Health of Serbia 2012. p. 65.
- Health Institutions Network Plan ("O.G. of RS", No 42/06, 119/07, 84/08, 71/09, 85/09, 24/10).
- Article 98 of the Law on Health Care ("O.G. of RS", No 107/05, 72/09, 88/10, 99/10, 57/11, 119/12, 45/13).
- DILS (Joint Ministry of Health and World Bank Projects). Introducing Information System into Primary Health Care in the Republic of Serbia. <a href="http://www.dils.gov.rs/documents/files/avgust2011/MoH&WB%20Projects%20Newsletter%20No.%204.pdf">http://www.dils.gov.rs/documents/files/avgust2011/MoH&WB%20Projects%20Newsletter%20No.%204.pdf</a> (accessed 10 September 2013).
- Government of RS. Fiscal Strategy for 2013 with projections for 2014 and 2015. <a href="http://mfp.gov.rs/UserFiles/File/dokumenti/2012/Nacrt%20fiskalne%20strategije%20za%202013">http://mfp.gov.rs/UserFiles/File/dokumenti/2012/Nacrt%20fiskalne%20strategije%20za%202013</a> %20godinu%20sa%20projekcijama%20za%202014 %20i%202015.pdf (accessed 9 September 2013).
- Gajic-Stevanovic M, Dimitrijevic S. Health Care System and Expenditures in Serbia from 2004 to 2010. Belgrade: Institute of Public Health of Serbia 2011. p. 21 and p.23. <a href="http://www.batut.org.rs/index.php?category\_id=50">http://www.batut.org.rs/index.php?category\_id=50</a> (accessed 8 September 2013).
- Djukic P. Developing HTA frameworks in emerging markets: the road ahead. The case of Serbia. Eurohealth 2010; 16(4): 14-15.
- WHO data base. Medical devices in Republic of Serbia.
   <a href="http://www.who.int/medical devices/countries/srb.pdf">http://www.who.int/medical devices/countries/srb.pdf</a> (accessed 8 September 2013)
- Jekic IM, Katrava A, Vuckovic-Krcmar M, Bjegovic-Mikanovic V. Geopolitics, economic downturn and oversupply of medical doctors: Serbia's emigrating health professionals.
   In: Wismar M, Maier CB, Glinos IA, Dussault G, Figueras J. Health Professional Mobility and Health Systems. Evidence from 17 European countries. Copenhagen: WHO and European Observatory on Health Systems and Policies 2011. 541-568.
- Republic Fund of Health Insurance. Yearly Report <a href="http://www.rfzo.rs/finansijski-izvestaji-main/fin-izvestaji">http://www.rfzo.rs/finansijski-izvestaji</a> (accessed 8 September 2013).
- Bylaw on correctional coefficient, the highest percent increase of basic salary, criteria
  and measures for the part of salary which is earned on the basis of work performance,
  as well as the way of calculation of salaries for employees in health institutions ("O.G.
  of RS", No 100/11, 63/2012, 101/2012).
- Republic Fund of Health Insurance. Diagnostic Related Groups.
   http://www.rfzo.rs/component/content/article/329--dsg-info
   (accessed 8 September 2013).
- Book of rules about conditions to perform health care in health organizations and other forms of health services ("O.G. of RS", No 43/06, 112/09).

- SORS. Statistical Pocketbook of the Republic of Serbia 2013. Belgrade: Statistical Office of the Republic of Serbia 2013: p. 81.
- Project funded by the EU: Development of Palliative Care Services in the Republic of Serbia. <a href="http://www.palliativecareserbia.com/home.html">http://www.palliativecareserbia.com/home.html</a> (accessed 12 September 2013).
- Institute of Public Health of Serbia. Report about quality improvement in health care institutions of the Republic of Serbia. Belgrade: Institute of Public Health of Serbia 2012.
- Government of the Republic of Serbia. National Strategy for Youth ("O.G. of RS", No. RS 55/08).
- Cvejić S, Babović M, Petrović M, Bogdanov N, Vuković O. Social exclusion in rural areas of Serbia. Belgrade: UNDP Serbia, Sector for inclusive development 2010. 84-86.
- Bogdanov N, Tomanović S. Cvejić S, Babović M, Vuković O. Access to services of rural area for women and children in Serbia and measures for improvement Belgrade: UNICEF Serbia 2011. 38-41.
- Ministry of Health, Working group for guidelines. Obesity. Belgrade: Faculty of Medicine University of Belgrade 2004.
- Ministry of Health, Working group for guidelines. Selection and administration of antibiotics in general practice. Belgrade: Faculty of Medicine University of Belgrade 2004.
- Dinkić M, Branković A. Economic Analysis of introduction of Roma health mediators in the system of health care institutions in Serbia. Belgrade: Institute of Economic Sciences 2011.
- Praxis. Analysis of the Main Problems and Obstacles in Access of Roma to the Rights to Health and Health Care. Belgrade: Praxis 2011.
   <a href="http://www.praxis.org.rs/index.php/en/reports-documents/praxis-reports/item/587-testing-the-implementation-of-the-ombudspersons-recommendations-regarding-vulnerable-persons; www.praxis.org.rs">http://www.praxis.org.rs/index.php/en/reports-documents/praxis-reports/item/587-testing-the-implementation-of-the-ombudspersons-recommendations-regarding-vulnerable-persons; www.praxis.org.rs</a> (accessed 12 September 2013).
- Law on Public Health ("O.G. of RS", No 72/09).
- Serbian Government. <a href="http://www.srbija.gov.rs/pages/article.php?id=45625">http://www.srbija.gov.rs/pages/article.php?id=45625</a> (accessed 12 September 2013).
- Statistical Office of the Republic of Serbia. Municipalities and regions in the Republic of Serbia, 2011.
   <a href="http://webrzs.stat.gov.rs/WebSite/Public/PublicationView.aspx?pKey=41&pubType=1">http://webrzs.stat.gov.rs/WebSite/Public/PublicationView.aspx?pKey=41&pubType=1</a> (accessed 12 September 2013).
- Ministry of Health of Republic of Serbia.
   <a href="http://www.zdravlje.gov.rs/showpage.php?id=32">http://www.zdravlje.gov.rs/showpage.php?id=32</a> (accessed 22 September 2013).
- Republic Fund of Health Insurance. <a href="http://www.eng.rfzo.rs/index.php/abou-main">http://www.eng.rfzo.rs/index.php/abou-main</a> (accessed 22 September 2013).
- Agency for Accreditation of Health Care Institutions of Serbia. http://www.azus.gov.rs/en/ (accessed 12 September 2013).

- Serbian Government. The Health Policy of Serbia.
   www.prsp.gov.rs/download/Zdravlje.doc (accessed 12 September 2013).
- Decision on Healthcare Development Plan of the Republic of Serbia ("O.G. of RS", No 88/10).
- <a href="http://www.rfzo.rs/index.php/uredbe-docs/329--dsg-info">http://www.rfzo.rs/index.php/uredbe-docs/329--dsg-info</a> (accessed 8 September 2013).
- Ministry of Health, Working group for guidelines.
   <a href="http://www.zdravlje.gov.rs/showpage.php?id=145">http://www.zdravlje.gov.rs/showpage.php?id=145</a> (accessed 12 September 2013).
- Book of rule on quality of health care indicators ("O.G. of RS", No 49/10).
- Commission Staff Working Paper. Serbia 2012 Progress Report accompanying the Communication from the Commission to the European Parliament and the Council "Enlargement Strategy and Main Challenges", SWD(2012) 333 final, Brussels, 10 October 2012.
  - http://www.ec.europa.eu/enlargement/pdf/key\_documents/2012/package/sr\_rapport\_2012\_en.pdf (accessed 21 September 2013).
- Law on Protection of Population from Communicable Diseases ("O.G. of RS", No 125/04).
- National Strategy for Control and Prevention of Chronic Non Communicable Diseases ("O.G. of RS", No 22/09).
- Law on Organ Transplantation ("O.G. of RS", No 72/09).
- Six by-laws were published in the following Official Gazettes: ("O.G. of RS", No 89/12, 112/12).
- Law on Cell and Tissue Transplantation, Law on Blood Transfusion, Law on Infertility Treatment by Applying In Vitro Fertilization Procedures ("O.G. of RS", No 72/09).
- ("O.G. of RS", No 15/13, 19/13, 37/13, 41/13, 51/13).
- Law on Higher Education ("O.G. of RS", No 76/05, 100/07, 97/08, 44/10, 93/12).
- Strategy for Education Development in Serbia ("O.G. of RS", No 107/12).
- Law on Conclusion and Implementation of International Agreements ("O.G. of RS", No 32/13).
- Republic Fund of Health Insurance.
   http://www.rfzo.rs/zastita-ino-actual/medjunarodni-sporazumi-actual (accessed 21 September 2013).
- Republic Fund of Health Insurance. <a href="http://www.rfzo.rs/ekartica-info-menu/ekartica-podaci-menu">http://www.rfzo.rs/ekartica-info-menu/ekartica-podaci-menu</a> (accessed 21 September 2013).



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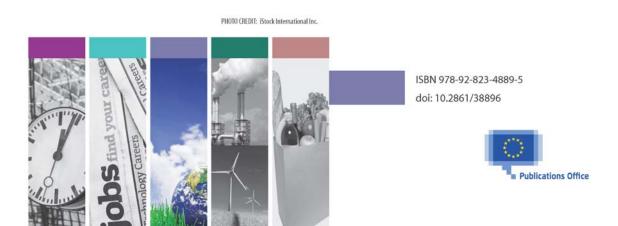
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