

Chapter 28: Consumer and health protection

The *acquis* under the Consumer and Health Protection chapter consists of horizontal policy instruments, including financial support, regulatory and governing measures, as well as vertical policies. These describe in detail the mechanisms, on the one hand, for the protection of the consumer's safety and his/her economic interests and, on the other hand, human public health.

The *acquis* in the area of consumer protection includes the following instruments: a general financing framework and rules for the governing of consumer protection at the European Union (EU) and Member State level, including injunctions and access to justice, together with a measure for enforcement co-operation by Member States public authorities (CPCS). It also covers aspects related to the consumer's general product safety, such as dangerous imitations, liability for defective products and the EU's Rapid Alert System (RAPEX), as well as topics like sale of consumer goods and associated guarantees, unfair contract terms, price indications, doorstep selling, distance selling, distance marketing of financial services, consumer credits, misleading and comparative advertising, unfair commercial practices, timeshare, package travel and rights of flight passengers.

The *acquis* in the area of public health comprises measures as regards the general financing framework and measures for governing this area. It also deals with issues related to tobacco control, communicable diseases, blood, tissues and cells, mental health, drug abuse prevention, health inequalities, nutrition, alcohol related harm reduction, cancer screenings, healthy environments including prevention of injury, promotion of safety and European action in the field of rare diseases.

Member States need to transpose the *acquis* into national legislation. The implementation and enforcement of consumer and health protection policies require adequate administrative capacities and infrastructure at national, regional and local level. As regards public health, adequate administrative capacity is needed to properly implement and enforce EU health legislation especially in the field of blood, tissues and cells. As regards consumer protection, this refers to effective market surveillance and appropriate independent judicial and out-of-court dispute resolution mechanisms. It is also necessary to raise public awareness, consult with the public and involve consumers actively in effective policy implementation, thus informing and educating the consumer and ensuring a role for consumer associations.

I. CONSUMER PROTECTION

A. Horizontal aspects

- 1. Please describe the scope of your consumer protection policy. Is consumer protection recognised as a specific policy in your country? Are there specific rules on consumer protection in other policy areas?**

Consumer protection policy in the Republic of Serbia includes a group of regulations and institutions for the protection of health, safety and economic interests of consumers as natural persons who procure goods or services on the market for purposes other than their business or other commercial activity, in relation with traders, i.e. legal or natural persons acting on the market within their business activity or for other commercial purposes.

Consumer protection is recognised as a special policy in the Republic of Serbia.

Consumer protection is a constitutional category. Article 90 of the Constitution of Serbia stipulates that the Republic of Serbia shall protect consumers, strictly prohibiting activities directed against health, safety and privacy of consumers and all other dishonest activities on the market.

Article 78 of the Stabilisation and Association Agreement between the European Communities and their Member States and the Republic of Serbia prescribes the obligation of the Republic of Serbia to co-operate in order to align the standards of consumer protection in Serbia to those of the Community, by means of implementing a policy of active consumer protection, in accordance with Community law, including the increase of information and development of independent organisations, harmonisation of legislation, effective legal protection for consumers in order to improve the quality of consumer goods and maintain appropriate safety standards, monitoring of rules by competent authorities, providing access to justice in case of disputes and exchange of information on dangerous products.

The main legal framework is the Law on Consumer Protection (Official Gazette of RS No. 73/2010), whose enforcement began on 1 January 2011 and that contains norms regulating fundamental consumer rights, the conditions and means of consumer protection, the rights and obligations of consumer protection organizations and associations, establishment of an alternative dispute resolution scheme (ADR) for consumer disputes, and the rights and obligations of state authorities in the field of consumer protection.

Based on the 2005 Law on Consumer Protection (Official Gazette of RS, No. 79/05), the National Programme for Consumer Protection for the period 2007-2012 was adopted, which specifies the main objectives and tasks of consumer protection policy, plans and methods, dynamics and indicators of further development, task holders and time limits, and the necessary personnel, financial and organisational capacities. The national programme is implemented through annual operational plans.

Articles 124 and 153 of the 2010 Law on Consumer Protection prescribe the obligation for the Government of the Republic of Serbia to adopt a five-year Consumer Protection Strategy within 6 months from the date of enforcement of the law, establishing long-term goals and activities necessary for the overall realisation of the consumer protection policy and an appropriate action plan.

Rules important for consumer protection in other areas of public policy are present in special regulations on advertising, general product safety, food safety, e-commerce, contract and torts, competition, trade, telecommunications, etc. Therefore, apart from the Law on Consumer Protection being the primary document for this field, there is a series of other legal acts and by-laws important for the consumer protection system.

Considering the importance of financial services, the National Bank of Serbia took up the protection of financial services consumers. Namely, within the Consumer Protection Project launched in 2006, the National Bank of Serbia started with the process of establishing a system for the protection of financial services consumers in all areas relying on the positive experiences in the field of protection of insurance service consumers, and in 2007 it formed a Centre for Financial Services Consumers.

2. Please describe the institutional set-up for consumer affairs in your country.

The institutional framework for consumer protection in the Republic of Serbia is comprised of two segments, the first being state institutions, and the other the non-governmental sector, i.e. consumer protection organizations. Recognizing the fact that consumer protection is a multidisciplinary field, the existing system in the Republic of Serbia is set up of the following:

- The Government of the Republic of Serbia – creating consumer protection policy;
 - Within the Government, there is a National Council for Consumer Protection as a consulting body gathering all relevant stakeholders;
- The Ministry of Trade and Services – holder of consumer protection policy.
 - Within the Department for Trade, Prices and Consumer Protection, there is a Division for Consumer Protection (directly responsible for the implementation of consumer protection policy, proposes the Consumer Protection Strategy, undertakes measures and activities for improving the consumer protection system and is in charge of harmonisation of regulations with relevant consumer-related EU law).
 - Within the division, there is a Consumer Protection Centre as a free-of-charge consumer hotline and a macro-analytic nexus.
 - The Market Inspection Department, which applies consumer protection measures in administrative procedure.
- Non-governmental, autonomous organizations for consumer protection and their associations
- Courts – regular court procedure. There is no special procedure *stricto sensu* for consumer protection
- No special bodies for out-of-court settlement of consumer disputes are planned – out-of-court settlement is carried out by various actors (please see more about that in answer to question 5.)

Apart from the Ministry of Trade and Services, the following institutions within their competences deal with affairs that directly or indirectly refer to consumer protection, namely: the Ministry of Health, the Ministry of Agriculture, Forestry and Water Management, the Ministry of Environment and Spatial Planning, the Ministry of Economy and Regional Development, the Ministry of Labour and Social Policy, the Ministry of Mining and Energy, the Ministry of Telecommunications and Information Society, the National Bank of Serbia, the Commission for Protection of Competition, Republic Agency for Telecommunications (RATEL), the Energy Agency, the Energy Efficiency Agency, the Standardization Institute, etc.

The National Bank of Serbia carries out activities in the field of protection of rights and interests of financial service consumers and providing information and financial education. As it holds the initiative for proposing laws from its field of competence, the

National Bank of Serbia prepared a draft law regulating the protection of financial service consumers, which was adopted by the Government.

By considering complaints of financial service users and conducting the mediation process, the National Bank of Serbia offers necessary help in solving disputes between financial institutions whose work it supervises (banks, insurance companies, leasing companies and voluntary pension funds management companies) and users of their services, and at the same time takes a series of activities aimed at preventing new disputes by means of providing information and education for financial service consumers.

3. It should be specified whether there are bodies within the public administration which are competent for:

a) General co-ordination of consumer affairs: is general competence on consumer policy allocated to one designated authority, which is responsible for taking initiatives and for coordinating actions in the consumer area?

The Ministry of Trade and Services, under the Law on Ministries (Official Gazette of RS No. 65/2008), has general competence for the consumer protection policy and monitoring the situation in this area. With a view of improving the system and co-operation of competent authorities, organizations and other consumer protection holders, the National Consumer Protection Council acts within the government as a consulting body (Article 126 of the Law on Consumer Protection), comprising representatives of ministries and other state authorities and holders of public authorities, consumer protection organizations, commercial and professional chambers and other stakeholders on the market, and independent experts in the field of consumer protection. Its competences include in particular the participation in the drafting of a Consumer Protection Strategy and implementation of action plans, reporting to the government on the situation in the area of consumer protection, and proposing measures and activities to improve the situation, especially in view of counselling, assistance and informing consumers and the public on relevant issues. The national council shall be presided over by the minister in charge of consumer protection issues.

b) Market surveillance/general product safety: are there independent administrative structures and enforcement powers monitoring the market for consumer goods, in order to detect breaches of product safety rules and to ensure they are corrected? This would include dealing with consumer complaints and infringement of rules. [Specific questions on product safety and market surveillance are to be found in section B. below.]

The institutional framework for market surveillance/product safety in the Republic of Serbia is set up of the following state bodies:

Table: Fields of market surveillance/product safety and administrative capacities of competent bodies (The data are taken from the Market Surveillance Strategy – September 2010)

Ministry/competent authority	Inspection/field of surveillance	Number of inspectors/persons authorized for surveillance	Total number of staff
Ministry of Trade and Services	Market Inspectorate: General surveillance: Consumer protection; protection of intellectual property rights holders other general procedures of inspection surveillance Technical surveillance: General product safety; Conformity of non-food products with technical requirements for products	485	495
Ministry of Economy and Regional Development/Directorate for Measures and Precious Metals	Measurement instruments	20	120
Ministry of Labour and Social Policy	Labour Inspectorate	273	323
Ministry of Infrastructure	State roads Road transport Railway traffic Waterway traffic Air traffic	8 23 3 19 0	11 31 6 32 3
Ministry of Health	Health inspection Sanitary inspection Medicines and medical devices (for human use)	47 230 1	50 243 13

Ministry/competent authority	Inspection/field of surveillance	Number of inspectors/persons authorized for surveillance	Total number of staff
Ministry of Mining and Energy	Pressure equipment	8	8
	Equipment and protection of system of the use in potentially explosive environment in mining facilities only	7	8
Ministry of Telecommunications and Information Society	Telecommunications	-	-
Ministry of Agriculture, Forestry and Water Management	Veterinary	347 ¹	347
	Phytosanitary	96 ²	96
	Agriculture	126	126
	Water management	28	28
	Forestry and hunting	61	61
Ministry of Environment and Spatial Planning	Environment	127	133
	Construction	9 ³	9
	Spatial planning	-	-
Ministry of Interior	Emergency situations – security from fire	182	
Ministry of Finance/Customs Administration	Customs surveillance		2706

This overview refers to the authorities of the Republic of Serbia, in their competence for implementation of activities and taking measures to make sure that the products fulfil

¹ – Including the units on border

² – Including the units on border

³ – The data refers only to the Ministry; inspectors of local self-government units are not included

requirements regulated by technical regulations and do not endanger health, safety of consumers and other aspects of public interest.

The Market Inspection Department in the Ministry of Trade and Services is the coordinator (contact point) in the system for rapid exchange of information on dangerous products, established by the Law on General Product Safety (Official Gazette of RS, No 41/09) and the Regulation on the Method of Setting Up and Operation of the System of Rapid Exchange of Information on Dangerous Products (Official Gazette of RS, No 89/09).

**STRUCTURE OF FILED CONSUMER COMPLAINTS AND MEASURES
UNDERTAKEN BY MARKET INSPECTORATE IN THE FIELD OF CONSUMER
PROTECTION, BY YEARS**

Year	Total number of filed complaints	STRUCTURE OF FILED COMPLAINTS							MEASURES UNDERTAKEN				
		Consumer complaint procedure	Illegal work	Misleading advertising	Non-issuance of receipts	Overcharged prices	Inaccurate measuring	Other complaints	Request for economic offence	Request for initiating an infringement proceedings	Complaints to the court of honour	Decision ordering meeting justified buyers' requests	Decision banning performance of activity
2008	5,169	1,040	377	40	334	36	9	3,333	18	396	44	98	172
2009	5,818	3,566	775	70	363	140	72	833	34	543	1.874	187	278
2010	5,471	2,694	955	67	379	166	38	809	19	442	52	1.243	298

c) Market surveillance/protection of economic interests of consumers: are there independent administrative structures and enforcement powers monitoring the market for consumer goods and services, in order to detect breaches of rules protecting the economic interests of consumers and to ensure they are corrected? This would include dealing with consumer complaints (individual complaints and cases harming the collective interests of consumers) and infringement of rules. [See also section C. below.]

- Information should outline mandate, responsibilities and powers (e.g. of investigation, to seize the courts, etc.), as well as structure and organisation of the

services in charge of consumer policy, including links between central, regional and local level.

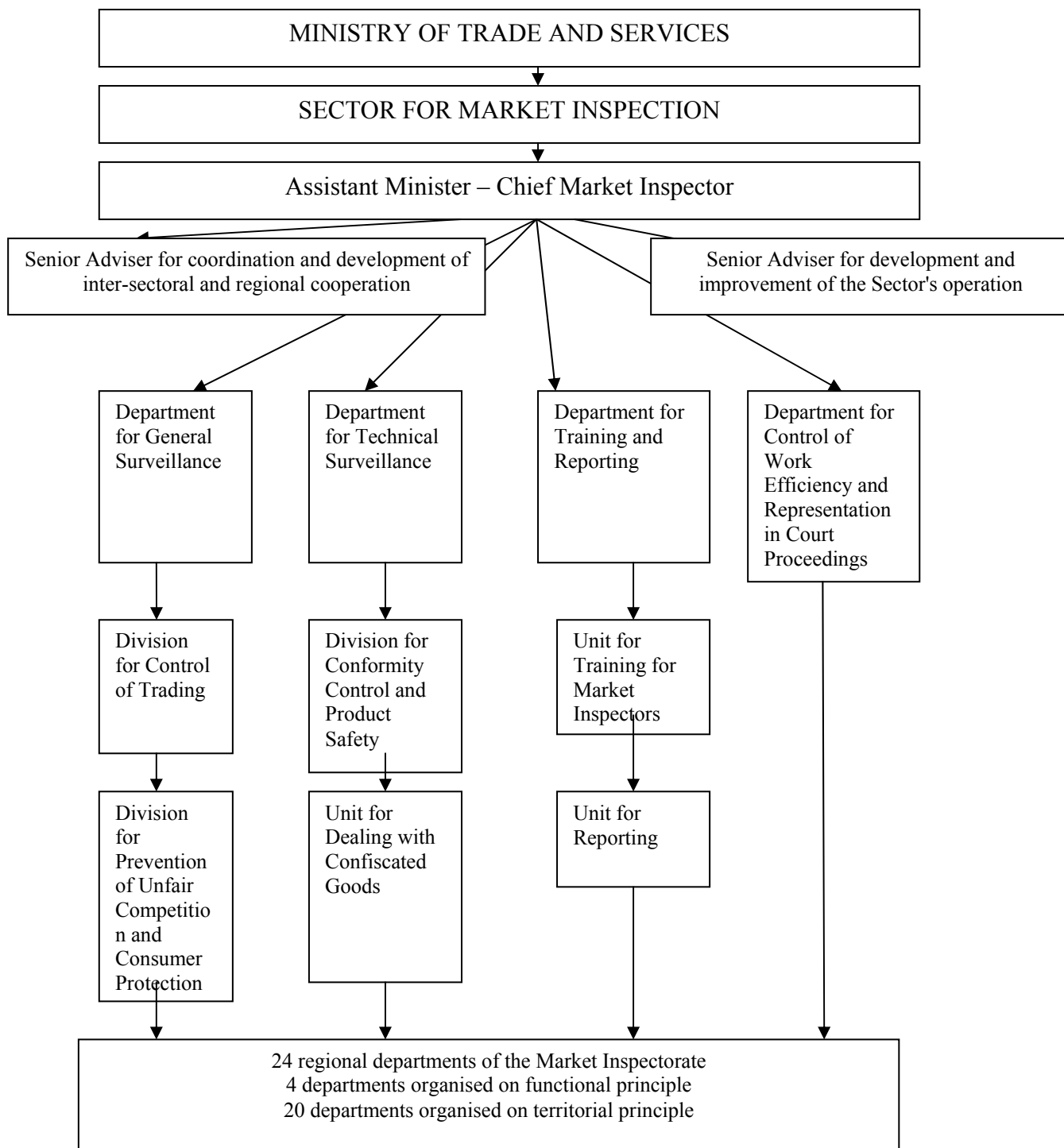
- **Please indicate human and financial resources allocated to each sector.**
- **Please explain how co-ordination between competent authorities is ensured.**
- **Please explain how you deal with infringements of Law on Consumer Protections harming the collective interest of consumers in cross border cases.**

The protection of the economic interests of consumers is one of the basic forms of consumer protection, according to data of market inspection acting upon consumers' complaints. Enforcement powers for monitoring are regulated in Articles 148 and 149 of the Law on Consumer Protection (Official Gazette of RS, No 73/10), which does not exclude the use of surveillance powers, that inspectors have under Articles 22-33 of the Law on Public Administration and under Article 58 of the Law on Trade (Official Gazette No 53/10).

The given legal framework, apart from judicial protection, regulates special powers for consumer protection in administrative/inspection proceedings and regulates competences of market inspection for surveillance in the fields of trade and services and tourist inspection in the field of tourism. Apart from repressive measures, competent authorities shall also take preventive measures, as a regular activity done under the annual work plan. The annual work plan is prepared and adjusted depending on the number and content of received applications (complaints) and requests from consumers and consumer organizations.

Administrative/inspection proceedings for consumer protection is conducted by the Market Inspection Department in the Ministry of Trade and Services, which is authorized to act upon individual or collective requests of consumers. Mainly, this department receives individual consumer requests that are solved under fast-track procedure. The Market Inspection Department organized a service on duty for reception and solving of these requests.

The Market Inspectorate is territorially in charge of surveillance in the field of consumer protection for the territory of the Republic of Serbia. Coordination of work is done through the Department for General Surveillance in the headquarters of the Market Inspectorate, and direct enforcement of powers is conducted through 24 area units, according to the following organizational scheme:



There are 485 market inspectors employed in Market Inspectorate. The means for the work of the Market Inspectorate are provided from the budget (programme/project budget), on the basis of unified/integrated plan of the Ministry of Trade and Services, where in 2010 a total of RSD 38,217,000.00 (\approx EUR 362,250) was provided for the Market Inspection Department, i.e. for the Programme of Market Control and Surveillance.

The Market Inspection Department provides coordination among competent authorities in the part of exchange of information on dangerous products done via the established NEPRO system and this means obligatory co-operation of all authorities in possession of information on safety of marketed products. There is also co-operation in relation to solving consumer complaints. The Market Inspectorate organizes joint meetings and workshops with other competent authorities in charge of market surveillance.

The Market Inspectorate co-operated with the Republic Broadcasting Agency and the Administration for Games of Chance in solving consumer complaints in relation to unfair commercial practices (false and misleading advertising). Authorizations for ordering measures are regulated in Articles 105 and 106 of the Law on Advertising (Official Gazette of RS, No 79/05).

The Ministry of Trade and Services of the Republic of Serbia formed within the Department for Consumer Protection on 18 March 2010 a free call centre for consumer protection, devoted to the processing of economic complaints of consumers and counselling. The centre's purpose is twofold - it acts both as a hub and a classifier – if the consumer's complaint alleges the violation of a certain administrative provision by the trader, it is forwarded to the competent inspection and for civil issues and advice, the centre forwards the cases to the NGO-led and governmentally subsidized regional advisory centres. With a view of forming such a universal system, the Ministry of Trade and Services announced in 2010 a public call for projects for opening 4 regional advisory centres for consumers, managed by non-governmental associations for consumer protection. The consumer protection organizations selected in the competition received governmental financial aid for executing project task – counselling users in their respective regions, including processing complaints forwarded from the Consumer Protection Centre. Regional advisory centres are also obliged to try and mediate between consumers and traders in order to reach an amicable solution to the problem, or if the consumers so choose, give legal aid via hired attorneys in order to represent them before the court. They submit regular reports on their work to the Ministry of Trade and Services in order to justify funding and monitor the macro situation.. Co-operation of the non-governmental and government sector is carried out in this way with the general purpose of providing macro-analytical data, the basis for policy decisions and preventive collective activity, aid in individual cases and creation of a unified database. In the period from 18 March to 1 December 2010 the Centre for Consumer Protection received 2080 complaints, 1603 of them are considered resolved⁴.

The courts represent the ultimate authority for the protection of costumers' economic interests. Special norms in the Law on Consumer Protection envisage powers for consumer

⁴ Until November 2010, a complaint had this status if the consumer was contacted and advised on his/her legal rights and potential next steps or it was forwarded to the competent inspection body. With the launch of work of the new regional advice centres, complaints with the status "resolved" are those where after the contact of both sides, the consumer exercised his/her right, was informed that he/she had no legal grounds, or was instructed about the possibility of launching a judicial procedure, with the assistance and support of lawyers employed by the advisory centres.

protection organizations to initiate a procedure for protecting consumers' collective interests against unfair contract terms and unfair commercial practices. None of the stated actions hamper the consumer in an attempt to resolve the problem in an out-of-court procedure.

Special formal and institutional procedures for cross-border co-operation in resolving consumers' economic problems are currently not carried out.

The protection of financial service consumers, as previously mentioned, are carried out within the National Bank of Serbia – the Centre for Financial Service Users, which has a staff of 12. Based on examination of grounds of complaints and irregularities detected in the work of financial institutions, the Centre for Financial Service Consumers through its activities stimulates financial institutions to correct their operations that are not in compliance with regulations and good practices.

The National Bank of Serbia in 2008 published recommendations for banks to stimulate them to conclude contracts with more precise terms and at the same time promote good practice of co-operation in the part that refers to change of interest rates and the currency clause. However, as the stated recommendations had no binding character, the National Bank of Serbia passed a Decision on the General Terms of Business Applied by Banks in Relations with Natural Person Clients (Official Gazette of RS, No 74/2009), regulating this issue. The same is applied to problems noticed with other financial institutions whose work is supervised by the National Bank of Serbia.

Surveillance of the implementation of the Law on Consumer Protection in the area of tourism is done by the Department of Tourist Inspection of the Ministry of Economy and Regional Development, in regular surveillance and upon costumers' complaints. Tourist inspectors of the Department of Tourist Inspection are in charge of surveillance in the whole territory of the Republic of Serbia. Tourist inspectors are deployed in five units. There are 93 tourist inspectors employed in the Department of Tourist Inspection. Employees in the Department for Tourism provide necessary information to the consumers' questions and give official opinions on enforcement of legal provisions, and upon filed complaints and applications, inspectors of the Department of Tourist Inspection act in line with the law.

Tourist inspectors shall have powers in the field of consumer protection to establish the factual situation by means of direct control, i.e. to establish whether the consumer's request is justifiable, particularly in exercising the rights in the area of tourist travels. Tourist inspectors provide assistance in finding an agreement on disputed issues and return the money to the consumer for an unprovided service. Tourist inspectors are authorized to file a report to the competent court for the criminal act, administrative violation or an economic offence, i.e., to file a request for launching an infringement procedure once they establish a violation of the law from competence that requires a sanction.

d) Are there regular statistical processes which monitor the levels and evaluation of prices for consumer's goods and services? Are there surveys intended to determine the level of satisfaction with consumer goods or the percentage of consumers who have switched their service provider?

The Republic Statistics Office collects data on a monthly basis on the prices of goods and services in retail trading. Based on the collected data, average prices for selected products

are calculated, as well as the price index for groups and subgroups of products. These data are used for the analysis of the levels and dynamics of prices.

For now only a draft version of methodology for calculating the index of consumer satisfaction has been made, under which research is to be conducted quarterly for a certain number of activities and the Satisfaction Index shall be calculated for each quarter, which will result in a single composite index at the end of the year. The total index is calculated as a weighted average of the indices in selected activities.

4. Have consultation structures or procedures been established in order to allow consumer interests to be represented in discussions on consumer policy, when drafting and implementing legislation?

In preparation and drafting of the Law on Consumer Protection, in accordance with the common practice in public administration, a working group for law drafting was formed. The group included experts in this field from the ministries, representatives of consumer protection organizations and relevant representatives of the academic community. After drafting the law, a public debate⁵ may be organized by putting the draft law on the Ministry website, and organizing forums and conferences. In this way, all meritorious opinions are collected, considered and included into the draft. Such a draft is submitted to other relevant public institutions (ministries, agencies) for an official opinion and only upon the adoption of their remarks is submitted to the government. After the government adopts it, it is forwarded to the parliament for consideration, amendments and final adoption. The bill is also discussed at the meetings of the Committee for Trade and the Committee for European Integration of the National Assembly, with participation of representatives of consumer organizations.

The Law on Consumer Protection (Official Gazette No 73/10, Article 126) stipulates the establishment of a National Council for Consumer Protection, as an advisory and consultative body and the continuation of the previous Minister's Council. The National Council, whose purpose is to improve co-operation between competent authorities, organizations and other stakeholders of consumer protection, is set up of representatives of ministries and other public institutions, consumer protection organizations, business and professional chambers and other market participants, and independent experts in the field of consumer protection. Representatives of consumer protection organizations who, together with other members of the Council, equally take part in formulating consumer policy, the drafting of a Consumer Protection Strategy and annual programmes of consumer protection, monitor the implementation of legislation for consumer protection and run the initiative for drafting new or amending the existing legislation.

The Law on Consumer Protection (CPL) (Articles 129, 130) provides for a category of registered organizations, in accordance with recommendations of the European Consumers' Organization (BEUC). Registered organizations have additional entitlements – such as

⁵ In the case of Law on Consumer Protection, there were several public discussions, in which consumer protection organizations and other relevant stakeholders, including commercial interests, had the opportunity to present their positions. Some of the public discussions were held at: Niš Regional Chamber of Commerce (17 September 2009), Valjevo Regional Chamber of Commerce (22 September 2009), Kragujevac Regional Chamber of Commerce (28 September 2009), Belgrade – Movement for Consumer Protection (6 October 2009), Zaječar Regional Chamber of Commerce (09 October 2009), Vojvodina Chamber of Commerce, Novi Sad (12 October 2009), Subotica Regional Chamber of Commerce (12 October 2009), Užice Regional Chamber of Commerce (16 October 2009), Belgrade Chamber of Commerce (27 October 2009), Pančevo Regional Chamber of Commerce (11 September 2010)...

participation in consultative bodies in the area of consumer protection and the right of representation of consumers in court proceedings (including injunctive measures prohibiting unfair business practices and unfair contract terms, Art. 137).

Contacts and consultations with consumer organizations take place on a regular basis, by exchanging formal letters, by telephone and in personal contact. On important consumer policy issues, meetings with consumer organizations are organized regularly.

5. Access to justice: which measures are in place, if any, to facilitate consumers' access to justice through the courts to seek individual redress? Are there measures to simplify and speed up small claims litigation? Do out-of-court bodies exist which provide alternative dispute resolution systems (e.g. mediation, arbitration or conciliation systems)?

The consumer has the right to address a court to protect his/her rights, in accordance with general rules of judicial procedure. There are no special provisions or procedures facilitating access for the consumers as such before the court in civil proceedings. There are no specific measures that enable accelerated procedure only for consumer small claims.

Article 132 of the Law on Consumer Protection reiterates the general rule that the resolution of consumer disputes may be resolved out-of-court. The Law on Arbitration (Official Gazette of RS 46/04) and the Law on Mediation (Official Gazette of RS 18/05) are the main regulations governing these procedures. From the institutional side, several professional associations offer mediation schemes – Serbian Chamber of Commerce, National Bank of Serbia (Centre for the Protection of Financial Service Consumers, mediation in disputes arising between users of financial services and commercial banks, within which the procedure is conducted by employees in possession of licence of authorized mediators), the National Association of Tourist Agencies (YUTA - Arbitration Court; resolves disputes arising under the contracts between travel agencies and passengers).

The Government of the Republic of Serbia established a Centre for Mediation as a public institution, where the solution to a disputable issue may be found (it became operational in March 2007). Of course, mediation before this body is not free of charge and is possible only upon mutual consent. According to the training programme (regulated by the Ministry of Justice), more than 500 mediators were educated, and so far sections of the Mediation Centre have been formed in Belgrade, Subotica, Bačka Palanka, Zrenjanin, Šabac, Novi Sad, Niš, Kruševac, Kraljevo, Jagodina, Leskovac, and sections in Novi Pazar, Pirot, Pančevo and Sremska Mitrovica are being prepared. At the initiative of the Serbian Chamber of Commerce, the opening of special sections of this centre at regional chambers of commerce started, with a view of resolving commerce-related disputes in the field in a faster and cheaper way.

Many consumer organizations mediate between consumers and traders in an informal way, including regional advisory centres. There are courts of honour within the chambers of commerce of Serbia and Belgrade competent to pronounce measures to chamber members for violation of good commercial customs and ethics.

Dispute of financial service consumers with a financial institution may be resolved in the course of acting upon complaint, and also in the mediation procedure carried out by the Centre for Financial Service Consumers of the National Bank of Serbia. Within the Centre for

Financial Service Consumers, this procedure is conducted by employees in possession of licence of authorized mediator of the Mediation Centre.

Articles 465 to 478 of the Law on Civil Procedure (Official Gazette of RS 125/04) envision a special procedure for small claims that may be applied to consumer disputes. Small value claim shall mean money claims not exceeding the amount of RSD 100,000 (\approx EUR 950) (except for real estate, labour relations and trespassing). The procedure is accelerated to a certain measure – the defendant is sent the legal suit together with the court summons, the response to the legal suit is not required, no preparatory hearing is held, a special appeal is allowed only against the decision terminating the proceedings, failure to appear of the duly summoned plaintiff shall be considered a withdrawal of the suit, failure to appear of the duly summoned defendant shall mean a judgement by default (if both sides fail to come, it shall be considered a withdrawal of the suit), unless the facts supporting the claim are contrary to the evidence brought by the plaintiff or generally obvious and well-known facts.

6. Is there in the consumer area a court or an administrative procedure which enable entities such as consumer organisations/public authorities to seek an injunction to stop an illegal practice of a trader and to describe the system?

The Law on Consumer Protection, in Articles 137-146, provides for a special procedure prohibiting unfair contract terms and unfair commercial practices, and the seizure of illegally acquired material gain. The claim may be submitted by a damaged consumer or a registered consumer protection organization or association, in the event of a breach of collective interest (Article 137). The proceedings shall be initiated before the competent court in accordance with regulations governing civil action. The same court shall have jurisdiction in proceedings for imposing provisional measures ordering the suspension of the application of unfair contract terms or stoppage of unfair commercial practices at the proposal of the applicant, until a final court decision upon the request is made. Apart from these particular rules, the provisions of the Civil Procedure Code shall generally apply for the procedure to ban unfair terms in consumer contracts, the prohibition of unfair commercial practice and the seizure of illegally acquired material gain.

The ministry responsible for consumer protection, under Article 141, shall be obliged to publish on its website the available court practice regarding the filed requests and decisions, based on the data received from the ministry responsible for justice, in order to make this data available to wider public.

Under Article 143, the court shall, upon the proposal of an authorized person, determine the nullity of the contract terms in accordance with the rules on unfair contract provisions that are prescribed by the same law (Articles 44–48) i.e. determine that certain conduct is unfair commercial practice (Article 19–25); order the trader to immediately stop using the unfair contract terms in their operations with consumers, i.e., to stop with unfair commercial practices; order the trader to correct at his own expense the public announcement that pursuant to the provisions of this law is a form of unfair commercial practice; order that the decision is announced at the expense of the trader or the person recommending or supporting unfair contract terms in the operation with consumers. Request for injunctive relief is reserved for the court and no independent administrative procedure is envisioned.

In the practice of market inspection, based on rules of general administrative and inspection procedures and operation of public administration authorities, complaints of

consumer organizations are accepted on behalf of a wider number of damaged consumers and actions are taken upon these appeals with the participation of consumer organizations involved in the process. In this way, consumer organizations are given an opportunity to explain the specific problems of consumers and their demands. Also, complaints of other bodies explaining observed violations of the laws are received, which is followed by inspection controls.

7. Has the government drawn up any education, information and awareness-raising programme on consumer issues, which would help consumers be aware of their rights and able to exercise them?

The National Programme for Consumer Protection stipulates continual activities on informing and educating consumers. To raise awareness of consumers about their rights but also about the general consumer policy, the Government of the Republic of Serbia carried out a series of educational and informative actions:

- In co-operation with the **CARDS 2006** project – **“Strengthening the Consumer Protection System in Serbia” (ZAP project)**, the first project in the field of consumer protection in Serbia funded by the European Union, and whose main beneficiary of the project is the Ministry of Trade and Services of the Republic of Serbia, **produced a series of 7 leaflets**. The topics of leaflets are some of the key issues of current consumer problems in Serbia, such as promotional travels, mobile phones, electronic commerce, forced purchases, TV quizzes, consumer cards and hidden costs. Marking the occasion of World Consumers’ Day, on 15 March 2010, the brochures were distributed in 163 municipalities in Serbia and inserted in daily newspapers. Given that young people are very active consumers and their awareness of the rights and obligations is essential to understanding the market, the Ministry of Trade and Services in collaboration with ZAP project in 2009 developed and distributed more than 7,000 calendars with useful instructions in the field of protection of consumer rights in 497 secondary schools. The content of the calendar, in addition to general topics of purchase, savings, advertising, hidden costs, were the topics particularly interesting for this age: the use of the Internet, mobile phones, the use of cosmetics, tattoos, fast food, etc;
- **Creating a poster “Education of Consumers in the Field of Services”**, that in an illustrative way presents the most important provisions of the Law on Consumer Protection. At the same time, typical situations with an average consumer in the Republic of Serbia are presented, where his/her consumer rights are threatened, and also suggestions are given to service providers how to operate in accordance with the provisions of the law. This bolsters awareness and aids in reinforcing competitiveness of businesses in the service sector in the Republic of Serbia. The poster contains contact institutions to be addressed in cases of violation of consumer rights (the Department of Market Inspection and the Department for Services of the Ministry of Trade and Services).
- **Distribution of educational themed materials** "Consumer Protection and the Stabilization and Association Agreement", "Product Safety and the Stabilization and Association Agreement" and "A Guide to Shopping on the Internet";
- **Initiating the publishing of a newspaper supplement "Consumer" in the daily newspaper “Politika”**, which discusses current consumer issues not only from the

perspective of state institutions but also consumer protection organizations. Further technical and financial support to the work of this newspaper supplement was provided;

- A public call was conducted in 2009 for funding projects of consumer protection organizations and their associations themed **"Information and Education of Consumers"**, worth RSD 4 million. The following two projects were selected for financial support: the print magazine "Consumer Reporter" and electronic magazine "Consumer-info";
- **The making and distribution of two leaflets** for the implementation of the new Law on Consumer Protection themed "Unfair Commercial Practice" and "Guarantees";
- The making and distribution of 10,000 informative stickers about the Consumer Protection Centre hotline countrywide via the 4 regional advisory centres and traders.

Representatives of public administration actively participated in professional seminars as lecturers, in numerous round tables and public debates, and were actively involved in the presentation of the new Law on Consumer Protection to consumers and business sector. In order to educate consumers about their legal rights, provide a current situation assessment and present planned activities to improve the position of consumers, representatives of public administration participated in interviews with representatives of electronic and printed media and appeared in numerous television and radio shows.

The Ministry organized two seminars on "Project Cycle Management" in order to strengthen the capacity of consumer organizations, i.e. present them with the procedures for preparing and carrying out projects financed from domestic and foreign sources of financing, particularly EU funds. Also, in co-operation with the ZAP project, the following seminars and workshops were organized: "Consumer Organizations Management", "Inclusion of Consumer Protection Organizations in the Implementation of Consumer Policy", "Consumer Counselling", "Collective Court Actions", "Project Cycle Management", "Out-of-Court Resolution of Consumer Disputes", "Vulnerable Consumer".

The Department of Market Inspection, as the beneficiary of the IPA 2010 project "Strengthening the Market Surveillance of Non-Food and Food Products in Serbia" in the preparatory activities prepared a brochure and a leaflet explaining which authorities in Serbia are responsible for market surveillance and which activities and measures are planned in that surveillance. Also, a leaflet was prepared explaining why it is important that consumers should require the issuance of a receipt for the purchased goods or services. The market surveillance programme for 2011 was made available to consumers, so that it could be adapted to their interests, during its realization in the planned period. The Ministry of Trade and Services published on its website recommendations of the market inspection intended for consumers.

Activities aimed at informing and educating users were carried out in the field of financial services, as well. Namely, the National Bank of Serbia as a member of an international network of countries engaged in financial education within the OECD published the OECD recommendations and prepared a study on the need for financial education of citizens and the manner of its implementation. Within these activities, a new website of the National Bank of Serbia was launched – "Your Money" www.tvojnovac.nbs.rs – intended for consumers of financial services and the general public. The content of the site is written in clear, understandable language that is adapted to the general public. Also, offices for financial education of citizens were opened within five branches of the National Bank of Serbia

(Belgrade, Novi Sad, Kragujevac, Niš, Užice) on 5 January 2009, by which the National Bank of Serbia provided citizens across Serbia with comprehensible and comprehensive information about financial products offered on our financial market. In November 2010 three forums for citizens in the branches of National Bank of Serbia were organized. Such activities will be conducted in the course of 2011 in other cities in Serbia with the active participation of the education office.

The National Bank of Serbia adopted a Decision on the General Terms of Business Applied by Banks in Relations with Natural Person Clients that directly promote the increase of consumer information, because on the one hand, it obliges the banks to provide all necessary information about their products and services, and on the other hand, clients are given the possibility to obtain at different stages of purchase and use all the information necessary for making a decision about using a particular product or service.

8. Do non-governmental organisations representing consumer interests exist in your country? If so, please describe their situation: how many are there? When were they created? How is their membership composed? Are they representative of consumer interests at national level? Is the government promoting and assisting their development? What are their objectives? Which kind of activities do they carry out? What are their main sources of financing? How many staff do they employ?

Non-governmental organizations, including consumer protection organizations, are established in Serbia and act in according to the Law on Associations (Official Gazette of RS, No 51/09). There are 62 registered consumer protection organizations in the Republic of Serbia, most of which are members and function within the following 5 major associations:

1. Consumers' Association of Serbia (APOS) – 6 consumer protection organizations
2. Consumers' Centre of Serbia (CEPS) – 10 consumer protection organizations
3. National Organization of Consumers of Serbia (NOPS) –20 consumer protection organizations
4. National Consumers' Alliance of Serbia – 10 consumer protection organizations
5. Alliance of Consumer Organizations of Serbia (SOPS) – 4 consumer protection organizations

No and Decision No	Name of union/association	Contact person	Address
1 5790/03 7433/09	Consumers' Association of Serbia (APOS)	Edina Popov Ivana Gruber Helena Miličević	21000 Novi Sad Dr Svetislava Kasapovića 32/VI/32
2 14196/08	Consumers' Centre of Serbia (CEPS)	Vera Vida	11000 Belgrade Tadeuša Koščuška 36
3 7807/04	National Organization of Consumers of Serbia (NOPS)	Goran Papović	Office of the president: 21000 Novi Sad Uroša Predića 5
4 14178/08	National Alliance of Consumers of Serbia (NSPS)	Petar Milutinović Maja Georgijevska	11000 Belgrade Visokog Stevana 31
5 534/96 BU 799/09	Alliance of Consumer Organizations of Serbia (SOPS)	Milić Marković	16000 Leskovac Vojvode Mišića 22

6 5722/03	Movement for Consumer Protection – Belgrade	Petar Bogosavljević	11000 Belgrade Savska 9/III
7 5758/03 (NOPS)	Consumers Association New Belgrade	Zoran Bošnjak	11070 New Belgrade Autoput 2 Jurija Gagarina 205/22 (home)
8 11544/03 (CEPS)	Centre for Education and Protection of Consumers – Belgrade	Stana Vranić Dugalić Vera Vida	11000 Belgrade Terazije 43
9 12385/03 (NSPS)	Advisory Consumer Centre Čukarica – Belgrade	Ljiljana Veljković Zoran Veljković	11000 Belgrade Kedrova 8/17
10 12493/ 07	Republic Union of Consumers	Denis Perinčić Miloš Skendžić	11000 Belgrade Vojvode Stepe 26 11070 New Belgrade Narodnih Heroja 63, 1.17
11 5372/03	Association for Protection of Rights of Users of Telecommunication, Information- Communication, TV and Radio Services Telekom bra	Tihomir Živanović	11000 Belgrade Cara Lazara 10
12 11563/ 07	Citizens association RE-AKCIJA (RE- ACTION)	Jasmina Lechleitner	11000 Belgrade Duvanjska 5 (Dimitrija Tucovića 83)
13 13290/08 (NOPS)	Consumer Organization “Hram”	Natalija Vranešević Dragan Vranešević	11000 Belgrade Krušedolska 1 b (Vračar)
14 831/ 02	Centre for Consumer Protection and Promotion of Citizens’ Quality of Life “Forum”	Jovan Jovanović Života Cvetković (Deputy)	18000 Niš Generala Bože Jankovića 9/III
15 754/97 13679/2008(NOPS)	Niš City Organization of Consumers	Prof Dr Ljiljana Stanković Mr Milisav Milićević Novica Randelović	18000 Niš Starca Vujadina 8 a (Patrisa Lumumbe 6/37)
16 834/03	Association of Citizens Consumers of Electric Energy Niš	Zlatko Stojković	18000 Niš Bulevar Nemanjića 20a/4
17 7959/05 (NOPS)	Consumer Organization of Pirot	Dragana Lilić	18300 Pirot Srpskih vladara 90/IV
18 51/98 (NOPS)	Prokuplje Municipality Consumer Organization	Snežana Apostolović	18400 Prokuplje Darinke Nestorović 30
19 91/02 (NSPS)	Sokobanja Consumers Movement	Saša Mihailović	18230 Sokobanja Dragovićevo 16
20 8460/05 (NOPS)	Consumer Organization Doljevac	Dragan Alić	18410 Doljevac 18411 Belotinac
21 10354/06 (NOPS)	Consumer Organization “Zvezda”	Miroslava Knežević Petrović	18420 Blace Svetog Save 2/4 Kralja Petra 70
22 12316/07 (NOPS)	Consumer Organization of Pčinja District – Vranje	Živko Stamenković Aleksandra Novaković	17500 Vranje Beogradska 39
23 5/ 70 233/90 BU 560/09	Leskovac City Consumer Organization	Milić Marković	16000 Leskovac Vojvode Mišića 22

(SOPS)			
24 84/02 (NOPS)	Vlasotince Municipality Consumer Organization	Novica Jovanović	16210 Vlasotince Trg oslobođenja 7 a
25 5731/03 (APOS)	Bor Consumers Movement	Zoran Andrejić Damir Budrovac	19210 Bor Đorđa Andrejevića Kuna 4/1
26 14098/08	Advisory Centre for Consumer Protection Negotin	Vladimir Nikolić	19300 Negotin JNA 1/11
27 517/03 (NOPS)	Consumer Organization Kragujevac	Zoran Nikolić	34000 Kragujevac Kralja Aleksandra I Karadorđevića 98 (PO box 84) Sime Tepića 23
28 6801/04 (NOPS)	Consumer Organization Kruševac	Olivera Veselinović Jelena Zdravković	37000 Kruševac Čupićeva 13
29 9952/05 (on 17.12.2009. left NOPS)	Association for Consumer Protection "Kruševac"	Nebojša Smiljković	37000 Kruševac Šumadijska 54
30 12170/07 (NOPS)	Consumer Organization Raška	Srđan Arsović	36350 Raška Igora Nikića 6
31 13887/08 (NOPS)	Consumer Organization Užice	Milan Nikolić	31000 Užice Dimitrija Tucovića 52 (Mage Magazinović 26/61)
32 5568/03 (NSPS)	Association of Consumers and Users of Services Čačak	Srboljub Milošević	32000 Čačak Karadorđeva 17
33 6671/04 (SOPS)	Consumer Organization Jagodina	Ljubiša Andrejić	35000 Jagodina Maksima Gorkog 5
34 10006/05 (NSPS)	Centre for Consumer Protection Valjevo	Vladica Đurić Nebojša Nožica	14000 Valjevo Rudnička bb Dimitrija Tucovića 37a
35 9604/05	Movement for Protection of Consumers and Services Valjevo	Ratko Bjelić	14000 Valjevo Suvoborska 171
36 13196/08 (NOPS)	Consumer Organization Valjevo	Slobodan Petronijević Dragan Janković Predrag Martinović	14000 Valjevo Naselje Oslobođilaca Valjeva 24 (office in local community)
37 10173/06 (NOPS)	Centre for Consumer Protection Šabac	Milenko Jelesić	15000 Šabac Adama Lazarevića 38
38 7941/05 (AOPS)	Association of Consumers and Users of Public Services	Dragana Simić Antonijević	15000 Šabac Jovana Cvijića 15/40
39 5520/03 (APOS)	Požarevac Consumers Movement	Dragana Stojković	12000 Požarevac Trg Radomira Vujovića 10/29
40 2608/01	Free Citizens of Požarevac	Ljiljana Živanović Bogdan Živanović	12000 Požarevac Sindelićeva 4
41	Consumer Organization	Milić Stanojević	11300 Smederevo

15097/09 (NOPS)	Smederevo	Ognjen Petrovski	Karađorđeva 18/1 (apartment of Ognjen P.)
42 946/93 (SOPS)	Vojvodina Consumers Movement	Radojka Nikolić	21000 Novi Sad Alberta Tome 2 a
43 851/91 (SOPS)	Novi Sad Consumers Movement	Radojka Nikolić	21000 Novi Sad Alberta Tome 2 a
44 3042/01 (NOPS)	Vojvodina Association for Consumer Protection	Goran Papović	21000 Novi Sad Uroša Predića 5
45 4363/02 (APOS)	Association of Consumers and Users of Public Services	Borislava Dejanović	21000 Novi Sad Trg Slobode 2
46 8779/05	Association of Consumers of Products and Services of Public and Public Utility Companies “Lege artis”	Slobodan Vlaisavljević	21000 Novi Sad Marije Bursać 117
47 247/04 (AOPS)	Association of Consumers	Ilija Zrnić	24000 Subotica Save Šumanovića 2
48 231/03 (no longer in APOS)	Citizens association JAVNOST	Milorad Santrač	24000 Subotica Aleja Maršala Tita 28/10
49 14518/09 (CEPS)	Centre for Education and Protection of Consumers – Bačka Topola	Aniko Dudaš	24300 Bačka Topola Sutjeska 12
50 11569/07 (CEPS)	Senta Municipality Centre for Consumer Protection	Ištvan Kiralj	24400 Senta Ardapova 92 c
51 13725/08 (CEPS)	Centre for Consumer Protection Kanjiža	Hajnalka Harmat	24420 Kanjiža Adi Endrea 21
52 10585/06 (NOPS)	Consumer Organization “Polaris” Zrenjanin	Slobodan Eremić	23000 Zrenjanin Pupinova 6 a (Karađorđev trg 15)
53 12862/07 (NOPS)	Kikinda Association of Consumers (UPOK)	Aleksandar Korać	23300 Kikinda Mikronaseje-Blok B-Lamela 2/12
54 12846/07 (CEPS)	Centre for Consumer Protection Čoka	Dušica Božin	23320 Čoka Maršala Tita 7
55 8185/05 (NOPS)	Centre for Consumer Protection “Pančevo”	Miroslava Matić	26000 Pančevo Ilariona Ruvarca 3/2
56 87/99 (NOPS)	Consumers Movement Pančevo – South Banat	Tomislav Beker	26000 Pančevo Moravska 6/5
57 8511/05 (NOPS)	Association of Consumers of Pančevo Municipality	Dobrosav Uskoković Tomislav Beker	26000 Pančevo Vojvođanski Bulevar 42 (Moravska 6/5)
58 339/99 (NSPS)	Movement for Consumer Protection	Svetozar Đerić	26000 Pančevo Cara Dušana 104
59 8124/05 (APOS)	Citizens Association for Consumer Protection “Košava”	Olgica Lukač	26300 Vršac Svetosavski trg 10 (Shopping centre Bahus, shop 16, Sterijina 34)
60 12364/07 (CEPS)	Centre for Education and Protection of Consumers – Alibunar	Dragana Mamojka Marijana Bugarin	26310 Alibunar Miloša Crnjanskog 72
61 5824/03 (NSPS)	Bela Crkva Consumers Movement	Jelena Pavlović	26340 Bela Crkva Vojske Jugoslavije 45 a
62 12366/07 (CEPS)	Centre for Education and Protection of Consumers – Bela Crkva	Smiljana Jovanović Jelena Đurašević	26340 Bela Crkva Partizanska 9
63 12365/07 (CEPS)	Centre for Education and Protection of Consumers –	Zoran Cimeša Vladimir Kiseljev	26360 Plandište Đure Jakšića 25

	Plandište		
64 9239/05 (NSPS)	Educational Centre for Consumer Protection Glogonj	Maja Georgijevska	26202 Glogonj Culture Centre "Mladost" 1.maja 82
65 12656/07 (CEPS)	Centre for Education and Protection of Consumers – Kovačica	Ferenc Doša	26101 Kovačica Čaplovičova 13
66 11856/07 (NSPS)	Centre for Consumer Protection of Kačarevo Local Community	Slobodan Ćurčić	26212 Kačarevo Maršala Tita bb
67 13862/08 (CEPS)	Centre for Consumer Protection Indija	Slavica Rodić Zdenka Jokić	22320 Indija Vojvode Stepe 24

The prevalent number of the total number of abovementioned actors was established in the period from 2001 to 2008. The overall influence of organizations, despite large numbers, is small and mostly connected to municipalities and local actors. Associations strive to represent the interests of consumers at the national level. A key function and role of consumer organizations is to inform and advise consumers, promote and protect consumer interests, run comparative tests of goods and services, and represent consumers before the institutions, with the aim of raising awareness and strengthening the position of consumers in a market economy. There is no adequate centralized data on membership and sources of funding for consumer protection organizations and associations.

The Government of the Republic of Serbia started with the practice of financial support to consumer protection organizations in 2007. Since 2008, in concordance with European practices, the system changed from linear funding to project financing for consumer protection organizations through public calls for the provision of incentive funds from the budget of Ministry of Trade and Services. The Ministry of Trade and Services awarded incentives for consumer organizations for the themes "Enhancing Consumer Protection in the Republic of Serbia" in 2008, "Informing and Advising Consumers" in 2009, and in 2010 "Regional Consumer Counselling" for 4 advisory centres, whose activities are distributed according to regional principle.

Year 2007

Allocated funds: **7.940.000,00 (≈ EUR 75,260)**

Name of consumer protection organization/association	Location	Responsible person	Amount of allocated funds
National Organization of Consumers of Serbia	Belgrade	Milić Marković	1.824.000,00 (≈ EUR 17,290)
Consumers' Association of Serbia (APOS)	Novi Sad	Edina Popov	456.000,00 (≈ EUR 4,320)
Movement for Consumer Protection – Belgrade	Belgrade	Petar Bogosavljević	240.000,00 (≈ EUR 2,275)
Organization of Consumers Leskovac	Leskovac	Milić Marković	240.000,00 (≈ EUR 2,275)
Centre for Consumer Protection "Forum"	Niš	Jovan Jovanović	240.000,00 (≈ EUR 2,275)
Vojvodina Association for Consumer Protection	Novi Sad	Goran Papović	240.000,00 (≈ EUR 2,275)
Organization of Consumers Kragujevac	Kragujevac	Zoran Nikolić	240.000,00 (≈ EUR 2,275)
Association of Consumers and	Novi Sad	Borislava Dejanović	240.000,00

Users of Public Services			(≈ EUR 2,275)
Association of Consumers New Belgrade	New Belgrade	Zoran Bošnjak	120.000,00 (≈ EUR 1,138)
Centre for Education and Protection of Consumers – Belgrade	Belgrade	Vera Vida	120.000,00 (≈ EUR 1,138)
Organization of Consumers Pirot	Pirot	Dragana Lilić	120.000,00 (≈ EUR 1,138)
Prokuplje Municipality Organization of Consumers	Prokuplje	Snežana Apostolović	120.000,00 (≈ EUR 1,138)
Sokobanja Consumers Movement	Sokobanja	Saša Mihailović	120.000,00 (≈ EUR 1,138)
Organization of Consumers Doljevac	Doljevac	Dragan Alić	120.000,00 (≈ EUR 1,138)
Organization of Consumers “Zvezda”	Blace	Miroslava Knežević Petrović	120.000,00 (≈ EUR 1,138)
Vlasotince Municipality Organization of Consumers	Vlasotince	Novica Jovanović	120.000,00 (≈ EUR 1,138)
Bor Consumers Movement	Bor	Zoran Andrejić	120.000,00 (≈ EUR 1,138)
Organization of Consumers Kruševac	Kruševac	Olivera Veselinović	120.000,00 (≈ EUR 1,138)
Association for Consumer Protection “Kruševac”	Kruševac	Nebojša Smiljković	120.000,00 (≈ EUR 1,138)
Association of Consumers and Users of Services Čačak	Čačak	Srboljub Milošević	120.000,00 (≈ EUR 1,138)
Organization of Consumers Jagodina	Jagodina	Ljubiša Andrejić	120.000,00 (≈ EUR 1,138)
Centre for Consumer Protection Valjevo	Valjevo	Nebojša Nožica	120.000,00 (≈ EUR 1,138)
Centre for Consumer Protection Šabac	Šabac	Milenko Jelesić	120.000,00 (≈ EUR 1,138)
Association of Consumers and Users of Public Services	Šabac	Dragana Simić Antonijević	120.000,00 (≈ EUR 1,138)
Požarevac Consumers Movement	Požarevac	Dragana Stojković	120.000,00 (≈ EUR 1,138)
Novi Sad Consumers Movement	Novi Sad	Radojka Nikolić	120.000,00 (≈ EUR 1,138)
Association of Consumers of Products and Services of Public and Public Utility Companies “Lege artis”, Novi Sad	Novi Sad	Slobodan Vlasisavljević	120.000,00 (≈ EUR 1,138)
Association of Consumers	Subotica	Ilija Zrnić	120.000,00 (≈ EUR 1,138)
Citizens association JAVNOST	Subotica	Milorad Santrač	120.000,00 (≈ EUR 1,138)
Centre for Consumer Protection Senta	Senta	Abruš Seleš	120.000,00 (≈ EUR 1,138)
Organization of Consumers “Polaris” Zrenjanin	Zrenjanin	Slobodan Eremić	120.000,00 (≈ EUR 1,138)
Centre for Consumer Protection “Pančevo”	Pančevo	Miroslava Matić	120.000,00 (≈ EUR 1,138)
Association of Consumers of Pančevo Municipality	Pančevo	Dobrosav Uskoković	120.000,00 (≈ EUR 1,138)
Consumers Movement Of Pančevo – South Banat	Pančevo	Tomislav Beker	120.000,00 (≈ EUR 1,138)
Citizens Association for Consumer Protection “Košava”	Vršac	Olgica Lukač	120.000,00 (≈ EUR 1,138)
Bela Crkva Consumers	Bela Crkva	Jelena Pavlović	120.000,00

Movement			(≈ EUR 1,138)
Educational Centre for Consumer Protection Glogonj	Glogonj	Maja Georgijevska	120.000,00 (≈ EUR 1,138)
Movement for Protection of Consumers and Services Valjevo	Valjevo	Ratko Bjelić	120.000,00 (≈ EUR 1,138)
Association of Citizens Consumers of Electric Energy Niš	Niš	Zlatko Stojković	120.000,00 (≈ EUR 1,138)
Centre for Consumer Protection of Kačarevo Local Community	Kačarevo	Slobodan Ćurčić	90.000,00 (≈ EUR 853)
Advisory Consumer Centre Čukarica – Belgrade	Belgrade	Ljiljana Veljković	60.000,00 (≈ EUR 568)
Consumers Organization of Pčinja District – Vranje	Vranje	Živko Stamenković	60.000,00 (≈ EUR 568)
Organization of Consumers Raška	Raška	Srđan Arsović	60.000,00 (≈ EUR 568)
Centre for Education and Protection of Consumers – Alibunar	Alibunar	Dragana Mamojka	60.000,00 (≈ EUR 568)
Centre for Education and Protection of Consumers – Bela Crkva	Bela Crkva	Smiljana Jovanović	60.000,00 (≈ EUR 568)
Centre for Education and Protection of Consumers – Plandište	Plandište	Vladimir Kiseljev	60.000,00 (≈ EUR 568)
Republic Union of Consumers	Belgrade	Miloš Skendžić	50.000,00 (≈ EUR 474)
Centre for Education and Protection of Consumers – Kovačica	Kovačica	Ferenc Doša	40.000,00 (≈ EUR 380)
Kikinda Association of Consumers	Kikinda	Aleksandar Korać	20.000,00 (≈ EUR 190)

Year 2008

Allocated funds: **6.707.680,00** (≈ EUR 63,580)

Project	Name of consumer protection organization/association	Location	Responsible person	Amount of allocated funds
LAZAR THE CONSUMER AND JECA THE CONSUMER	Organization of Consumers Pirot	Pirot	Dragana Lilić	669.980 (≈ EUR 6,350)
DOCTOR'S OFFICE TAILORED FOR PATIENT'S NEEDS	Citizens association RE-AKCIJA (RE-ACTION)	Belgrade	Jasmina Lehlajter	1.685.000 (≈ EUR 15,970)
MEET YOUR CONSUMER RIGHTS	National Organization of Consumers of Serbia	Belgrade	Milić Marković	1.997.800 (≈ EUR 18,936)
LET'S LEARN OUR RIGHTS	Centre for Education and Protection of Consumers	Belgrade	Vera Vida	1.670.000 (≈ EUR 15,830)

Counselling IMPLEMENTATION OF THE NEW LAW ON CONSUMER PROTECTION AND COMPLEMENTARY LEGISLATION WITH A CENTRAL CEREMONY FOR 15 MARCH – WORLD CONSUMER RIGHTS DAY	National Organization of Consumers of Serbia	Belgrade	Milić Marković	684.900 (≈ EUR 6,490)
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Year 2009

Allocated funds: **3.725.000,00 (≈ EUR 35,308)**

Project	Name of consumer protection organization/association	Location	Responsible person	Amount of allocated funds
BOLSTERING THE QUALITY AND VOLUME OF INFORMATION IN THE MAGAZINE “CONSUMER REPORTER”	Consumers’ Association of Serbia (APOS)	Novi Sad	Edina Popov	1.850.000,00 (≈ EUR 17,535)
ELECTRONIC EDITION OF THE MAGAZINE "CONSUMER-INFO"	Vojvodina Association for Consumer Protection	Novi Sad	Goran Papović	1.875.000,00 (≈ EUR 17,770)

Year 2010

Allocated funds: **4.112.740,00 (≈ EUR 38,983)**

Project	Name of consumer protection organization/association	Location	Responsible person	Amount of allocated funds
Regional Advisory Center for South and Eastern Serbia	Centre for Consumer Protection “Forum”	Niš	Jovan Jovanović	1.028.940,00 (≈ EUR 9,753)
Regional Advisory Center for Šumadija and Western Serbia	Organization of Consumers Jagodina	Jagodina	Ljubiša Andrejić	1.030.000,00 (≈ EUR 9,763)
Belgrade Advisory Center	Centre for Education and Protection of Consumers	Belgrade	Vera Vida	1.024.000,00 (≈ EUR 9,706)
Regional Advisory Center for Vojvodina	Consumers’ Association of Serbia (APOS)	Novi Sad	Edina Popov	1.029.800,00 (≈ EUR 9,761)

Along with project funding, the Ministry organized a series of educational activities for representatives of consumer protection organizations in the field of Project Cycle Management. Representatives of consumer protection organizations were actively involved as

members of the Minister's Council for Consumer Protection. A representative of the National Consumer Organization of Serbia, as a member of the working group, was involved in the drafting of the Law on Consumer Protection, and NGOs participated in numerous public debates on the draft law. Also, a representative of the National Consumers Organization of Serbia was involved in the work of the Commission for Monitoring Prices and Living Standard that the Government of the Republic of Serbia formed at the proposal of the Ministry of Trade and Services in order to mitigate the effects of economic crisis on the purchasing power and standard of living. The National Consumer Organization of Serbia, the Consumers' Association of Serbia (APOS) and Movement of Consumers of Belgrade are associated members of Consumers International.

In addition to the aforementioned funding by the ministry, the budgets of local governments and donations from international organizations represent modest sources of funding. The problem of insufficient funding is accompanied by lack of office space, equipment and connection with relevant state authorities and other consumer protection organizations, which hampers their efficiency. According to unofficial data of the ministry, most of the work in the consumer protection organizations is organized on a voluntary basis, with little employed staff.

9. Have you developed any relations with other countries on consumer protection issues (e.g. cross-border co-operation activities, exchange of information and best practices, etc.)?

The co-operation of state authorities of the Republic of Serbia with other countries in the field of consumer protection takes place through the exchange of information on relevant national regulations in this area and their implementation, but also through concrete activities.

Since 2007, the Republic of Serbia has been included in the Project sponsored by the government of Germany, GTZ Project Open Regional Fund - Legal Reform - Project Harmonization of legal framework and establishing a network of institutions for consumer protection in the region (Serbia, Macedonia, Croatia, Montenegro, Bosnia and Herzegovina and Albania), with the aim of intensifying co-operation between the countries of the region. The main objectives of the project are strengthening consumer protection by establishing consistent policy in the countries of Southeast Europe, a higher level of consumer protection in line with EU standards and fostering an improved goods and services market in the region.

Also, constant dialogue with other countries in the field of consumer protection is led through the participation of the Republic of Serbia in international conferences and return visits of colleagues with a view of deepening regional co-operation. In this regard, the Ministry of Trade and Services organized in 2010 on Zlatibor Mountain a conference on "Regional Co-operation in the Field of Competition, Consumer Protection and European Integration", which was attended by the delegation of Bosnia and Herzegovina. The participants presented the current legal framework, as well as completed and future activities in its promotion and implementation.

The Ministry of Trade and Services in October 2010 signed a Memorandum of Understanding with the National Administration for Consumer Protection of the Republic of Hungary. The aim of the memorandum is co-operation of authorities responsible for consumer protection and market surveillance in ensuring effective market surveillance and consumer

protection system by exchanging information and best practices, particularly in the area of control and testing goods and services.

A Protocol on Co-operation between the Ministry of Trade and Services of Serbia and the Ministry of Trade and Tourism of Republika Srpska was signed. The subject of co-operation is the assistance in the development of important new laws to be adopted in the next two years, particularly in the area of consumer protection and product safety, where the experience of Serbia will be valuable. Under this agreement, two workshops on the transposition of relevant EU regulations into national law have already been organized.

A Memorandum of Technical Assistance in the European integration process was signed between the governments of Slovenia and Serbia. Co-operation in the field of consumer protection through organization of workshops and conferences and development of information systems for consumer protection was agreed on and shall be implemented in the first half of 2011.

Co-operation in the field of consumer protection was discussed during a study visit of representatives of the Ministry of Trade and Services of Serbia to the Czech Ministry of Industry and Trade in January 2010.

The Market Inspectorate is included in regional market surveillance projects financed from IPA funds and carried out through workshops and seminars to exchange experience and information between market surveillance authorities in the region and the customs authorities.

B. Product safety-related measures:

Legislation

10. In the framework of your consumer protection policy, indicate whether the following sectors are covered and to what extent they are in line with the relevant EU *acquis*:

- General Product Safety Directive (2001/95/EC)

Directive 2001/95/EC was transposed into the Law on General Product Safety (Official Gazette of RS No 41/09), which has been applied in Serbia since 11 December 2009. This law determines the criteria for assessment of conformity of products with the general requirement for safety obligations of producers and distributors, terms and the manner of informing consumers, as well as the exchange of information on the health and safety risks of a product. The law applies to the general product safety for consumers and other users.

- RAPEX Guidelines (Decision 2010/15/EU)

The following by-laws for implementation of the Law on General Product Safety were enacted in 2009: Regulation on the Method of Setting Up and Operation of the System of Rapid Exchange of Information on Dangerous Products (Official Gazette of RS, No 89/09) and Rulebook on the Form and Content of Notification on Dangerous Products (Official Gazette of RS, No 112/09).

In this way, binding, harmonized and coordinated co-operation of competent authorities and organizations is established in sharing information about dangerous products presenting a risk to health and safety of consumers and other users and exchange of

information, both measures undertaken by authorities and voluntary activities undertaken by producers and distributors.

The competent authorities in the system of rapid exchange of information are: Customs Administration on the one hand, and inspections that monitor general product safety in accordance with the powers bestowed by Article 18 of the Law on General Product Safety, especially market inspection, health and sanitary inspections, labour inspection and other inspections that within their powers possess information on dangerous products and the risks of these products on health and safety of consumers and other users.

Consolidation and distribution of information on dangerous products to which the Regulation applies is conducted by the Ministry of Trade and Services through market inspection. For the operation of this system, the Department of Market Inspection uses IT equipment and software (NEPRO, as the equivalent of RAPEX), procured with funds from the CARDS 2006 programme.

- marketing restrictions of child-resistant and novelty lighters (Decision 2006/502/EC as prolonged by Decisions 2007/231/EC, 2008/322/EC, 2009/298/EC and 2010/157/EU)

According to the register of valid technical regulations managed by the Ministry of Economy and Regional Development, Department for Quality Infrastructure, there are no specifically prescribed technical or other requirements for lighters. Decisions 2006/502/EC, 2007/231/EC, 2008/322/EC, 2009/298/EC and 2010/157/EU) will be incorporated into the legal system upon accession to EU, and, for now, they are not envisaged within harmonisation with EU legislation. In this sense, safety of lighters is covered by the Law on General Product Safety.

- Marketing prohibition of products containing the biocide dimethylfumarate (Decision 2009/251/EC as prolonged by Decision 2010/153/EU)

According to the Law on Biocidal Products, Article 33 (Official Gazette of RS, No 36/09), which is harmonised with EU Directive 98/8/EC and Article 33, the Serbian Chemicals Agency shall prescribe a ban or restriction for placing on the market and use of biocidal products or active substance in accordance with the Law on Chemicals. The Decision 2009/251/EC has not yet been transposed into the relevant by-law – Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment (Official Gazette of RS, No 89/10).

- Food-imitating Products Directive (Directive 87/357/EEC)

Directive 85/374/EEC concerning misleading products is fully transposed into the text of the Law on General Product Safety. Article 6 of the Law on General Product Safety bans the production, export, import and marketing of misleading products. Please note that in Serbia misleading products are considered dangerous products, which means that all general rules on general product safety are applied on them, apart from those rules that are characteristic only for misleading products.

- Liability for defective products (Directive 85/374/EEC)

Directive on liability for defective products has been transposed into the Law on Consumer Protection (Official Gazette No 73/10).

11. Do you have legislation concerning liability for defective products?

As stated above, the appropriate legislation on non-contractual strict liability is included in the Law on Consumer Protection, Chapter I, Articles 4-5 (definitions and scope of application), and Chapter VII, Articles 59-65. It covers issues such as the definition of defect, the existence of damage, strict liability, release exemptions from liability, joint accountability, and the expiration of claims.

Also, Article 179 of the Law on Contract and Torts (Official Journal of FRY No 31/93) prescribes in a general way the accountability of persons who market the items they manufactured, and which, because of the defect that the producer was not aware of, represent a damage risk for persons or things. If the producer failed to take all necessary measures to prevent the damage that could have been predicted, by warning, safe packaging, or through other appropriate measure, he/she shall be held accountable.

12. Are there legal provisions in force establishing the principle of strict liability or liability without fault of the producer in cases of damage caused by a defective product? If such provisions are in force, is there a rule of joint liability in cases where more than one person is liable for the same damage?

Article 61 of the Law on Consumer Protection regulates that the producer shall be liable for damages resulting from defective products, regardless of whether he/she knew of the defect. Article 63 provides that, if several persons are responsible for the same damage, they shall be held accountable jointly – which is a concretization of Article 206 of the Law of Contract and Torts. Serbian law defines joint liability as liability within which any person liable for damage is responsible to the creditor for the entire obligation and the creditor is entitled to request from any person responsible the fulfilment of the entire obligation, but if one debtor fulfils the obligation in full, everybody is relieved, with a mutual right to recourse. Each of the solidary debtors may be indebted with a different deadline and conditions of fulfilment.

13. If legal provisions on product liability are in force, what products do they cover? Are some products excluded from the scope of these rules? What is the definition of "damage"?

The Law on Consumer Protection (Article 5, Paragraph 1, item 12)) defines a product as any goods or service, including immovable property, rights and liabilities, and, pursuant to the provisions governing the liability of producer for defective products, a movable object that is separate or incorporated into another movable or immovable property, including energy that is produced or collected for providing light, heat or motion.

There is no foreseen exception by types of products. Article 59 defines defect as a situation in which a product does not provide the security that is rightly expected considering all the circumstances, including advertising and the reasonable expectations for use of the product when it is placed on the market. These considerations do not include the case of a better quality product later placed on the market.

Article 5 Paragraph 1, item 25), defines damage in terms of the provisions on liability of producers for defective items as a consequence resulting from death or bodily injury, and as a result of destruction or damage to any part of property that the damaged party normally uses for personal use or consumption. The Law on Contract and Torts, as a general law regulating compensation of damage (regardless of the liability for defective products), contains a ban on causing damage in Article 16, basis of responsibility in Article 154, including the possibility of prescribing strict liability by particular laws in Article 154 and defines damage as reduction of someone's assets (standard damage) and preventing its increase (lost gain).

14. If legal provisions on product liability are in force, how is the producer defined, what are the rules applicable to burden of proof?

Under provisions on producer's responsibility for defective items (Article 5 Paragraph 1, item 15) of the Law on Consumer Protection), the producer is a person:

- (1) manufacturing or importing finished products, goods, raw materials and component parts to the Republic of Serbia for sale, rent, lease or other modes of transfers,
- (2) representing himself as a producer by putting their name, trademark or other mark on the goods,
- (3) trader with products that does not contain information on the producer if it fails to inform the damaged party on the identity of the producer or the person from whom the product was procured,
- (4) trader of imported products which contain information about the producer, but does not contain information on the importer.

Article 60 determines that the burden of proof lies with the damaged party - who is entitled to the compensation for damage if he/she can prove to have suffered it, that the product had a defect and that there is a causal link between this defect and damage, where the damaged party has the right to compensation for consequential damages under the general rules of responsibility.

15. If legal provisions on product liability are in force, are there any rules exempting the producer from liability (e.g. producer did not put the product into circulation, the defect causing the damage came into being after the product was put into circulation by the producer, the product was not manufactured for profit making sale, the product was neither manufactured nor distributed in the course of producer's business, the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered, the defect is due to compliance of the product with mandatory regulations issued by the public authorities)?

The provisions on exemption from product liability are contained in Article 62 of the Law on Consumer Protection. The producer shall not be held liable for the damage caused by defective products if he can prove that:

- 1) they did not put the product for sale;
- 2) there was no defect at the time when the product was placed on the market or that it appeared later;

3) they did not produce a product intended for sale or any type of marketing and that the product was not manufactured within the producer's regular activities;

4) the defect was due to the compliance of the product with mandatory regulations issued by the public authorities.

The producer of integral part of the product shall not be liable for damage caused by defective products if the defect is proven to be attributable to product design or that it is a result of instructions given by the producer. The condition of scientific and technical knowledge at the time the product was put into circulation is not accepted as grounds for exemption from liability under Serbian law.

16. If legal provisions on product liability are in force, is the producer's liability altered when the damage is caused both by a defect in the product and by an act or omission of a third party?

Article 60 Paragraph 3 of the Law on Consumer Protection provides that the producer may be partially or fully exempted from liability for the damage caused by defective products if the damaged party or person under its responsibility contributed to that damage with his/her own fault. If the damage from defective products was partly contributed by a third party, solely the producer shall be held liable.

17. If legal provisions on product liability are in force, are there any rules on expiration of liability?

Under Article 64 of the Law on Consumer Protection, rights to a claim for damages from defective products shall expire within three years from the date the damaged party was aware of the damage, the existence of the defect and the identity of the producer. The objective term of expiration begins to run from the moment of placing the defective product on the market and is 10 years.

18. Do you have any plans to modify the existing legislation? Please give details and timetables.

The previous Law on Liability of Producers of Defective Products (Official Gazette of RS, No 101/05), which was abolished with the start of enforcement of the 2010 Law on Consumer Protection, was not fully compliant with the *acquis*. By derogating this regulation and by transferring these rules into the Law on Consumer Protection, the regulation was rounded up and harmonized with the EU and it gave the answer to certain questions that arose in practice.

Currently there are no plans for further changes to the regulations in this respect.

Implementation and enforcement

19. Please comment on the important aspects of the infrastructure for general product safety as described below by referring to your national system for market surveillance:

a) market surveillance/enforcement authorities with defined responsibilities and sufficient powers and resources to monitor the compliance of products with the directive and to react to complaints;

In accordance with the scope of work of competent authorities, under the Law on Ministries and special laws governing the area of technical requirements for products and actions of surveillance authorities, inspection surveillance in the field of product safety in the Republic of Serbia was organized on the level of the entire state, particularly in line ministries within which operate inspection or other authorities, i.e. departments, divisions or other organizational units assigned to monitor the safety of certain products, product groups or certain aspects of the risks that products have to the health and safety of consumers. General rules for the acting of these authorities are common whereas there are different rules regulated by special laws regulating the acting of the competent authority in specific, special aspects of surveillance. There is a two-level system of decision-making in the application of inspection measures, i.e. there is a possibility to review decisions of the competent inspections, with shorter time limits for appeal, mostly eight days from the day of the handover of the act on the undertaken measure, whereas the general term for appeal in other administrative proceedings is 15 days. This approach and shorter terms for using legal remedies for reviewing decisions on the measures of inspection surveillance is justified by the urgency of implementation of the measures taken to protect the health and safety, i.e. consumer protection, and other public interests.

All inspection authorities are empowered to respond to consumer complaints and to file their complaints to judicial authorities to punish violators. However, monitoring of issued fines and their enforcement is made more difficult due to the lack of IT infrastructure and network of inspection and judicial authorities. Communication in that part is done through regular, classic post, and the inspectors are responsible to keep records on the work, imposed measures and the outcome of these measures. There are initiatives to keep the records in electronic form so as to develop software for recording work and thus build an internal database within the authority.

In the course of 2008 and 2009, the Market Inspection Department launched a project aimed to improve the keeping of records and reporting (Network of Inspection Authorities) in order to improve internal records and reporting in the first phase, and to establish a connection with other inspection bodies in subsequent phases, namely with the Customs Administration, judicial authorities, the business registers and with those bodies that have the infrastructure and databases available for more effective work of the market inspection. The first phase of this project was conducted and a software solution for recording and reporting of work was implemented within the approved budget. The continuation of this project is of great importance for the improvement of work of the market inspection and connecting it with other inspections so the continuation of the activities is planned during the implementation of medium-term financial plan of the Ministry of Trade and Services.

Co-operation was established between the Ministry of Economy and Regional Development, the Ministry of Trade and Services – the Market Inspection Department, and the Ministry of Finance – the Customs Administration, in the field of exchange of information and data relevant for the effective implementation of activities and measures of market surveillance, planning of joint activities and development of information infrastructure, in a manner that is in accordance with the protocol of these bodies.

In co-operation with EU experts, the Market Inspectorate will be given guidelines for an overall regulation of market surveillance under the new Law on Market Surveillance, which will transpose the provisions of Regulation (EC) No 765/2008. This will establish an appropriate structure of market surveillance in the Republic of Serbia based on the principles of market surveillance in the European Union.

The Market Surveillance Strategy contains trends of development of co-operation and coordination at the national, regional and international levels.

b) rapid and well functioning legal system for taking measures in cases of breaches of the legislation and for appropriate means of redress in respect of measures taken;

Inspection authorities in Serbia have the power to quickly undertake measures in cases of violations of the law.

Pursuant to Articles 22-33 of the 1999 Law on Public Administration the rights and duties of inspectors are as follows:

- 1) to review general and specific acts, records and other documents;
- 2) to examine and take statements from responsible and interested persons;
- 3) to inspect the business premises, buildings, production facilities, equipment and goods;
- 4) to take samples of goods and other items for analysis, expertise, and the like;
- 5) to order the measurements performed by another professional organization, when a company or other organization alone or through a particular professional organization carries out measurements in the respective fields, and the measurement results provide a basis for it;
- 6) to take other measures and actions for which he/she is authorized by law or regulation.

Inspectors are independent in their work within the powers stipulated by the law and other regulations and are personally responsible for their own work.

The inspector shall inform the Minister on the emergence of significant violation of independence and illegal influence on his/her work.

The inspector shall be responsible in particular:

- 1) if in the performance of surveillance, he/she fails to take, propose or determine the measure for which he/she is authorized,
- 2) if he/she fails to propose or initiate procedure before the competent authority for the illegalities or irregularities,
- 3) if he/she exceeds the limits of his/her powers.

The inspector shall write a report for each completed inspection and activity, containing the established situation and proposed, i.e. prescribed measures.

The report shall be submitted to the company or institution and another organization or citizen whose business operations or actions were inspected. The company, institution and other organization, or citizen shall inform the inspector on the measures ordered in the report.

The inspector within the limits of his/her powers may:

- 1) order the enforcement of measures and actions in a decision, setting a deadline;
- 2) impose a mandatory fine;

- 3) press charges for criminal or civil offence to the competent authority and apply for legal proceedings;
- 4) issue an interim order or prohibition under the law;
- 5) adopt security measures in case of danger to life and health or other public interests;
- 6) inform other authority if there are reasons for taking measures for which that authority is in charge;
- 7) launch an initiative before the competent body for termination of enforcement, or cancellation or repeal of regulations or other general act of the body, or organization that is responsible for public administration, i.e. for the suspension of the general act of a company, institution and other organization if they are not compliant with the Constitution and the law;
- 8) take other measures and actions for which he/she is authorized by law or other regulation.

The inspector in the exercise of surveillance co-operates with other inspectors, judicial authorities, magistrate bodies and other interested authorities and organizations.

The inspector is required to take and propose necessary preventive measures and actions to prevent violations of the law and regulations.

Authorities, companies, institutions, and other organizations, i.e. citizens, shall be obliged to allow inspector to perform his/her affairs without disruption, provide access to necessary documents and provide other requested assistance.

The inspector shall be obliged to act upon complaints of citizens, companies and other organizations in relation to the affairs of his/her power and to inform the applicants about the results of the procedure.

If the inspector determines that violating a regulation resulted in a criminal act, breach of business conduct, offence or breach of labour duty the application of which is under surveillance, he/she shall be obliged to submit a report for the criminal act or breach of business conduct, application for initiating an infringement procedure and request for establishing responsibility for breach of duty.

The authority or organization acting upon the filed application for initiating an infringement procedure and request for establishing responsibility for breach of duty shall be obliged to inform the inspector on the result.

If during inspection surveillance it is established that the general act of authority or organization is not in compliance with the law or other regulation, the inspector shall point out to this to the authority or organization that passed such act and shall suggest that irregularities are removed within 60 days.

If authority or organization does not act upon proposal from paragraph 1 of this Article, the inspector shall inform the authority responsible for taking measures against acts that are not in conformity with the Constitution, law and other regulations.

The inspector shall be bound to keep the data obtained during surveillance or received during surveillance from authorities, organizations and citizens as business secret.

Person with relevant university degree, professional examination for the work in public administration and at least three years of working experience, shall be eligible to perform inspection affairs. Exceptionally, the law may determine that inspectors with post-secondary degree shall be eligible for certain less complex inspection surveillance jobs.

The inspector shall have his/her ID during surveillance, to prove that he/she is an inspector.

The form of ID and the manner of its issuance shall be determined by the minister in charge of administration affairs.

Under the Law on Technical Requirements for Products and Conformity Assessment and the Law on General Product Safety, market surveillance authorities shall be authorized to take measures limiting the supplies on the market, prohibition of placing products on the market or supplies on the market, withdrawal or recall of products if it is determined that the products are not compliant with technical regulations or with general product safety requirements.

Under Article 22 of the Law on Technical Requirements for Products and Conformity Assessment, a competent inspector is authorized to take measures limiting the supply to the market, withdrawal or recall of products in conformity with the law, if it is established that the product that conforms to technical regulations may jeopardize the public interest, especially if it compromises safety, life and health of people, safety and health of animals and plants, environment, safety of consumers and other users and property (safeguard clause).

Under Article 9 of the Law on General Product Safety, the authority responsible for taking appropriate measures in accordance with powers regulated by this and other laws (below: competent authority) may take appropriate action if there is evidence that the product is dangerous although the product meets safety requirements stipulated by special regulations from Article 2 of this law, i.e. meets the criteria for conformity assessment from Articles 7 and 8 of the Law on General Product Safety.

If due to certain circumstances in the course of market surveillance the inspection authority estimates that the product is dangerous, action of withdrawal or recall of the product from the market may be taken even if the producer fulfils and proves to have fulfilled all technical requirements (safeguard clause).

A competent market surveillance inspector in controlling product safety shall be authorized to take all measures prescribed by Articles 17 and 18 of the Law on General Product Safety, including:

- 1) for each product;
 - to organize, to an appropriate extent, the checking of product features that affect its safety, until the final stage of its use, or wear and consumption;
 - to order the delivery of information to consumers and other users;
 - to take samples of product in order to examine the properties that affect its security;
- 2) for each product that may pose a risk in certain circumstances:
 - to order that the product on the market is marked with suitable, clear and comprehensible warnings about the risks that the product may present;
 - to condition the marketing of such product with prior fulfilment of additional conditions so the product is made safe;
 -

3) for each product that could pose a risk for certain persons, to order that such persons are promptly and adequately warned of the risk, including issuing a warning through the media;

4) for each product that may be dangerous, to temporarily prohibit the offering, display, delivery, and making available of the product, during the time needed to verify product characteristics that may affect the safety and health of consumers and other users;

- for each dangerous product, to prohibit the offering, display, delivery, and making available of the product and ensure implementation of appropriate measures and prohibitions;
- to order or to organize its urgent withdrawal, and alert consumers to the risks that the product represents;
- to order, coordinate or, if necessary, organize with the producers and distributors the recall of the product from consumers and other users, including measures of forced recall of products, and the destruction of such a product in an appropriate manner by and paid by producer or distributors;

5) for each misleading product, to ban the production, export, import and marketing of such products.

Compensation in respect of the measures taken (compensation of the damage), as a rule, is realized in court proceedings under the complaint filed by the damaged party.

Under Article 73 of the Law on Trade, trader the shall be entitled to compensation of the damage in the case of annulment of the decision ordering a measure, in the amount of the actual damage and expenses for realization of the measure. Claim for compensation may be filed to the ministry responsible for trade, for out-of-court settlement.

c) systematic approaches (surveillance programs, follow up of scientific and technical knowledge, review and revision of the functioning of the activities) to ensure the effectiveness of market surveillance;

The recently adopted Strategy of Market Surveillance (Official Gazette of RS, No 68/10), requires a systemic approach to the implementation of activities and taking measures of market surveillance. With the assistance of EU experts priorities for the surveillance programme in 2011 were drafted. The Strategy envisages monitoring of scientific and technical knowledge and adaptability in the implementation of market surveillance.

d) system for co-operation between market/surveillance bodies with responsibilities in relation to enforcement of different types of consumer products as well as with customs (Regulation (EC) No 339/93, Regulation (EC) No 765/2008 replacing as of 1 January 2010 the Regulation (EC) No 339/93);

This co-operation has been explained in responses to questions 10 and 19a. The planned Law on market surveillance will transpose the provisions of Regulation 765/2008.

e) defined methodology for risk-assessment and access to technical expertise and competent and independent testing facilities for checking conformity of products;

Market surveillance activities are carried out according to risk assessment and market surveillance measures are taken based on tests conducted by authorized laboratories.

The methodology of risk assessment is defined and used as the main instrument of market surveillance, based on information available to market surveillance authorities, including notifications of producers and distributors of products and information on products that authorities obtain when over viewing available international databases. For the needs of the authorities that apply the methodology of risk assessment, joint workshops and training for entrepreneurs are organized. Guidelines for risk assessment are published on the website of the Ministry of Trade and Services (www.mtu.gov.rs) along with a Form for notification of dangerous products, to facilitate communication between producers and distributors and authorities for market surveillance, especially in the part where the data on risk according to the defined methodology of risk assessment are to be filled in.

The list of independent institutions responsible for checking the conformity of products is on the website of the Accreditation Authority of Serbia www.ats.rs.

f) access to information on product dangers to the public respecting professional secrecy and restrictions required for monitoring and investigation activities;

Information about dangerous products are available to the public on NEPRO portal, which is an electronic database available to the general public on the basis of the Regulation on the Method of Setting Up and Operation of the System of Rapid Exchange of Information on Dangerous Products, which was adopted in accordance with the Law on General Product Safety.

Article 13 of the Law on General Product Safety regulates the conditions, the method of informing and exchange of information on dangerous products. Information available to the competent authority in relation to the risk of products for safety and health of consumers are available to the public.

Based on the Law on General Product Safety and laws regulating free access to information of public importance, the authority shall submit to any person, upon his/her request, information on the risks of a product, and information on undertaken measures and activities of competent authority, producer and distributor, with the aim of removing or reducing the risk to an acceptable level.

The data on the measures and activities of producer and distributor may not be made public if the information relates to scientific, technical or technological solution representing a trade secret.

g) system for co-operation and information with producers and distributors and consumer associations with regard to providing and receiving information and exchange of experiences;

Market surveillance authorities co-operate with producers and distributors and consumer organizations to exchange experience and information, based on which they plan, carry out activities and take appropriate measures. This approach to market surveillance is based on the application of the Law on General Product Safety and is one of the basic principles of market surveillance, which will be further developed through the implementation of strategies of market surveillance, which the Government adopted on 2 September 2010.

Consumer organizations and representatives of chambers of commerce are represented in the Minister's Council for Consumer Protection and will also be represented in the National Council for Consumer Protection, under the new legislation.

h) system for providing rapid information to consumers and businesses through the media;

In addition to informing consumers and business subjects through NEPRO portal, press releases area also prepared and to be published through electronic and print media.

i) system for ensuring administrative co-operation with other countries;

The system of co-operation with other countries was developed within the framework of regional projects of CARDS and IPA. In the previous period, such co-operation related to the organization of joint workshops, training and exchange of experiences. There are needs and initiatives for administrative forms of co-operation. Several regional meetings were held discussing the needs, ideas and forms of co-operation of market surveillance authorities in the region. This was one of the crucial topics at the workshop which was organized in the framework of CEFTA WEEK in Belgrade in mid-November 2010.

Under a memorandum of co-operation between the Administration for Consumer Protection of Hungary and the Ministry of Trade and Services of the Republic of Serbia, Department of Market Inspection and the mentioned Administration launched co-operation to exchange information and experience in conducting surveillance in the area of consumer protection.

j) co-operation with the national standardisation body with regard to the use of standards under the directive and to ensure co-operation of all parties concerned (including consumers) in the development of standards related to consumer products;

Representatives of market surveillance authorities participate in working groups for developing standards. This results in an exchange of information that market surveillance authorities find in connection with the implementation of standards, especially regarding the accidents related to consumer products.

The co-operation of all ministries with the Institute for Standardization of Serbia, as the national standardization authority, undergoes through the Ministry of Economy and Regional Development, in whose authority are the operations in the field of standardization. Upon the request of the Ministry of Economy and Regional Development, and pursuant to the Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of RS, No. 36/09) and the Law on General Product Safety (Official Gazette of RS No 36/09), the **Institute for Standardization of Serbia** is preparing a list of Serbian standards and related documents transposing harmonized European standards and related documents in accordance with the General Product Safety Directive. The list of harmonized standards is published in the Official Gazette of RS.

Under the Law on Standardization (Official Gazette of RS No 36/09), Article 4, there is a right of voluntary participation of all stakeholders in standardization activities. For the purposes of this law, the stakeholders are government bodies, companies, entrepreneurs, consumer organizations and other legal and natural persons who show an interest in standardization.

Pursuant to Article 7 Paragraph 2 of the Law on General Product Safety, the minister of economy and regional development issued the Rulebook on Establishing the List of Serbian Standards in the Field of General Product Safety (Official Gazette RS, No. 58/10), which includes 35 Serbian standards in the field of general product safety.

k) systems for collection of product related injury data (such as the EU EHLASS programme);

There is not a systematized way of collecting product related injury data.

l) number of controls carried out and the results, the reasons for the controls (own initiative/complaints), type of products controlled, the geographical coverage of the controls, the way the controls have been carried out (ocular examination/testing).

Statistical data on controls and inspections initiated by complaints are presented in the answer to the question 3 b).

The following data refer to the number of performed controls, results and inspections done at the initiative of the market inspection:

Year	Type of product	Number of controls	Measures		
			Decision – order for removal of irregularities	Withdrawn from the market	Report to judicial organs
2008	Textile products	2692	723		314
	Electrical appliances	746	120		79
	Cosmetics/chemical products	3.367	18		12
	Furniture	299	43		39
	Toys	85	186		20
	Oil and oil derivatives	757	24		45
	Construction material	711	186		91
	Other	1.629	240		
2009	Textile products	2,198	555		298
	Protection helmets	288	39		55
	Detergents/products for hygiene	1871	27		16
	Electrical appliances	398	45		45
	Lubricants, industrial oils and related products	450	24		16
2010	Dangerous products- {}-	455		31.367	

	Compliance of products	981	247		131
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SAMPLED PRODUCTS – 2010

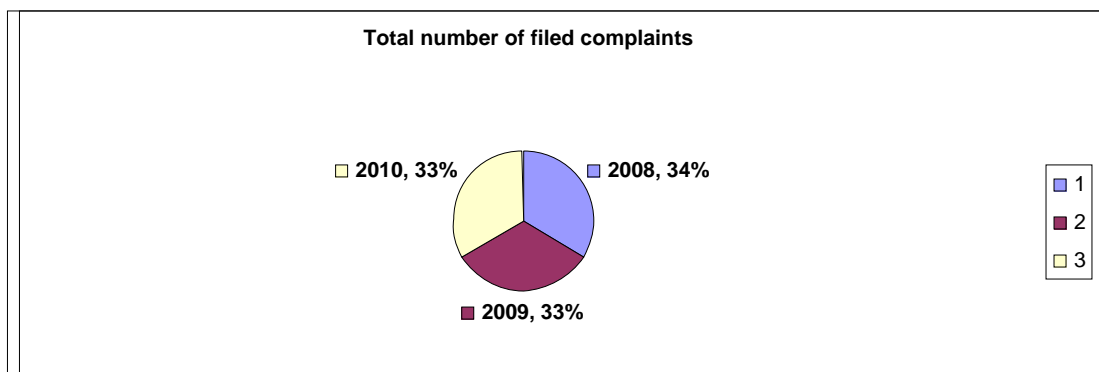
Name of product	Number of taken samples	Number of samples that did not comply with regulated requirements/standards	Regulation/standard
Fuel	44	15	Rulebook for liquid fuels of oil origin, and requests of standards SRPS EN 590
Liquid oil gas	5	1	Standard SRPS EN 589
Motor oil	10	1	Rulebook on technical requirements for lubricants, industrial oils and related products
Gas bottles for household	9	1	Standard
Fuel tanks	5		
Coal	10	1	Standard
Antifreeze	10		
Chargers for mobile phones	10		
Textile and footwear	30	4	Declared quality
Electrical appliances	15	-	Rulebook on electrical equipment for use within set voltage limits

20. Please give some indication of the level of activities in the field of market surveillance by providing statistics, as available, referring to some of the following examples:

a) number of complaints received, from whom and actions undertaken;

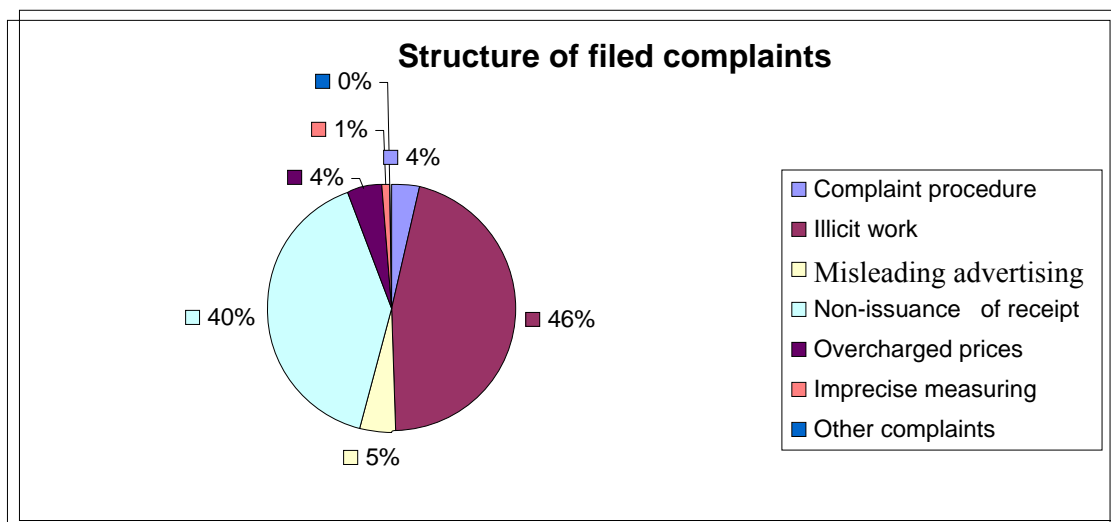
Statistical data of the market inspection on the number of received consumer complaints relating to violation of regulations and undertaken measures are given in the response to the question 3 b).

Here please find detailed graphic overview of these data.



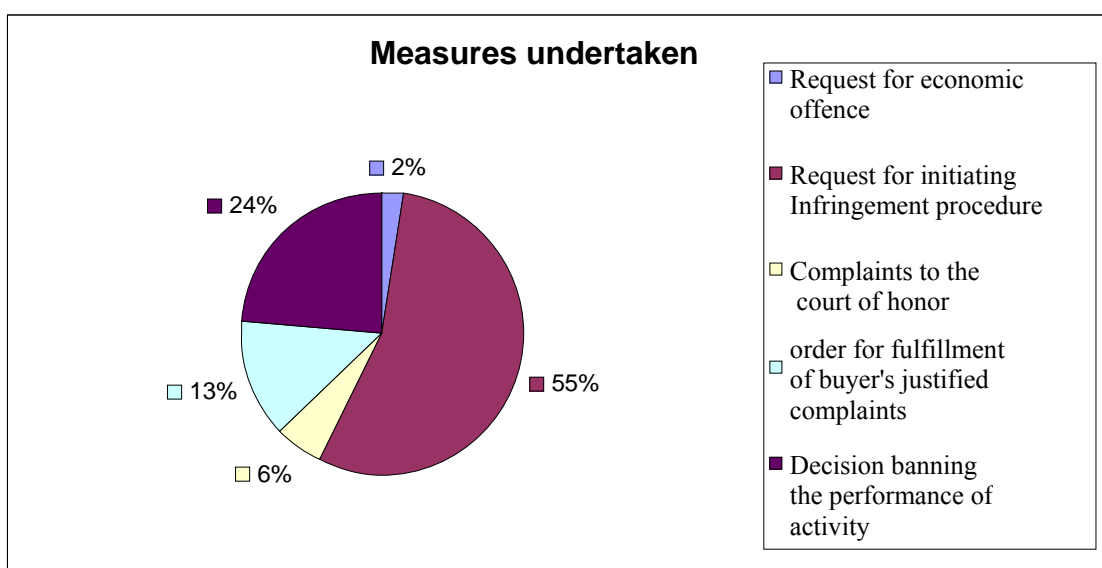
TOTAL NUMBER OF FILED COMPLAINTS

- 2008 - 34%
- 2009 - 33%
- 2010 - 33%



STRUCTURE OF FILED COMPLAINTS

- complaint procedure - 4%
- illicit work - 46%
- misleading advertising - 5%
- non-issuance of receipts - 40%
- overcharged prices - 4%
- imprecise measuring - 1%
- other complaints - 0%



UNDERTAKEN MEASURES

- request for economic offence - 2%

- request for initiating infringement procedure - 55%
- complaints to the court of honour - 6%
- order for fulfillment of buyer's justified complaints -13%
- decision banning the performance of activity - 24%

Statistical data of the market inspection on conducted activities and undertaken measures of market surveillance (product safety) are given in the response to the question 19 l).

Table with data on actions by tourist inspectors acting upon consumer complaints in the field of tourism in 2008 and 2009:

Year	Number of received consumer complaints	Number of complaints for		Number of complaints for economic offence	Number of complaints for criminal acts	Number of requests for initiating infringement procedure	Number of complaints to the court of honour	Number of decisions: Order for removal of irregularities	Fulfilment of consumer requests through settlement with travel agencies
		<i>Catering</i>	<i>Tourism</i>						
2008.	1437	1003	434	1	3	520	9	485	152
2009.	1417	1068	349	/	1	502	2	461	73

Ministry of Health – Sanitary Inspection Division

1. Number of received complaints:

- 1.1. from legal persons, entrepreneurs182
- 1.2. from consumers648
- 1.3. taken over from other ministries32

2. Which actions were taken:

- 2.1. referred....to other ministries116
- 2.2. executed extraordinary inspections...746
- 2.3. taken food samples21
- 2.4. taken samples of objects of general use19
- 2.5. taken swabs1450

The metrological surveillance in the Republic of Serbia refers to the production, trading, import, installation, use, maintenance and repair of measuring instruments and is done to check whether those measuring instruments meet prescribed requirements, i.e., whether those measuring instruments are used in compliance with the law and other regulations in the field of metrology, and also to check the accuracy of quantities marked and contained in the pre-packed products. This is regulated by the Law on Metrology (*Official Gazette of RS, No. 30/10*), that entered into force on 15 May 2010.

The Regulation on the Manner of Performing Metrological Surveillance (*Official Gazette of RS, No. 88/10*), that more closely regulates the manner of performing metrological

surveillance entered into force on 1 December 2010. In accordance with this Regulation, metrological surveillance may be regular and extraordinary. Regular metrological surveillance is conducted according to the plan of metrological surveillance adopted by the Directorate for Measurements and Precious Metals. Extraordinary metrological surveillance is conducted at the request of authority in charge, stakeholders or ex officio.

Bearing in mind the above-stated, we point out that the Directorate for Measurements and Precious Metals through persons authorised for conducting metrological surveillance started carrying out metrological surveillance only upon entering into force of the new Law on Metrology.

In relation to that, we point out to the following activities in the performance of metrological surveillance, particularly to the surveillance done upon citizens' complaints (a total of 38 received complaints) for the following measuring instruments:

- Appliances for measuring liquid fuels – four metrological surveillances (six measuring instruments were put out of use, with the term for eliminating the deficiencies of 30 days);
- Water meters, extraordinary inspection of measuring instruments in use – 32 metrological surveillances (it was established that 17 measuring instruments worked to the detriment of users or the validity period of the Directorate's seal expired);
- Electricity meters, extraordinary inspection of measuring instruments in use – two (measuring instruments working regularly);
- Non-automatic weighting instruments used at green-markets (metrological surveillance envisaged as of 4 January 2011).

b) number and types of measures taken by market surveillance authorities;

The number and type of measures undertaken by the market inspection in the field of market surveillance are given in the response to the question 19 l).

The Ministry of Health – Sanitary Inspection Division

Number and type of undertaken measures:

1. Measures ordered through a decision:

1.1. Number of adopted decisions	221
1.2. Number of adopted decisions for elimination of deficiencies	145
1.3. Number of adopted decisions – ban of use	41
1.4. Number of adopted decisions – ban of trading	21
1.5. Number of adopted decisions – on destroying of food	9
1.6. Number of adopted decisions – on destroying of items of general use	5

2. Penalties

2.1. Number of mandatory fines	53
2.2. Number of requests for initiating infringement procedure	111
2.3. Number of complaints for economic offence	35

The Ministry of Environment and Spatial Planning – data on the number and type of measures undertaken by inspection services in the jurisdiction of this ministry are contained in the response to the question number 13 in Chapter 27.

The Ministry of Labour and Social Policy – the Inspectorate for Labour – is not in possession of statistical data on all cases in relation to general safety of products used in the

process of work – work equipment and means and equipment for personal protection at work – because every addressing of employees (if any) is controlled within regular inspection surveillance, and, for now, statistical data about that are not kept.

The most frequent established deficiencies in the surveillance in the field of safety and health at work refer to the lack of prescribed documentation in the Serbian language for means and equipment for personal protection at work and work equipment, on the basis of which the user could make a risk assessment in relation to the use of the product.

The most frequent addressing of employees to labour inspection refers to employers failing to procure means of personal protection.

In all cases when employees addressed the labour inspection in order to exercise their rights in relation to the Law on General Product Safety, labour inspectors directed them to other authorities.

The Ministry of the Interior – the Department for Emergency Situations - performs inspection surveillance and surveillance over the legality of acts in compliance with the Law on Protection from Fire, the Law on Explosive Substances, Inflammable Liquids and Gases and the Law on Trading of Explosive Substances.

This means establishment of spatial conditions – locations, surveillance over the presence of fire and explosion protection measures in investment and technical documentation and their implementation after the construction, as well as during exploitation of facilities, devices and installations. Within its scope of jurisdiction, this authority conducts inspection surveillance over the trading of explosive substances (explosives, gunpowder, pyrotechnic devices, initial means...).

The Strategy of Market Surveillance stipulates that market surveillance over equipment under pressure and simple vessels under pressure will be conducted by inspection for equipment under pressure and market inspection.

Inspection of equipment under pressure performs inspection surveillance over the production and surveillance over extraordinary and regular checkups of equipment under pressure.

In the period from January to November 2010, a total of 2,410 cases were registered in the Division for Inspection of Equipment under Pressure, of which 2,001 case procedures were completed, and inspection surveillance over the following equipment under pressure was conducted:

1. Steam and hot water tube boilers	198
2. Pressure vessels	1071
3. Steel bottles, movable vessels	27,257

Mining inspection performs surveillance of equipment and protection of system for the use in potentially explosive environment in mining facilities.

Mining facilities working in potentially explosive environment are underground exploitation coal mines, surface exploitation coal mines (coal crushing plants, accumulation stations, petroleum stations), coal drying plant, coal classification facility, separation and flotation. Potentially explosive environment in underground mining facilities may be caused by the presence of methane and explosive dust, whereas potentially explosive environment in surface mining facilities may be caused by explosive and inflammable dust, explosive gases and steam.

There are 10 pits threatened with methane and explosive coal dust in underground coal exploitation facilities in the territory of Serbia. When performing regular inspection checkups, mining inspection ordered correction of irregularities for 130 cases in 2010 and for 120 cases in 2009 in regard to safety of counter explosive electrical devices and installations, periodical checkups and testing, and certification.

For now, there is no official institution in Serbia that can categorise pit areas by the degree of danger from explosive coal dust and methane.

In surface exploitation, when performing regular inspection checkups in 2009, there were irregularities on spots threatened with explosive and inflammable coal dust in 45 cases as well as 35 cases on spots threatened with explosive atmosphere (explosive gases and steam). In 2010, there were irregularities on spots threatened with explosive and inflammable coal dust in 40 cases as well as 30 cases on spots threatened with explosive atmosphere (explosive gases and steam). Most of the ordered measures mainly referred to irregularities in terms of safety of counter explosive electrical devices and installations, periodical checkups and testing, and certification.

The Directorate for Measurements and Precious Metals, through persons in charge of performing measuring surveillance, performed surveillance according to the plan of metrological surveillance of the Directorate for Measurements and Precious Metals for 2010, namely for the following measuring instruments:

- Mass measuring instruments – 35 metrological surveillances (29 measuring instruments were temporarily put out of use, with the term for eliminating the deficiencies);
- Appliances for measuring liquid fuels – two metrological surveillances (10 measuring instruments were temporarily put out of use, with the term for eliminating the deficiencies);
- Taximeters – 45 metrological surveillances (37 measuring instruments were temporarily put out of use, with the term for eliminating the deficiencies);
- Electricity meters – four metrological surveillances (22 measuring instruments were temporarily put out of use, with the term for eliminating the deficiencies).

The indicators of planned metrological surveillances include, apart from lack or expiry of validity trade mark of the Directorate for Measurements and Precious Metals, non-conformity with the Certificates on approval of measuring instrument type. In relation to that, we point out that domestic manufacturers produce measuring instruments in compliance with valid metrological regulations, whereas the transposition of European directives referring to measuring instruments (MID, 2004/22/EC) and non-automatic weighting instruments (NAWI, 2009/23/EC) is planned for 2011.

c) number and types of measures taken by customs authorities;

Customs authorities implement the Decision on establishment of goods whose import, export, transit require certain certificates (Official Gazette of RS, No. 7/10 of 19 February 2010) which, inter alia, enforces the Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of RS, No. 36/09 of 15 May 2009). Customs authorities control whether importers submitted certificates on conformity prescribed by the above-mentioned law, as well as whether the submitted certificates correspond to the declared goods. The code for conformity certificate is inserted in section 44 of the customs declaration

“Submitted Certificates and Additional Information”. In the territory of the Republic of Serbia, for the period from 1 April – 20 December 2010 there was a total of 73,578 declared goods for which certificate on conformity was submitted.

d) number and types of product safety cases dealt with by the courts, average time-frame for a decision and average time for enforcement;

Enforcement of the Law on General Product Safety began on 11 December 2009 and there are still no data on judicial practice.

e) number and type of rapid-alert measures notified to and from the central point and documentation on follow-up to such notifications;

Number of notifications submitted to the central contact point	Type of notification	Documentation submitted along with notification
10	Notification of Producer/Distributor on recall of product	Photograph of the product
		List of companies that are informed about dangerous product
		Copy of notification published in the printed media
138	Notification from market inspector of the Area Unit	Photograph
		Laboratory report
		Inspection report
Number of notifications sent from the central contact point	Type of notification	Documentation submitted along with notification
1	Notification for the Customs Administration	Data on dangerous product originating from import
		Other data and photographs accessible through the system of rapid exchange of information NEPRO
66	Notifications to the public	Notifications with information on dangerous product and data of relevance for the public
		Photograph

f) activities undertaken (meetings, information documents etc.) for ensuring co-ordination between authorities and interaction with economic operators and consumer organisations;

Within the project “Analysis of the Serbian legal framework and institutional structure in the market surveillance area”, that was launched in the second half of 2009 and was completed in May 2010, there were several working meetings gathering representatives of all market surveillance authorities, representatives of the Serbian Chamber of Commerce, the Customs Administration and other stakeholders. Printed educational and informational materials, including the documents published within the European project “Enhancing Market Surveillance through Best Practice” (EMARS) and Guidelines for joint Rapid Alert System for non-food consumer products (RAPEX), were provided for all the participants of the

project. Also, educational and informational activities were conducted (round tables, workshops, seminars, the printing and distribution of brochures, leaflets, etc.), with the aim of introducing all stakeholders with the content of the Law on General Product Safety, the Rulebook on the Form and Content of the Notification on Dangerous Products and the Regulation on the Method of Setting Up and Operation of the System of Rapid Exchange of Information on Dangerous Products, that are applied since December 2009/January 2010.

The result of these activities is also attained agreement on the manner of co-ordination of market surveillance through a government authority, which will be established in the first phase of implementation of the Market Surveillance Strategy that was adopted on 2 September 2010.

g) information activities directed to the public;

Information activities directed to the public are conducted through electronic and printed media, website and NEPRO portal.

h) routines and meetings between product safety authorities and customs to ensure co-ordination of the customs control;

Co-operation was established between the Ministry of Economy and Regional Development, the Ministry of Trade and Services – the Market Inspection Department, and the Ministry of Finance – the Customs Administration, in the field of exchange of information and data relevant for the effective implementation of activities and measures of market surveillance, planning of joint activities and development of information infrastructure, in a manner that is in accordance with the protocols of these bodies.

There is co-operation in the exchange of information upon written request, through e-mail and at working and educational meetings. There are planned, approved and launched projects aimed at promoting this co-operation and co-ordination.

i) details of systems for ensuring a systematic approach to control activities;

The System of Rapid Exchange of Information on Dangerous Product (NEPRO) ensures a systematic approach to control activities. Apart from the Market Inspection, also connected to this system are the Customs Administration, Labour Inspection and Sanitary Inspection. A systematic approach to work is ensured by the software – Network of Inspection Authorities that for now connects central sections of the market inspection with sections of area units with the aim of connecting the market inspection with other market surveillance authorities and the Customs Administration.

The Market Inspection Department created a plan of controls for 2011 in co-operation with EU experts and involving other market surveillance authorities.

The Ministry of Trade and Services plans to draft a law on market surveillance in co-operation with other market surveillance authorities by which Resolution 765/2008 would be transposed.

j) statistics on injuries related to products;

We are not in possession of statistical data on injuries related to products.

k) systems established to ensure consumer participation in relevant standardisation work;

A technical working body, the commission for standards and related documents for the area of consumer protection, was established within the Institute for Standardization of Serbia. The commission is tasked with providing conformity of Serbian standards and related documents with international and European standards in the area of products intended for consumers. This commission is made up of representatives of the Ministry of Trade and Services, representatives of consumer organisations, scientific and educational institutions and representatives of the business sector. Representatives of the consumer organisations are represented in the Expert Council for General Areas of Standardisation of the Institute and are members of the Institute's assembly.

l) statistics relating to sales figures of consumer products, origin of the products etc.

Statistical data based on monitoring the enforcement of the Law on General Product Safety for the whole territory of the Republic of Serbia for the period January – November 2010 are as follows:

Description of products	Undertaken measure of product's withdrawal -quantity-	Origin of product:
Electrical vessel for making coffee	1,450	Produced in the Republic of Serbia
Decorative Christmas tree bulbs	606 items 464 metres	Produced in China
Power sockets	697	Unknown producer/origin
Gas cylinders	15	Unknown producer/origin
Hose for butane cylinders	13	Produced in the Republic of Serbia
Table lamps	80	Unknown producer/origin
Ladders	5,567	China
Lighters	52	Produced in China
Cables for pulling vehicles	6	Unknown producer/origin
Hair dryer	3	Imported origin
Textile products	11,954	China, Turkey; Serbia
Helmets	87	China
Footwear	1,228	China
Swimming seats	32	Unknown producer/origin

21. For which of these product categories have you carried out specific market surveillance activities in the last three years?

In recent years, there has been no special surveillance over the below products that could contain certain hazardous chemicals. Products containing chemicals have so far been controlled from the aspect of health safety, which was controlled by the Ministry of Health through sanitary inspectors. However, the Law on Chemicals (Official Gazette of the RS, No 36/09), that defines a legal framework for restriction and ban on placing on the market of certain products, was adopted in 2009.

All restrictions and bans on placing on the market of certain products in the EU were transferred into the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment (Official

Gazette of RS, No 89/10) that came into effect on 7 December 2010. This Rulebook has been conformed to provisions of Annex XVII of Regulation (EC) 1907/2006 – REACH.

Inspectors of the Ministry of Environment and Spatial Planning are in charge of surveillance of implementation of provisions of this Rulebook in industrial facilities and wholesale, and inspectors of the Ministry of Trade and Services perform such surveillance in retail sale.

a) Child-care articles (e.g. teething rings, pacifier chains, baby walkers, folding cots);

The following phthalates CAS No: 117-81-7, 84-74-2, 85-68-7, 28553-12-0, 26761-40-0, 68515-49-1 and 117-84-0, and the conditions of restriction are:

1. Shall not be used as substances, or in mixtures, at concentrations higher than 0.1% by weight of the plastic materials, in toys and childcare articles.
2. Toys and child-care articles containing these phthalates in a concentration higher than 0.1% by weight of the plastic material shall not be placed on the market.

Given that the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment came into effect on 7 December 2010, there are still no data on undertaken activities of market surveillance.

The Market Inspectorate ordered the withdrawal of 117 carry-cots in 2010 from the aspect of general product safety.

b) playground equipment;

We are not in possession of any statistical data.

c) furniture (e.g. bunk beds, flammability of upholstered furniture);

The following substances CAS No 8001-58-9, 61789-28-4, 84650-04-4, 90640-84-9, 65996-91-0, 90640-80-5, 65996-85-2, 8021-39-4, and the conditions of restriction are:

Wood treated with these substances shall not be used:

- inside buildings, whatever their purpose,
- in toys,
- in playgrounds,
- in parks, gardens and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,
- in the manufacture of garden furniture,
- for the manufacture and use and any re-treatment of:
 - containers intended for growing purposes,
 - packaging that may come into contact with raw materials, intermediate or finished products destined for human or animal consumption, and
- other materials which may contaminate the articles mentioned above.

Given that the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment came into effect on 7 December 2010, there are still no data on undertaken activities of market surveillance.

The Market Inspectorate ordered the withdrawal of 9 pieces of furniture in 2010 from the aspect of general product safety.

d) do-it-yourself equipment (e.g. ladders);

In 2010, there were activities and measures of market surveillance that included the measure of prohibition of distribution of sale of 5,567 items of ladders.

e) leisure equipment (e.g. bicycles, climbing equipment, bounce castles);

The Market Inspectorate ordered the withdrawal of 87 items of motorcycle helmets in 2010 from the aspect of general product safety.

f) clothing (flammability risks, strangulation risks);

The following substances CAS No: 126-72-7, 545-55-1, 59535-65-1, and the conditions of restriction are:

1. They shall not be used in textile products, such as clothes, underwear and canvases that come to skin contact.
2. Products from item 1 containing this substance shall not be placed on the market.

Given that the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment came into effect on 7 December 2010, there are still no data on undertaken activities of market surveillance.

The Market Inspectorate ordered the withdrawal of 11,954 pieces of clothes in 2010 from the aspect of general product safety.

g) decorative articles (e.g. imitation fruit, Christmas decorations, candles);

In 2010, there were activities and measures for prohibition of distribution of sale of 606 items and 464 metres of decorative lights from imports (origin: China).

h) products containing chemicals (e.g. phthalates in PVC-products, biocide dimethylfumarate in shoes, clothing and furniture);

Provisions of the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment define all products for which prohibition and restrictions apply.

Given that the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment came into effect on 7 December 2010, there are still no data on undertaken activities of market surveillance.

i) products for children, other than toys (e.g. products attractive to children, children's swim seats, playpens);

The Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment defines products for child-care – please see answer under a).

Given that the Rulebook on restrictions and bans on production, marketing and use of hazardous chemicals that pose unacceptable risk for human health and environment came into effect on 7 December 2010, there are still no data on undertaken activities of market surveillance.

The Market Inspectorate ordered the withdrawal of 32 children's swim seats in 2010 from the aspect of general product safety.

j) cigarette lighters;

In 2010 the Market Inspectorate ordered the withdrawal of 52 lighters resembling toys.

k) laser pointers;

We do not possess any statistical data.

l) medicines.

As for market surveillance activities in the last three years in the area of medicines, there are two types of surveillance:

- regular surveillance, planned on annual level and means surveillance of pharmacies, wholesale and producers of medicines,
- extraordinary, performed upon request of parties, or at the request of the Agency for Medicines and Medical Means (ALIMS).

22. For product-categories for which no activities were carried out: what was the reason that no activities were carried out?

Activities of market surveillance were planned and taken on the basis of risk assessment, i.e. analysis of consumers' complaints to certain types of products. There were no complaints from consumers for this type of products.

23. For product-categories for which no activities were carried out: choose randomly some of the products falling under the categories of products under question 21 as examples to provide answers to the following questions:

a) Why did you choose these products?

Examples:

Accidents involving the product.

Risk reported by the manufacturer.

Risk reported by conformity assessment (testing, certification) bodies.

Risk reported through an alert network.

Risk reported through a national alert network (e.g. hospital services).

Action by consumer associations or an individual consumer.

Complaint from a competitor.

Information from another country (bilateral contact).

Risk reported by customs.

Special risk covered by a sectoral or seasonal surveillance programme.

Random check.

1. Textile products were taken as an example because in 2010 most cases of withdrawal from the market referred to this kind of product.

The information about chemical risks that textile products contain and information available from international databases (RAPEX) for dangerous textile products, including products for children at risk of choking (e.g. pyjamas with laces), were used in the media and information booklets of consumer organizations. Information from other countries was used in the work.

2. In the example of textile carry-cots, the importer identified the risk of suffocation and made a voluntary decision to recall the product and notified the Market Inspectorate in Serbia, and the Market Inspectorate in co-operation with inspections of other countries established that the producer notified all distributors in region about this. The importer published the information on the recall on its website and in the media. In this case, the importer submitted a notice of the risk to the contact point in the national network for alerting.

b) How was the surveillance organised for these products?

Examples:

Timing and frequency of checks (e.g. before placing on the market, during customs clearance, after placing on the market, in use).

Locations where the checks were carried out (e.g. places of design, manufacture, packaging, storage, sale, in use, goods transport vehicles, roadside checks, customs control).

Control procedures (e.g. documentary or in-situ checks, visual checks (marking, etc.), requests for technical documents, sampling, testing in government laboratories, testing in private laboratories).

Resources used (e.g. administrative and judicial authorities involved, numbers of staff assigned, spending).

Time elapsing between the first check and final decision.

1. An order was issued from the headquarters of the Market Inspectorate regarding the control of textile products with an explanation how to carry out activities and undertake measures, including sampling and testing of compliance with technical requirements and the criteria for general product safety. The control order contained information on the type of risks and guidelines for risk assessment.

The order determined the period for control, and when the activity is planned by an annual work plan, it is carried out continuously throughout the year.

Controls are performed in retail stores, and if necessary, in the warehouses, distribution centres, manufacturing site, and others.

Documents are checked and samples of products are taken and delivered to an accredited laboratory, selected by public call in accordance with the procedure of public procurement (tender).

For example, in 2010 there were 30 samplings of textile products, for which the reports by accredited laboratories were received. According to these reports, three samples did not meet the prescribed requirements of compliance.

Human and material resources of the Market Inspectorate were used. Budgetary funds in the framework of market control (RSD 38,217,000.00) are listed in the answer to question no. 3 c) indent 2.

Time elapsing between the first check from the moment of testing compliance with the prescribed requirements to a final decision based on the report of the accredited laboratory is 3 to 7 days.

2. The contact point issued an order to branch offices with information forwarded from the notification of the importer and implementation of the voluntary measure as decided by the importer was followed till the end. The information on this dangerous product was published on NEPRO portal to inform the general public.

c) Which measures were taken as a result of the checks? (If the measures were temporary, for how long did they apply?)

Examples:

Product deemed compliant.

Party responsible merely required to bring the product into compliance.

Product banned from the market until brought into compliance.

Product withdrawn from the market until brought into compliance.

Product impounded.

Product ordered to be destroyed.

Product recalled.

Information and warning for consumers (how?).

Recall of the product from consumers (how?).

Civil or penal sanctions (to whom?).

1. As a result of check, measures were taken to withdraw the product from the market.

This measure was taken in 247 cases because of incomplete declarations, defects in the operating instructions, technical instructions and so on.

The Market Inspectorate did not seize the products for safety reasons.

The Market Inspectorate's reports filed to judicial authorities for violating the rules on product safety are given in the table in answer to question 19 l).

2. As a result of check, measures were taken to recall the product from consumers. This measure was taken as a voluntary measure of producer and distributors who informed the Market Inspectorate about this. Implementation of that measure was supervised by the Market Inspectorate.

Consumers were informed about this case in the media, on the importer's website and on NEPRO portal.

24. Have the results of these activities and the experience acquired influenced subsequent market surveillance activities?

The mentioned activities and the experience of their undertaking significantly influenced future activities, but also the plans and priorities for 2011, given that this concerns the implementation of new regulations.

25. Who were informed about the activity and/or the outcome – in general or with regard to specific products (e.g. media, other countries, etc.)?

The public was informed through the media about the activities and the final results related to specific products and the information of public importance. Producers and distributors that have subsidiaries in other countries in the region provided information to the competent authorities in other countries, on their websites and through the media.

26. What practical difficulties were encountered in carrying out the activities?

Training for the practical application of regulations are related to the process of harmonization with EU legislation and enforcement of a certain regulation, so there is an urgent need for strengthening the administrative capacity of the Market Inspectorate, in particular through additional training and knowledge check.

C. Non-safety related measures (protection of economic interests of consumers)
Legislation

27. In the framework of your consumer protection policy, indicate whether the following sectors are covered and to what extent they are in line with the relevant EU *acquis*:

- certain aspects of the sale of consumer goods and associated guarantees (Directive 1999/44/EC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Articles 4-5, Chapter VI, Articles 49-58. Sanctions are given in Chapter XIII, Article 151.

- unfair terms in consumer contracts (Directive 93/13/EEC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Article 5, Chapter V, Articles 44-48 and Chapter XIII, Article 133-146.

- indication of the prices of products offered to consumers (Directive 98/6/EC)

The Law on Consumer Protection takes the relevant provisions in Chapter I, Article 5, Chapter II, Articles 6-18, with penal sanctions in Article 151.

- contracts negotiated away from business premises (Directive 85/577/EEC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Articles 4-5, Chapter IV, Articles 28-43, with penal sanctions in Article 151.

- distance contracts (Directive 97/7/EC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Articles 4-5, Chapter IV, Articles 28-43, with penal sanctions in Article 151.

- distance marketing of consumer financial services (Directive 2002/65/EC amending Directives 90/619/EEC, 97/7/EC and 98/27/EC)

The Law on Consumer Protection in Chapter I, Articles 4-5, Chapter IV, Articles 28-43, contains certain norms relevant for the field of financial services.

The Law on the Protection of Financial Service Users, that is currently in the process of adoption, in co-operation of the Ministry of Trade and Services and the National Bank of Serbia, should transpose the provisions of this directive.

- credit agreements for consumers (Directive 2008/48/EEC)

The 2005 Law on Consumer Protection in Articles 29 and 30 contained basic provisions in relation to consumer credit, that did not adequately transpose this directive. The National Bank of Serbia in co-operation with the Ministry of Trade and Services prepared a draft law on the protection of financial service consumers.

- misleading and comparative advertising (Directive 2006/114/EEC)

The new Law on Advertising, currently undergoing the governmental procedure, should fully transpose the provisions from this directive. The current Law on Advertising (Official Gazette No 79/05), covers this matter in Chapter III, Articles 30-33, but it is only partially harmonized with EU regulations.

- unfair commercial practices (Directive 2005/29/EC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Article 5, Chapter III, Articles 19-27 and Chapter XIII, Article 137-146.

- certain aspects of timeshare, long term holiday product, resale and exchange contracts (Directive 2008/122/EC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Articles 4-5, Chapter X, Articles 111-123 and 151.

- package travel, package holidays and package tours (Directive 90/314/EEC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Articles 4-5, Chapter X, Articles 93-110 and 151.

- injunctions for the protection of consumers' interests (Directive 2009/22/EC)

The Law on Consumer Protection transposes the relevant provisions in Chapter I, Article 5, and Chapter XIII, Article 137-146.

- principles applicable to the bodies responsible for out-of-court settlement of consumer disputes (Commission Recommendation 98/257/EC)

Articles 132-136 in Chapter XII of the Law on Consumer Protection contain basic provisions regulating out-of-court settlement of consumer disputes. These norms are of general nature and do not adequately transpose the Commission recommendations. Please see more on this in response to the question 28.

- principles for out-of-court bodies involved in the consensual resolution of consumer disputes (Commission Recommendation 2001/310/EC)

Please see previous answer.

- pre-contractual information to be given to consumers by lenders offering home loans (Commission Recommendation 2001/193/EC)

In addition to the Decision on the General Terms of Business Applied by Banks in Relations with Natural Person Clients, which is partially compliant with EU legal acts regulating the area of protection of consumers users of financial services, we point out that the Bill on protection of users of financial services, which was prepared by the National Bank of Serbia in co-operation with the Ministry of Trade and Services, transposes Consumer Credit Directive 2008/48/EC, Commission Recommendation 2001/310/EC on the principles for out-of-court bodies involved in the consensual resolution of consumer disputes and Commission Recommendation 2001/193/EC on pre-contractual information to be given to consumers by lenders offering home loans.

28. Please indicate for each of the above listed pieces of legislation the basic features of the respective legislation, including enforcement mechanisms, and plans for reform. With regard to the Recommendations on ADR please indicate the ways in which Alternative Dispute Resolution bodies in Serbia comply with Commission Recommendation 98/257/EC and Commission Recommendation 2001/310/EC.

- certain aspects of the sale of consumer goods and associated guarantees (Directive 1999/44/EC)

The Law on Consumer Protection lays down the general provisions applicable to a sales contract between a trader and a consumer: the delivery of goods, the transfer of risk (up to the moment of delivery to the consumer or person he entitled, the risk is borne by the trader – if the consumer terminates the contract or claims compensation for damages due to non-conformity, the risk remains with the trader), obligations regarding conformity with the contract goods and contractual guarantees.

The law introduces the category "conformity of goods" to the sales contract, providing a legal warranty of two years. Presumptions with regards to the conformity of delivered goods are the following: the goods have to comply with the description given by the trader; possess the qualities of the presented sample or model; to be fit for any particular purpose for which the consumer requires them and which was known or must have been known to the trader at the time of the conclusion of the contract; to be fit for the purposes for which goods of the same type are normally used; or to show the quality and performance normal in goods of the same type and which the consumer may reasonably expect, given the nature of the goods and taking into account any public statements on the specific characteristics of the goods made

about them by the trader, the producer or his representative, particularly in advertising or on labelling.

The trader shall be held liable for any lack of conformity which exists at the time of the risk transfer, regardless of whether he was familiar with it or not, as well as for any lack of conformity which occurs after the risk transfer, if the causes existed beforehand. The trader shall not be held liable if at the time of the conclusion of the contract it was known or must have been known to the consumer that the goods are not in conformity with the contract or if the lack of conformity is due to the material supplied by the consumer. Any lack of conformity which becomes apparent within six months of the risk transfer shall be presumed to have existed at that time and the burden of proof is on the trader. Where the goods do not conform to the contract, the consumer is entitled to have the lack of conformity remedied by repair or replacement in the first instance, and, secondly to have the price reduced or the contract rescinded, unless remedying the lack of conformity would cause the trader a disproportionate effort (if it imposes costs on him which, in comparison with the price reduction or the rescission of the contract are excessive, taking into account the value of the goods if there was no lack of conformity and the significance of the lack of conformity; whether the lack of conformity may be remedied without significant inconvenience to the consumer). The producer vouches for the fulfilment of trader's obligations for conformity. The trader has the right to demand redress from its predecessor in the supply chain in accordance with general rules of the contract law.

Under Article 56 of the Law on Consumer Protection, the term “guarantee” means any statement by which its issuer gives a certain promise concerning goods, which is legally binding under the conditions laid down in the statement, as well as in related advertising and lasts for the period the trader obligated himself in the guarantee statement. Guarantees, therefore, in the Serbian law represent an additional, voluntary and contractual step which the trader undertakes in order to offer greater benefits to the consumer - but such statements are binding. One of the ways in which it might be proven is by means of a guarantee sheet, a document in written or electronic form or on durable medium, containing all the data from the guarantee, presented in a clear and legible manner, in easily comprehensible language, particularly the data on consumer rights in case of the lack of conformity, the name and address of a guarantee issuer, the content of the contractual guarantee and the conditions for exercising rights laid down in the contractual guarantee, particularly the duration of the guarantee, its area of applicability and inability to be transferred, if the rights provided for in the guarantee are not transferrable. The guarantor shall issue a guarantee sheet upon the request of the consumer. The validity of the guarantee is not affected by the violation of obligations of the guarantor and the consumer may demand that the guarantee be fulfilled in accordance with the given statement. The guarantee neither excludes nor affects the consumer rights concerning conformity of goods to the sales contract. In concluding sale contracts and in related advertising, the trader shall refrain from using the term "guarantee" and other terms with similar meaning, if according to the contract the consumer acquires no more rights than envisaged by the law.

- unfair terms in consumer contracts (Directive 93/13/EEC)

The Law on Consumer Protection stipulates the rules in cases of consumer contracts containing unfair terms, including special terms, the content of which the consumer has either negotiated or could have negotiated with the trader, and general provisions which were predetermined by the trader or a third party.

A contract term shall be binding on the consumer in so far as it is expressed in plain, intelligible language, and understandable to a reasonable person as educated and informed as the particular consumer at the time of contract formation. Contract terms shall be made available to the consumer in a manner which gives him a real opportunity of familiarizing with them before the conclusion of the contract, with regard to the means of communication used in negotiation. A contract term shall be binding on the consumer if the consumer has agreed to it. If a specific contract term was formulated by the trader in such a way as to consider the consumer to have accepted it unless he explicitly opts out, this can not be inferred as to indicate consent. In cases of doubt about the meaning of a term, the interpretation most favourable to the consumer shall prevail.

The law provides for invalidity as a sanction for unfair contract terms. The law considers it to be the case if the following requirements are met: it results in a significant disproportion in contractual obligations of the parties to the detriment of the consumer, it causes execution of the contract to be disadvantageous to the consumer without justifiable explanation or causes execution of the contract to be substantially different from what the consumer legitimately expected, if it defies the transparency requirements of the trader or the principle of good faith. In order to determine whether a contract term is unfair in a specific case, it is necessary to consider the nature of the goods or services to which the contract relates, the circumstances as of the time of contract formation, the remainder of the terms of the contract or of another related contract, the manner in which the contract was drafted and the information about its content communicated to the consumer.

The law transposes the black (considered unfair in all circumstances, forbidden) and gray (the trader proves that they are unfair in a given case) list of unfair contract terms from the Annex of the Directive. The Law also provides for court-ordered injunctions and stoppage measures for unfair contract terms. The proposal can be brought to the court by the damaged consumers or registered consumer protection organizations and associations.

Decision on the General Terms of Business Applied by Banks in Relations with Natural Person Clients specifies that written contract that the bank concludes with its client must contain minimum conditions laid down in this decision, as well as that contract terms must be clear, complete, precise, unambiguous and understandable for the client. Subject to the obligation of the client must be determined and/or determinable in such manner that during contractual period the client may be informed at any time on circumstances, manners and conditions under which the amount of his obligation may be altered.

- indication of the prices of products offered to consumers (Directive 98/6/EC)

The Law on Trade (Art 41) and the Law on Consumer Protection (Art 5-14) transpose the Directive 98/6/EC comprehensively, including the requirements for indication of “total retail” prices i.e. “selling price” (including taxes, possible public sales, accompanying goods and additional costs), as well as unit price. If the unit price of goods and/or services is equal to the selling price, the trader is not obligated to indicate the unit price of goods and/or services. If, for a certain type of packaged goods, the net weight and drained weight may be indicated, the trader may indicate the price per a unit of drained weight. If goods are not packaged but measured in the presence of the consumer, the trader shall indicate the unit price only.

The price indication obligations also apply to related advertising.

There are also specific rules for price indication in services, electricity, gas, central heating and water, gas stations and parking places, catering facilities etc.

- contracts negotiated away from business premises (Directive 85/577/EEC)

According to the Law on Consumer Protection, a contract is considered to be concluded away from the business premises if it was concluded outside of a trading facility or business premises of the trader (shop, parlor, bureau, office) intended for sale or rendering services, including, for example, fair booths, but in the synchronised physical presence of both the trader and the consumer.

Apart from the requirements of Article 16 of the Law on Consumer Protection, in these cases, the trader has an additional duty to provide certain information under Article 28 of the Law on Consumer Protection: the address of the place of business of the trader or the one he is representing where the consumer may send a complaint, the existence and way of accessing a code of conduct which the trader subscribes to etc. The law specifically regulates the obligation of the trader to inform the consumer on the right of withdrawal, the conditions and manner for exercising it, and to present that information on the purchase order, which shall contain a withdrawal form. An off-premises contract shall only be valid if the consumer signs an order form, and, in cases where it is not on paper, if the consumer receives a paper copy (Article 32)

The trader shall fulfill the obligations laid down in the contract concluded off the business premises within 30 days from the day on which he receives the purchase order from the trader, except otherwise agreed. Under the law, the consumer is not permitted to request advance payment from the consumer before fulfilling his obligations.

The deadline for the withdrawal from the contract concluded off the business premises is 14 days from the day on which the consumer signed the purchase order. If the trader fails to inform the consumer on his right of withdrawal, the deadline of 14 days begins on the day on which the consumer receives a notice regarding his right of withdrawal in a written form or on a durable medium. In this case, the consumer may terminate the contract at any time, including the period prior to the reception of the late notice on the right of withdrawal.

The withdrawal by one party marks the termination of the obligations of the trader and consumer to execute contractual obligations. The trader shall reimburse any payment received from the consumer within thirty days from the day on which he is informed of withdrawal, with the interest on arrears. If the consumer exercises his right of withdrawal from an off-premises contract, any ancillary contracts shall be automatically terminated, without additional costs for the consumer.

In respect of off-premises contracts, the right of withdrawal shall not apply to the following:

- contracts for the supply of foodstuffs, beverages or other goods intended for everyday consumption in the household, selected in advance by the consumer by means of distance communication and physically supplied to the consumer's home, residence or workplace by the trader who usually sells such goods on his own business premises;
- contracts for which the consumer, in order to respond to an immediate emergency, has requested the immediate performance of the contract by the trader; still, if on

this occasion the trader provides or sells additional services or goods other than those which are strictly necessary to meet the immediate emergency of the consumer, the right of withdrawal shall apply to those additional services or goods.

In contracts for which the consumer has specifically requested the trader, by means of distance communication, to visit his home for the purpose of repairing or performing maintenance upon his property the consumer can withdraw if the trader provided services in addition to those specifically requested by the consumer or goods other than replacement parts necessarily used in performing the maintenance or in making the repairs, in respect of those additional services or goods.

- distance contracts (Directive 97/7/EC)

Under the Law on Consumer Protection, a distance contract is a contract concluded without direct presence of the trader and the consumer at the same place and the same time. It is typical for this type of contracting for the trader to offer goods or services using some of the means for distance communication (for example, mailing standard letters or catalogues, addressed or unaddressed printed material in the press, automatic or personal phone calls, e-mail, TV shopping etc.), and the consumer to respond by using the same or some other means of communication. Apart from the information requirements of Article 16, the trader is obliged to provide certain additional information under Article 28, such as the conditions and procedures for exercising the right of withdrawal, the address of the place of business of the trader or the one he is representing where the consumer may send a complaint, the existence and way of accessing a code of conduct which the trader subscribes to etc. If the trader makes a telephone call to the consumer with a view to concluding a distance contract, he is obliged to disclose his identity and the commercial purpose of the call at the beginning of the conversation.

The law specifically regulates the obligation to inform the consumer on the right to withdrawal and present the information in written form prior to the distance contract conclusion or at the latest, when delivering goods or rendering services. The consumer may exercise his right of withdrawal within a period of fourteen days following the conclusion of the contract. If the consumer explicitly agrees that provision of the service should start before the expiry of the fourteen days period, he may not withdraw from the contract after the performance has begun. If the trader does not inform the consumer on his right of withdrawal on time, the deadline begins from the day on which the consumer receives a notice from the trader regarding his right in written form or on a durable medium. In these cases, the consumer may terminate the contract at any time, including the period of time prior to the reception of the late notice on the right to withdrawal. The exercise of the right of withdrawal terminates the obligations of the parties within 30 days from the day of the reception of the statement. The trader shall reimburse any payment received from the consumer according to the contract, with the interest on arrears. If the consumer exercises his right of withdrawal any ancillary contracts shall be automatically terminated, without additional costs for the consumer.

In respect to distance contracts, the right of withdrawal shall not apply as regards to the following: services where performance has begun, with the consumer's prior express consent, before the end of the withdrawal period; when it comes to the supply of goods or services for which the price is dependent on fluctuations in the financial market which cannot

be controlled by the trader and for the supply of sealed audio or video recordings or computer software which were unsealed by the consumer or gaming and lottery services.

When it comes to distance contracts, the law specifies the limits on the usage of certain means of communication, such as direct advertising, mailing of unordered merchandise and advertising by means of distance communication.

- unfair commercial practices (Directive 2005/29/EC)

Unfair commercial practices are forbidden. The burden of proof regarding the veracity of data on goods that the trader has submitted before, during or after the conclusion of the contract is on the trader. Commercial practices are presumed to be unfair if they 1) are contrary to demands of professional attention and 2) significantly infringe or are likely to infringe economic conduct, in relation to the product, of an average consumer whom those practices concern, or the conduct of an average member of the group, when those practices concern a group. The commercial practices are considered as significantly infringing to the economic conduct of the consumer if they significantly diminish his ability to make rational choices, encouraging the consumer to make economic decisions he would not have made otherwise, with the exception of permitted advertising, which can imply the making of exaggerated statements or statements that should not be taken literally.

Unfair commercial practice is an open and umbrella term, which specially consists of misleading, aggressive commercial practices and the failure by the trader to provide information according to the law.

According to the law, misleading commercial practices involve misleading an average consumer through incorrect information or some other way, in respect to the existence or nature of goods, their basic characteristics, the trader's obligations and reasons for certain market behavior, prices, details of technical support, the identity and trader and consumer rights. This includes the creation of an overall impression (regardless of the accuracy of information provided) via advertising or violation of the code of conduct which the trader has accessed. If the trader, taking into consideration all the circumstances of a given case, space and time limitations of means of communication used and informative measures undertaken, fails to provide substantial information necessary for an average consumer to make a reasonable decision, encouraging or being likely to encourage an economic decision he would not have made otherwise, and/or conceals substantial bits, provides untimely, unintelligible or ambiguous information or fails to disclose the commercial purpose of his address, thus encouraging or being likely to encourage an average consumer to make an economic decision he would have not made otherwise it shall be considered as misleading commercial practice. The black list of commercial practices that are presumed to be misleading in all cases has been transposed from the Annex of the Directive, as well.

According to Article 24 of the Law on Consumer Protection, a commercial practice shall be regarded as aggressive if a trader, taking into consideration all the circumstances of a given case, by harassment, compulsion, including physical force or undue influence (abuse of a position of power), impairs or threatens to impair the freedom of choice or conduct of an average consumer in relation to a certain product, thus encouraging or being likely to encourage the consumer to make an economic decision he would not have made otherwise. The criteria for determining aggressive commercial practices are the following: the time,

place, nature and duration of a commercial practice, the use of threatening or insulting language or conduct, conscious misuse of accidents or unfortunate circumstances that affect the consumer's reasoning or the setting difficult or disproportionate non-contractual obstacles for exercising a consumer's contractual right. The black list of commercial practices which are presumed to be aggressive regardless of the circumstances of the case has been adopted, in conformity with the Annex of the Directive.

The law envisages the possibility of establishing, control and informing the consumers on the application of the trader's code of conduct in the field of unfair commercial practices, with the assistance of the Ministry. Article 11 of the Directive provides for injunctions against unfair commercial practices ordered by the court and initiated by the damaged consumers and registered consumer organizations and associations. The court has the authority to proclaim certain commercial practices unfair, order the trader to suspend unfair commercial practices without delay (under additional sanctions), order the trader to correct the part of an advertisement that is considered unfair at his own expense, order the trader to communicate through media at his own expense that according to the decision of a competent court he has been granted an injunction on unfair consumer contract terms or unfair commercial practices and special penalty measures for seizing illegally obtained gains, if the trader fails to fulfil his obligations within the deadline.

-certain aspects of timeshare, long term holiday product, resale and exchange contracts (Directive 2008/122/EC)

In the field of timeshare, the Law on Consumer Protection follows the approach of Directive 2008/122/EC and regulates four appointed contracts: (1) Timeshare contract; (2) Long-term holiday product contract; (3) Timeshare resale contract; and (4) Timeshare exchange contract.

Before the conclusion of the contract, the trader shall provide the consumer interested in timesharing detailed information (about the real estate, its indications, basic features and location, services of common interest to which the consumer may have access, price, including remuneration for services of common interest, remuneration for the usage of the common system of devices, etc.) in the standard information forms. Such information shall be provided free of charge, on paper or another easily accessible durable medium, in a clear and comprehensible manner. In case of advertising timeshares, the trader shall emphasize the possibility and manner of obtaining information on all the necessary details, and if timeshare is offered for sale to the consumer in person, at a promotion or sales event, the trader shall ensure that the information is available to the consumer at any time during the event. The contract shall be concluded in written form, on paper or another durable medium, and shall contain all the details that the consumer has been provided with prior to the conclusion of the contract. The information shall form an integral part of the contract, and they shall not be altered unless the parties expressly agree otherwise, or unless the changes are the consequences of force majeure. At the moment of its formation, the consumer shall receive at least one copy of the contract.

The consumer has a right to withdraw from a timeshare contract within 14 days without providing any explanation. The trader shall inform the consumer on the right of withdrawal and its duration prior to the conclusion of the contract, and the consumer signs under this provision. The withdrawal period is extended if the trader fails to submit a standard

withdrawal form to the consumer or to inform the consumer on the details he should have provided prior to the conclusion of the contract. The consumer shall inform the trader of his decision to withdraw on a paper or another durable medium, either in a statement addressed to the trader drafted in his own words, or using the standard withdrawal form. The exercise of the right of withdrawal by the consumer terminates the obligation of the parties to perform or to conclude a contract and the consumer shall neither bear any additional cost nor be liable for any value corresponding to the service which may have been performed until withdrawal.

According to the Law on Consumer Protection the fulfilment of any advance payment, collaterals, explicit acknowledgement of debt or any other obligations to a trader or any third party is prohibited before the expiry of the withdrawal period and shall have no legal effect. Certain derogations concerning the ban on advance payment exist in the timeshare resale contract, by which a trader, for consideration, assists a consumer to sell or buy a timeshare or a long-term holiday product, any advance payment is prohibited before the actual sale has taken place or before the trader has otherwise discharged all his duties under the resale contract. The consumer may demand the back sale of the timeshare or long-term holiday product contracts, if the trader fails to counsel a consumer while selling or buying a timeshare or long-term holiday product.

All the traders in the chain of sale of timesharing, as well as the intermediaries, shall be jointly liable to the consumer for performance under the contract and for the consequences of non-performance. The evidence of security for touristic travels in the event of insolvency is also laid down.

- package travel, package holidays and package tours (Directive 90/314/EEC)

Directive 90/314/EEC is currently undergoing revision and at the time of drafting the Law, a draft directive which could have been used was not published. Yet, some significant decisions of the European Court of Justice provide answers on some disputed questions, which in the older directive were pretty numerous. Those decisions were taken into consideration when drawing up the Law on Consumer Protection (e.g. the definition of package tours from the Law on Consumer Protection takes into consideration the decision of the European Court referring to the case C-400/00 which concerns the term "package tours". The term "package tour" from the Law on Consumer Protection was expanded to include the contract on the stay of a student or pupil with the host family abroad lasting for three months or more.

In this section of the Law on Consumer Protection, the terms "trader" and "consumer" are broadened compared to the basic definition. Apart from a person who professionally organizes package tours, the notion of 'trader' shall include a person who provides travel and tourism services to the consumers outside of his trade, business, craft or profession, such as sport associations, charity and other non profit organizations . The term "consumer" has been expanded to mean a natural person who is travelling for purposes relating to his trade, business, craft or profession, as well as a natural person who is travelling as a beneficiary, on the basis of the contract between the trader and a third party, for instance a child who is travelling on a basis of contract between the trader and the parent.

The Law on Consumer Protection envisages the complete and accurate list of information the consumer shall be provided with by the trader prior to the conclusion of the contract on package tours, which has been slightly expanded compared to 90/314/EEC, following the discussion on the future revision of the directive. The Law on Consumer

Protection guarantees to the consumer the right to withdrawal, but obligates him to reimburse the costs to the trader, as well as profit lost in case of untimely withdrawal. The trader shall inform the consumer prior to the conclusion of the contract on the manner in which such reimbursement is being calculated, which must be economically justifiable and proportionate to the time remaining to departure. If the consumer exercises his right of withdrawal with justifiable reasons which could not have been predicted, avoided or removed, the trader has the right to demand the reimbursement of administrative costs only.

The trader is obligated to provide package tours in conformity with the contract and is responsible for lack of such conformity. Package tours are considered to be in conformity with the contract if it has all the features and value that the trader explicitly and tacitly guaranteed to the consumer, especially if it is in accordance with its regular or agreed purpose. The Law on Consumer Protection contains provisions on a series of mutual obligations between the trader and, to a certain extent, the consumer during the contractual period in accordance with the principle of good faith. Such are, for example, the obligation of the trader to provide immediate help to the consumer in case of lack of conformity; the responsibility of the trader for damage in case of lack of conformity, which in accordance with the decision of the European Court of Justice on the case C-168/00 includes moral damage; the rule that the consumer loses his right to demand the reduction in prices if he unconscientiously fails to point to lack of conformity with contractual services.

According to the Law on Consumer Protection, the trader shall provide sufficient evidence of security for the refund of the price of the package tour in case of non-performance due to insolvency of the trader, as well as the necessary expenses of the consumer's return to the place of departure in case of insolvency of the trader. The trader may meet his obligations by means of either insurance against insolvency or an unconditional bank guarantee collectable on first call.

- out-of-court consensual resolution of consumer disputes (Commission Recommendation 98/31/EC)

The Law on Consumer Protection defines a consumer dispute that may be resolved out-of-court in a confidential and urgent proceeding, in which the parties are equal. The Law regulates such matters on a general level, with reference to the primary regulations for ADR – the Law on Arbitration (Official Gazette No 46/06) and the Law on Mediation (Official Gazette No 18/05). Although the main principles (impartiality, transparency, efficiency) which are regulated by the aforementioned acts are basically the same, the harmonization with specific demands of the Recommendation referring to out-of-court resolution of consumer disputes is not on an adequate level.

General procedures and institutions (including those mentioned in the answer No 5), are organized in accordance with general principles of out-of-court resolution – voluntariness, equality, privacy, confidentiality, urgency (Article 33 of the Law on Arbitration and Articles 3 to 7 of the Law on Mediation).

The National Bank of Serbia adopted in 2005 the Decision on the Protection of Rights and Interests of Policyholders, Insured and Third Damaged Parties in Mediation Aimed at Peaceful Settlement of Insurance Disputes (Official Gazette of RS, No 46/2005), and in 2006 the Decision Specifying Conditions and Manner of Dealing With Bank Customer Complaints

(Official Gazette of RS, No 114/2006) that regulate the mediation procedure conducted in conformity with the Law on Mediation (Official Gazette of RS, No 18/05).

- principles for out-of-court bodies involved in the consensual resolution of consumer disputes (Commission Recommendation 2001/310/EC)

Please see the previous answer.

The National Bank of Serbia adopted Decision on the Manner and Procedure of Implementing General Terms of Business Applied by Banks in Relations with Natural Person Clients (hereinafter referred to as: the Decision), which came into force on 7 September 2009, and which provides for the obligation of a bank to adopt an act comprising minimum conditions prescribed for products and services which the bank offers, and which specifies that clients may obtain all necessary information prior to the purchase or when using certain product in order to become familiar with their rights and obligations in detail on time.

The Decision partly incorporates recommendations provided for in the following acts of *EU acquis*:

- distance marketing of financial services intended for consumers (Directive 2002/65/EC amending Directives 90/619/EEC, 97/7/EC and 98/27/EC)
- credit agreements for consumers (Directive 2008/48/EEC)
- pre-contractual information which the creditors offering housing loans are obligated to provide to consumers (Commission Recommendation 2001/193/EC)

The bank shall enable the client to become familiar with general terms by informing him, at his own request, that he may obtain written information on general terms that the bank applies in relation to this request and demand appropriate explanations and instructions for the application of those terms.

The bank shall inform the client, at his own request, on the conditions regarding the acceptance of deposit, loan approval, opening, maintenance and closure of client account, as well as the issuance and usage of payment cards (bank offer).

The information on deposit acceptance and loan approval shall be determined and presented on the forms containing basic information on deposit, and/or loan, in a manner that would not mislead the client at any time. The bank shall provide the client with the form and inform him that he can, at his own request and free of charge, receive text of the agreement on deposit or loan – as a recommendation for its conclusion.

The bank shall also inform the client who intends to conclude the agreement on the opening, maintenance and closure of client account or on the issuance and usage of payment cards, that he may obtain, at his own request and free of charge, texts of those agreements – as a recommendation for their conclusion.

- misleading and comparative advertising (Directive 2006/114/EEC)

Provisions of Articles 30 to 33 of the Law on Advertising (Official Gazette of RS, No 79/05) relate to false, misleading and comparative advertising. Advertising that promotes untrue information of the identity of an advertiser, his activity, goods or services; the

omission of important data, the usage of imprecise and ambiguous terms, outdated statements or other information which lead to misconception regarding the identity of an advertiser, his activity, goods or services (type, characteristics, quality, origin) and other recommendations communicated to advertisement recipient is prohibited.

The same is true for advertising imitating or copying another person, his activities, goods or services and advertising of goods or services as an imitation or faithful copy of goods or services which represent a trademark, as well as usage of the protected material of trademark or other mark by which competitor is recognisable. The use of reputation or an advertising message of another person is not allowed without that person's consent.

According to Article 53 of the Law on Advertising, the comparison of previous and current prices of goods and services in advertising shall be prohibited, if the previous price indicated is fictive, if the previous price was considerably higher than the market price, if the previous price has been in offer for the negligible period of time or goods have never been offered at that price and if the difference between the previous and current price is negligible.

Full-scale approximation with Directive 2006/114/EEC will be carried out by adopting the new law on advertising, which is in the final stages of drafting and ready to be submitted to the Government for consideration and adoption of the draft law on advertising.

The bank shall advertise its goods and services pursuant to general terms, in a clear and comprehensible form, and such advertising shall not contain incorrect information, or information which could create false impression regarding the conditions under which the client uses such goods and services.

When advertising deposits and loans from its offer through media,
– on its premises (via brochures, advertising leaflets etc.) and web page, the bank shall precisely and clearly specify the costs of the client, as well as the following data:

- type of deposit or loan,
- the amount and applicability of annual nominal interest rate,
- effective interest rate,
- the currency in which deposit is accepted or loan approved,
- the period on which deposit is accepted or loan approved,
- criteria for indexation/revalorization of deposit or loan.

- injunctions for the protection of consumers' interests (Directive 2009/22/EC)

The Law on Consumer Protection, when dealing with the procedure of granting injunctions against unfair contract terms and unfair commercial practices transposes Directive 2009/22/EC. Article 137 envisages the right of the consumer whose right or interest has been injured, and of registered consumer protection organizations or associations to submit their request to the competent court for cessation of using unfair contract terms, unfair commercial practices, or seizing illegally obtained gains (in accordance with general rules on obligations).

According to the procedure, the court is authorized to declare any term in consumer contracts deemed to be unfair void and certain commercial practices unfair, to request from the trader to suspend without delay the conclusion of unfair terms and cessation of unfair commercial practices and to correct the part of an unfair advertisement, at his own expense or to request from the trader to communicate through media, at his own expense, that the

competent court has granted an injunction against him. The injunction according to which the trader must suspend the application of unfair contractual provisions or unfair commercial practices until the court reaches its final decision is envisaged.

The value of the dispute is equal to the total value of goods or services in individual cases provided for in the demand up to a maximum amount of 500.000 RSD (\approx EUR 4,740) . A call for resolving a dispute via ADR is a procedural requirement.

If the trader against whom a final decision has been reached fails to act in accordance within the given deadline, any person who has a justifiable interest may submit a request for confiscation of illegally obtained benefits to the court. If in individual cases concerned the value of goods or services is less than RSD 2,000 (\approx EUR 19) per consumer, the court shall determine reimbursement for illegally gained pecuniary benefits in the form of the payment of sum equal to the total amount of goods or services in cases in which unfair contractual provisions or unfair commercial practices are confirmed, up to a maximum 5% of the total annual income of the trader, calculated in accordance with competition regulations, for the benefit of the budget of the Republic of Serbia.

The application of the law that regulates civil proceedings is prescribed, and Article 141 provides for the obligation of the Ministry to publish case-law in relation to submitted demands, according to data received from the ministry in charge of justice affairs.

29. Please indicate whether within the framework of your consumer protection policy there are in place public authorities that are capable of assuming the obligations imposed by Council Regulation 2006/2004 on Consumer Protection Co-operation.

Council Regulation 2006/2004 has not been implemented in the legal order of the Republic of Serbia. Still, inspection authorities and agencies authorized for surveillance for certain areas have the basic capacity to take over the obligation from the regulation, with necessity of further capacity building, professional advancement and staff training.

1. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising	Ministry of Trade and Services – Market Inspectorate RATEL
2. Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises	Ministry of Trade and Services – Market Inspectorate
3. Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers	National Bank of Serbia Ministry of Trade and Services – Market Inspectorate
4. Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities	RATEL
5. Council Directive 90/314/EEC on package travel, package holidays and package tours	Ministry of Economy and Regional Development – Tourist inspection
6. Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts	Ministry of Trade and Services – Market Inspectorate
7. Directive 2008/122/EC of the European Parliament and of the Council of 14 January 2009 on the protection of consumers in respect of certain aspects of timeshare, long-term holiday product, resale and exchange contracts	Ministry of Economy and Regional Development – Tourist inspection
8. Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of Distance Contracts	Ministry of Trade and Services – Market Inspectorate
9. Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers	Ministry of Trade and Services – Market Inspectorate
10. Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees	Ministry of Trade and Services – Market Inspectorate
11. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the internal market	Ministry of Trade and Services – Market inspection Ministry of Telecommunications and Information Society – Inspection for postal services, inspection for telecommunication and informatics
12. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	Ministry of Health
13. Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services	National Bank of Serbia Ministry of Trade and Services – Market inspection

14. Regulation (EC) No 261/2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights	/
15. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market	Ministry of Trade and Services – Market inspection

The Law on Consumer Protection regulates the system and strategy of consumer protection as well, marking the competent ministry and other authorities and organizations within their competences, consumer protection organizations and associations, commercial and professional chambers and other stakeholders as holders of consumer protection. To improve the consumer protection system and co-operation of competent authorities, organizations and consumer protection holders, the Government of the Republic of Serbia forms a national consumer protection council.

Bearing in mind that the National Bank of Serbia controls the operations of banks and other financial institutions, i.e. supervises the performance of insurance activities, the National Bank of Serbia shall within its competences take all necessary activity to secure that financial institutions act in compliance with valid regulations.

30. Specify which authorities are competent for drafting the relevant legislation and how legislation is passed (primarily through parliamentary procedure or ministerial orders or decrees).

The Ministry of Trade and Services, as competent ministry in charge of consumer protection issues, under the Law on the Ministries, is responsible for preparing laws regulating the field of consumer protection. Common practice in preparing a law is forming a working group for creating a working version of the law, made up of experts in the particular fields, representatives of consumer organizations, business community and other interested parties, and experts from the ministry. In the case of preparing the new Law on Consumer Protection (2010), there was also professional help from foreign experts, through the project of support of the European Commission (ZAP project). After the drafting of the working version of the law, the text was a subject of public debate, done in thematic meetings and by reception of individual remarks and comments. Upon conclusion of this procedure, the Ministry creates a final draft that is sent to an inter-governmental analysis for other ministries and state authorities to give their opinion. Based on the given remarks and opinions, the text is harmonized and adopted, which the government sends to the parliament for consideration and adoption.

By-laws are passed by the authority set by law which is the basis for its adoption. As a rule, this would be the government or the competent minister.

Based on the provisions of the Law on Consumer Protection, the government more closely regulates the legal framework by a regulation in terms of criteria for establishing

vulnerable consumers in certain fields of services of general economic interest, at the proposal of the minister and minister in charge of a certain area (Article 84), and content of the form for unilateral rescission of timeshare, long-term holiday benefits contract, timeshare resale and exchange contracts, at the proposal of the minister and minister in charge of a certain area (Article 113).

At the proposal of the ministry in charge of consumer protection and with participation of the National Consumer Protection Council set up of all the relevant stakeholders, the government adopts a Consumer Protection Strategy, that sets long-term goals and activities necessary for an overall exercising of the policy of consumer rights and consumer interests, and an action plan for implementation of the strategy (Articles 124. and 126).

The minister in charge of consumer protection affairs regulates the legal preconditions for the registration of consumer protection organizations and associations, the content and the manner of keeping records, and content of the application form (Article 129).

The National Bank of Serbia is in charge of passing regulations in the area of operation of banks and other financial organizations whose work it supervises, and is in charge of giving opinion and suggestions in relation to the modifications and amendments to the law on consumer protection referring to protection of financial service consumers.

31. Please indicate additional existing legislation protecting consumers' economic interests (e.g.: rules on sales promotions, rules on advertising, rules on price reductions, general labelling requirements on products).

Apart from the Law on Consumer Protection, certain issues in the field of protecting consumers' economic interests, such as the general rules on advertising products and services, sale promotions, manner of refunding etc. are regulated by the Law on Advertising, Articles 49-60 (Official Gazette 79/2005). The Law on Trade (Official Gazette No 53/10), regulates the rules on declaration, display of price and sale incentives, such as sales, promotions, discounts, etc. (Articles 40, 41 and 44).

Regulations of the National Bank of Serbia in the field of financial service consumers:

- Decision Specifying Conditions and Manner of Dealing with Bank Customer Complaints (Official Gazette of RS, No 114/2006);
- Decision on General Terms of Business Applied by Banks in Relations with Natural Person Clients (Official Gazette of RS, No 74/2009);
- Decision on Terms and Conditions for Performing Exchange Operations (Official Gazette of RS, No 67/2006, 68/2006 - corr., 116/2006, 24/2007, 50/2007, 118/2007, 120/2008, 11/2010 and 18/2010);
- Decision on Minimum Conditions for the Conclusion of the Financial Lease Contract and the Manner of Disclosing the Leasing Fee and Other Costs Arising From the Conclusion of Such Contract (Official Gazette of RS, No 4/2006, 64/2006, 15/2009 and 7/2010);
- Decision on the Protection of Rights and Interests of Policyholders, the Insured and Third Damaged Parties in Mediation Aimed at Peaceful Settlement of Insurance Disputes (Official Gazette of RS, No 45/2005);

- Decision on the Advertising of Voluntary Pension Funds and Standardized Advertisement Text (Official Gazette of RS, No 23/2006);
- Decision on Detailed Content and Standardized Format of the Contract of Membership in Voluntary Pension Fund (Official Gazette of RS, No 9/2009);
- Decision on Detailed Content and Standardized Format of the Prospectus of a Voluntary Pension Fund (Official Gazette of RS, No 23/2006);
- Decision on Opening, Maintaining and Transferring Individual Accounts of Voluntary Pension Fund Members (Official Gazette of RS, No 24/2008);

Implementation and enforcement

32. If public authorities exist to protect the economic interests of consumers, please specify the powers at their disposal and give some examples of activities carried out, including the powers and activities in cross border cases.

Article 147 of the Law on Consumer Protection regulates competence for surveillance over the implementation of the law, granting authority to the ministry in charge of consumer protection, tourism affairs, energy and telecommunications through appropriate inspection bodies. This kind of surveillance protects consumers' economic interests.

In conducting inspection surveillance, the competent inspector shall have all rights, duties and powers laid down in the Law on Consumer Protection and the laws governing inspection surveillance in a particular field. The competent inspector shall be authorized to check whether the trader displays the prices in line with the Law, states commercial purpose of information to consumers before concluding a contract, has unfair commercial practices, sends packages that the consumer has not ordered, advertises via means of long distance communication contrary to the law, abuses the term “guarantee”, responds to the consumer’s complaint within 14 days, advertises or offers package travel or timeshare contrary to the law, submits a guarantee for payment inability for package travel or timeshare

If the competent inspector notices some of these defects, he/she shall issue an administrative decision whereby the trader shall be ordered to remove the defect. If the trader fails to remove the established defect within the time limit set in the decision, the inspector shall issue a decision on temporary ban on sale of goods or providing services, until such defect for which the measure was pronounced is removed.

The National Bank of Serbia started a process of establishing the function of protection of financial service users in all segments of financial sector under its supervision.

By forming a special organisational part – the Centre for Financial Service Consumers, the National Bank of Serbia initiated the establishment of the institute of protection of financial service consumers and continued to provide citizens in even more active way with the assistance in exercising their rights, both in terms of understanding and the use of services of the financial sector.

If the user of a financial institution whose work is supervised by the National Bank of Serbia thinks that his/her rights in relation to a bank, insurance company or voluntary pension fund management company have been violated, i.e., that any of the mentioned financial institutions does not adhere to the good business practices, the user must first try to address the financial institution directly in order to resolve the problem. If dissatisfied with the

provided answer, the consumer has the right to submit a written objection. If the financial institution fails to submit the answer or if the user is dissatisfied with the offered solution, he/she may issue a complaint to the National Bank of Serbia.

The National Bank of Serbia - the Centre for Financial Service Consumers – shall consider the consumer's complaint, seek opinion from the financial institution and if it establishes that it is possible to reach a peaceful resolution of the dispute in the mediation procedure, it shall suggest the organisation of mediation, if both parties agree.

Therefore, the Centre for Financial Service Consumers does not make a decision upon consumer's complaint, nor does it impose any measures to financial institutions.

Bearing in mind that banks inform the National Bank of Serbia about complaints submitted to these institutions and keep records of the complaints submitted to the National Bank of Serbia, the highlights of those complaints are registered and information about that is submitted to the competent control sector. The control sector takes the given information into consideration when conducting regular control of business operations. Those who filed complaints are not informed about the undertaken measures.

The National Bank of Serbia is not in charge of acting upon possible objections in relation to cross-border disputes.

33. Please provide details on enforcement of legislation in the area of financial services, in particular on consumer credit.

Chapter 9 – Financial Services explains in detail the enforcement of legislation in the area of financial services. The National Bank of Serbia is in charge of controlling the enforcement of the Decision on General Terms of Business Applied by Banks in Relations with Natural Person Clients, as well as for the enforcement of all other decisions regulating financial service consumer protection.

The Bill on Protection of Financial Service Consumers also introduces the jurisdiction of the National Bank of Serbia for undertaking appropriate measures in the case of failing to act in conformity with that law.

II. Public Health

A. Horizontal aspects

34. The Commission White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013', Document COM(2007) 630 final, sets out the health strategy of the European Union (EU). The Second Programme of EU Action in the Field of Health 2008-2013 (Decision 1350/2007/EC) is a key instrument to support the Strategy's objective. Does your country have a health strategy? What are the main priorities? Are activities being implemented in these areas? If so, give a brief description. Examples are:

- **Health mainstreaming**
- **Health promotion activities**
- **Surveillance and preparedness activities**
- **Innovation in health/health technologies**
- **Gender dimension**
- **Health literacy programmes**
- **Consultation mechanisms**
- **Health status analysis and reporting (to support national health policy cycles, as public health problems and their determinants – in different population groups – are important for policy makers).**

Republic of Serbia has health strategy. In the beginning of the process of reforming of the health sector, basic elements and core of the changes were defined in the document Better Health for All in third millennium. This document had three strategic components: Health Policy of Serbia (2002), Vision of Health Care system in Serbia and Strategy and Action plan of the reform of Health Care System. This document is based upon Declaration of the WHO of responsibility of state institutions for health in the all Member States, Universal Declaration on Human Rights as well as European Policy and Health Goals for all in 21st century.

Objectives defined in the Health Policy of Serbia:

1. Preserving and improving the health status of the Serbian population and strengthening the health potential of the nation
2. The provision and promotion of fair and equal access to health care for all citizens of Serbia, as well as improved health care of vulnerable population
3. Setting the user (patient) at the center of the health care system
4. Sustainability of the health system with transparency and selective decentralization in the management of resources and expanding range of sources and funding
5. Improving performance, efficiency and quality of health care system with definition of specific national programs in the area of human resources, network institutions, technology, and medical supplies
6. Defining the role of the private sector in providing health services population
7. Improving human resource base of health care (human resources for health).

Health has a tremendous impact on the capability of individuals to live their daily lives, on the contribution to the social and economic development, meaning, on the overall success of a country. Therefore, health should be seen as a considerable national resource, which deserves continuous strategic development. Besides the aforementioned, the right to health and health care is one of the basic human rights, and everyone should enjoy being in their best possible health – every individual in the Republic of Serbia should have the opportunity to choose a healthy lifestyle and live a life in an environment that is conducive to health.

The Republic of Serbia Health Care Development Plan (hereinafter: the Plan) is an expert and a political document, which has been adopted on November 23rd 2010. by National Assembly, and it will be used to guide the development of the health care system, while having in mind the overall development of society. This document defines the basic aims and directions of

health care development in the Republic of Serbia, and represents the end result of an expert-led consultation process.

The Plan represents an instrument for the further development of the health care system and the changes that should mark the coming period when it comes to the improvement and the establishment of the balance between the efficiency and the effectiveness, and between the quality and the safety of health care at all levels of the system, while, at the same time, taking into consideration various circumstances related to social trends, demographic changes, the level of educational and cultural achievements of the population, the health status of the population, as well as a number of other factors that could influence sustainable health care development.

The Basis for the Adoption of the Plan

The Plan is adopted based on Article 16 of the Health Care Law (“The Official Gazette of the Republic of Serbia”, no. 107/05 and 72/09 – other laws), taking into consideration the strategies and national programs passed by the Government, namely: the Health Policies of Serbia (2002); the Poverty Reduction Strategy (2003); the National Millennium Development Goals in the Republic of Serbia (2006); the Republic of Serbia Youth Health Development Strategy (2006); the National Strategy on Ageing 2006-2015 (2006); the Tobacco Control Strategy (2007); the Mental Health Protection Development Strategy (2007); the National Strategy on Sustainable Development (2008); the Strategy for the Fight Against Drugs (2009); the Strategy for the Prevention and Control of Chronic Non-communicable Diseases (2009); the Strategy for Improvement of the Roma Population Situation (2009); the Republic of Serbia Public Health Strategy (2009); and others.

35. Please provide information on the health status of the population in your country. This should include gender specific and combined information on key health indicators such as infant mortality and life expectancy; patterns of mortality and morbidity; situation with regard to communicable and sexually transmitted diseases, healthy life years. To this end, please see DG Health and Consumers website on European Community Health Indicators (ECHI) and consider as an example to follow this first set of key health indicators. (http://ec.europa.eu/health/indicators/echi/list/index_en.htm).

Indicators of vital demographic statistics

The following tendencies are characteristic for the natural movement of the population in Serbia:

- Reduction of birth rate – birth rate fell (per 1000 people) from 10.4/1000 live births in 2002 to 9.6/1000 live births in 2009.
- Reduction of birth rate – birth rate fell (per 1000 people) from 13.7/1000 live births in 2002 to 14.2/1000 live births in 2009.
- Reduction of population growth rate – population growth rate (per 1000 people) has a decreasing trend, from -3.3 in 2002 to -4.6 in 2009;
- Reduction of general infant mortality rate – since 2002 infant mortality rate per 1000 of live births was reduced from 10.1 to 6.7, in 2008, while in 2009 there was an increase of this indicator to 7.0.

Vital events, Serbia, 2002 – 2009.

INDICATOR	2002	2003	2004	2005	2006	2007	2008	2009
birth rate (per 1000 people)	10,4	10,5	10,5	9,7	9,6	9,2	9,4	9,6
General mortality rate (per 1000 people)	13,7	13,8	14,0	14,3	13,9	13,9	14,0	14,2
Population growth rate (per 1000 people)	-3,3	-3,3	-3,5	-4,6	-4,3	-4,7	-4,6	-4,6
Mortality rate (per 1000 live births)	10,1	9,0	8,1	8,0	7,4	7,1	6,7	7,0

Source of data: Republic Institute for Statistics of the Republic of Serbia

Unfavourable demographic indicator is also age structure of the population. The data of the 2002 census confirm the fact that the population of Serbia is in the trend of progressive ageing. Namely, people older than 65 represented 16.5% of the overall population.

Life expectancy

Life expectancy at birth in the period 1997 through 2009 for men and women alike showed a mild rising trend. In 2009, life expectancy was 71.1 years for men and 76.4 for women, while in 1997 the numbers were 69.6 and 74.6 for men and women, respectively.

Infant mortality rate

The infant mortality rate as an important and sensitive indicator of health status and health care of the population and also of socio-economic and related conditions has showed a persistently falling trend. Over the studied period, the infant mortality rate fell from 12.1/1000 live births in 1997 to 7.0/1000 live births in 2009.

Health condition of the population

The health condition of the population was, apart from the ageing of the population, influenced by negative social and economic trends in the last decade of the last century. The nation's health potential was used out, which is why we cannot expect negative indicators of health to stop and wanted improvement of these indicators, at the time of social and economic recovery, with all difficulties that a transition of the state and society brings with itself.

Morbidity

National Health Survey in Serbia in the year 2006 showed that over a half of the adult population of Serbia (55.9%), reported one of the 19 listed chronic diseases. The most common disease was elevated blood pressure (23.0%); it was followed by rheumatic joint diseases (16.8%), elevated blood lipids (7.9%), kidney diseases (6.0%) and allergies except for asthma (5.3%)

Morbidity in primary health care

The most common registered groups of diseases in primary health care in 2009 were respiratory system diseases with 26.1%, factors influencing the health condition with 11.4%, blood circulation system with 9.1%, urinary-sexual system diseases with 6.5% and diseases of muscular and skeletal system 5.4%. These groups of diseases make 59.0% of the total morbidity while other causes of diseases are represented with 41.0% in the total morbidity of the population. The order and structure of the most common groups by areas of primary health care and by years differ insignificantly.

Hospital morbidity

According to the hospitalization reports (individual reports) the total of 1,065,083 people were treated in hospitals in Serbia in 2009. Of these persons treated in hospitals in 2009, 486,779 were men (45.7%) and 578,304 women (54.3%). By the ICD-10 the ranking of the three most common groups of diseases, conditions and injuries treated in hospitals is the following:

1. Diseases of the circulatory system (IX) 158,911
2. Neoplasms (II) 148,625
3. Diseases of the digestive system (XI) 92,619

The most common single cause of hospitalization in men in 2009 was inguinal/groin hernia. The second most common cause was chest pain, followed by diabetes, insulin dependant form, other chronic obstructive pulmonary disease, and stroke/cerebral infarct – the dying of cerebral tissue. With all stated causes of hospitalization, there was a trend of increase for the period from 2000 to 2009.

Excluding hospitalizations because of spontaneous birth delivery, the most common cause of hospitalization in women in 2009 was the malignant breast tumour (S50). In 2000, this disease was not on the top-ten list of most common causes of hospitalization in women, with hospitalization rate of 1.2 per 1000 people. In 2007, hospitalization rate in the case of malignant breast tumour was 3.0 per 1000 people, and in 2009 it climbed to 4.0 per 1000 people. The other most common causes for hospitalization of women are: diabetes, insulin dependant form, high blood pressure of unknown cause, stroke/cerebral infarct – the dying of cerebral tissue, and chest pain.

Chronic non-communicable diseases that are the biggest public health problem

Non-communicable diseases (heart and heart vessels diseases, malignant tumours, diabetes, obstructive lung disease and others) have been dominant for decades in our national pathology and represent the biggest public health problem. National/population registries have been formed for acute coronary syndrome, cancer and diabetes.

Acute coronary syndrome

Acute coronary syndrome (ACS), acute myocardial infarction and instable angina pectoris, are one of the main health problems. According to data from the registry for ACS, there are currently 22,058 cases diagnosed with ACS in Serbia. ACS incidence in Serbia was 300.1 per 100,000 people.

Cancer

Based on the data from the registry for cancer in central Serbia in 2007, 25,662 individuals suffered from malignant tumours (13,475 men and 12,187 women), and 14,373 individuals (8,290 men and 6,083 women) died of cancer. In central Serbia, in 2007, men suffered mostly from malignant tumours of lungs, colon and rectum, prostate gland and urinary bladder, while in women, malignant tumour was most frequently located on breast, colon, and rectum, cervix and lungs.

In central Serbia, in the course of 2007, men mostly died from malignant tumours of lungs, colon and rectum, prostate gland and stomach, while in women were most often the victims of malignant processes on breast, colon, rectum, and cervix.

Diabetes

It is estimated that today in Serbia there are nearly 600,000 individuals diagnosed with diabetes, making 8.2% of the population. The number of persons with type 2 diabetes is many times larger (95%) in comparison to those with diabetes 1. According to the data from the population registry for diabetes, 274 newly discovered individuals younger than 29 were diagnosed with type 1 diabetes in 2008. In the same year, there were 15,409 newly registered individuals with diabetes type 2.

Mortality

In 2009, the rate of mortality from all causes of death per 1000 people (general mortality) was 14.2 per 1000 people. In the mortality structure, heart and heart vessel diseases were the cause of more than half of deaths (54.8%), and every fifth person who died (20.6%) was a victim of malignant tumour. Over the past decade, there has been a reduced number of recorded deaths from 57.2% in 1999 to 54.8% in 2009, but also recorded was the increase in the number of deaths from malignant tumours from 17.1% in 1999 to 20.6% in 2009.

Mortality rate from malignant diseases in the past nine years increased from 247.4 in 2002 to 287.3 per 100,000 people in 2009 while the mortality rate from diabetes also increased from 34.1 in 2002 to 41.9 per 100,000 people in 2009.

Morbidity and mortality from communicable diseases

Communicable diseases today do not represent a major health problem in Serbia, primarily thanks to regular vaccination and relatively good taking of other preventive measures.

In 2009, there were 431,666 reported cases of communicable diseases, primarily respiratory communicable diseases, with incidence of 5872.83 per 100,000 people. In comparison to 2008 (incidence rate of communicable diseases was 4791.3/100,000), in 2009 there was a smaller number of epidemics of communicable diseases, but with a much larger number of patients, because of the new influenza epidemic of greater importance.

The number of patients with pulmonary tuberculosis in 2009 was 1630 cases (incidence of 22.17/100,000), which is a significant decrease compared to 2003 when the incidence was 37.9/100,000. This may be interpreted by introducing the Directly Observed Treatment Short Course (DOTS) in 2002 and implementing Guideline for TBC control, and a significant trend of decline in the number of new cases of pulmonary tuberculosis.

245 persons died from the consequences of communicable diseases in 2009, with mortality rate 3.32/100,000, this being the highest value since 1999 (1.99/100,000). Increased mortality compared to 2008 (2.57/100,000) is a consequence of the new flu epidemic, during which 52 people died by the end of 2009.

Vaccinable diseases

In 2009, there were 302 persons with diseases that can be prevented with vaccines, making 0.07% of the total communicable diseases and is the lowest value in the observed five year period. The absence of diphtheria and human rabies is still maintained. The last case of poliomyelitis caused by wild poliovirus registered in Serbia was in 1996. Europe in 2002 declared the eradication of polio and has since then maintained the status of region/country without polio. The incidence rate of measles in 2009 recorded a value of only 0.01/100,000.

Immunizations

Planned immunizations against diphtheria, tetanus, pertussis (DTaP) and polio (OPV) were carried out with high coverage of 97.4%. Furthermore, revaccination of children in the second year of life, revaccination of preschool and school children against tetanus, diphtheria and poliomyelitis were carried out with high coverage above 96%. MMR vaccination coverage was 95.9% and revaccination coverage was 95.3% (at age 7) and 88.8% (at age 12).

Hepatitis B vaccination (introduced in calendar of vaccination in 2005) coverage of children was 95.2% in the first year of life and 61.8% in the 12th year of life.

HIV and AIDS

In the period from 1985, when first cases were registered, until 2009, there was a total of 1489 *Morbus HIV (AIDS)* reported patients, 970 (65%) of whom died. In the course of 2009, there were 52 newly infected persons registered (incidence rate 0.71 per 100,000 people), while 25 persons died (mortality rate 0.34 per 100,000 people). Thanks to the available and effective antiretrovirus therapy, there has been a reduced number of registered AIDS infected and death cases in the past ten years. Access to the HAART (higher active antiretroviral therapy)

With reference to descriptive data, please specify also:

a) What data is produced nationally, who has access to them and to what degree are they comparable to other EU countries?

In Serbia, the following is considered as health data: data on population's demographic and social characteristics, behaviour and lifestyles (personal risk factors), air pollution, water quality, disposition of solid and liquid waste (environmental risk factors), mortality and morbidity of the population, use of services (utilization of services by the population) and health systems performance – resources (health institutions, human resources, equipment) and activities/provision and quality of services, as well as data on financial resources and expenditures for health care (National Health Accounts).

Regarding the comparability of data with other EU countries the Republic of Serbia reports on the regular, yearly basis, the set of data for health indicators (mortality data on causes of death, maternal mortality, human resources, use of service, etc), as well as health indicators (smoking prevalence, nutritional status, etc.) to the WHO Health for All Database.

The Republic of Serbia has had a Focal point expert in the ECHIM Project (European Community Health Indicators) since 2007. Development of the health indicators methodology in Europe, especially ECHI-Short list that comprises 88 indicators, is closely monitored, which means it is completely up-to-date with the ECHI requirements. Serbia belongs to the group of “other” countries. For the ECHI short list of indicators based on European Health Interview Survey, Serbia applies majority of questions in its national health survey. Serbia complies well with other ECHI indicators that are in compliance with Eurostat or WHO Office for Europe requirements. Due to the necessity for uniform reporting in the EU and the use of best possible theory and practice for the development of ECHI indicators, Serbia like all other member states organizes the system with a view of having all indicators from the list.

b) What is available on access to and use of health care, funding of primary and secondary care, morbidity, mortality, incidence rates, hospital facilities, health personnel, healthy life years, regional differences?

According to Network Plan, there is a total of 375 state-owned health institutions, namely: 167 primary health care units, 41 pharmacies, 16 primary level institutes, five health centres, 40 general hospitals, 40 special hospitals for acute and chronic conditions and rehabilitation, five clinical-hospital centres, six clinics, 13 institutes, Military Medical Academy, four clinical centres, 37 institutes and departments with activities on several levels, four of which are institutes and 23 are public health departments.

The total number of beds in stationary health institutions in Serbia in 2009 was 39,572 (excluding daily hospital beds) or 540.6 beds per 100,000 people. The number of provided beds in Serbia is somewhat lower than in the European region (656 per 100,000 people), and somewhat higher compared to the EU average (530 per 100,000 people).

Health institutions from the Network Plan employed a total of 114,175 employees in 2009.

In early 2009, there were over 5,000 forms of privately-owned health services registered in the Republic of Serbia (health institutions and private practice), of which there were 7 primary health care units, 72 hospitals, 136 polyclinics, around 1,200 doctor's offices, 2,000 dental offices, 1,400 pharmacies and 200 various laboratories and diagnostic consulting offices.

In 2009 all health institutions (both state and private) in the Republic of Serbia disposed with the following: two positron emission tomography devices (PET scanners) (0.27 per one million of people), 38 magnetic resonance devices (MR) (5.17 per one million of people), 90 computerized tomography devices (CT) (12.24 per one million of people), 14 linear accelerators (LINAC) (1.9 per one million of people) and 75 mammography devices (10.2 per one million of people), two of which are mobile digital mammography devices.

The average number of visits to primary health care service units in 2009 was 8, which is considerably above the EU average (6.8).

In 2009, there were 15.5 hospitalized people per 100 people, which is below the European region's average (WHO 18.3 and EU 17.7 per capita).

The website of the Public Health Institute of Serbia “Dr Milan Jovanovic – Batut” www.batut.org.rs contains data on the resources, work of health institutions and use of health care published in the Health Statistical Yearbook and National Health Account: indicators of

expenditure; indicators of health consumption; analyses of sources of financing health care protection (financiers and providers of health services, analysis of resources, macroeconomic variables) and financing public health services.

c) What is the number of health staff physicians, nurses and dentists other staff per capita?

The total number of doctors in institutions from the Network Plan in 2009 was 20 825; the number of dentists – 2,273; the number of nurses and technicians – 39,853.

Based on the number of employees in health institutions from the Network Plan, there is a provided level of 284 doctors per 100,000 people, while the number in the EU is somewhat higher – 321 doctors per 100,000 people. There are 90 doctors per 100,000 people in primary health care, or one doctor per 1,112 people. If provision of the population with doctors compared to the total number of licensed doctors in the Republic of Serbia is observed (28,413 according to data from the Medical Chamber of Serbia), it amounts to 387 doctors per 100,000 people.

The number of medical nurses-technicians (including the employees in health institutions from the Network Plan) per 100,000 people is 572, while the number in the EU is by one-third higher – 745 doctors per 100,000 people. However, if we consider the total number of licensed medical nurses and medical technicians (50 801 according to the data from the Chamber of Medical Nurses and Medical Technicians of Serbia), the provision of the population with medical nurses is closer to the EU average, totalling 721 medical nurses per 100,000 people.

d) What is the average length of stay in hospitals and institutions?

The average length of stay in all hospitals in Serbia has been continuously decreasing for many years. In the year 1997 it was 13.3 days while in 2009 it was reduced to 9.4 days, bringing it closer to the average value in the EU (8.7 days).

e) What are the main determinants of diseases?

Social and economic health determinants

Social and economic health determinants are unbreakably tied and strongly interconnected and dependant on each other. The period after 2000 in the Republic of Serbia was marked by positive trends of a series of social and economic indicators, such as the growth of gross domestic products, relative monetary stability and growth of allocation in the field of health consumption. However, low level of GDP and high unemployment rate represent a serious limiting factor for sustainable financing of health care.

Life habits

Life habits are directly connected or are by themselves risk factors, such as smoking, hypertension, hypercholesterolemia, alcohol, obesity, inadequate diet and physical inactivity, which result in the appearance of chronic non-communicable illnesses of greater public health importance. The given risk factors are numerous chronic non-communicable illnesses, whose

occurrence, given the multifactor etiology, is connected to the presence of two or more of the stated risk factors.

National Health Survey, Serbia, 2006, showed that: 33.6% of adult population smoke; 23% said they have hypertension, while 46,5% have hypertension or potential hypertension; 40.3% consume alcohol on daily basis or occasionally; 18.3% are obese and 74.3% are not physically active enough.

Compared to the previous survey from 2000, data for the adult population in Serbia show that in 2006 the prevalence of smoking was reduced by 6.9%, alcohol consumption by 7.2% and physical inactivity by 12%. In the same period, the prevalence of hypertension grew by 2% and obesity by 1%.

Prevalence (%) of risk factors in adult population of Serbia, in 2000 and 2006

Risk factors	Prevalence (%)	
	2000. -	2006. -
Smoking	40.5	33.6
Hypertension	44.5	46.5
Alcohol	47.5	40.3
Obesity	17.3	18.3
Physical activity three times per week	13.7	25.7

Source: National Health Survey, Serbia, 2000 and 2006.

The National Health Survey, Serbia, 2006, provided precious data on social and economic health determinants, health status based on self-assessment of individuals, functional abilities, use of health care services and expenditures associated with health care and lifestyles in particular because these surveys are the only source of data. These data enable evaluation of policies and programmes in the period between two surveys, identification of priority problems and implementation of pertinent measures and activities for health promotion and health care of the population, monitoring of the health status and epidemiological trends of diseases, formulation of health policy objectives and defining the health system development strategy. Detailed presentation refers to the following:

Prevalence of high blood pressure

Measurements showed elevated systolic (≥ 140 mmHg) or diastolic (≥ 90 mmHg) blood pressures in 46.5% in adults, or that they took medications to reduce blood pressure, i.e. they had hypertension or potential hypertension (high blood pressure). In 2006 the percentage of hypertensive population was higher in comparison with 2000, when it was 44.5%. Hypertension was more common in men, residents over 45 years of age, in Southeast Serbia and in those with the lowest education level (62.7%), the poorest (53.1%) and poorer (49.3%) according to wealth index.

Antihypertensive medications were used by 24.1% adults in Serbia. Every second person with hypertension or potential hypertension (51.3%) took antihypertensive medications, which is significantly more than in 2000 (46.5%). The percentage of regular medication users was significantly higher in women (62.1%), and significantly lower in men (42.5%). Also, this percentage increased in the population over the age of 55, those living in Southeast Serbia (59.8%), residents with a lower education level (56.9%) and those with the income per household member exceeding RSD 15,000 (56.6%).

Nutritional status

Based on the body mass index (BMI), 38.3% of the population had optimum weight, one in two was overweight (54.5%), subdivided as 18.3% obese and 36.2% pre-obese. There were also 2.3% of people underweight. The highest percentage of obese people was found among the population with the lowest education level (23.1%), medium strata according to the wealth index (20.8%) and the populations of Vojvodina (20.5%) and Eastern Serbia (21.4%), while the pre-obese status was more prevalent in men (42.2%) and the richest group (38.3%). The percentage of obese and pre-obese people increases with age until 64, whereas in the population of older than 75 a significant decrease in the percentage of obesity is noted.

Monitoring and counselling relating to risks for chronic non-communicable diseases

Almost every second adult inhabitants of Serbia received advice for change of lifestyle (49.7%). In the year preceding the survey, more than one-third of the population made at least one change in health-related attitudes (37.8%).

Diet

One of the main indicators of healthy life-styles/healthy diet is the consumption of fresh fruit and vegetables. Fresh vegetables were eaten daily by 54.8% of adults, which is significantly more than in 2000 when only 42.4% did so. In Vojvodina and Central Serbia a significantly lower number of people used fresh vegetables in their daily diet (44.0% and 49.3%, respectively). Fresh fruit was eaten as part of the everyday diet by 44.0% of the population. The frequency of fresh fruit consumption has increased in comparison with 2000 when it was 34.4%. The population of Western Serbia and Belgrade used fresh fruit significantly more (51.4% and 51.0%), compared to those living in Central Serbia (35.4%) and Vojvodina (40.4%). The rich and richest people used fresh fruit and vegetables more often.

One in five adults in Serbia (19.9%) never thought of health implications when choosing what to eat. When selecting their diet, the people older than 75, the population of Southeast Serbia and the poorest part of the population seemed to think least about health.

Alcohol consumption

The percentage of adults who drink over 50 grams of ethanol daily is an indicator of heavy drinking. In 2006 the group at high risk for development of chronic illnesses resulting from excessive use of alcohol comprised 3.9% of adult population of Serbia. In Eastern Serbia there was a higher recorded percentage of population belonging to this group (7.6%) and the group of the poorest (6.1%).

Knowledge on HIV/AIDS

90.5% of adult residents knew that HIV and AIDS exist, significantly more in urban settlements than elsewhere. The level of information about HIV and AIDS was the highest in Belgrade, and significantly lower in Western and Southeast Serbia.

Somewhat more than a third of the population of Serbia (37.9%) knew where they could get tested for HIV. Knowledge of the place where they can get tested was more prevalent in women and less in men. In Serbia 4.2% of adults have been tested for HIV. Access to

HAART (higher active antiretroviral therapy) is provided and expenses of therapy are covered by Republic Health Insurance Fund.

Less knowledge in relation to prevention of HIV infection, and more prejudice against the infected persons were registered in Western Serbia, among the population of non-urban settlements, the poor and uneducated groups. Still, compared to 2000, the year 2006 recorded a higher percentage of population having no prejudice to HIV infected people, mostly in 35-45 age group, rising from 13.7% to 18.9%. In 2006, the largest growth in the number of people of this age group free of discriminatory attitude stood at 29.2% in 2006.

Somewhat more than one-fifth of the young in Serbia (20.3%) aged 15 to 24 had sufficient knowledge on HIV and AIDS, i.e. they identified correctly ways of preventing sexual transmission and at the same time denied misconceptions relating to transmission of HIV, their number having tripled in comparison to 2000 (7.3%).

Population risk factor burden

The number of years of life lost corrected in relation to incapability (DALI/1000 residents) for certain risk factors by sex in 2000 and at the same time largest risk factor burden in men in 2000 could be attributed to smoking, followed by hypertension, physical inactivity and obesity. Women were mostly burdened with hypertension, then physical inactivity, smoking and obesity.

Total risk factor burden was higher in men than women.

Years of life lost corrected in relation to incapability (DALI/1000 residents) for certain risk factors by sex, Serbia 2000.

Risk factors	DALI/1000	
	Men	Women
Smoking	35.2	12.5
Hypertension	21.7	17.5
Hypercholesterolemia	3.1	1.7
Alcohol consumption	5.7	1.5
Obesity	14.9	12.2
Physical inactivity	19.5	16.3

Source: The Burden of Disease and Injury in Serbia. Belgrade: Ministry of Health of the Republic of Serbia; 2003

Environment

Environment with its physical, chemical, social and psychosocial factors has an important influence on people's health, although their effect on health may be noticed mostly after many years.

The percentage of people who have water connection in house, i.e. apartment, is high and stands at 95.2%, while safe sources of drinking water are used by 99.1% of the population, which shows a high percentage of connections to the water supply system and availability of drinking water. The quality of drinking water varies from district to district and depends on the origin of water itself, composition of land and technical and technological treatment of

water processing. In the past ten years, there has been a noticed trend of improved microbiological safety and physical and chemical quality of drinking water.

The influence of air pollution contributes to the development of chronic respiratory diseases. The main sources of air pollution are in the energy sector (thermal plants), oil refineries, local heating plants, household boiler furnaces fired on liquid and solid fossil fuels, traffic, non-sanitary deposits of solid waste, while the main causes of air pollution include burning poor quality lignite, irrational and inefficient energy use, inefficient technologies of burning fossil fuels, and inadequate maintenance of industrial facilities. The largest air polluters include oil refineries in Pančevo and Novi Sad, cement plants in Beocin, Kosjeric and Popovic and chemical combines in Pančevo, Kruševac, Šabac and Smederevo. Continual measurement of basic parameters of air pollution is being conducted in more and more settlements.

A particularly critical field is management of solid and liquid waste materials, especially medical waste. Waste is collected unselectively, so communal waste often contains certain categories of industrial and medical waste. When solid waste is concerned, the biggest problem is its uncontrolled depositing and creating “wild” deposits. With a view of removing and reducing the influence of risk factors on health of the population a multisectoral approach has been intensified in recent years. The solving of the problem of medical waste, by introducing its organized depositing, was launched in 2006 and is successfully continuing.

f) What are the diseases that cause most premature deaths and disabilities?

According to the Serbian Burden of Disease Study (SBDS) from 2003, there was a total of 104 042 deaths in Serbia or 13.8 deaths lost per year per 1,000 residents in 2001. Of these, 53,751 (51.7%) occurred among males and 50,291 (48.3%) among females. Men had 6.9% more death outcomes from all causes than women.

Premature mortality measured by Years of Life Lost was responsible for **814,022** years of life lost or 107.8 YLLs lost per year per 1,000 residents (with used rate of reduction of 3% per annum) in Serbia in 2000. Men lost 31.3% more years of life than women. Cardiovascular diseases, cancers and injuries were responsible for 80% of the total mortality burden in both men and women.

36. With reference to the institutional framework and administrative capacity, please answer to the following questions:

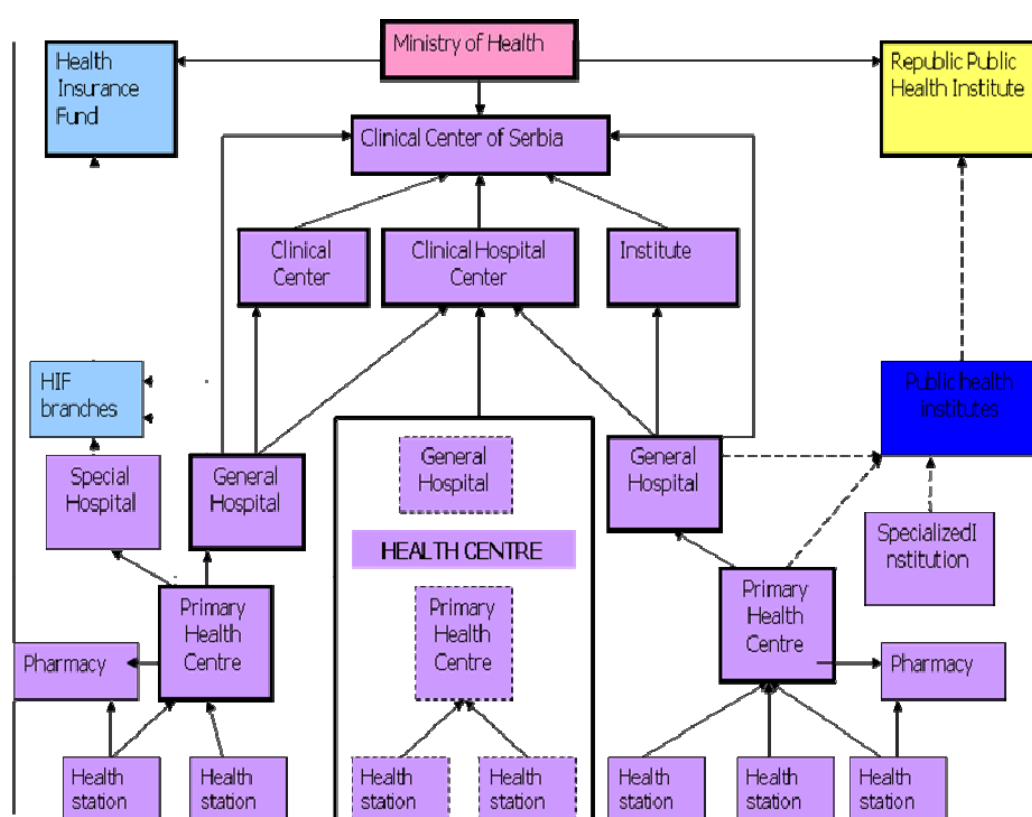
a) Who are the main actors involved with public health in your country? How many people are currently working in the Ministry of Health and Social Welfare and the other public health institutions?

After the rationalization, the Ministry of Health has employed 304 people in total.

State secretary	2
Sector for Health Care	19
Sector for health insurance and financing in health	23

Sector for Inspection	19+ 214 health inspectors throughout Serbia
Secretariat of the Ministry	19
Independent advisors	2
Cabinet of Minister	1
Department for Biomedicine	4
Total	303

The answer to this question is contained in the answer to the question 35.b).



b) As candidate countries need to transpose all EU health *acquis* into their national legislation and enforce this legislation, adequate administrative and institutional capacity, and infrastructure is needed to apply the EU rules and standards at national, regional and local level. Please describe the current situation in your country. Are there any plans for changes?

The obligations defined in the previous National Programme for Integration have been met within the prescribed terms.

The adoption of the Law on Removal and Transplantation of Human Body Parts (transplantation) for Therapeutic Purposes was envisaged. Instead of the said law, on 31

August 2009, the National Parliament of the Republic of Serbia adopted three laws that were approximated with the following EU Directives:

- Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- Directive 2006/17/EC implementing the directive of the European Parliament and of the Council on particular requirements for the donation, procurement and testing of human tissues and cells;
- Directive 2006/86/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for coding, processing, preservation, storage and distribution of human tissues and cells.

The adopted laws governing the said areas are as follows: The Organ Transplantation Law, the Cell and Tissue Transplantation Law and the Law on infertility treatment by applying in vitro fertilization procedures.

On 31 August 2009, the National Parliament of the Republic of Serbia adopted the Law on blood transfusion activities ("Official Gazette of RS" no. 72/09), in accordance with the directives governing the standards for ensuring the quality and safety of blood and blood components.

At the Government session of 26 March 2009, the Public Health Strategy approximated with the EU Action Plan in the sphere of public health for the period between 2003 and 2008 was adopted ("Official Gazette of RS", No. 22/09), and on 31 August 2009, the National Parliament of the Republic of Serbia adopted the Law on Public Health ("Official Gazette of RS" no. 72/09), approximated with the EU Strategy for the period from 2008 - 2013. The Strategy for Providing Adequate Quantities of Safe Blood and Blood Components in the Republic of Serbia was published in the "Official Gazette of RS" no. 20/09, was approximated with the recommendations of the World Health Organization, as well as with the Directive 2002/98/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of blood and blood components; the Directive 2001/83/EC amending this document, as well as the Recommendations of the Council of Europe No. R(88)4 and No.R(95)15 in relation to blood components clearly showing the need for the establishment and improvement of well organized services for blood transfusion with the recognizable quality standards.

The following decrees have been approximated with the Council of Ministers Recommendation of 2 December 2003 in relation to carcinoma screening:

- Regulation on the national program for the prevention of colorectal carcinoma, published in the "Official Gazette of RS" no. 20/09.
- Regulation on the national program for the prevention of breast cancer, published in the "Official Gazette of RS" no. 15/09.
- Regulation on the national program for the prevention of cervical cancer, published in the "Official Gazette of RS" no. 54/08.
- Regulation on the national program "Serbia Against Cancer", published in the "Official Gazette of RS" no. 20/09.

The preparation of the national program, screening, personnel education and good practice guide improvement in cooperation with the republic expert commission in charge of that field are currently in place.

The preparation of the national program, improvement of public health and quality of oncological healthcare, good practice guide improvement and screening arrangement in cooperation with the republic expert commission in charge of oncology is ongoing. Above mentioned regulations are in line with the recommendation of the Council of Ministers from 2nd December 2003. related on cancer screening.

Priorities

The Rulebook on the requirements with respect to safety of products of general use that may be circulated ("Official Gazette of SFRY", no. 26/83, 61/84, 56/86, 50/89 and 18/91) was amended and approximated with the Directive 88/378/EEC with respect to toy safety and with the Directive 76/768/EEC with respect to cosmetics.

The Law on protection of the population from exposure to tobacco smoke was drafted and adopted by the national parliament. This law governs the restriction measures for tobacco products for the protection of population from the exposure to tobacco smoke, control of smoking and monitoring of the implementation of the law. The law has been approximated with the EU regulations in this area, and in particular with the Green Paper – towards a Europe free of tobacco smoke: policy options at EU level" of the European Commission published in 2007 and the Framework Convention on Tobacco Control of the World Health Organization that was ratified by the Republic of Serbia on 9 February 2006 and came into effect on 9 May 2006.

The Law on general use products will have been passed by the end of 2011 and it will have been approximated with the following directives:

- Directive 78/142/EEC – materials with vinyl chloride monomer;
- Directive 81/432/EEC – method of analysis of vinyl chloride released by materials;
- Directive 82/711/EEC - testing migration of the constituents of plastic materials;
- Directive 2002/72/EEC – relating to plastic materials and articles intended to come into contact with foodstuffs;
- Directive 89/109/EEC – relating to materials and articles intended to come into contact with foodstuffs, Directive 85/572/EEC – the list of simulants, Directive 80/590/EEC, Directive 84/500/EEC – ceramic articles intended to come into contact with foodstuffs, Directive 93/11/EEC concerning the release of the N-nitrosamines;
- Directive 2002/16/EC - on the use of certain epoxy derivatives in materials.

37. With reference to the health system reforms, please describe:

a) any on-going or planned reforms;

The Law on Health Insurance (Article 146) defines the issue of a physician that a patient chooses for at least one-year period in the sphere of general practice or occupational medicine, paediatrics, gynaecology and dentistry.

Adults patients are entitled to have a chosen physician in the sphere of general practice and women and girls older than 15 should have a chosen physician – a gynaecologist.

A chosen physician:

- should be committed to the promotion of health and preventive health services (e.g., performing screening – for breast cancer, cervical cancer, diabetes, etc.),
- should warn patients against factors posing risk to health,
- should recommend a healthy life style to his/her patients.

To achieve these objectives, the Ministry of Health of the Republic of Serbia and the European Union implemented the project “Support to the implementation of capitation model in primary healthcare centres in Serbia”, funded by the European Union. The activities on the project started in September 2007 and lasted until the end of 2010.

The objective of the project was to ensure technical and professional assistance in restructuring and improving the operation of primary healthcare centres so as to ensure fast and efficient healthcare services to patients. The restructuring process of primary healthcare centres relies on the principle of a chosen physician. This reform will be accompanied by a new funding method of primary healthcare services (capitation).

The project includes 28 primary healthcare centres - Subotica, Kikinda, Pančevo, Sombor, Novi Sad, Sremska Mitrovica, Šabac, Požarevac, Kragujevac, Čuprija, Zaječar, Užice, Čačak, Kruševac, Niš, Pirot, Leskovac, Novi Beograd, Zemun, Palilula, Voždovac, Zvezdara, Smederevo, Savski Venac, Vračar, Kraljevo, Valjevo and Vranje. The project includes the purchase of the computer equipment for 28 primary healthcare centres worth of 2 million Euro.

The design and implementation of a new hospital payment system, one that rewards output and quality of services produced, is essential to guide Serbian hospitals on their way to improved productivity, thus reducing public spending inefficiencies. Reform of the payment mechanism implies directing efforts to five different activities:

- (1) the introduction of a National Minimum Data Set (NMDS),
- (2) the selection of a Procedure Coding System (PCS),
- (3) the use of a Case Mix Grouper (CMG) for the final categorization of patients,
- (4) the implementation of the Activity Based Costing methodology and
- (5) the formulation and implementation of clinical pathways.

b) What was the scope of the previous reforms (since 1990)?

Health care system in the Republic of Serbia since 1992 has been governing by two system documents: Law on Health Care and Law on Health Insurance. During 1996 the Amendments based upon these two documents has been adopted. These laws are strictly centralized health care system.

It were few attempting to engage reforms of health system during the 1990-1999, but the purposeful and comprehensive activities for reforming the Serbian healthcare system started after the arrival of the new democratic forces, as of 2001. The reform of the Serbian healthcare system includes the achievement of the following objectives of healthcare policy: Preservation and improvement of the population's health and enhancing the national health potential, equitable and equal access of all citizens to healthcare services for the same needs, as well as the improvement of healthcare services for vulnerable population groups.

In 2003, the Ministry of Health of the Republic of Serbia defined the vision of the primary healthcare reform by 2015 (Vision of the Health Care in Serbia document). In the meantime, this vision was converted into legal regulations of a binding character for all stakeholders.

The vision of primary healthcare reform by 2015:

- clearly identify healthcare levels (HC) - primary, secondary, tertiary,
- enhance the role of HC as a “gatekeeper” to higher levels of HC (ensure that the primary HC should absorb over 80 percent of all services),
- switch the focus of primary HC from curative to preventive healthcare,
- ensure even, equal and equitable use of healthcare services by all users,
- enhance and define patient’s rights,
- perform decentralization of the responsibility for primary HC (involvement of local community in funding and decision-making),
- develop “market” models of funding HC,
- ensure and regulate the participation of private sector in provision of HC services.

c) Are the reforms monitored and evaluated? If so, to what degree?

The process of reform of the health care is continuously monitored and evaluated, and in order to prepare comprehensive development plan, the overview of the current state of health care in the Republic of Serbia has been made. Overview is based on the data from the reports from various research studies conducted in the Republic of Serbia in the period from 2000 to 2009 (the Citizens of Serbia Health Survey 2000 and 2006; the Children and Women of Serbia Multiple State Indicator 2000 and 2005; the Life Standard Study 2002 and 2007; the Disease and Injury Preoccupation in Serbia, 2003; the European Study on the Use of Alcohol and Other Drugs Among the Youth of Serbia, 2008; the World Bank report no. 48620-YF *Serbia: Doing More with Less*, 2009); as well as a number of other reports, statements, analyses, and publications of the Ministry of Health of the Republic of Serbia, the Institute for Public Health of Serbia “Dr Milan Jovanovic-Batut” (the Analytic Study 1997-2007 – the Health of the Citizens of Serbia; the Health and Statistical Yearbook of the Republic of Serbia; the Republic of Serbia – Chosen Health Indicators), the Statistical Office of the Republic of Serbia (the Statistical Yearbook of Serbia; Demographic Statistics; Labor Force Survey; Household Budget Survey), the Ministry of Finance of the Republic of Serbia, and the National Health Insurance Institute. For the purposes of indicator comparison with the EU member states and other countries of the WHO European Region, the data from the WHO “Health For All” database was used (either data from 2007 or the most recent data available).

d) What part of the health care system should be reformed?

In accordance with The Republic of Serbia Health Care Development Plan (hereinafter: the Plan), which has been adopted on November 23rd 2010 by National Assembly of the Republic of Serbia, the aims of the health policy of the Republic of Serbia are the following:

1. The preservation and the improvement of the state of health of the citizens of Serbia and the strengthening of the nation’s health potential;
2. Fair and equal access to health care of all of the citizens of Serbia, so that their health needs can be addressed adequately, as well as the improvement of health care of vulnerable groups;
3. Making the user (the patient) the focal point of the health care system;
4. The sustainability of the health care system, accompanied by transparency and selective decentralization of resource management, as well as the dissemination of the sources and manners of financing;

5. The improvement in functioning, efficiency, and quality of the health care system and defining separate national programs related to resource management, the institutional network, technology, and medical supplies;
6. Defining of the role of the private sector in the provision of health care services to the citizens;
7. The improvement of the health care cadre basis (human resources for health).

Many of the aims of the health policy have been fulfilled to a certain extent, such as the development of the health care institutional network or ensuring that there is an adequate number of health care personnel per capita, especially in primary health care, but it is necessary to further follow and reexamine the fulfillment of such aims in light of the ever-changing environment. Moreover, it is necessary to speed up the process of fulfillment of certain aims, such as the number of citizens who have selected their chosen family doctor, the quality assurance, decentralization, etc., as well as begin fulfilling a considerable number of other aims – the health care financial sustainability (new resources and manners of financing) or the establishment of a functioning relationship between state-run and privately-owned health care services.

The main aim of the Plan, its main premises being contained in the aims of the health policy, is the preservation and the improvement of the state of health of the citizens of the Republic of Serbia, and the sustainability of the health care system. In order to achieve this, it is necessary to achieve solidarity and equality (between the healthy and the ill, the poor and the rich, the elderly and the young), as well as gender equality, while paying special attention to vulnerable groups, to respecting the rights of citizens, and to informing the citizens of the obligations they have towards their own health. The health care system needs to provide physically, geographically and economically accessible, integrated (vertical integration of the primary, secondary, and tertiary level of health care, and horizontal integration of the entire system in relation to the local communities) health care of adequate quality (continuous health care quality improvement and the right of the users to choose their own doctors and to be informed), as well as ensure the development of health care cadre, the sustainability of financing, the decentralization of health care management and financing, and shift its focus to the citizen as the center of the health care system.

It should be specially mentioned that this Plan is being adopted in times when our country, similar to numerous other countries around the world, is facing the effects of the world economic crisis of 2008, and is working hard to prevent the escalation of the negative consequences of the crisis for the economy and other spheres of society, including health care as well.

The world economic crisis led to the reexamination of the basic values of all societies and communities around the world, while the response of the health care system and the state to these challenges should be moderate and ensure social justice, on one hand, and, on the other, insist on the economic prospects of investing in health and emphasizing the social and economic determinants of health.

That is why it is of immense importance to view the fulfillment of this Plan as a cycle, in which, besides the determination of priority issues and the analysis of their causes, the main stage is establishing specific aims that ought to be met within a defined time period. The stage of making decisions regarding the application of adequate measures and activities is not any less important. The evaluation, as the last stage, represents an integral activity based on which

“weak spots” can be detected and the sustainability of individual solutions assessed, followed by redefining of certain aims in order to fulfill the goals defined in the Plan.

e) In particular, what eHealth strategy exists in the country? How embedded is it with the overall health strategy and with the strategic orientation and investment plans in health? In particular, how does it (plan to) contribute to patient safety, healthcare quality (measurement and improvement), health professionals' efficient use of time and coordination of care?

Very important and strategic oriented document named Rulebook on more detailed contents of technological and functional requirements for the establishment of the integrated health information system was adopted in November 2009 and it defines the rights and roles of healthcare professionals in the management of patient domain data (right to enter and data access right) - Chapter 2.3.1, compliance with the basic rights for personal data protection - Chapter 2.8. In the next period and by 2012, the health information system will have been established in Serbia. The current IT project will result in the implementation of the information system in all primary healthcare institutions and in more than 80% of secondary and tertiary healthcare institutions. A special emphasis will be made on telemedicine. Currently, telemedicine is present in several healthcare institutions, for example, the General Hospital in Valjevo receives the consultations from the top experts at the Clinical Centre of Serbia. All the requirements referred to in the Rulebook on more detailed contents of technological and functional requirements for the establishment of the integrated health information system have been harmonized with the framework of the European Committee for Standardization (CEN) in relation to health informatics: the overall architecture of the health information system, including the communication and exchange of messages, data privacy and information security.

The actual cross-border cooperation brings forth an active participation of the national associations of health informatics in the European institution EFMI and EuroRec. The ProRec Serbia, as a full member of the EuroRec is the participant of one of the EuroRec projects - EHR-Q-TN, funded by the European Committee (2009-2012). It is a Thematic Network project that prepares the health community across Europe for systematic and comparable quality assurance and certification of e-Health products, more specifically of the Electronic Healthcare Record systems. The project promotes software certification by validating the EuroRec functional statements (over 1.400 statements), translating a substantial set of them in over 20 different European languages and by validating the EuroRec certification tools and certification procedures.

f) How is Health in All Policies being incorporated as a horizontal priority?

According to the horizontal principle of the EU, health is a significant element of the strategies adopted at the governmental level of the Republic of Serbia.

The Health policy is part of great number of strategic documents which have been adopted and implemented on a Governmental level:

Poverty Reduction Strategy (2003); the National Millennium Development Goals in the Republic of Serbia (2006); the Republic of Serbia Youth Health Development Strategy (2006); the National Strategy on Ageing 2006-2015 (2006); the Tobacco Control Strategy (2007); the Mental Health Protection Development Strategy (2007); the National Strategy on Sustainable Development (2008); the Strategy for the Fight Against Drugs (2009); the

Strategy for the Prevention and Control of Chronic Non-communicable Diseases (2009); the Strategy for the Roma Population Situation (2009); the Republic of Serbia Public Health Strategy (2009), Children's Environment and Health Action Plan (2009.) etc.

g) How is Health being considered for the future drafting of a national strategic reference framework for the use of structural funds?

The preparation of the Strategic Framework for the period 2012-2013 is currently in place. Health has been included in the Operational Program "Economic Development" and the Priority Axis "Environment" and it should take part in the projects relating to the improvement of water supply systems and quality of potable water since water quality is controlled within the network of institutes and public health agencies that must be adequately equipped. Further, medical waste poses environmental threats and when referring to the resolution of the problem of toxic waste, all categories of toxic medical waste should be taken into account. In addition to that, the network of public health institutes and agencies performs the measurements of air quality in local environment and the improvement of their capacities is of significance for local communities and local networks for monitoring air quality. Partner-like resolving of the problem of de-institutionalization and social inclusion of vulnerable groups between the Ministry of Health and the Ministry of Labour and Social Policy should have a special place in the Operational Program "Human Resources Development", in the Priority Axis "Social Inclusion". All these facts will be taken into account in the final wording of the Strategic Framework.

h) What kind of healthcare quality indicators are used in your country?

The orientation towards the organized, systematic approach to a continuous improvement of healthcare quality has been in place since 2004, and in July 2010 the Ministry of Health adopted a new Rulebook on healthcare quality indicators ("Official Gazette of RS" no. 49/10). This Rulebook defines the process and outcome healthcare quality indicators monitored in all primary, secondary and tertiary healthcare institutions. Special attention was paid to waiting lists, a patient's safety, a user's satisfaction with healthcare services, satisfaction of health institution employees, acquisition and renewal of employees' knowledge and skills, as well as the work of the commissions for the improvement of quality within health institutions.

i) How are the different health stakeholders, in particular health professionals and patients, involved in the definition, validation, implementation and evaluation of healthcare strategies? What governance mechanisms are set in place for such purpose?

The process of adoption of strategic documents includes the presentation of a draft document to the public and after a certain period of time the document is subject to public discussion. The final text includes the comments with respect to which consensus has been reached during a public discussion. During this process, the so-called "Consensus Conferences" are organized for the professional public, i.e., for health professionals at which the proposed documents are subject to professional discussions. Further, periodical surveys of the population's satisfaction with the quality of healthcare services as well as job satisfaction of health care providers are conducted in the Republic of Serbia, through which strategies are implemented. The first such survey was conducted in 2004 and other surveys have been periodically conducted.

38. What share of the mental health services is provided within institutions? Are there other ways to get treatment (community based care)? What are the selection criteria for admission to and release from institutions? Who develops treatment plans? What are the patients' rights?

The patients are examined in all psychiatric institutions in Serbia in accordance with the expertise level (primary, secondary, tertiary). Certain healthcare centres (at the primary level) employ psychiatrists that are in charge of mental health problems. The major number of the patients is referred by primary HC physicians to the institutions at the secondary and tertiary level where they are examined by expert teams deciding what kind of medical care will be required (an outpatient facility, hospital wards, day hospital, full hospitalization). The criteria for the admission of patients for hospital treatments are well-known and depend on clinical picture and decompensation – a team of experts will decide whether a patient with a mental problem will be admitted for treatment at the department for treating acute conditions, whether they will be fully hospitalized or admitted to day hospital. Patients are discharged from hospital by departmental teams depending on the condition of a patient. The patients with the most severe symptoms are admitted to intensive care departments and afterwards transferred to departments where patients with less severe symptoms are treated. Treatments are usually continued in day hospitals and in outpatient facilities where the patients are treated by their own psychiatrist as long as it is necessary.

Treatment plans are made by departmental teams. Each patient is presented to the team and an individual treatment plan is made.

Patient's rights are respected within the general patient rights prescribed under the Healthcare Law. The National Committee for Mental Health prepared the draft Law on the protection of rights of persons with mental disorders within the Mental Health Project of the Stability Pact for the South-East Europe (2000-2008) and submitted it to the minister of health in December in 2004. Each psychiatric institution employs an ombudsman that takes care of patients' complaints.

There are established community care centres like, for example, in the municipality of Medijana in Niš (in the south of Serbia) which was established as a pilot centre within the Mental Health Project. The Institute for Mental Health in Belgrade also has a community care centre for prevention and treatment in the municipality of Voždovac, where young drug addicts and adult alcohol addicts are treated together with their families.

The major number of psychiatric institutions in Serbia have day hospitals for the treatment of neurotic disorders, personality disorders, affective and psychotic disorders, as well as for addiction treatments (for example, the Institute for Mental Health in Belgrade).

39. What are your current health expenditures, as a percentage of GDP, and in absolute terms (in Euro), and how are they structured, including the amount spent in the public sector and the private sector, the amount spent on prevention, and health promotion?

Health care financing in the Republic of Serbia is essentially based on the Bismarck model, since over 90% of the funds to exercise the right to compulsory health insurance funds provided from the compulsory health insurance. However, based upon Law on Health Care, financing of health care services is provided from the budget of the Ministry of Health, for persons not covered by compulsory health insurance and who are exposed to increased risk of

morbidity (uninsured persons, refugees and internally displaced persons from the territory of the Autonomous Province of Kosovo and Metohija, the recipients social welfare and others) as something that characterizes Beverage model. Therefore, health financing system in Serbia is mixed, which is characterized almost exclusively by public sources of funding, because funding is mostly generated from the contributions and the budget.

Healthcare in the Republic of Serbia is financed also by donations and loans, and direct payment by users of health care (participation and payment services are not provided from the compulsory health insurance after 2003 and patient get bill for legal payment).

For each charged participation health institution is obliged to issue a bill which provided HIF. If the insured believes that his participation, and health services wrongfully collected, shall have the right to your home branch to submit the request for reimbursement, ie. refundable.

The total amount of participation which the insured can pay in a calendar year is limited to no more than half the monthly salary or pension paid for the last month of the calendar year.

The total amount paid participation in health institutions in 2009, based on reports on the financial operations Republic Health Insurance Fund is RSD 1,164,959.00, which represents 0.65% of total revenues for 2009.

Compulsory health insurance provides the insured the right to health care and to compensation in accordance with the Health Insurance Act (Official Gazette of RS, no. 107/05 and 109/05). Compulsory health insurance is provided and implemented in the Republic Health Insurance Fund (hereinafter referred to as HIF).

In addition to the mandatory, the Law on Health Insurance regulates health insurance. Regulation of the Voluntary Health Insurance (Official Gazette of RS, no. 108/08 and 49/09) stipulates the types of voluntary health insurance coverage, terms, conditions and procedure for organization and implementation of voluntary health insurance.

Distribution of financial resources and payment service providers

Total expenditures for health care can be divided into public and private. Public expenditures account for expenditures from public funds (compulsory health insurance, the Republic budget, the autonomous province and local government budgets). Also, public expenditures and investments in the health care system from state funds as a fund of the National Investment Plan for the construction of infrastructure and financing of medical equipment. Private expenditure on health care from private sources, such as direct payments (and payment of participation by users of health care) and voluntary insurance.

In 2007, according to the Institute of Public Health of Serbia "Dr Milan Jovanovic Batut", total expenditures for health care in the Republic of Serbia amounted to 9.6% of gross domestic product (GDP). The share of public expenditures for health care in GDP was 6.1%. Thus, public expenditures on health care amounted to 63.8% and 36.2% of total private expenditure for health care.

Total expenditures for health care, the resident observed, showing a steady increase in the period 2003-2007, and in 2007 they reached 384 Euros or 525 U.S. dollars per capita. Observing spending on health care as a percentage of GDP in 2007, the Republic of Serbia was above the EU average (8.9%), or approximately at the level of Denmark (9.8%), Greece

(9.6%) and Iceland (9.3%). Serbia was also over the Czech Republic, Hungary, Italy, Poland, Slovakia and other European countries. However, due to the relatively low level of GDP, Serbia allocates, in absolute terms, relatively small funds for health care in comparison with other European countries.

The distribution of funds collected from the compulsory health insurance or pay compensation for health care facilities providing health care (costs for salaries, transportation costs, energy consumption, costs of medicines, medical supplies and built, the cost of food and other needs of the users or the insured) is the responsibility of HIF.

Total revenues in the account HIF for 2009 amounted to 178,979,564,000 dinars, ie. 1,864,370,458 euros. In relation to that amount, 69% funds of social contributions and 1.5% are transfers from the Ministry of Health.

The structure of expenditures from the compulsory health insurance in 2009, the highest percentage of earnings had 104,000 employees (contracted number) in health care facilities - 48%, the cost of health care services (energy, vaccines, medicines, supplies and built-in material, etc..) - 32%, drugs dispensed on prescription - 13% compensation for sick leave and travel expenses - 4% of compensation (for supplies and funeral expenses) - 2%, while the processing costs of health insurance and payment of interest and loans totaled 2.14% of total expenditures.

Payment of health services is determined by the contract with health care providers, or purchase plan of the health institution in the estimate of funds planned HIF. The work plan contains the number and type of health services and the number and structure of employees. Salaries of employees in health care networks are paid from the Plan in accordance with the Law on salaries in state bodies and public services ("Official Gazette of RS, no. 34/01 and 62/06) and the regulation on the calculation and payment of salaries of employees in public services. To implement the plan of health care providers submit reports on health services in accordance with the act of HIF which set the criteria and standards for contracting with health care providers.

Regarding the structure of health care expenditures in 2009 to:

- primary health care of 40,179.09 million dinars, or 24.25% cost of health care or 22.66% of total expenditures. In relation to the plan these costs have been achieved with 99.17%;
- secondary and tertiary health care of 88,138.24 million dinars, or 53.19% of the expenditure of health care or 49.71% of total expenditures. These costs are committed to 100.00% of the plan.

From the Ministry of Health in 2009 the program Preventive health care allocated 27,319,954.73 Euros (2,622,715 654.72 RSD), which makes 49% of the total budget of the Ministry. Capital investment in the health care system to the fullest extent financed by the Republic, an autonomous province and local government budgets, as well as from donations.

From the Ministry of Health in 2009 to finance the construction of health institutions invested 66,000,000.000 RSD.

From the World Bank and European Investment Bank for the same purpose in 2009 was invested a total of 947,916,454 RSD i.e. 9,874,130 Euros, which is 18% of the total budget of the Ministry.

Part of the funds used to finance health care is provided billing services not covered by the health insurance fund. Amount collected from service in 2010 in the State health sector amounted to RSD 6,635,989,021.29

Bearing in mind that the Republic of Serbia registered and 3,033 private medical clinics (of that 1,268 is clinics and 1,765 dental practices), a significant part of health care financed by users themselves, as evidenced by turnover of private medical clinics, which was in 2010 amounted to 12,274,899,205 dinars. Proportion collected dental services in the private sector in total amounted to 1,535,111,825, which represents 50% of the collected in state institutions.

Because of incomplete fiscalization and tax records of operations of private health sector traffic data collection and health services available to the tax administration should be taken with caution because, in reality, the scope and level of collection services is significantly higher.

40. With specific reference to health promotion and disease prevention:

- what measures are you taking to improve health promotion and disease prevention, e.g., 3 types of cancer screenings (colorectal, breast and cervical)?

The following activities are in place with specific reference to health promotion and disease prevention:

- developing, participating in and monitoring the implementation of interventional health promotion community such as:
 - health promotion programs in primary healthcare institutions;
 - health promotion programs in polyvalent patronage service;
- developing, implementation, coordination, monitoring and evaluation of health promotion programs, including national campaigns, in view of acquiring knowledge and attitudes in relation to healthy life style and reducing risk factors for infectious and non-infectious diseases;
- Developing, coordination and building on partnerships between governmental, private and civil sector for resolving public health community issues;
- implementation of education and vocational training of health professionals and associates in the sphere of health education;
- development and implementation of the program for the health promotion of special and vulnerable population groups (children, pregnant women, nursing mothers, aged persons, marginalized groups), such as:
 - the program for health promotion of elementary school children
 - the program for health promotion of high school children
 - the program for oral health preservation and promotion of children and youth of the Republic of Serbia
 - health educational program in pre-school institutions "Healthy Kindergarten".
- health information of the Serbian population through a continuous work with the media;
- implementation of the program for the protection of population from infectious diseases for the part of health education.

In the sphere of prevention and control of infectious diseases, the activities include organization, implementation and control of epidemiological surveillance over infectious diseases, surveillance over hospital infections.

The immunization program includes:

- surveillance over mandatory active immunization of persons of a particular age,
- mandatory immunization of persons exposed to particular infectious diseases,
- active immunization based on clinical indications,
- and active immunization of passengers in international traffic by the application of measures prescribed by the law with the purpose of protecting the population from infectious diseases, their prevention, suppression, removal and extermination.

The activities implemented in the sphere of prevention and control of leading chronic non-infectious diseases includes:

- the assessment of the prevailing risk factors responsible for the incidence of the leading chronic non-infectious diseases (CND) on the basis of the results of population, targeted and other researches.
- the activities prescribed under the action plan of the National Strategy for CND Prevention and Control are currently in place. Based on the conducted research it is possible to identify the risk population groups for the intervention regarding the promotion of healthy life styles.

The program activities in the sphere of prevention and control of the leading CND have been regulated in more detail:

- by the National program “Serbia Against Cancer” whose integral parts are the National program for the prevention of colorectal cancer, National program for the prevention of breast cancer and the National program for the prevention of cervical cancer;
- by the National program for the prevention and control of cardio-vascular diseases in the Republic of Serbia by 2020 – “Serbia for a Healthy Heart”;

These programs has been financed from the budget of the Ministry of Health, and the funds are providing by collection of excise duties on tobacco products.

The Rulebook on the contents and scope of healthcare rights under mandatory health insurance coverage and on co-payment for 2010, clearly defines the prevention activities in accordance with the national programs.

The first systematic medical examination has been envisaged for persons between 19 and 35 years of age and it includes a general clinical examination and systematic examination, basic laboratory analyses and other examinations depending on the present risk factors. A systematic examination for persons aged 35 and over has been envisaged to take place every second year, with additional examinations as appropriate, while the tests for the presence of faecal occult blood, digital rectal examination (DRE) and prostate examination by palpation have been envisaged to take place once a year for persons aged 50 and over. Colonoscopy of high risk patients has been envisaged to take place once in three years.

The first preventive gynaecological examination has been envisaged for women aged 15 and over, the re-examination once in three years, with breasts examination by palpation once in 5 years. Women aged 25-69 should undergo the annual targeted examination in view of early detection of cervical and breast cancer, while women aged between 30-69 are given

recommendations and instructions for self-examination of breasts. Women aged 40 and over should undergo the annual clinical examination of breasts, while women aged between 45-69 should undergo mammographic examination once in two years.

41. Are you implementing the OECD manual “A system of health accounts”? If no, when are you planning to do so?

There are no legal preconditions for the institutionalization of the National Health Accounts and Ministry of Health is in procedure of drafting Law on Medical Documentation in which will be defined methodology of data collecting and establishing National Health Accounts.

The instructions “A system of Health accounts” Version 1.0. have been applied since 2005 within the Serbian National Public Health Institute. Serbia is a member of the OECD group for auditing the Health Accounts System by means of electronic discussion, since 2008.

42. With reference to cross-border healthcare, please specify the following:

a) Do you have cross-border arrangements for treating patients with any EU Member State or candidate countries?

The Republic of Serbia entered into Social Insurance Agreements covering health insurance based on the principle of insurance and on the principle of reciprocity with the following countries:

Based on the principle of insurance:

Austria, Belgium, Germany, Netherlands, Luxembourg, France, Romania, Italy, the Czech Republic, FYROM, Croatia, Bosnia and Herzegovina, Hungary (only hospital costs and transportation costs), Montenegro.

The insurees from these countries during their temporary stay in our country, as well as our insurees during their temporary stay in those countries are entitled to urgent and necessary medical care. Insurees must have bilingual forms – certificates of the right to receive healthcare services so as to exercise their healthcare rights.

As regards the application of the convention with France, healthcare services are directly charged to the French insurees - tourists during their temporary stay in our country and they are issued the invoice for the provided healthcare services.

Based on the principle of reciprocity:

United Kingdom, Bulgaria, Slovakia, Poland and Hungary.

The provision of healthcare services has been regulated with these countries based on the principle of reciprocity which means that the insurees of one contracting country during their temporary stay in the territory of another contracting country may receive urgent and necessary healthcare based on the Agreement at the cost of the country of their temporary stay.

The Republic Institute for Health Insurance issued 7,569 certificates in 2009 for the temporary stay of insurees in the countries with which Serbia has entered into the agreement.

The persons insured in the Republic of Serbia are referred to abroad to undergo the treatments of diseases regulated by the Rulebook on the requirements and manner of referring the patients to treatments abroad, to the following institutions (that the RIHI has entered into agreements with):

1. The Harley Street Clinic, London.
2. Herzzentrum Leipzig GmbH, Leipzig.
3. Centre cardio-thoracique de Monaco, Monaco.
4. Gottsegen Hungarian Institute of Cardiology, Budapest.
5. Deutsches Herzentrum Berlin, Berlin.
6. Great Ormond Street Hospital, London.
7. Instituto Per l'Infanzia 'Burlo Garofolo', Trieste.
8. Ospedale San Gerardo, Monza.
9. IRCCS Policlinico San Mateo, Pavia.
10. IGR-Institut Gustave-Roussy, Paris.
11. Ospedale S.Camillo-Forlanini, Rome.
12. Ospedale riuniti di Bergamo, Bergamo.
13. Ospedale civile maggiore, Verona.
14. Klinik für Knochmarktransplantation und Hematologi, Oberstein.
15. AKH-Allgemeines Krankenhaus der Stadt Wien, Vienna.
16. The Chaim Sheba Medical Center, Tel-Hashomer.
17. Schneider Children's Hospital, Tel Aviv.
18. Bnei Zion Hospital, Haifa.
19. Groupe hospitalier Necker, Paris.
20. Azienda sanitaria ospedaliera O.I.R.M.-S.Anna, Turin.
21. Klinikum der Johannes Gutenberg, Mainz.
22. Ospedale riuniti di Bergamo, Bergamo.
23. University Urology clinic, Heidelberg
24. Schneider Children's Hospital, New York.
25. Universitäts Spital Zurich, Zurich.
26. Universitätsklinik für Kinder-und Jugendheilkunde, Innsbruck.
27. Azienda Ospedaliera di Verona, Verona.
28. The Scientific institute for neurosurgery, Budapest.
29. Research-practical center of endovascular neurona, Kiev.
30. Clinic of Neurology, Pecs.
31. KBC Zagreb, Klinika za neurokirurgiju, Zagreb.
32. MGH Massachusetts General Hospital, Boston.
33. Centre hospitalier Sainte-Anne, Paris.
34. Ospedale Bellaria C.A. Pizzardi, Bologna.
35. Saint Bartholomew's and The Royal London Hospital, London.
36. Policlinico Gemelli, Rome.
37. Hacettepe universitesi, Ankara
38. Universitätsklinikum Aachen, Aachen.
39. Cliniques universitaires Saint-Luc, Brussels.
40. Universitäts-Augenklinik, Erlangen.
41. Queen Victoria Hospital, London.
42. Hospital ophtalmique Jules Gonin, Lausanne.
43. Centre Hospitalier Universitaire Vaudois, Vaudois.
44. KF GU MNTK 'Microhirurgiya glasa', Kaluga.
45. John Hopkins International, Baltimore.
46. Na Homolce Hospital, Prague.
47. Eye clinic of Karl's University, Prague.
48. Hadassah University Hospital, Jerusalem.
49. Kerckhoff Heart-Center, Bad Nauheim.
50. Universitätsklinikum Leipzig, Leipzig.

51. Universitätsklinikum Heidelberg, Heidelberg.
52. Landeskrankenhaus-Universitätsklinikum Graz, Graz.
53. Groupe Hospitalier Pitie-Salpetriere, Paris.
54. Universitätsklinikum Bonn, Bonn.
55. Krankenhaus Mara GmbH, Bielefeld.
56. Acibadem Healthcare Group, Istanbul.
57. Gamma Knife Radiosurgery-Goethe University, Frankfurt.

b) What is the annual flow of patients into and from your country by sending/receiving country?

The Republic Institute for Health Insurance referred the patients to treatments abroad, as follows:

In 2004, 31 referred patients, the costs amounted 57,790,000 RSD (\approx EUR 547,772,511).
 In 2005, 59 referred patients, the costs amounted 62,290,000 RSD (\approx EUR 590,426,540).
 In 2006, 64 referred patients, the costs amounted 106,000,000 RSD (\approx EUR 1,004,739,336).
 In 2007, 104 referred patients, the costs amounted 107,180,000 RSD (\approx EUR 1,015,924,170).
 In 2008, 148 referred patients, the costs amounted 187,140,000 RSD (\approx EUR 1,773,838,862).
 In 2009, 202 referred patients, the costs amounted 259,000,000 RSD (\approx EUR 2,454,976,303).

The patients were sent for treatments in the field of cardio surgery, neurosurgery, gastroenterology, neurology, ophthalmology, otorhinolaryngology, oncology and haematology, orthopaedics, urology, nephrology.

c) What is the annual expenditure (percentage of GDP and total amount in Euro) for treatments of patients from your country abroad?

The costs of treatments abroad amounted in total 569,804,269.52 RSD. (RIHA data for 2009) out of which:

- 1) healthcare under the Social Insurance Agreement (insurees temporarily staying abroad, and/or in the country that the Republic of Serbia entered into the said Agreement in need of urgent healthcare) – 312,425,797.50 RSD,
- 2) healthcare provided to insurees living abroad (persons working abroad, diplomatic representatives pay their own costs and the RIHI reimburses the costs upon their return to Serbia) – 7,391,744.63 RSD,
- 3) the costs of referring the patients to treatments abroad (in accordance with the Rulebook on referring the patients to treatments abroad) – 249,986,727.39 RSD, which amounts 2,505,630.22 EUR at the medium exchange rate.

The participation of the costs of treatments abroad in the gross domestic product of the Republic of Serbia (2.953.5 billion RSD) in 2009 amounts 0.0193%, and separately, and/or per listed items:

- 1) healthcare under the Social Insurance Agreement - 0.0106%,
- 2) health insurance of persons temporarily working and living abroad – 0.0002%,
- 3) the costs of referring insured persons to treatments abroad – 0.0085%.

d) Irrespective of arrangements, what information on cross-border is gathered at the moment?

The records have been kept regarding the number of insured persons referred to treatments abroad and regarding the treatment costs. The Republic Institute for Health Insurance also keeps records on the number of insured persons under the social insurance agreements and on the costs of provided healthcare services.

43. Are your health institutions members of any European or WHO networks? If so, which ones?

The Republic of Serbia is a member of the World Health Organization and the cooperation has been performed through the programs defined within the Two-Year Cooperation Agreement.

Minister of Health of the Republic of Serbia is member of the Executive Board of the WHO.

The Republic of Serbia is member of the South-Eastern European Health Network

Great number of health institutions and professional associations are the members of many European associations.

44. With reference to health information and knowledge, are your health statistical institutions members of any Eurostat network? If so, which ones?

The cooperation with Eurostat is conducted exclusively through the Statistical Office of the Republic of Serbia (SORS). In this phase of association to the EU, our country does not have a membership in Eurostat institutions, but mostly the status of an observer. The Ministry of Health has recently received the request by SORS to propose the representatives for technical groups (Healthcare data -CARE, Causes of death statistics -COD, Health and disability interview surveys -HIS and Morbidity statistics -MORB) within the project "European Statistical System Network project on Public Health Statistics - (ESSnet-PH)", which has been done.

45. The EU has established a network of competent authorities in health information and knowledge. Does your country have the administrative capacity, including human and material resources, to participate in the work of such a network? Please describe the system used to collect, analyse and report health data and information in your country.

There are institutional and human capacities for work within the Public Health Statistics - EUROSTAT, WHO, as well as lack of financial resources.

The national health statistical system managing the Serbian National Public Health Institute is a part of the national statistical system administered by the Statistical Office of the Republic of Serbia. It is important for the national statistical healthcare system that the data should be channelled from all health institutions (in most cases without the data from private sector), to 22 regional public health institutes. Regional public health institutes send the data to the Serbian National Public Health Institute. The Serbian National Public Health Institute collects, stores, processes and analyzes health statistical data. The National Public Health

Institute provides a major contribution in the flow of information intended for the Ministry of Health.

The national health statistics and informatics currently operates in accordance with the adopted legal documents: laws, by-laws or regulations, as a legal basis for collection of health data, from 1978 to 2009. They are given below in chronological order with some necessary comments.

1. Law on Records in the Field of Healthcare (“Official Gazette of SFRY”, No. 28/78)
Comment: Health Records Act is a corresponding English name for the Serbian Law on records in the sphere of healthcare (covers medical documentation, reporting, etc.)

2. Guidelines for unique methodological principles and statistical standards for keeping health records (“Official Gazette of SFRY”, No. 13/79)

2.1. Methodological document. Guidelines for registration of health data of interest for the whole country, collection and reporting on data. The Institute for safety at work documentation, Niš; 1978.

3. Law on Health Records (“Official Gazette of SRS”, No. 14/81, 23/85, “Official Gazette of RS no. 44/91, 53/93, 67/93, 48/94)

4. Rulebook on keeping medical documentation, procedure of entering data and report preparation (“Official Gazette of SRS” No. 40/81)

5. Guidelines for unique methodological principles and statistical standards for keeping health records, preparation and submission of reports in the sphere of health care (“Official Gazette of SRS”, no. 54/81)

6. Law on Health Records (“Official Gazette of SRY”, No. 12/98)
Comment: The International Classification of Diseases ICD (10th revision) was officially introduced in the Serbian healthcare system. ICD – 10 was published by the Federal Institute of Public Health, and trainings for ICD-10 use were delivered during 1997.

7. Guidelines for unique methodological principles and statistical standards for keeping health records (“Official Gazette SRY”, 6/2000)

Comment: In accordance with these Guidelines, two forms were accepted throughout the country: Summary report on diagnosis, health problems and injuries for primary healthcare services (Form No. SI-06), Individual notification report on infectious diseases (Form No. DI-07/1) and Cancer Notification Form, i.e. Individual notification of a person ill with cancer (Form No. DI-08/1)

8.Regulation – Rulebook on medical documentation, record keeping and reporting on personnel, equipment, construction of premises and medicines in health institutions (“Official Gazette of RS” No. 29/2000)

Comment: This act prescribes the obligation for the Serbian National Public Health Institute to establish the human resources database and medical equipment database in the health sector.

9. The Law on infectious diseases (The Law on protection of population from infectious diseases) (“Official Gazette of RS”, no. 125/04)

10. Rulebook on the procedure of issuing and the form of death certificate (“Official Gazette of RS”, No. 08/05)

11. Explanation with the reasons for the introduction of the revised birth certificate form (signed by the Minister of Health, No. 200-00-01/05-02)

12. Rulebook on reporting infectious diseases and other cases prescribed by the law. (“Official Gazette of RS”, No. 98/05)

13. Rulebook on immunization and chemoprophylaxis (“Official Gazette of RS” No. 11/06)

14. Law on Healthcare (“Official Gazette of RS”, No.107/05)

Chapter VIII, Subchapter 6. Keeping Medical Documentation and Records, Article 73, first paragraph: “A healthcare facility, private practice, social security institutions, penitentiary institutions, medical faculties that are engaged in a certain type of healthcare practice, as well as other legal persons engaged in certain types of healthcare practice in compliance with the law, shall keep medical documentation and records and within specified timeframes submit individual, summary, and periodic reports to the competent institute of public health, as well as to other organizations in the manner laid down by a separate law.”

15. Rulebook on quality of healthcare indicators (Ministry of Health, No. 110-00-198/07-02)

16. Regulation on the program for the development, organization and operation of the Integrated Health Information System – “e-health” (RS Official Gazette No. 55/09)

17. Rulebook on more detailed contents of technological and functional requirements for the establishment of integrated health information system (RS Official Gazette No. 95/09)

Important legal documents closely related to and in use with all above mentioned laws and by-laws are as follows: the Law on Protection of Personal Data (“Official Gazette of RS”, No. 97/08, 104/09), the Law on Free Access to Information of Public Importance (“Official Gazette of RS”, No. 120/04, 54/07, 104/09) governing the access to data, i.e., the collection, processing, reporting and distribution of data from primary registered individual health documentation and all the data derived from individual medical documentation. The same refers to the data collected from national interviews and the researches conducted with respect to the population’s health.

At this moment, after many years, the development of the Law on Healthcare Records is in place. This Law and subsequently its by-laws will govern the area of healthcare data, from the initial registration to the individual use and aggregation of healthcare data.

46. With reference to health workforce, please specify the following:

a) is there mobility of clinical staff (nurses/doctors) to/from your country to EU Member States, candidate and potential candidate countries, or others? If so, in which numbers and to which countries?

There are individual cases since medical faculty degrees must be nostrified if they practice medicine and we do not have enough data.

b) How is healthcare staff appointed, and what is the distribution of health personnel across the country?

Health institutions employ medical staff in accordance with the job systematization. The planning mechanisms for state owned Health institution include the Personnel Plan adopted in accordance with the Rulebook on more detailed requirements for healthcare practice in healthcare institutions and issued by the Ministry of Health. New job posts are subject to the approval of the Ministry of Health.

c) How many move across borders?

According to the National Employment Service, the number of medical workers sent to work abroad is 16 (8 in Germany and 8 in Libya).

d) Education and training

Doctors are educated at faculties of medical sciences, and specialty, sub-specialty, master and doctoral degrees are higher educational levels. Medical training includes a doctor's internship, while skills are acquired at specialty internships.

e) Where is the healthcare staff trained?

Doctors are trained in healthcare institutions (primary healthcare centres, hospitals).

f) To what educational level are nurses trained (e.g. degree level)?

Nurses pursue high school, college and university studies.

g) What are the mechanisms for planning the number of health medical doctors and nurses trained? E.g. is a *numerous clauses* in operation?

The plan for pre-graduate high school, college and university education of health workers are prepared by the Education institutions, which are under responsibility of Ministry of Education.

Specialty and Sub-Specialty Internship Plan for all Health Institutions are subject to the approval by the Ministry of Health.

h) Does the number of staff correspond to the needs of the population?

Yes, it corresponds at the national level. Although the number of healthcare staff meets the requirements at the national level, there is still a territorial imbalance. Thus, in 2008 the number of doctors (employed in the Network Plan institutions) per 100.000 citizens in administrative counties ranged between 151 (Srem Administrative County) and even 437 (Niš Administrative County), while the number of nurses ranged from 314 (Srem Administrative County) and 657 (Zaječar Administrative County).

i) Is training paid for out of the public purse or does the student pay full cost?

Training costs are under jurisdiction of the Ministry of Education.

j) Are there any policies to try and retain doctors and nurses in the health system?

The health policy of the Republic of Serbia has a clear concept that supports education in healthcare practice and its further improvement as a necessary pre-condition for quality human resources potential and thus higher national healthcare standards.

In relation to that, investments in the education of middle healthcare staff represent a reversible process that in its final outcome means its preservation as a serious, respectable investment of the whole Serbian healthcare system.

k) Is there any estimate of numbers of trained health professionals not currently working in healthcare?

The National Employment Service disposes of the data on estimates (and/or numbers that change perhaps at a daily level) of the number of trained healthcare professionals not engaged in healthcare practice and looking for a job. At the same time, please note that there are records on the number of healthcare professionals involved in the work process through the RIHI payroll record – and, of course through healthcare professionals chambers (Serbian medical doctors and dentists, chambers, pharmacists' chambers, chambers of biochemists and chambers of medical nurses and technicians).

B. Tobacco

47. With reference to tobacco control, what are the gender specific and combined smoking rates in your country by age groups (in percentages)?

Serbia has a great prevalence of smoking among adults and one of the highest prevalence for women smokers in the European region. Smoking is a leading individual cause of a great number of diseases (heart and blood vessels diseases, respiratory tract diseases, cancer and many other problems) that may be prevented in Serbian population. People who quit smoking significantly reduce the risk in relation to many diseases.

The national review "Condition of health, health needs and use of healthcare services in Serbia" was conducted in 2000 by the Serbian National Public Health Institute and showed that the prevalence of adult smoker in population amounted 40,5%, i.e., that every second man and every third woman in Serbia were smokers. After several years of the implementation of overall measures for tobacco control imposed by the Ministry of Health of the Republic of Serbia, the research of the condition of health of Serbian population was repeated in 2006 and showed a significant reduction of the smoking rate in adults by 6,9% in comparison with the year 2000. The reduction of number of smokers was greater among male (by 9,8%) than among female population (by 3,8%).

Year:	Smoking prevalence (%)
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	Total	Males	Females
2000.	40,5	47,9	33,7
2006.	33,6	38,1	29,9

The exposure to tobacco smoke at home was higher for women (62,1%), while males were more exposed to tobacco smoke at work (49%). The greatest exposure to tobacco smoke at home (64,6%) and at work (50,5%) was identified with respect to persons holding university degrees (66,8% and 51,8%). With respect to age, the exposure to tobacco smoke at home was highest in the age groups between 20-30 and 35-44.

Detailed data on smoking prevalence in Serbia may be found in the Report on the compliance of legislation for tobacco control and measures in Serbia with the WHO Framework Convention on Tobacco Control: <http://www.who.int/fctc/reporting/srb/en/index.html> .

48. With reference to the following list of *acquis*, please answer to the questions below a) to b):

-Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

-Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

-Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages

-Commission Decision 2005/1452/EC of 26 May 2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in annex 1 to the Directive 2001/31/EC of the European Parliament and of the Council

- Commission Decision 2006/1502/EC amending Commission Decision C(2005) 1452 final of 26 May 2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in Annex 1 to Directive 2001/37/EC of the European Parliament and of the Council

Directive 2007/65/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities

- Council recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control

- Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control

- Council Council Decision 30/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control The Recommendation

has been adopted by the Council on 30 November 2009 and its publication will follow in due course.

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full text in English.

The following laws, regulating the area of tobacco control, are in force in the Republic of Serbia:

Title	Date of issue	Bearer	Official Journal	Entry into Force
Law on Excise Duties	2001-2010.	Ministry of Finance of the Republic of Serbia	Official Gazette of the Republic of Serbia, no. 22/01, 73/01, 80/02, 43/03, 72/03, 43/04, 55/04, 135/04 and 46/05, 3/10	8 days after the day of publication of the Law in Official Gazette of the Republic of Serbia
Law on Advertising -regulating the conditions and manner of advertising, rights and duties of advertisers, producers and transmitters of advertisements, as well as receivers of advertisements; contains a special chapter Advertising of tobacco products -prohibits: Advertisement of tobacco on TV, radio, press, in cinemas, marketing of the products on TV, in movies, promotional discounts, non-tobacco products with tobacco brand name, distribution of free samples of cigarettes, promotional discounts, sponsorship of contests, public and sport events, as well as sponsorship of individuals taking a part in such events and contests, sponsorship of events in which minors participate or those events that primarily target the youth.	16. September 2005	Ministry of Trade, Tourism and Services	Official Gazette of the Republic of Serbia, no. 79/2005	21. November 2005
New Law on Tobacco <ul style="list-style-type: none"> Introduced ISO standards for testing and measuring of tobacco products; 	21. December 2005	Ministry of finance	Official Journal of the Republic of Serbia, no. 101/2005	1. January 2006
<ul style="list-style-type: none"> Again gave effect to prohibition of selling of tobacco to minors; 				21. November 2005
<ul style="list-style-type: none"> Prohibited sale via vending machines and self-service showcases; 				21. November 2005

<ul style="list-style-type: none"> Introduced new regulation for licensing of retailers; 				21. November 2005
<ul style="list-style-type: none"> Established specific budget for prevention activities related to tobacco control; 				21. November 2005
<ul style="list-style-type: none"> Prohibited expressions such as “low-tar”, “light”, “ultra light” and “mild”; 				1. January 2007
<ul style="list-style-type: none"> Introduced new measures for disclosure of tobacco products for all producers-warnings that should provide information on toxic contents of tobacco products, especially on tar, nicotine and carbon monoxide. 				1. January 2007
<ul style="list-style-type: none"> Introduced the rule that each unit, parcel or package of tobacco product is to carry strong health warning, in compliance with international standards. 				1. January 2007
Law on Protection of Population from Exposure to Tobacco Smoke	5. May 2010	Ministry of Health of the Republic of Serbia	Official Gazette of the Republic of Serbia, no. 30/2010	180 days after the day of publication of the Law in Official Gazette of the Republic of Serbia

In addition, on 17 January 2007, the Government of the Republic of Serbia adopted Strategy and action plan of tobacco control of the Republic of Serbia based on WHO Framework Convention on Tobacco Control. The strategy of tobacco control of the Republic of Serbia is adopted for the period 2007-2015 and Action plan of tobacco control for the period 2007-2011.

WHO Framework Convention on Tobacco Control is ratified in the Republic of Serbia on 8 February 2006 and came into force on 9 May 2006.

The report on compliance of the regulative and tobacco control measures with WHO Framework Convention of Tobacco Control that is sent to the Convention Secretariat in 2008 and is available at the web site <http://www.who.int/fctc/reporting/srb/en/index.html> is enclosed.

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

Since the provisions of the current Law on Advertising are not completely harmonised with *acquis communautaire*, and taking into account market relevance of the new media (insufficiently covered by the current law), a special working group within the Ministry of Trade and Services is appointed to draft the new Law on Advertising. The task of the working

group is to prepare the Draft Law on Advertising that will transpose the following EU directives:

- Directive 89/552/EEC of the European Parliament and of the Council
- Directive 97/36/EC of the European Parliament and of the Council
- Directive 2007/65/EC of the European Parliament and of the Council
- Directive 2006/114/EC of the European Parliament and of the Council
- Directive 2003/33/EC of the European Parliament and of the Council
- Directive 2005/29/EC of the European Parliament and of the Council

It is planned for the Draft Law to be submitted to the Government for approval in III quarter of 2010, and then to the National Assembly for adoption.

c) In cases where neither of the above exists, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable? Please explain, also indicating the envisaged timetable.

Please, see the answer to the same question under a) and b).

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the EU legislation listed above?

The necessary administrative capacities of MTS for enforcement of the Law on Advertising exist within the Sector for Market Inspection, but continuous training of the staff is needed, as well as technical equipment and improvement of work organization. Please, note that a significant role in surveillance in the field regulated by this law belongs to the Republic Broadcasting Agency (RBA), which is not under the responsibility of this line ministry.

e) Serbia ratified the WHO Framework Convention on Tobacco Control (FCTC). What are your experiences of the implementation of the FCTC? Are you participating in the follow-up of the FCTC, including the work of the Conference of the Parties and Intergovernmental Negotiation Bodies?

Republic of Serbia ratified FCTC on 8 February 2006. The Convention entered into force in Serbia on 9 May 2006. First (two-year) implementation report was submitted to the Convention Secretariat on 15 May 2008 and is available on the Convention website. <http://www.who.int/fctc/reporting/srb/en/index.html>.

In addition to the measures described in the report, in May 2010 Serbian parliament adopted new smoke-free legislation and full implementation started on 11 November 2010. New law completely bans smoking in health and social care facilities, educational, cultural, sport facilities, at meetings, in all public administration buildings, in facilities where drugs and food are prepared or stored, shopping centres etc. In other working places a special room can be established for smokers, according to strict standards termed in the legislation. Regarding restaurants and bars, completely smoke-free are only those which belong to buildings in which smoking is completely banned. Significant fines are imposed also on owners and managers of buildings in which smoking is banned. Until 6 December 2010 general compliance is very good.

Delegation of the Republic of Serbia participated at COP3 in Durban, South Africa, in 2008, in all INB meetings, as well as in recently organized COP 4 in Punta del Este, Uruguay.

C. Communicable diseases

49. With reference to communicable diseases please:

a) Describe your epidemiological surveillance (diseases monitoring) system, in particular the reporting mechanism, involved parties and their respective roles, as well as the list of communicable diseases notified to the national competent public health authority.

Epidemiological surveillance of communicable diseases in Republic of Serbia is implemented in cooperation of the Institute of Public Health of Serbia and network of 23 institutes of public health in Serbia that are competent at the territory of 25 districts, pursuant to the Law on Protection of Population from Communicable Diseases (Official Gazette RS 125/2004) and Rulebook on reporting of communicable diseases and other cases laid down by Law on Protection of Population from Communicable Diseases (Official Gazette RS 98/05) and relates to 70 communicable diseases that must be reported.

Municipal level activities are:

- Clinical and, pursuant to available possibilities, laboratory diagnostics and classification of case (preliminary or final)
- Reporting of cases (reporting- zero, urgent, individual, consolidated), weekly, monthly on district level
- Collection of sample materials for laboratory testing in agreement with district level and laboratory
- Simple table and graphic presentation and periodical and annual reporting.

District level (network of Public Health Institutes) activities are:

- Processing and investigation of case that is impossible to perform on municipal level (e.g. collection of samples from contacts and cases, transport of samples to referent laboratory)
- Analysis of data from municipal level in regard to:
 - Epidemiological connection of cases under surveillance
 - Trends of diseases at district territory
 - Success of defined control objectives implementation
- Providing additional laboratory analysis and diagnostics procedures to the extent possible at this level
- Investigation of “suspicious” disease outbreak
- Providing feedback to municipal level
- Providing zero reports pursuant to article 5, copies of urgent reports of suspicions and reports of illnesses and deaths due to the diseases defined in article 7 and article 12 of the

Rulebook⁶ and three month submission of reports on carriers of HIV antibodies that are coded to protect personally identifiable information and reports on outbreak or end of communicable disease epidemic to central level, i.e. to Public Health Institute of Serbia

- Submissions of seven-day (weekly), monthly, three-month and annual reports pursuant to the criteria and time limits defined by the Rulebook.

NB: Zero report declares absence of AFP, small pox and CRS;

consolidated report: scarlet fever, Chlamydia infection, chickenpox, scabies, streptococcal pharyngitis and tonsillitis, flu identified virus and flu unidentified virus and pneumonia;

urgent report declares suspicion of existence of disease: cholera, plague, smallpox, yellow fever, viral hemorrhagic fever, poliomyelitis, diphtheria, measles and botulism.

Supervision activities of the central level are:

Policy for all activities of health service related to implementation of the policy, i.e. Program is created at this level through control and prevention of diseases. The central level has a key role in support to district and municipal levels by providing services that can not be implemented at those levels:

- Highly specialized laboratory and epidemiological services
- Education, expert-methodological support and work coordination
- Qualification for solving problems of national concern
 - Analysis of global, regional and national trends of diseases and directing of disease control resources to high risk areas
 - Cooperation with other countries and international institutions on response to outbreak of diseases of international concern pursuant to International Health Rulebook⁷ and on common decision-making of the countries related to objectives of control or elimination of diseases under surveillance
 - Access to alternative sources of information such as national referent laboratories that should offer data on identification of unusual micro organisms
- Providing global support and coordination of national surveillance activities
- Providing laboratory diagnostics that is not available at district/regional level
- Analysis of data from district/regional intermediate level:
 - Epidemiological correlation
 - Trends
 - Control objectives success
- Expert support to district/regional intermediate level:
 - Processing (resolving) of cases
 - Laboratory examination
 - Epidemiological examination
 - Education
 - Logistics (technical support)

⁶ Rulebook on reporting of communicable diseases and other cases laid down by Law on Protection of Population from Communicable Diseases, Official Gazette of RS number 98, 2005

⁷ World Health Assembly, International Health Regulations, Genève, 2005

- Providing feedback to district level
- Submitting reports to WHO pursuant to international obligations
- Coordination and cooperation with non-medical sectors such as agriculture, veterinary medicine and ecology when required (regarding diseases transmitted by food, water, vectors)

Examination of case

Epidemiological investigation, pursuant to Law on Protection of Population from Communicable Diseases, is conducted for the purposes of detection of source and manner of spreading of communicable diseases and detection of communicable disease epidemic, determination of cause of communicable disease epidemic and prevention and combating of the diseases.

Epidemiological investigation is implemented by institutes, i.e. public health bureaus in cooperation with community health centers, in the following cases:

Suspicion that there is a case of communicable disease:

- Cholera
- Plague
- Smallpox
- Yellow fever
- Viral hemorrhagic fever
- Poliomyelitis
- Diphtheria
- Measles
- Stomach typhus
- Paratyphus
- Other salmonellosis
- Shigellosis
- Campylobacteriosis
- Yersiniosis
- Tularaemia
- Anthrax
- Brucellosis
- Leptospirosis
- Listeriosis
- Whooping Cough (Pertussis)
- Meningococcal diseases
- Legionellosis
- Syphilis
- Gonorrhoea
- Lyme diseases
- Ornithosis- psittacosis
- Q fevers
- Rabies
- Tick-borne encephalitis

- Viral hepatitis (B, C, E)
- HIV disease
- Malaria
- Leishmaniasis
- Tetanus
- Trichinellosis
- Inborn rubella syndrome
- Botulism and
- Creutzfeldt-Jakob disease

b) Describe your alert and response system, in particular the communication mechanism, risk assessment and risk management of public health emergencies of international concern in the field of communicable diseases, involved parties and their respective roles; provide some examples which illustrate how this system operates.

Alert is conducted at the territory for which the institute, i.e. health protection bureau, i.e. Public Health Institute of Serbia estimates to be exposed to the hazard of: Outbreak of communicable disease epidemics in natural disasters, catastrophes and organized mass gatherings, during spread of communicable disease epidemic and after taking prevention measures during communicable disease epidemic, appearance of new or insufficiently known communicable disease, appearance of insufficiently defined symptoms and conditions, biological agent in the case of suspicion on use of agent. The alert is raised immediately after detection of danger and is on until there are the reasons for it.

By amendment to the Rulebook on internal organization and systematization of activities of the Public Health Institute Dr. Milan Jovanovic Batut, dated 8 March 2010, the Communication Centre of Disease Control and Prevention was established.

One of the essential activities of this Centre should be improvement of communication regarding communicable diseases, early detection, risk assessment and early response to crisis in public health on national and international level.

The mission of the Centre is to improve communication regarding communicable and other diseases and population health risk factors complying with ECDC recommendations and EU standards and grounded on activities of epidemiology reporting and application of contemporary information and communication technologies.

Pursuant to the Strategic plan of the Centre, the strategic programs regarding improvement and development of communication mechanisms related to detection of threats, risk assessment and introducing of measures are:

- Introduction and performance of epidemic reporting activities
- Development of SOP
- Development of operating plan in the case of extraordinary occurrence in public health
- Organising trainings for simulation of alertness in the case of extraordinary occurrence in public health
- Establishing mechanisms for reporting to ECDC.

The basic role of the Communication Centre is to set frames for early detection of risks and threats for the health of population caused primarily by communicable diseases, but also by biological agents and causes of unidentified origin. It is also necessary to develop mechanisms of early response and reporting on new situation and threats to enable efficient and timely response in cooperation with Disease Control and Prevention Centre of the Institute.

c) Indicate if you have adopted a national epidemic preparedness plan, including pandemic influenza preparedness plan. Moreover, since 5 February 2008 International Health Regulations (2005) entered into force in your country. Indicate your National IHR Focal Point and what is your timetable to develop national action plans to implement and meet IHR (2005) requirements in order to strengthen national capacity.

National communicable disease epidemic preparedness plan is defined for pandemic flu, importing of wild poliovirus, registering of morbili. Control and prevention of communicable diseases epidemic is stipulated by the Law on Protection of Population from Communicable Diseases (Official Gazette of RS no. 125/04) and Rulebook on reporting of communicable diseases (Official Gazette of RS no. 98/05), Article 13. Report on communicable disease epidemic is made by a doctor of medicine, epidemiologist of public health institute/bureau who detects epidemic and who submits the report to Public Health Institute of Serbia on appropriate form, immediately, and not later than within three days of the detection of epidemic. In the case of communicable disease epidemic caused by consumption of food and water originating from the objects under sanitary surveillance, administrative body competent for sanitary surveillance activities at the territory where the epidemic is detected is immediately informed in a manner appropriate for early notification. Epidemic alert is cancelled after expiration of the time of double longest incubation period determined for communicable disease that caused the epidemic.

National centre for implementation of International health rulebook is Public Health Institute Dr Milan Jovanovic Batut and the timeline for implementation of International Health Rulebook is the period 2009-2012.

d) Indicate your immunization programs, and the level of coverage.

Immunization is implemented pursuant to the Rulebook on immunization and protection by means of medications (Official Gazette of RS 11/06). Immunization against certain communicable diseases includes: obligatory active immunization of individuals of appropriate age (against tuberculosis, poliomyelitis, diphtheria, tetanus, whooping cough, measles, mumps and rubella, hepatitis B, diseases caused by H influenza type 6), obligatory immunization of individuals exposed to certain communicable diseases (against hepatitis, rabies, tetanus), active immunization of individuals pursuant to clinical indications (against flu caused by H influenza type 6, diseases caused by streptococcus pneumonia, meningococcal meningitis, whooping cough DTaP), active immunization of international travelers (yellow fever, meningococcal meningitis, stomach typhus, cholera, diphtheria and other communicable diseases).

TIMETABLE OF OBLIGATORY IMMUNIZATION OF INDIVIDUALS OF APPROPRIATE AGE

BCG- immediately upon birth, i.e. during the first month after birth
HB- the first dose+ *HBIG (newborns HBsAg + mothers)
HB- during the second month after birth, the second dose
DTP, OPV, Hib- during the third month after birth (immediately upon turning two months) the first dose
DTP, OPV, Hib- after turning three and a half months, the second dose
HB, DTP, OPV, Hib- after turning six months, the third dose
MMR- at the age of 12 to 15 months
DTP, OPV- at the age of 17 to 14 months
OPV, MMD, DT- at the age of seven, before starting the first grade of elementary school
Hep B- at the age of 12 three doses (0,1,6) if the child has not been vaccinated before
OPV, dT- at the age of 14, in the last grade of elementary school
TT- at the age of 30 R4, at the age of 40 R5, at the age of 50 R6, at the age of 60 R7

Estimated and official immunization coverage in Serbia in 2009 (table is placed in the annex to this chapter)

RESULTS OF IMMUNIZATIONS (%) IMPLEMENTED IN REPUBLIC OF SERBIA DURING THE PERIOD 1999 TO 2009

REPUBLIC OF SERBIA											
Implemented immunization	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
DTP 3 vaccination	97	97	97	97	97	98	97	97	98	98	97
OPV 3 vaccination	97	97	97	97	98	98	97	97	98	98	97
MMR vaccination	92	87	95	93	95	97	95	96	97	96	96
HB vaccination 1 year							65	92	94	94	95
HB vaccination 12 years								57	80	78	62
HiB vaccination								74	91	97	96
CENTRAL SERBIA											
DTP 3 vaccination	97	97	97	98	97	98	97	97	98	98	98
OPV 3 vaccination	97	97	97	97	97	98	97	97	98	98	98
MMR vaccination	91	88	95	93	95	96	94	96	97	96	95
HB vaccination 1 year							57	91	93	92	95
HB vaccination 12 years								58	75	72	54
HiB vaccination								79	92	97	97
VOJVODINA											
DTP 3 vaccination	97	97	97	97	98	97	97	96	98	97	97
OPV 3 vaccination	98	97	97	97	98	97	98	97	98	98	97
MMR vaccination	94	82	97	94	96	97	98	96	97	98	98
HB vaccination 1 year							87	96	96	97	97
HB vaccination 12 years								55	93	96	83
HiB vaccination								62	89	98	96

e) Provide the following information regarding communicable diseases:

50. Is there/Are there plan(s) of action for an outbreak at national level? If yes, please provide a translation of one.

Pursuant to the Law on Protection of Population from Communicable Diseases and the Rulebook on Reporting of Communicable diseases and other cases laid down by the Law on Protection of Population from Communicable Diseases, epidemiological investigation is performed in the case of outbreak of any communicable disease epidemic.

Report on communicable disease epidemic is submitted by competent epidemiologist of the Institute/Bureau of Public Health to the Institute of Public Health of Serbia on appropriate form, immediately, and not later than within three days of the detection of epidemic. In the case of communicable disease epidemic caused by consumption of food and water originating from the objects under sanitary surveillance, administrative body competent for sanitary surveillance activities at the territory where the epidemic is detected is immediately informed in a manner appropriate for early notification.

Epidemic alert is cancelled after expiration of the time of double longest incubation period determined for communicable disease that caused the epidemic.

The bureaus of public health at the territory of Autonomous Province of Vojvodina shall submit report on and cancellation of epidemic alert to the Institute of Public Health of Vojvodina that submits them to the Institute of Public Health of Serbia.

To improve the surveillance, minimal data set of the report should contain:

- Number of exposed/ diseased/ hospitalized people
- Number of deaths
- Date of the first case, linear list of cases
- Analysis of source of infection and transmitting mechanism
- Analysis of factors contributing to outbreak and spread of epidemic and risk of appearance of new cases
- Basic demographic and topographic analysis (gender, age, group/collective classification, place and time of infection, topographic spread of epidemic if significant)
- Epidemic prevention measures applied
- Assessment of further epidemic flow (eradication, combating, spreading, autoregulation)

Plan of action to sustain polio-free status 2009-2011 in Serbia and Plan of action to eradicate morbili and rubella and to prevent congenital rubella infection in Serbia are enclosed.

51. Is there a legal basis for monitoring anti-microbiological resistance? How is the system organised?

There is a legal basis (Article 14 of the Law- resistance of bacteria to anti-microbiological medicals is subject to mandatory reporting), but without implementing legislation, i.e. Rulebook (that has been announced) that would regulate this area more precisely.

The laboratory of the Institute of Public health of Vojvodina was appointed a referent anti-microbiological resistance laboratory within EU funded project Strengthening the Services of

public health laboratories in Serbia By taking insight into reports on hospital infections frequency it is observed that there is not unique standard and methodology for defining of anti-microbiological resistance; namely, two standards are applied (CLSI and EUCAST), American and European, which is problematic when it is necessary to compare and evaluate data.

52. Can you provide the Commission with the curriculum of training in epidemiological specialisation?

Medical faculties of the Universities of Belgrade, Novi Sad, Nis and Kragujevac organize and conduct training in epidemiological specialization.

53. What is the number of hospital departments and the number of beds for the treatment of communicable diseases?

Pursuant to data of the year 2009, number of hospital departments for treatment of communicable diseases in stationary health institutions in Serbia is 28, with 788 beds.

54. Is there a quality assurance system implemented for laboratory performance? How many laboratories have an accreditation?

There is a quality assurance system implemented for laboratory performance, conducted by Accreditation body of RS. Pursuant to the latest data from 31 December 2008, 5 laboratories were accredited pursuant to SRPS ISO/IEC17025 standard.

55. With reference to the following list of *acquis*, please answer to the questions below a) to b):

Basic act

Decision no. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community - Official Journal L 268/1;03.10.1998

Amending Acts:

-Regulation (EC) N° 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty - Official Journal L 284/1;31.10.2003

-Regulation (EC) N° 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the EC Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four- Official Journal L 188/14; 18.07.2009

2003/534/EC: Commission Decision of 17 July 2003 amending Decision N° 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC

as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases - Official Journal, L 184/35; 23.07.2003

2007/875/EC: - Commission Decision of 17 July 2003 amending Decision N° 2119/98/EC of the European Parliament and of the Council and Decision 2007/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/6355/EC as regards the case definitions for communicable diseases - Official Journal, L 344/48; 23.07.2003

Implemented measures

2000/96/EC: Commission Decision of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council - Official Journal, L 28/50; 03.02.2000

2000/57/EC: Commission Decision of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council. Official Journal, L 21/32; 26.01.2000

2002/253/EC: Commission Decision of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision N° 2119/98/EC of the European Parliament and of the Council - Official Journal, L 86/44; 03.04.2002

Amending Acts:

- Commission Decision 2003/534/EC of 17 July 2003 amending Decision N° 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases- Official Journal L 184/35; 23.07.2003

2003/542/EC: - Commission Decision of 17 July 2003 amending Decision N° 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases - Official Journal, L 185/55; 24.07.03

2007/875/EC: - Commission Decision of 18 December 2007 amending Decision N° 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions - Official Journal, L 344/48; 28.12.2007

2008/351/EC: Commission Decision of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases - Official Journal, L 117/40; 01.05.2008

-2008/426/EC: Commission Decision of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council - Official Journal, L 159/46; 18.06.08

-2009/312/EC: Commission Decision of 2 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases - Official Journal, L 91/27; 03.04.2009

Commission Decision 2009/363/EC of 30 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council - Official Journal, L 110/58; 01.05.2009

Commission Decision 2009/539/EC of 10 July 2009 amending Decision 2000/96/EC on communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council - Official Journal, L 180/22; 11.07.2009

Decision 2009/540/EC of 10 July 2009 amending Decision 2002/253/EC as regards case definitions for reporting Influenza A(H1N1) to the Community network- Official Journal L 180/24; 11.07.2009

Commission Decision 2009/547/EC of 10 July 2009 amending Decision 2000/57/EC on early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council - Official Journal, L 181/57; 01.07.2009

Basic act

-Regulation (EC) N° 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control- Official Journal L 142/1;30.04.2004

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

There are the Law on Protection of Population from Communicable Diseases (Official Gazette of RS no. 125/04) and the Rulebook on Reporting of Communicable diseases and other cases laid down by the Law on Protection of Population from Communicable Diseases (Official Gazette of RS no. 98/2005).

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

Against the Decision of the Minister of Health of RS, dated 16 July 2010, a special working group has been established to prepare Draft Law on Protection of Population from Communicable Diseases. The task of the working group is to create Draft Law complying with International Health Rulebook and legislation of the World Health Organization.

Deadline for completion of draft version is 31 March 2011.

After establishment, the Working Group has implemented the following activities:

- Evaluation of communicable disease surveillance system
- Systematic study of legislation of other countries
- Analysis of European Union legislative
- Analysis of International Health Rulebook
- Obtaining opinions of competent institutions on enforcement of existing Law

- Analysis of existing Law
- Appointing members of working groups for making of implementing legislation in the field of communicable diseases, particularly:
 - Rulebook on Epidemiological Surveillance of Communicable Diseases
 - Rulebook on Reporting of Communicable Diseases and Epidemics, Epidemiological Investigation and Research
 - Rulebook on Immunization
 - Rulebook on Obligatory Physical Examinations of Certain Categories of Employees and their Education on Protection of Population from Communicable Diseases
 - Rulebook on Prevention and Control of Hospital Infections
 - Rulebook on Obligatory Health Surveillance, Transport, Isolation and Quarantine
 - Rulebook on Application of International Health Rulebook
 - Rulebook on Types of Obligatory Physical Examinations of Certain Categories of Population
 - Rulebook on custody of remains of deceased persons
 - Rulebook on Identification of Communicable Zoonosis Diseases that are being Reported
 - Rulebook on Laboratory Examinations to Identify Communicable Disease Cause
 - Rulebook on Establishment and Work of Communicable Disease Commission of the Republic of Serbia

c) In cases where neither of the above exists, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

Please, see the answer to the same question under a) and b).

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the EU legislation listed above?

Yes, our country has necessary capacities to fulfill the requirements of the Union.

56. Please fill out the below table on structures and mechanisms of communicable diseases in Serbia.

STRUCTURES AND MECHANISMS	REFERENCES	COUNTRY COMMENTS /INPUT
1. Structure and/or authorities which, at country level and under responsibility of that country, are competent at national level and are charged with collecting information relating to the epidemiological surveillance of communicable diseases	Article 1 Decision 2119/98/EC Article 9 Decision 2119/98/EC Article 1 Decision 2000/57/EC Article 4 Decision 2000/96/EC	1) Listing of structure(s) and authority(-ies) Epidemiological surveillance is organised and conducted by institutes of public health in co-operation with health centres, in compliance with the Law on Protection of Population from Communicable Diseases, Official

		<p>Gazette of RS No. 125/2004.</p> <p>2) Contact details of country's counterpart(s)</p> <p>3) Knowledge of structures at EU level</p> <p>Experts, epidemiologists or contagious diseases of the National Institute for Public Health of Serbia are familiar with the main guidelines</p>
<p>2. Procedures for the dissemination of the relevant surveillance data at EU level</p>	<p>Article 1 Decision 2119/98/EC</p>	<p>Knowledge of EU procedures</p> <p>Experts, epidemiologists or contagious diseases of the National Institute for Public Health of Serbia are familiar with the main EU procedures</p>
<p>3. Competent public health authorities in the country responsible for determining the measures which may be required to protect public health</p>	<p>Article 1 Decision 2119/98/EC</p>	<p>1) Listing of public health authority(-ies)</p> <p>The Ministry of Health of the Republic of Serbia, the Public Health Institute of Serbia, network of institutes and departments in the territory of the Republic of Serbia</p> <p>2) Contact details of country's counterpart(s)</p>
<p>4. Definitions of "epidemiological surveillance" and of "prevention and control of communicable diseases"</p>	<p>Article 2 Decision 2119/98/EC</p>	<p>1) Listing of terminology used at national level</p> <p>Epidemiological surveillance is a continuous, systematic collection, analysis and interpretation of data on communicable diseases, and sending feedback information. Article 3(2) of the Law).</p> <p>Preventing the occurrence of communicable disease is a set of measures that are constantly being implemented in order to preclude the occurrence of infections or communicable disease (Article 3(3) of the Law).</p> <p>-() -Preventing the occurrence of</p>

		<p>communicable disease is a set of measures that are constantly being implemented in order to preclude the occurrence of infections or communicable disease (Article 3(4) of the Law).</p> <p>2) Reflection on coherence between national and EU</p> <p>Terminology is mainly harmonised</p>
<p>5. Communicable diseases to be progressively covered by epidemiological surveillance</p>	<p>Article 3 Decision 2119/98/EC</p> <p>Article 4 Decision 2000/96/EC</p> <p>Annex 1 Decision 2000/96/EC</p>	<p>1) Listing of communicable diseases and special health issues at available national level</p> <p>Under the Law on Protection of Population from Communicable Diseases (Official Gazette of RS No. 125/2004, 70 communicable diseases must be reported with a view of protection of health of the population in the Republic of Serbia (Article 2(1)).</p> <p>If there is a danger from contagious disease not stated in paragraph 1 of Article 2 and that may jeopardise health of the population of the Republic of Serbia, at the proposal of the minister of health it can be decided that appropriate measures regulated by law are applied as well as measures that the nature of the disease implies.</p> <p>2) Listing of dedicated surveillance networks available at national level</p> <p>The Public Health Institute of Serbia, network of institutes and departments in the territory of the Republic of Serbia</p> <p>3) Listing of communicable diseases requiring case reports at national level</p> <p>Epidemics and communicable diseases which require urgent reporting if there is a doubt and</p>

		<p>if there be any danger of communicable disease not listed in paragraph 1 of Article 2 and that may harm the health of the population of the Republic of Serbia</p>
<p>6. Criteria for selection of communicable diseases of special areas to be covered by epidemiological surveillance</p>	<p>Article 3 Decision 2119/98/EC Annex 1 Decision 2000/96/EC</p>	<p>1) Listing of criteria available at national level</p> <p>Epidemics and communicable diseases which require urgent reporting if there is a doubt and if there be any danger of communicable disease not listed in paragraph 1 of Article 2 and that may harm the health of the population of the Republic of Serbia</p> <p>2) Reflection on coherence between national and EU criteria</p> <p>Amendments necessary</p>
<p>7. Case definitions for reporting communicable diseases, including clinical, laboratory and epidemiological criteria as well as case classifications</p>	<p>Article 3 Decision 2119/98/EC Article 5 Decision 2002/253/EC -{}--{}-Annex Decision 2002/253/EC</p>	<p>1) Listing of criteria available at national level</p> <p>There are definitions for measles, AFP, congenital rubella syndrome, flu, nosocomial infections.</p> <p>Measles</p> <p>-{}-Clinical case definition (suspected case):</p> <p>Every person with high temperature, and</p> <p>Maculopapulous rash (not vesicular), and</p> <p>cough, rhinorrhea (runny nose) or conjunctivitis (red eyes)</p>

		<p>Clinically confirmed: case that meets the clinical case definition criteria, with which sample on measles was not tested and that is not epidemiologically linked ⁸ to the laboratory-confirmed case.</p> <p>Laboratory-confirmed: case that meets the criteria for clinical case definition and is laboratory-confirmed.</p> <p>Epidemiologically linked case: case that meets the clinical case definition criteria, not tested on measles, and there is no epidemiological link to the laboratory-confirmed case.</p> <p>Rejected case: suspected case of measles, that is fully examined, including the collection of an adequate blood sample, which according to the criteria of serological evidence of measles virus infection cannot be classified, i.e., the case that does not meet the criteria of either clinically or laboratory-confirmed case.</p> <p>Imported case: the case of measles which originated outside the country/region in the period within 7-18 days before the rash, or rubella case that arose out of the country/region within 14-21 day before the rash. Virus genotype should be consistent to the exposure by the geographic area.</p> <p>Case linked with imported case: case that is part of the chain of transmission, that originates from imported case.</p>
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⁸ Epidemiological link is defined as direct contact with other laboratory-confirmed case, 7-18 days before the occurrence of pox.

		<p>Rubella</p> <p>Clinical case definition (suspected case):</p> <p>Each case with the following signs and symptoms:</p> <p>maculopapular rash, and</p> <p>cervical, suboccipital or post-auricular adenopathy, or arthralgia/arthritis.</p> <p>Clinically confirmed: The person has a disease that meets the criteria specified in the definition of suspected cases of rubella.</p> <p>Laboratory-confirmed: Laboratory-confirmed case is a suspected case with a positive serologic test for rubella to IgM antibodies or virus detection (e.g. PCR or viral isolation).</p> <p>NB: False positive test results for rubella IgM antibodies may be reported in patients with other viral infections (e.g. acute infection of Epstein-Barr virus (infectious mononucleosis), recent cytomegalovirus and parvo virus infection, or in the presence of rheumatoid factor). Patients who have laboratory confirmation of recent infection with measles are excluded.</p> <p>Epidemiologically linked case: person who has a disease which corresponds to the clinically-confirmed case of rubella, the sample is not tested for rubella,</p>
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		<p>but there is an epidemiological link⁹ with laboratory-confirmed case.</p> <p>Rejected case: suspected case of rubella, that is fully examined, including the collection of an adequate blood sample, which according to the criteria of serological evidence of rubella virus infection cannot be classified, i.e., the case that does not meet the criteria of either clinically or laboratory-confirmed case.</p> <p>Congenital rubella syndrome</p> <p>Suspected case of the DRC</p> <p>infant aged 0-11 months with a heart defect, or a cataract, or deafness</p> <p>and/or</p> <p>infant whose mother has suspected or confirmed rubella infection during pregnancy</p> <p>Clinically confirmed case of the DRC: In infants, with whom doctor specialist detects two complications out of the following:</p> <ul style="list-style-type: none"> — cataract, — Congenital glaucoma, — Congenital heart defect, — Hearing loss,
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⁹ Epidemiological link is defined as direct contact with other laboratory-confirmed case, 14-21 days before the occurrence of pox.

		<p>— Pigment retinopathy or</p> <p>specialist doctor detects one of the following signs:</p> <p>— Purpura,</p> <p>— Splenomegaly,</p> <p>— Microcephaly,</p> <p>— Mental retardation,</p> <p>— Meningoencephalitis,</p> <p>— Radiolucent bone disease,</p> <p>— Jaundice within 24 hours of birth</p> <p>Clinically confirmed case of the DRC: Each infant with clinically confirmed DRC has a positive serological finding of IgM rubella - specific antibodies (100% of these infants will be positive at the age of 0 to 5 months, 60% at the age of 6-11 months). Where there are laboratory possibilities for detection of rubella virus in samples of nasopharyngeal swabs or urine in infants with suspected KRS, laboratory confirmation of the DRC is provided (60% of these infants excrete virus at the age of 1-4 months, 30% at the age of 5-8 months, 10% at age of 9-11 months).</p> <p>AFP case definition</p> <p>Clinical case definition</p> <p>Any person under 15 years of age with acute flaccid paralysis*, or</p> <p>any person with paralytic illness at any age who is suspected of poliomyelitis.</p> <p>*including Guillain-Barré Syndrome</p>
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		<p>Laboratory-confirmed case</p> <p>The case of acute flaccid paralysis in which wild polio virus was confirmed by means of isolation.</p> <p>Case classification</p> <p>Suspected case is the case that meets the criteria for clinical case definition.</p> <p>The confirmed case is the case of acute flaccid paralysis (AFP) in which wild polio virus was confirmed by means of isolation.</p> <p>Importation status</p> <p>Indigenous case is each case for which it cannot be proved that it was imported (laboratory confirmation based on type that is in circulation).</p> <p>Imported case is the case that has a source of infection outside the country (certain territories), the beginning of the disease is within 3 to 35 days from entering the country.</p> <p>For classification of AFP cases in the system of active surveillance, there are three options:</p> <ol style="list-style-type: none"> 1. rejected poliomyelitis 2. confirmed poliomyelitis 3. case compatible with polio (polio-compatible case points to
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		<p>failures in monitoring system to adequately handle the case of AFP and thus enable it to be classified, either as "confirmed" or "rejected" polio. Such cases should be monitored temporally and spatially).</p> <p>NB: These definitions are consistent with the recommended definitions in the WHO documents bearing in mind the stated objectives in the WHO European Region with regard to these diseases (reduction of the DRC, the elimination of illness and maintaining the status "polio free").</p> <p>Flu-like illness</p> <p>Disease in which there is a sudden occurrence of fever (above 38), followed by muscle and joint aching, dry cough and symptoms of the upper respiratory tract (according to Professional methodological guide for epidemiological surveillance of influenza in the 2010/2011 season in the Republic of Serbia)</p> <p>Definitions of nosocomial infections taken from the CDC, translated and printed as a manual issued by the Institute of Public Health of Serbia in 1998 (reprinted in 2009)</p> <p>2) Reflection on coherence between national and EU case definitions</p> <p>New legislation on the communicable disease that is in progress shall include definitions in line with the EU.</p>
8. Nature and type of data and information to be collected and transmitted in the field of epidemiological surveillance and	<p>Article 3 Decision 2119/98/EC</p> <p>Article 5 Decision 2002/253/EC</p>	1) Listing of data (nature and type) and information for collection and dissemination at

the ways in which such data are to be made comparable and compatible	Regulation (EC) 851/2004)	<p>national level</p> <p>Data on epidemiological surveillance over communicable diseases, their occurrence and movement in the territory of the Republic, are systematically compiled, analysed, and interpreted.</p> <p>2) Reflection on comparability and compatibility of epidemiological data at national and EU level</p> <p>Amendments necessary</p>
9. Epidemiological and microbiological surveillance methods	<p>Article 3 Decision 2119/98/EC</p> <p>Article 5 Decision 2002/253/EC</p> <p>Regulation (EC) 851/2004)</p>	<p>1) List of methods</p> <p>Routine collection of data on communicable diseases on the basis of reports of communicable diseases in accordance with the law; ALERT early warning system based on control of syndromes, sentinel surveillance, population monitoring, sentinel hospital SARI, early detection and monitoring of ARDS in the field of monitoring of diseases such as influenza (during the season), collection of data on possible threats to public health at the Centre for Communication of the Institute for Public Health of Serbia; zero coverage (AFP, measles and rubella syndrome)</p> <p>2) Reflection on coherence between national and EU methods</p> <p>For certain diseases epidemiological surveillance methods comply with the methods of the EU</p>
10. Guidelines on protective measures to be taken	Article 3 Decision 2119/98/EC	Not applicable.
11. Guidelines on information and guides to good practice for the public	<p>Article 3 Decision 2119/98/EC</p> <p>Regulation (EC) 851/2004)</p>	Not applicable.
12. Appropriate technical means and the procedures by which the data will be disseminated and analysed	<p>Article 3 Decision 2119/98/EC</p> <p>Article 4 Decision 2000/96/EC</p> <p>Annex III Decision 2000/96/EC</p>	<p>1) Listing of technical means and procedures for data dissemination and analysis at national level</p> <p>Regional departments/ institutes</p>

	Regulation (EC) 851/2004)	<p>submit data by regular mail, e-mail and by fax and telephone in the case of emergency reports;</p> <p>There are electronic databases with possibility of analysis of data collected from the surveillance of influenza. (Population and sentinel surveillance)</p> <p>2) Reflection on compatibility of reporting tools and procedures for data dissemination and analysis</p> <p>Harmonisation and amendments necessary</p>
<p>13. Notification of information regarding the appearance or resurgence of cases of communicable diseases at national level, together with information on control measures applied</p>	<p>Article 4 Decision 2119/98/EC</p> <p>Regulation (EC) 851/2004)</p>	<p>1) Acknowledge of notification/reporting requirements for such information at national level</p> <p>The report is, by the regional office, forwarded in accordance with the provisions of the Rulebook on reporting of communicable diseases and other cases established by law, while the National Institute after checking the validity and relevance of data informs the public; there are direct communication channels in the network of departments/institutes towards the National Institute (special mail address)</p> <p>2) Listing of communications mechanisms and notification tools available at national level</p> <p>Weekly reporting on the population and sentinel surveillance of flu-like diseases; weekly and monthly reports on the movement of communicable diseases; weekly report on potential threats to public health; are submitted to the network of departments/institutes and other relevant institutions</p> <p>The public is informed through web sites and the media (www.batut.org.rs)</p> <p>3) Reflection on compatibility between national and EU</p>

		<p>notification systems</p> <p>Alignment necessary</p>
14. Notification of information concerning the progression of epidemic situation	Article 4 Decision 2119/98/EC Regulation (EC) 851/2004)	Stated in question no. 13
15. Notification of information on unusual epidemic phenomena or new communicable diseases of unknown origin	Article 4 Decision 2119/98/EC (Regulation (EC) 851/2004)	Stated in question no. 13
16. Notification of information in country possession on all cases of communicable diseases and new communicable diseases of unknown origin in non-EU countries	Article 4 Decision 2119/98/EC (Regulation (EC) 851/2004)	Stated in question no. 13
17. Notification of information concerning existing and proposed mechanisms and procedures for the prevention and control of communicable diseases, in particular in emergency situation	Article 4 Decision 2119/98/EC (Regulation (EC) 851/2004)	Stated in question no. 13
18. Notification of considerations which would help in co-ordination at EU level of efforts for the prevention and control of communicable diseases, including any counter-measures implemented	Article 4 Decision 2119/98/EC (Regulation (EC) 851/2004)	Stated in question no. 13
19. Information communicated under points 14-18 is promptly forwarded	Article 5 Decision 2119/98/EC (Regulation (EC) 851/2004)	<p>Reflection on how to improve existing mechanisms and tools in place at national level and on compatibility with EU notification/ reporting systems</p> <p>This is regulated by the new Law on Communicable Diseases and by-laws.</p>
20. Procedures for information, consultations and co-ordination under early warning and response system (EWRS)	<p>Article 6 Decision 2119/98/EC</p> <p>Article 2 Decision 2000/57/EC</p> <p>Annex 1 Decision 2000/57/EC</p>	<p>1) Acknowledge on such procedures at national level</p> <p>Early detection of abnormal signaling events as a kind of surveillance of influenza (according to the Professional methodological guide for epidemiological surveillance of influenza in the 2010/2011 season in the Republic of Serbia)</p>

		<p>2) Reflection on compatibility of procedures in place at national and EU level</p> <p>Alignment necessary</p>
21. Categories of communicable diseases	Annex Decision 2119/98/EC	<p>Comparison of scope</p> <p>All diseases from the Annex are covered by the surveillance</p>
22. Events to be reported within the early warning and response system (EWRS)	<p>Article 1 Decision 2000/57/EC</p> <p>Annex 1 Decision 2000/57/EC</p> <p>(Regulation (EC) 851/2004)</p>	<p>1) Listing of types of events reported at national level</p> <p>Implementation of one type of influenza surveillance also through early detection of the signalling, unusual events</p> <p>Comparison of scope</p> <p>Alignment necessary for other diseases</p>
23. Collection and information exchange on events and measures adopted in response to those events or indications for such events, e.g. by using the national surveillance system	<p>Article 1 Decision 2000/57/EC</p> <p>(Regulation (EC) 851/2004)</p>	<p>1) Acknowledge of such collection and information exchange on events and measures at national level</p> <p>The data are collected and analysed at the level of the National Institute from where feedback information with recommendations is sent</p> <p>2) Listing of national early warning and response systems</p> <p>Co-ordinated by the Public Health Institute of Serbia</p> <p>3) Reflection on compatibility of national and EU early warning and response systems</p> <p>Alignment necessary</p>
24. Contract tracing	<p>Article 2a Decision 2000/57/EC</p> <p>Annex III Decision 2000/57/EC</p> <p>(Regulation (EC) 851/2004)</p>	<p>1) Acknowledge of contact tracing activities at national level and their reporting through national early warning and response systems</p> <p>2) Acknowledge of specific procedures concerning processing of personal data relating to contact tracing</p>

		<p>activities at national level</p> <p>3) Reflection on compatibility of procedures for processing of personal data at national and EU level</p>
25. Seasonal influenza vaccination	Council Recommendation 2009/1019/EU	<p>1) Listing of national actions plans</p> <p>Vaccination against seasonal influenza is conducted in accordance with the Rulebook on immunisation and methods of treatment with drugs (Official Gazette of RS 11/06). In the past five years, about 300,000 persons are vaccinated on the average (or about 4% of the population), of which about 55% are persons over 65 years of age. EU Council Recommendation 2009/2019 regarding the coverage of 75% of the population aged over 65 years of age as well as chronically ill persons between the ages of 6 months and the older will be considered by 2014-2015 when making the new Rulebook on immunisation, after which a national action plan for realisation of this objective should be passed (if it is accepted).</p> <p>2) Information on their implementation</p>
26. Prevention and control of healthcare associated infection (HCAI)	Council Recommendation 2009/151/01	<p>1) Listing of national strategies</p> <p>The National Strategy is regulated by the health care programme for the protection of the population from communicable diseases from 2002 to 2010 (item 12) Evaluation and adoption of a new Programme for the next ten years are underway. The programme envisages strengthening the role of the Commission for nosocomial infection, formation of teams of trained persons for surveillance of nosocomial infections. The number of persons is dependent on the number of beds in a health</p>

		<p>care institution.</p> <p>In June 2010 amendments to the Rulebook on indicators of health care quality came into effect, especially in the chapter relating to patient safety (particularly the part relating to nosocomial infections).</p> <p>A reference laboratory for determining the resistance of bacteria causing nosocomial infections was chosen;</p> <p>There are no recommendations for the rational use of antimicrobial substances and for the control of their use at the national level.</p> <p>2) Information on their implementation</p> <p>The information that are necessary in accordance with the Rulebook on the quality of health care services (part on the safety of patients) and referring to nosocomial infections, provide routine surveillance of nosocomial infections</p>
27. Prudent use of antimicrobial agents in human medicine	Council Recommendation 2002/77/EU	As in 26.

D. Safety and quality of blood, human tissues and cells, organ donation and transplantation

56. With reference to the following list of *acquis*, please answer to the questions below a) to b):

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
- Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

- **Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events**
- **Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments**
- **Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells**
- **Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells**
- **Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells**
- **Commission Directive 2010/45/EU of the European Parliament and the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation**
- **Commission Communication on an Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM (2008)819/3).**

Questions:

a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.

Based on the strategy and action plan entitled "Better Health for All in the Third Millennium", the Ministry of Health of the Republic of Serbia in February 2003 adopted a strategy, plan and programme for healthcare reform and improvement of health services in Serbia. The results of such activities are the new Law on Healthcare and the Law on Health Insurance from 2005, with accompanying regulations.

A particular progress and a step forward in adapting and harmonising Serbian legislation with high European standards, regulations, organisation and the functioning, through consistency, quality control and quality, was made in 2009 with the adoption of four laws in the field of biomedicine and transfusion activities:

- The Law on Organ Transplantation,
- The Law on Transplantation of Cells and Tissues,

- The Law on Infertility Treatment and Procedures of Biomedical In Vitro Fertilization (BMIF) and
- The Law on Blood Transfusion Activities.

The Law on Organ Transplantation regulates the formation of the Directorate for Biomedicine within the Ministry of Health, which began functioning with the appointments of first employees on 3 June 2010. Ahead of this directorate are important tasks and challenges in establishing a comprehensive and sustainable system of activities, improvement and development of transplant activity for the purpose of treatment, the performance of activities of public administration and the creation of institutional capacity and resources for implementation of the new laws in practice and establishing co-operation and connecting with related EU institutions.

The project entitled "Serbia-Transplant" is underway, within which there is a broad campaign to promote the organ donation and raise awareness of the population about the need for organ donation and the need of larger-scale donation of organs, cell tissues and blood.

Activities are underway to establish new systems of functioning of health institutions that perform activities in the areas of medicine and biology, providing information to health workers, education of explanation and transplantation teams and co-ordinators, the formation of human and physical and technical capacities as well as educating employees in the Department of Biomedicine.

Legislation in the field of biomedicine and transfusion created conditions for performing transplantation of organs, cells, and tissues, blood transfusion activities and biomedical assisted fertilization (BMIF) in the Republic of Serbia, in accordance with the latest standards and guidelines of medical science and practice and the regulations of the European Union.

Acquis, regulations and directives of the EU have been implemented in the following regulations:

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003, Council Directive 2004/33/EC, of 22 March 2004. .

Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council;

Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council;

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004,

Commission Directive 2006/17/EC, of 8 February 2006,

Commission Directive 2006/86/EC, of 24 October 2006,

Guide to safety and quality assurance for the transplantation of organs, tissues and cells, 1st, 2nd and 3rd edition and addendum 2002 to 2009.

Recommendations for the preparation, use and quality assurance of blood components, 12th edition, 2006, the Council of Europe;

Publications and recommendations of the WHO, etc.

b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.

We are working on implementation following by-laws - Rulebook on detailed conditions for the implementation of these laws. The deadline for their product is 18 months from the date of the Direction for Biomedicine (total by the end of 2011) The Rulebooks will include achievements of modern science and practice through standards, guidelines, protocols, guidelines of good practice, internal organization, implementation and quality control, freedom of choice and decision making, medical records and more.

c) In cases where neither of the above exists, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.

All documents listed above, and attached are some of them.

d) Does your country have the necessary administrative capacity, including human and material resources, to fulfill the requirements laid down in the EU legislation listed above?

At this point we do not fully have required capacities, but the preparations for providing the capacities are underway. By intensifying activities, particularly those relating to the development of administrative capacities and human resources, we expect the fulfilment of these conditions to the optimum in a relatively short period of time.

e) Does your country have the necessary administrative capacity, including human and material resources, to fulfill the requirements laid down in the EU legislation listed above?

The Law on Organ Transplantation regulates the formation of the Directorate for Biomedicine within the Ministry of Health, which began functioning with the appointments of first employees on 3 June 2010. Ahead of this directorate are important tasks and challenges in establishing a comprehensive and sustainable system of activities, improvement and development of transplant activity for the purpose of treatment, the performance of activities of public administration and the creation of institutional capacity and resources for implementation of the new laws in practice and establishing co-operation and connecting with related EU institutions.

The project entitled "Serbia-Transplant" is underway, within which there is a broad campaign to promote the organ donation and raise awareness of the population about the need for organ donation and the need of larger-scale donation of organs, cell tissues and blood.

Activities are underway to establish new systems of functioning of health institutions that perform activities in the areas of medicine and biology, providing information to health workers, education of explanation and transplantation teams and co-ordinators, the formation of human and physical and technical capacities as well as educating employees in the Directorate of Biomedicine.

Legislation in the field of biomedicine and transfusion created conditions for performing transplantation of organs, cells, and tissues, blood transfusion activities and biomedical assisted fertilization (BMIF) in the Republic of Serbia, in accordance with the latest standards and guidelines of medical science and practice and the regulations of the European Union.

Activities on drafting accompanying by-laws – Rulebooks regulating closer terms for implementation of these laws – are underway. The deadline for their drafting is 18 months

from the date of establishing the Directorate of Biomedicine (no later than by the end of 2011, but we expect to complete them earlier).

The rulebooks will incorporate all the achievements of modern science and practice through standards, guidelines, protocols, guidebooks of good practice, internal organisation, implementation and quality control, traceability, freedom of choice and the decision-making, medical records and other.

f) Regarding the Action Plan on Organ Donation and Transplantation, do you have in place or plan to put in place any of the priority actions proposed?

Action Plan on donation and organ transplantation (2009-2015): Strengthening co-operation between Member States at its core contains 10 priority actions grouped into three main objectives:

- Increasing the availability of organs
- Improving the efficiency and availability to the transplantation system
- Improving quality and safety

Legislation in the field of biomedicine and transfusion created conditions for performing transplantation of organs, cells, and tissues, blood transfusion activities and biomedical assisted fertilization (BMIF) in the Republic of Serbia, in accordance with the latest standards and guidelines of medical science and practice and the regulations of the European Union.

The Law on Organ Transplantation stipulates and regulates the following:

- systemic regulation of the area of organ transplantation, i.e., taking organ or organ parts from living or deceased person for transplantation into the body of another person for the purposes of treatment, organisation of health service for transplantation, surveillance over the implementation of this law and the performance of public administration in the field of organ transplantation, as well as other issues of importance to the organisation and implementation of transplantation of organs or organ parts;
- creating conditions for carrying out organ transplantation in accordance with modern standards of medical science and practice, given that transplantation is a field of medicine that is developing intensively and offering great opportunities for treatment of so far incurable disease;
- creating conditions for the promotion of organ transplantation at the national and European level with the aim of informing and educating citizens about the importance of organ donation;
- regulating the field of organ transplantation in accordance with the regulations and standards of the European Union in this field.

Also, the Law on Organ Transplantation is harmonised with the regulations of the European Union in this field, namely with:

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004,
- Commission Directive 2006/17/EC of 8 February 2006,
- Commission Directive 2006/86/EC of 24 October 2006,
- Convention on Human Rights in Biomedicine.
- Framework protocol for implementation of the Convention on Human Rights in Biomedicine.

The Law on Organ Transplantation provides the application of the highest European standards and achievements in practice, data confidentiality, integrity and dignity of donors and recipients, as well as regular and continual external institutional control and surveillance (through the Directorate of Biomedicine of the Ministry of Health and through regular inspection activities), as well as permanent (internal) individual responsibility and control of quality of professional performance and functioning of the transplantation activity – work organisation and implementation of the Guidelines for Quality and Safety in the transplantation of organs, cells and tissues of the Council of Europe.

Activities under the action plan aimed at establishing a high quality and safe system of transplantation which is in accordance with the norms and goals set by enacting the Law on Organ Transplantation, which is compliant with the mentioned regulations of the European Union, whose part is the Action Plan on donation and transplantation of organs (2009-2015).

One of the most important aims of the action plan is the appointment of co-ordinators for transplantation in healthcare institutions that perform transplanting activity, which was the priority task of the Directorate of Biomedicine immediately upon its formation. So, co-ordinators were appointed for organ transplantation in healthcare institutions where brain death is diagnosed and established and where explanation and organ transplantation are done. Continuing education of co-ordinators for organ transplantation is conducted by sending transplant co-ordinators to trainings in Barcelona, "Advanced International Training Course in Transplant Co-ordination", which is supported by the Transplant Committee of the Council of Europe, in order to acquire specific professional knowledge related to the donation and organ transplants.

Transplant co-ordinators in the Republic of Serbia have an important (crucial) role in the organisation of the Republic Programme of Transplantation. They have a very responsible role in the organisation, implementation and linking of the overall transplant activities, so the access to the most professional education programmes provided efficient and quality implementation of the Programme of Transplantation in the Republic of Serbia.

Promotion of voluntary organ donation represents continual exploring and providing information to citizens about the importance of transplantation, the possibilities and conditions for organ donation, so that citizens could decide during their lifetime whether to become organ donors and so that they could let their family members know they wish to be organ donors.

The Serbian President and the Minister of Health called on all citizens to support the national campaign "Extend Life" that was launched in October 2009, and whose aim is to create a larger network of voluntary organ donors.

Promotion of voluntary organ donation, through the national campaign "Extend Life" is directed towards the general public to develop a positive attitude about organ transplants as well as towards healthcare workers to get educated and prepared for activities regulated by the law. The campaign is carried out continuously in all cities across Serbia.

The adoption and implementation of the Law on Organ Transplantation created conditions for the promotion of organ donating and raising citizens' awareness about the importance of transplantation, so as to increase the availability of organ transplants to those in need, to make

health services performing complex procedures of transplantation more efficient and accessible, which will increase the number of transplants and improve the quality and safety of healthcare in accordance with modern standards.

57. How are tissues and cells for reproductive use regulated in Serbia? Are there plans to transpose the *aquis* on quality and safety regarding these tissues and cells?

In the introductory part of the law stipulating general principles, ethical principles and safety, among other principles, the Article 6 stipulates that “transplantation procedure is performed in a manner which secures that the interests and welfare of individual predominate interests of society and science and which guaranties respect of dignity and interests of individual and his rights laid down by law, without discrimination”.

The personal integrity of donor and recipient and confidentiality of all data from medical records are guaranteed by numerous articles of the law and are incorporated as basic and the most important rule and right to complete law, to all segments of procedure of tissues and cells transplantation, from the beginning to the end.

All provisions of all segments of the Law are unambiguous, comprehensible and concise and specifically define what is allowed and what is “forbidden”.

The Articles 26 to 30 lay down certain unambiguously forbidden activities: Prohibition of announcement, i.e. advertisement of needs, namely offering of cells or tissues, prohibition of cell and tissues trade, prohibition of exchanging of cells, namely tissues (Article 29.) contrary to international agreement which secures the highest medical professional standards, safety, quality and prevention of transmitting of communicable diseases, while the approval for each particular case is issued by the minister against proposal of the Biomedicine Directorate and prohibition of (pursuant to the Article 30) use of cells and tissues in production of or making of cosmetics.

Exact provisions of the Law regarding freedom of choice, safety of procedure, risk assessment and confidentiality of data are equally unambiguous, and protection of personal integrity of donor and recipient of cells, namely tissues is secured by definition of these preconditions.

Article 24 stipulates obligation of the Biomedicine Directorate to keep Unique register on the level of Republic of cell, namely tissue donors, manner and procedure of keeping of records in the Register, data to be entered, manner of entering donors, keeping and protection of data, procedure of access to data and manner and procedure of providing and keeping of password for obtaining an approval for use of recorded data.

Article 25 stipulates availability of data of Unique register of donors (of cells and tissues) and clause 1 of the Article lays down that "data of Unique register of donors of the Republic are available only to persons authorized to request and obtain approval to use data recorded in the Register" and clause 3 of the same Article specifies that the Ministry can use only statistical data of the Unique register of donors.

Article 38 stipulates that “information on donor and recipient of cells, namely tissues are official secret to be kept as confidential by all individuals participating in transplantation procedure and individuals who have access to the information.

Article 39 prohibits distribution and use of data, and in clause 1 specifies that donating of cells, namely tissues is anonymous; clause 2 specifies that it is “forbidden” to give information on recipient to donor, namely his family, and vice versa. Clause 4 “forbids” officials participating in transplantation procedure to “give personal information about donor or recipient and information about individuals informed about intended or possible transplantation”. Clauses 5 and 6 lay down that “all personal information about donor and recipient, including data about genetics available to third parties, must be anonymous so that it is impossible to identify donor and recipient” and “for the purpose of protection of data, all participants of transplantation procedure are obligated to take measures of personal information protection and measures for protection against unauthorized obtaining of data, deleting or changing of data in the data base.

Article 41, 42 and 43 of the Law stipulate manner, procedure and data on donor, namely recipient to be collected, processed, recorded and used and medical records, period of keeping of records and protection of data on donor, namely recipient, while the Article 44 lays down “prohibition of use and taking out of personal information of donor, namely recipient”.

Article 49 of the Law lays down: “It is prohibited to take cells and tissues from living donor if there is a risk for life and health of the donor... , i.e. if the risk for living donor health is not proportional to expected benefits for recipient”.

Article 59 of the Law defines prohibition of taking of tissues in the case of brain death of individual who is not agreeable to it, pursuant to the written statement form.

The formed Biomedicine Directorate started its work upon appointment of its first employees on 3 June 2010 and it works on implementation of new laws in the field of biomedicine in practice, performs certain state administration tasks and raises institutional capacities and resources for application of new laws in practice.

At the same time, and maybe the most important, the Biomedicine Directorate performs regular and continual control and surveillance of organization and functioning of healthcare institutions engaged in the field of transplantation of cells and tissues, organs, transfusion activity and BMIF (Biomedical In Vitro Fertilization)- in the sense of compliance to requirements regarding staff, premises, equipment, keeping of medicine records and everything in relation to implementation of new legislative solutions.

Articles 9 to 13 of the Law lay down conditions for issuing, renewal or suspension of licence for transplantation activities and Articles 67 to 74 conditions regarding establishment and work of cell banks, namely tissue banks. Compliance with requirements is controlled by the Biomedicine Directorate pursuant to inspection surveillance of the Directorate and proposal of the director of Biomedicine Directorate - the Minister issues, renews or suspends license for transplantation activities of institutions. In that way, regular institutional control and surveillance of the activities is performed in authorized healthcare institutions. Internal expert control and surveillance are established in healthcare institutions by forming teams for transplantation activities (Article 9 of the Law), appointment of coordinator in each healthcare institution (Article 14. to 16), and through activities of Ethics Board in each healthcare institution (Article 17. of the Law). Besides, each bank of cell and tissue shall have Responsible person for quality management system (Article 76 of the Law).

In this way, regular and continual external institutional control and surveillance have been established (through Biomedicine Directorate of the Ministry of Health with its inspection) and regular (internal) individual responsibility and quality control of expert work and functioning of the transplantation activities system through its work organization.

Articles 98 to 100 define criminal responsibility, while Articles 101 to 103 define responsibility for offence of the individuals engaged in this activity, with severe sanctions for not complying with or violating this Law, and the sanctions are essential system for securing personal responsibility of employees and application of the law.

We consider personal integrity of donor and recipient and confidentiality of all data from medical records to be sufficiently guaranteed by numerous articles of the Law and incorporated as basic and the most important rule and right to complete law, to all segments of procedure of tissues and cells transplantation, from the beginning to the end.

E. Mental health, socio-economic determinants of health, health inequalities, drug abuse prevention, healthy lifestyle, nutrition, eHealth, alcohol abuse prevention, cancer screenings, and healthy environment including prevention of injury, promotion of safety and European action in the field of rare diseases

58. With reference to the following list of EU Council Recommendations, Council Resolutions and Council Conclusions in the filed of public health, please answer to the questions below a) to b):

Mental health

-2009/86/01/EC: Council Resolution of 18 November 1999 on the promotion of mental health

-Con. 02/6/01/EC: Council Conclusions of 15 November 2001 on combating stress and depression- related problems

-Con. 03/9688/1/EC: Council Conclusions of 2 June 2003 on combating stigma and discrimination in relation to mental illness

-Con. 05/9805/1/EC: Council Conclusions of 3 June 2005 on a Community Mental Health Action

- European Pact on Mental Health and Well-being, High Level Conference June 2008

- EU-Compass for Action on Mental Health and Well being: EU Member States Policy documents, recommendations and declarations; database of policies and good actions; reports and studies; implementation

When it comes to health policy of the Republic of Serbia, the following strategies were adopted that, among other things, provide a framework for activities in the field of mental healthcare, such as: Strategy of Development of Youth Healthcare from 2006, that is focused on addiction, Sustainable Development Strategy of the Republic of Serbia from 2008 and the Public Health Strategy from 2009. The product of several years of efforts to develop a comprehensive strategic document in the field of preservation and improvement of mental health was a Strategy of development of mental healthcare with an action plan. Sustainable Development Strategy of the Republic of Serbia sets preservation and promotion of mental health as a priority for public health through:

1. Development of legislation in the field of mental health and compliance with international standards,
2. Adoption and implementation of national strategies in the field of mental health,
3. Prevention of mental disorders (depression) and the promotion of mental health,
4. Improving services, human resources and education (prevention, development of mental health services at the local level, shortening hospital stay, development of day hospitals and outpatient treatment),
5. Raising the level of services and adoption of standards (good clinical practice, the criteria of accreditation, supervision and monitoring, etc.),
6. Development of intersectoral co-operation in the fields of relevant ministries (health, labour and social affairs, education, justice),
7. Public information and education.

The Government of the Republic of Serbia in January 2007 adopted the Strategy of development of mental healthcare with an action plan (hereinafter referred to as the national strategy). The national strategy was developed within the project of the Stability Pact for South Eastern Europe, “Enhancing social cohesion through strengthening community mental health services”, as an initiative to reform the mental healthcare in the region of South Eastern Europe, and because of serious and complex problems in this area, especially in the countries in transition. It is the product of work of experts of the National Commission for Mental Health, established in January 2003 by the Ministry of Health.

Identified areas of activity of the national strategy are as follows:

1. Law and human rights,
2. Organisation of services,
3. Prevention of mental disorders and the promotion of mental health,
4. Human resources, education and research,
5. Improving quality,
6. Information systems,
7. Intersectoral co-operation (partnership for mental health),
8. Representation and public advocacy.

Several projects in this area, financed by international funds, were launched. They are as follows:

1. Enhancing social cohesion through strengthening community mental health services (South-Eastern European Health Network, implemented in the period from 2002 to 2008),
2. The development of regional model of integrated services for mental health and social cohesion (MATRA Office – the Ministry of Foreign Affairs of the Kingdom of the Netherlands, the implementation is planned for the period from 2007 to 2010),
3. Promotion of mental health in the Republic of Serbia (EU IPA fund, Caritas Italiana, Caritas Serbia and Montenegro, implemented in the period from 2008 to 2010),

Mental Health Project for South Eastern Europe, “Enhancing social cohesion through strengthening of mental health in the community in South Eastern Europe” is part of broader efforts of South Eastern Europe to approach to the European Union. The initiative was launched in 1999 when the Stability Pact for South Eastern Europe was established, with the aim of strengthening social stability in the region by encouraging peace, democracy, human rights and economic prosperity. In 2001, the Stability Pact for South Eastern Europe as part of its initiatives related to social cohesion introduced health in its agenda, as one of five priority

areas. In September of the same year, the WHO Regional Office for Europe and the Council of Europe established Health Network of South Eastern Europe (hereinafter referred to as the Health Network). The aim of the Health Network was to improve public health in South Eastern Europe.

The signing of the Dubrovnik Declaration, in September 2001, at the Ministerial Conference for South Eastern Europe, whose emphasis was on improving the health of vulnerable groups in the region, created conditions for the implementation of projects to address these issues. The formal decision to start the Project of Mental Health in South Eastern Europe was made in Denmark in May 2002.

Health Network is currently made up of the following countries: Albania, Bosnia and Herzegovina, Croatia, Bulgaria, Moldova, Romania, Serbia, Montenegro and Macedonia. Bosnia and Herzegovina is the leader of this project in the region. The main objective of the project was to set up services for mental healthcare in the community in the centre of the mental healthcare system.

Characteristics of the mental health of citizens of the Republic of Serbia

The mental health of the population of the Republic of Serbia is characterised by an increased morbidity and mortality from mental health disorders and behavioural problems related to stress, as a result of events which the population was exposed to in the last decade of the twentieth century (the wars in the region; hyperinflation in 1993; sanctions imposed by the United Nations that lasted three and a half years, the NATO bombing in 1999, that lasted 11 weeks; social transition, financial crises and high unemployment rates). According to the data from the Institute of Public Health of the Republic of Serbia, the prevalence of mental and behavioural disorders increased by 13% from 1999 to 2002.

Disorders related to stress are not the only consequence of past years. Other disorders are also on the rise: depression, the number of suicides, disorders due to psychoactive substance abuse, psychosomatic disorders; delinquency and violence are on the extreme rise, especially among young people. According to the results of the survey "Burden of Disease and Injury in Serbia", ischemic heart disease, cerebrovascular disease, lung cancer, unipolar depression and diabetes accounted for almost two-thirds of the total burden observed for 18 health disorders in Serbia in 2000.

In Serbia there are 5 large psychiatric hospitals (in Gornja Toponica, Novi Knezevac, Vršac, Kovin and in Belgrade "Dr. Laza Lazarević"). In addition, there are 46 psychiatric departments in general hospitals as well as outpatient services in 71 municipal health centres. There are about 6,000 beds, of which 3,000 are the so-called bad beds because they are located in large hospitals. The average treatment duration is 31 days (in Belgrade) and 153 days in special psychiatric hospitals. In Serbia there are 947 psychiatrists, of whom 336 are working in Belgrade. This number is quite sufficient, but it should be noted that many of them work as neurologists, especially in the provincial areas.

Health inequalities

-Res. 00/C218/3/EC Council Resolution of 29 June 2000 on action on health determinants

-2003/488/EC: Council Recommendation of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence

-Notice 2008/C 326/09: EU Drugs Action Plan for 2009-2012

One of the priorities of healthcare development in Serbia is to reduce health inequalities. The aim of health policy is to influence that differences in healthcare are not deepened, but to reduce them through target and active measures of redistribution of healthcare goods and resources to the vulnerable parts of society.

In order to accomplish this goal, the Government of the Republic of Serbia through the Ministry of Health provided, through a process of reform of the Serbian health system, equal access to healthcare for all citizens regardless of their gender, age (children and the elderly being the vulnerable groups are protected in the area of promotion and preservation of health through a great number of documents that are based on the Law on Healthcare and the Law on Health Insurance).

This process is directed, primarily in the following way:

- The development of the financial stability of the health system, with equal access to healthcare services,
- Enhancing the quality of healthcare services and reducing inequalities in access to health care,
- Activities aimed at removing concrete barriers to the access to healthcare services such as waiting time, the burden of costs for medication and treatment, as well as administrative difficulties to getting access to healthcare services, and of course, by removing physical barriers to this access.

Drug abuse prevention and harm reduction

In the procedure of obtaining marketing authorisation, based on the data from the documentation, expert assessment and advisory role of the Commission for Medicines, the Agency for Medicines and Medical Devices classifies medicines in order to determine the relevant rules for issuing approval for marketing authorisation of a medicine (registration of medicines).

Medicines that have low toxicity, high therapeutic range, safety in overdose, minimal interaction, whose indications are well-known to the patient-user and are used for self-treatment, are given in pharmacies without a prescription.

Medicines containing narcotic drugs or psychotropic substances, in accordance with international conventions in this field, are dispensed in accordance with the specific regime of issuing regulated in the authorisation for the placing of those medicines on the market.

Medicines may not be dispensed or sold out contrary to the conditions set out in their marketing licence.

Also, the Agency provides information and education about medicines and provides information relevant to taking measures for rational use of drugs, thereby contributing to reduction of their abuse.

The law clearly defines the obligations of health workers, on the one hand, and representatives of the pharmaceutical industry, on the other, when it comes to informing on the expressed adverse reactions after the use of medicines. The information on safety of medicine use are the basis for the Agency to take regulatory measures in order to preserve public health.

The Law on Medicines and rulebooks regulating this area are harmonised with the following regulations:

- 2003/488/EC: Council Recommendation of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence
- Notice 2008/C 326/09: EU Drugs Action Plan for 2009-2012

Healthy lifestyle

-Con. 04/C221/EC: Council Conclusions of 2 December 2003 on healthy lifestyles: education, information and communication

The following activities are in place with specific reference to health promotion and disease prevention:

- developing, participating in and monitoring the implementation of interventional health promotion community such as:
 - health promotion programs in primary healthcare institutions;
 - health promotion programs in polyvalent patronage service;
- developing, implementation, coordination, monitoring and evaluation of health promotion programs, including national campaigns, in view of acquiring knowledge and attitudes in relation to healthy life style and reducing risk factors for infectious and non-infectious diseases;
- Developing, coordination and building on partnerships between governmental, private and civil sector for resolving public health community issues;
- implementation of education and vocational training of health professionals and associates in the sphere of health education;
- development and implementation of the program for the health promotion of special and vulnerable population groups (children, pregnant women, nursing mothers, aged persons, marginalized groups), such as:
 - the program for health promotion of elementary school children
 - the program for health promotion of high school children
 - the program for oral health preservation and promotion of children and youth of the Republic of Serbia
 - health educational program in pre-school institutions "Healthy Kindergarten".
- health information of the Serbian population through a continuous work with the media;
- implementation of the program for the protection of population from infectious diseases for the part of health education.

In the sphere of prevention and control of infectious diseases, the activities include organization, implementation and control of epidemiological surveillance over infectious diseases, surveillance over hospital infections.

The immunization program includes:

- surveillance over mandatory active immunization of persons of a particular age,

- mandatory immunization of persons exposed to particular infectious diseases,
- active immunization based on clinical indications,
- and active immunization of passengers in international traffic by the application of measures prescribed by the law with the purpose of protecting the population from infectious diseases, their prevention, suppression, removal and extermination.

The activities implemented in the sphere of prevention and control of leading chronic non-infectious diseases includes:

- the assessment of the prevailing risk factors responsible for the incidence of the leading chronic non-infectious diseases (CND) on the basis of the results of population, targeted and other researches.
- the activities prescribed under the action plan of the National Strategy for CND Prevention and Control are currently in place. Based on the conducted research it is possible to identify the risk population groups for the intervention regarding the promotion of healthy life styles.

The program activities in the sphere of prevention and control of the leading CND have been regulated in more detail:

- by the National program “Serbia Against Cancer” whose integral parts are the National program for the prevention of colorectal cancer, National program for the prevention of breast cancer and the National program for the prevention of cervical cancer;
- by the National program for the prevention and control of cardio-vascular diseases in the Republic of Serbia by 2020 – “Serbia for a Healthy Heart”;

These programs have been financed from the budget of the Ministry of Health, and the funds are providing by collection of excise duties on tobacco products.

The Rulebook on the contents and scope of healthcare rights under mandatory health insurance coverage and on co-payment for 2010, clearly defines the prevention activities in accordance with the national programs.

The first systematic medical examination has been envisaged for persons between 19 and 35 years of age and it includes a general clinical examination and systematic examination, basic laboratory analyses and other examinations depending on the present risk factors. A systematic examination for persons aged 35 and over has been envisaged to take place every second year, with additional examinations as appropriate, while the tests for the presence of faecal occult blood, digital rectal examination (DRE) and prostate examination by palpation have been envisaged to take place once a year for persons aged 50 and over. Colonoscopy of high risk patients has been envisaged to take place once in three years.

The first preventive gynaecological examination has been envisaged for women aged 15 and over, the re-examination once in three years, with breasts examination by palpation once in 5 years. Women aged 25-69 should undergo the annual targeted examination in view of early detection of cervical and breast cancer, while women aged between 30-69 are given recommendations and instructions for self-examination of breasts. Women aged 40 and over should undergo the annual clinical examination of breasts, while women aged between 45-69 should undergo mammographic examination once in two years.

Obesity: nutrition

-Con. 05/9803/EC: Council Conclusions of 3 June 2005 on obesity, nutrition and physical activity

As part of efforts to reduce the number of patients with chronic non-communicable diseases, tasks related to nutrition and physical activity in preventing chronic disease were performed.

The conclusions of experts on obesity, education about proper nutrition and physical activity with special attention are applied in the healthcare of vulnerable categories of population (infants, preschool and school children, adolescents and older age groups).

There are specialist services and counselling for healthy nutrition within healthcare institutions aimed at promoting healthy nutrition and physical activity as well as for treating obesity as a risk factor for the occurrence of chronic non-communicable diseases.

eHealth

-(December 2009) Council Conclusions on “Safe and efficient healthcare through eHealth”, on how best to introduce and make use of information and communication technology to improve healthcare, aiming at moving from theoretical experience exchange to concrete cross-border cooperation and creating a structure for cooperation that can gather and pass on the outcomes of all ongoing initiatives and projects in the area of eHealth.

-(July 2008) Commission Recommendation on cross-border interoperability of electronic health record system (lead by Directorate General Information Society), aiming to create a means whereby authorised health professionals can gain managed access to essential health information about patients (in respect of the fundamental right to the protection of personal data)

-(November 2008) Joint Communication on Telemedicine from Commissioners Reding and Vassiliou. The Joint Communication has launched a 4-year undertaking, aiming to facilitate patient access to secure and high quality healthcare, even in remote areas, through telemedicine services. The Communication focuses on telemonitoring for patients experiencing chronic diseases, in particular elderly people, and teleradiology bringing solutions to staff shortages. It highlights the need to provide evidence of impact, to engage health professionals and patients, to create legal certainty at EU and national levels, and to solve remaining technical problems.

-(May 2007) 409 standardisation mandate to the European Standardisation bodies (CEN, CENELEC and ETSI) in the field of Information and Communication Technologies, aiming at listing, agree on and recommend on existing standards relevant to eHealth.

The Strategy for Development of Information Society in the Republic of Serbia (Official Gazette of RS, No. 87/06) sets eHealth as one of the priorities and regulates the use of ICT to enable change in the healthcare system to improve public health, protection of health system users, reduce costs, save money and time and provide information for technical, scientific, administrative, accounting and management use.

Development of information technologies in the area of healthcare is defined by the strategic documents adopted in 2009:

Programme of work, development and organisation of Integrated Healthcare Information System- eHealth (Official Gazette, 55/09)

Rulebook on Detailed Contents of Technological and Functional Requirements for Implementation of Integrated Healthcare Information System- eHealth (Official Gazette, November 2009) (eHealth)

The Government of the Republic of Serbia, at the proposal of the Ministry of Health, adopted a Regulation on the programme of work, the development and organisation of integrated health information system “e-Health” (Official Gazette of RS, No. 55/09). This Regulation is the basis for defining priorities of the "Application of ICT in the healthcare system" which is an integral part of the Proposed Strategy for Information Society Development in the Republic of Serbia until 2020. The main role of information and communication technologies in the healthcare system is to support the execution of healthcare system activities, and to provide support to reform the healthcare system. It is expected that the Government of the Republic of Serbia will adopt the Proposed strategy by the end of the second quarter of 2010.

Implementation of the Programme of work, development and organisation of Integrated Healthcare Information System – eHealth (Action Plan covers activities until 2015) is currently being implemented through three major IT projects of the Ministry of Health financed by international institutions (IPA fund and World Bank's loans). The expected results of these projects are:

- Introduction of information technologies to complete primary healthcare (introduction of ICT to 157 healthcare centres and connecting 1,886 outpatient departments with main buildings of healthcare centres);
- Introduction of hospital information system in 30 stationary healthcare institutions;
- Networking of all healthcare institutions, of public sector, to common information communication network
- Continuation of work on regulations regarding this area (Rulebooks which should comply with the new Law on Healthcare Records, that is expected to be adopted in 2010 and further improvement and approximation of the Rulebook on Detailed Contents of Technological and Functional Requirements for Implementation of Integrated Healthcare Informational System with the mentioned law and EU regulations).

The economic crisis has deeply affected this area as well. Reduction of the budget of the Republic and budget of local self-governments, intended for the healthcare sector, has resulted in insufficient financial resources for implementation of the Action Plan until 2015.

Alcohol abuse prevention

-Con. (2009/C 302/07): Council Conclusions on Alcohol and health, 1 December 2009

-Con. 16165/06: Council Conclusions on EU strategy to reduce alcohol-related harm, 30 November- 1 December 2006

-COM(2006) 265 final: Communication from the Commission of 24 October 2006: An EU Strategy to support Member States in reducing alcohol related harm

-Rec. 01/458/EC: Council Recommendation of June 5 2001 on the drinking of alcohol by young people, in particular children and adolescents

-Con. 01/C175/EC: Council Conclusions of 5 June 2001 on a Community strategy to reduce alcohol-related harm

The use of alcohol is a risk factor for the occurrence of mental disorders, liver cirrhosis, hypertension, stroke, certain forms of cancers, and all kinds of injuries, especially those that occurred in traffic, while in pregnancy the use of alcohol may lead to the birth of children with fetal alcohol syndrome.

There are numerous legislative, regulatory or administrative provisions in force in the Republic of Serbia related to the drinking/consumption of alcohol and various measures aimed at reduction of health-related harm associated with alcohol abuse. However, these legislative and implementing acts are not systematised according to the areas, therefore it is very hard to summarise them.

Some of examples of the legislative and implementing acts that in some part cover these areas are:

1. Healthcare protection

- The Law on Public Health
- The Plan of Healthcare Covered by Mandatory Health Insurance in the Republic of Serbia for 2010

- The Regulation on Integrated Preventive Healthcare of Population from NCD

2. Education

- The Rulebook amending the Rulebook on Curriculum of Elementary Education, the Rulebook on School Excursions for Primary School Students (ban on smoking, consumption of alcohol and psychoactive substances for all participants of the school excursion)

3. Legislative acts in the area of labour and employment

- The Code of business ethics (ban on consumption of narcotics and alcohol during work and job-related performance)
- The Rulebook on Safety at Work
- Public enterprise collective agreements also contain provisions on the use of alcohol during job-related tasks performance, which is penalised by dismissal from work

4. The Criminal Code

5. The Law on Public Order and Peace

6. National strategies

- The National Youth Strategy
- The National Strategy for the Advancement of Women and the Promotion of Gender Equality
- The National Strategy for Prevention and Protection of Children against Violence
- The National Strategy for Development of Social Welfare
- The National Strategy for Development of Sport
- The National Strategy for Mental Health Protection Development
- The National Strategy for Youth Health Development
- The National Strategy for Combating Drug Abuse
- The National Strategy for Promoting the Position of the Roma
- The National Strategy for the Prevention and Control of NCD
- The Public Health Strategy

7. Rulebooks related to the area of trade and production

- The Rulebook on Labelling of Tobacco and Alcoholic Beverages and Excise Duties
 - Registry of Producers
8. Rulebooks related to traffic
 - The Law on Road Traffic Safety
 - The Law on Rail Traffic Safety
 9. Law on Donations and Humanitarian Aid
 10. Tax regulations are especially applied to this sort of goods
 12. A strategy related to alcohol is being prepared (Prevention of excessive alcohol abuse)

Abuse of Drugs

There are legal, regulatory and administrative documents in our country that relate to the abuse of drugs. Some of those documents were made and adopted by the Government in 2009, some were approved in 2010, but all of them are being implemented at this moment. Some documents were accompanied by assessment procedure (e.g. the National Strategy for Combating Drug Abuse). These documents are the documents of the Government, constructed in co-operation with experts and all stakeholders from Serbia, and they all comply with the needs and obligations of the Republic of Serbia during pre-accession phase on its road towards the European Union.

Strategic documents related to the promotion of mental health and prevention and rehabilitation of drug addicts are:

1. The National Strategy for Combating Drug Abuse in the Republic of Serbia (adopted in February 2009)
2. The Action Plan for implementation of the National Strategy for Combating Drug Abuse (adopted in February for the period 2009 to 2013)
3. The Law on Public Health – the Law was adopted by the Government in 2010 and this Law covers various area and activities aimed at promoting mental health and public health in Serbia.
4. The Draft Law on Psychoactive Substances is in the final phase of approval procedure at this moment.
5. The Criminal Code (Official Gazette of the Republic of Serbia, No. 85/05).

With regard to prevention, treatment and rehabilitation of drug abusers, the making of a Law on Prevention, Treatment and Rehabilitation of drug abusers is planned for 2010. This Law will be made with the support of the above-mentioned project (INSADA) financed by the EU, and EU experts will be engaged in order to obtain a Law on Prevention that will cover the reducing of damage, treatment and rehabilitation of drug abusers. The law is expected to be finalised by the end of 2010.

Human resources are not an issue. There is a need for additional training of employees already working in this field, pursuant to European guidelines and suggestions related to the good practice in the area of mental health and addiction.

International relations in this area are very important and will be defined as a priority in the upcoming years. The exchange of experience and knowledge is a key for improvement of the practice related to drugs in Serbia.

The management system structure in the field of drugs will be set up as defined by the National Strategy. The Law on Psychoactive Substances defines main structures of the office

or some drug unit laid down by the Ministry of Health that will be founded for better quality of management of prevention, treatment and rehabilitation of drug abusers in the Republic of Serbia.

The multidisciplinary approach and international co-operation are key preconditions for achievement of majority of objectives defined by the Strategy for Combating Drug Abuse, that was adopted in 2009.

Financial resources are highly required and there are no available resources for this issue due to restricted budget for 2010 in Serbia. For instance, the budget fund is insufficient for application of majority of modern techniques in the field of prevention, treatment and reduction of drug-related harm.

The current financial crisis has, of course, influenced this field of activity as well. At this point there is a project funded by the EU, which has supported a lot of networking procedures, which is very important. There is still a need for donations and grants. The Ministry of Health will keep working on making project proposals based on current needs in this area that will be financed in the near future. Furthermore, we will implement co-operation with countries of the region and with EU countries to the maximum extent possible, as the exchange of any knowledge and experience is very important for promotion of this field in the Republic of Serbia.

Cancer

-Rec. 03/878/EC: Council Recommendation of 2 December 2003 on cancer screening

-COM(2008) 882: Implementation of the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

-Con. 10/06/2008: Council Conclusions on reducing the burden of cancer
(http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSC_O-cancer.pdf)

-COM(2009) Communication from the Commission the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Action against Cancer European Partnership

-Con. 13/09/2010: Council Conclusions on action against cancer

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The Ministry of Health through a Decision of 6 August 2010 formed an Advisory Board for the implementation of programme for early detection and screening for breast, cervical and colon cancers.

The tasks of this Advisory Board shall be to:

- propose a model of organisation, monitor and control the implementation of national screening programmes;
- provide co-ordination and technical support to institutes of public health involved in the organisation of the implementation of local screening programmes;
- monitor and control the national database for screening;

- organise the collection of data on existing human, material and infrastructure capacities and prepare reports with recommendations for the development and the funding of screening programmes;
- establish an institutional basis for quality assurance, monitoring the implementation of screening programmes, as well as monitoring and evaluation of healthcare service providers involved in the programme;
- plan and implement activities in accordance with national and international standards.

The legal framework and existing strategic documents

The most important adopted legal documents relating to the implementation of programmes for early detection and screening for breast, cervical and colon cancers are:

- The National Programme “Serbia Against Cancer” (Official Gazette of RS, No. 107/05, 55/05, 71/05-correction, 101/07 and 65/08);
- The National Programme for the Prevention of Cervical Cancer (Official Gazette of RS, No. 54/08);
- The National Programme for the Prevention of Breast Cancer (Official Gazette of RS, No. 15/09);
- The National Programme for the Prevention of Colorectal Cancer (Official Gazette of RS, No. 107/05, 55/05, 71/05 – correction, 101/07 and 65/08);
- The Strategy for the Prevention and Control of Chronic Non-Communicable Diseases (Official Gazette of RS, No. 55/05, 71/05 – correction, 101/07 and 65/08)
- The Public Health Strategy in the Republic of Serbia (Official Gazette of RS, No. 55/05, 71/05 – correction, 101/07 and 65/08)
- The Strategy for Continuous Promotion of Quality of Healthcare and Safety of Patients (Official Gazette of RS, No. 55/05, 75/05 – correction, 101/07 and 65/08)
- The Strategy for Palliative Care (Official Gazette of RS, No. 55/05, 71/05 – correction, 101/07 and 65/08)
- The Tobacco Control Strategy (Official Gazette of RS, No. 55/05 and 71/05 - correction).
- The Law on Healthcare Protection (Official Gazette of RS, No. 107/05);
- The Law on Health Insurance (Official Gazette of RS, No. 107/05, 109/05 – correction);

The programme "Serbia Against Cancer" is an integrated, comprehensive, co-ordinated and sustained action of society, aimed at the preventable risk factors and socio-economic determinants of health, with the active involvement and responsibility of all sectors of society to improve and strengthen the healthcare system with a view of providing better prevention and control of malignant diseases.

The objectives of the "Serbia Against Cancer" programme, in the course of next five years, by using the existing resources in the best possible way, are to:

- improve the health of the nation,
- prevent the occurrence of malignant diseases (especially in patients at higher risk for their occurrence),
- reduce the number of new cases and deaths from malignant diseases,
- improve early detection of cancer,

- improve the diagnosis and treatment of malignant diseases, prolong life of cancer patients,
- provide patients with malignant diseases an appropriate standard of service at all levels
- of healthcare protection,
- improve the quality of life of cancer patients and their families and
- improve scientific research in oncology.

The principles of quality are based on the following:

- Guidebook “European guidelines for quality assurance in cervical cancer screening, 2nd edition, 2008” (International Agency for Research on Cancer)
- Guidebook “European guidelines for quality assurance in breast cancer screening and diagnosis, 4th edition, 2006,” (European Breast Cancer Network Co-ordination Office, International Agency for Research on Cancer) and “Guidelines on the standards for the training of specialised health professionals dealing with breast cancer” (European Society of Mastology (EUSOMA), European Journal of Cancer, 43, (2007) 660 – 675.

Since the adoption of national programmes, funds aimed at financing projects related to cancer prevention programmes are planned in the budget of the Ministry of Health. In the course of 2010, over fifty projects whose main goal is prevention and improving the treatment of malignant diseases were financed from the budget of the Ministry of Health. Over twenty training programmes for doctors were approved in the country and abroad for introducing new methods of treatment of malignant diseases. To begin implementation of national screening programmes for breast, colon and cervix cancers, additional conditions will be created during the year for the procurement of mammographs, colonoscopes and other supporting equipment for the centres where these programmes are to be implemented (the funds were provided from donations to the Government of Japan and the IPA pre-accession funds of the European Union).

Prevention against electromagnetic fields

-Rec. 99/519/EC: Rec. 99/519/EC: Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)

Prevention of injury and promotion of safety

-Rec. 01/C164: Council Recommendation of 31 May 2007 on the prevention of injury and the promotion of safety

In accordance with sectorial laws such as Law on health care, Law on labour and Law on emergencies, there are strictly defined measures for safety protection of public, personal and safety at work. Safety at home is not specially regulated, but there are regulations concerning constructor works, and position of devices at home as well. There are also legislation dealing with safety in public traffic. We need to emphasize that all safety issues are multisectorial, and under jurisdiction of Ministry of Labour and Social Affairs, Ministry of Internal Affairs, Ministry of Health, Ministry of Environment and Spatial Planning, etc.

Patient safety

- Council Recommendation of 15 November 2001 on prudent use of anti-microbial agents in human medicine

-Rec. 2009/C 151/07: Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of health care associated infections

The Ministry of Health developed a Strategy for continuous promotion of quality of healthcare and safety of patients (Official Gazette of RS, no. 55/05, 75/05 – correction, 101/07 and 65/08)

The strategic objectives are to reduce:

- Uneven quality of healthcare services;
- Unacceptable levels of variation in health outcomes of treated patients;
- Inefficient use of health technologies;
- Waiting time for medical procedures and interventions;
- Dissatisfaction of users with offered health services;
- Dissatisfaction of employees in the healthcare system;
- Expenses incurred because of poor quality.

The strategy is in line with the recommendations on patient safety of the Council of Europe from 2006.

The Institute of Public Health of Serbia “Milan Jovanović Batut” in 2009 through the district institutes of public health collected data on the quality of work of health institutions, analysed the indicators, and made a report on improving the quality of work in healthcare institutions in Serbia in 2009.

Some institutions, which are unique in their field in the Republic, analysed the indicators by themselves and submitted reports. Based on analysis of collected data, health centres and general hospitals in the Republic were ranked by quality.

Indicators monitored in primary healthcare since 2004 changed in recent reporting periods (6 or 12 months) also depending on the changeability of regulations by RIHI as well as the introducing of new or the redefining of old indicators in 2007. Compared to the previous year, which is characterised primarily by the change of the nomenclature of services in primary healthcare, electronic billing services, change and reporting of done services as well as service planning, there is a characteristic increase in the issuing of slips for diagnostic procedures and specialist consultations. In some services there was a decline in the percentage of preventive services, and in some an increase was recorded. In fact, this is a relative number, i.e., the portion of preventive services in the total number of all services. As the total number of services increased in all services, the absolute number of provided preventive services increased in all observed services, especially in gynaecological services.

From the analysis of indicators of quality of inpatient health institutions, it can be concluded that the average length of treatment in all institutions (also at secondary and tertiary level) decreased. The average length of preoperative hospital stay remained the same on the average – one day before surgery. Also, the mortality rate from myocardial infarction was reduced, while the mortality rate from cerebrovascular insult at the level of institution remained much the same through all periods of monitoring. The problems that are still present are reflected in

the poor and deficient information on autopsies and matching of clinical and autopsy diagnoses, as well as data on nosocomial infections.

Under the Rulebook on indicators of quality of healthcare (Official Gazette of RS, No. 57/07) from January 2008, the reporting on indicators of quality of keeping waiting lists for the selected procedure was transferred to an annual level in the manner defined by professional and methodological guideline.

In 2004, the number of patients on the waiting list for the Republic of Serbia was greater than the number of performed interventions/surgeries. With the introduction of software package in the RIHI and with better record keeping and control, on the one hand, and with increased confidence of patients in the availability of healthcare, on the other hand, this number grew slowly and the curve climbed to the number 65,469, which represents the total number of patients on waiting lists for all procedures in 2009. At the same time, the total number of performed interventions/surgeries to patients from waiting lists stood at 20,882 in 2004. This number quickly grew and in 2009 reached the total number of 94,428 patients from waiting lists who underwent the procedure.

This number was reached thanks to large investment of the Ministry of Health and the Republic Institute for Health Insurance through, primarily, equipment, procurement of devices, the training of staff, the opening of new centres (angio-halls), special contracts with medical institutions on additional financial resources for performing the services that are not within the scope of agreed-on plan of work, etc. Even with these results, what remains to be resolved in the upcoming period is the establishment of a National waiting list, whose formation is becoming more than justified with the introducing of indicators of the average length of waiting time and the ratio of total number of patients who are waiting in the reporting period. The national waiting list gives the option of sending the insured from a health institution with a long waiting list to another medical facility, where the waiting list is shorter.

Examining customer satisfaction has become a regular method for checking and improving the quality of work. The survey was conducted in all health facilities by using a planned examination method. Average grades in all primary healthcare services at the Republic level are equal and amount to 4.00. There are no differences in the regions either (excluding Kosovo and Metohija, that makes 0.5% of the sample), which points to the same quality of healthcare in all institutions and in all regions (Vojvodina, Central Serbia and the City of Belgrade). Mean satisfaction grade with hospital treatment as a whole, as well as certain examined aspects, have the highest value ever since the tests were launched. There is a great challenge placed before medical workers to keep this high grade in the coming years. More than half of employees in health institutions in the Republic of Serbia are satisfied and very satisfied at work. When observing the professional satisfaction of health workers, the percentage is even higher. General satisfaction of employees in healthcare institutions has not changed compared to 2008, and is higher compared to 2006 and 2007. In 2009, employees were most satisfied with the same job aspects that they were satisfied with in previous years.

After many years of experience in monitoring and improving quality (since 2004), a Conclusion was adopted that it is necessary to adopt a new Rulebook on quality indicators and that Rulebook was adopted on 30 June 2010 (Official Gazette 49/2010).

Quality indicators represent the information on provided health services. They offer an opportunity to prevent the occurrence of any problem that may result from poor quality of healthcare, so as to identify and correct the problems and allow the attaining of high standards of care and raising the average level of quality of care

European Action in the field of Rare Diseases

-Rec. 2009/C 151/02: Council Recommendation of 9 June 2009 on action in the field of rare diseases

-Dec. 2009/872/EC: Commission Decision of 30 November 2009 establishing a European Union Committee of Experts on Rare Diseases

-Dec. 2010/C 204/02: Commission Decision of 27 July 2010 on the appointment of the members of European Union Committee of Experts on Rare Diseases set up by Decision 2009/872/EC

Questions:

- a) Are there legislative, regulatory or administrative provisions in force in your country covering these areas? If yes, please send summaries and, if possible, full texts in one of the official EU languages.**
- b) In case there are no legislative, regulatory or administrative provisions in force, are there any drafts or proposals for these in the pipeline? If so, give details of these and of the timeline for their adoption.**
- c) In cases where neither of the above exists, are there any plans to start preparing proposals? Please explain, also indicating the envisaged timetable.**
- d) Does your country have the necessary administrative capacity, including human and material resources, to fulfil the requirements laid down in the EU legislation listed above? (Is there any impact observed from the current economic and financial crisis?)**

59. With specific reference to mental health, please answer to the following questions:

a) What are the measures you are taking to support the social inclusion of people with mental health problems? a) What are the measures taken to reduce the stigma and discrimination and to ensure human rights of people with mental health problems?

The Government of the Republic of Serbia in January 2007 adopted the Strategy of development of mental healthcare with an action plan (hereinafter referred to as the national strategy). The national strategy was developed within the project of the Stability Pact for South Eastern Europe, "Enhancing social cohesion through strengthening community mental health services", as an initiative to reform the mental healthcare in the region of South Eastern Europe, and because of serious and complex problems in this area, especially in the countries in transition. It is the product of work of experts of the National Commission for Mental Health, established in January 2003 by the Ministry of Health.

Identified areas of activity of the national strategy are as follows:

1. Law and human rights,
2. Organisation of services,

3. Prevention of mental disorders and the promotion of mental health,
4. Human resources, education and research,
5. Improving quality,
6. Information systems,
7. Intersectoral co-operation (partnership for mental health),
8. Representation and public advocacy.

Several projects in this area, financed by international funds, were launched. They are as follows:

1. Enhancing social cohesion through strengthening community mental health services (South-Eastern European Health Network, implemented in the period from 2002 to 2008),
2. The development of regional model of integrated services for mental health and social cohesion (MATRA Office – the Ministry of Foreign Affairs of the Kingdom of the Netherlands, the implementation is planned for the period from 2007 to 2010),
3. Promotion of mental health in the Republic of Serbia (EU IPA fund, Caritas Italiana, Caritas Serbia and Montenegro, implemented in the period from 2008 to 2010),

Mental Health Project for South Eastern Europe, “Enhancing social cohesion through strengthening of mental health in the community in South Eastern Europe” is part of broader efforts of South Eastern Europe to approach to the European Union. The initiative was launched in 1999 when the Stability Pact for South Eastern Europe was established, with the aim of strengthening social stability in the region by encouraging peace, democracy, human rights and economic prosperity. In 2001, the Stability Pact for South Eastern Europe as part of its initiatives related to social cohesion introduced health in its agenda, as one of five priority areas. In September of the same year, the WHO Regional Office for Europe and the Council of Europe established Health Network of South Eastern Europe (hereinafter referred to as the Health Network). The aim of the Health Network was to improve public health in South Eastern Europe.

The signing of the Dubrovnik Declaration, in September 2001, at the Ministerial Conference for South Eastern Europe, whose emphasis was on improving the health of vulnerable groups in the region, created conditions for the implementation of projects to address these issues. The formal decision to start the Project of Mental Health in South Eastern Europe was made in Denmark in May 2002.

Health Network is currently made up of the following countries: Albania, Bosnia and Herzegovina, Croatia, Bulgaria, Moldova, Romania, Serbia, Montenegro and Macedonia. Bosnia and Herzegovina is the leader of this project in the region. The main objective of the project was to set up services for mental healthcare in the community in the centre of the mental healthcare system.

b) Do you provide specialized mental health facilities for vulnerable groups such as old people, children, young people and refugees?

In Serbia there are 5 large psychiatric hospitals (in Gornja Toponica, Novi Knezevac, Vršac, Kovin and in Belgrade "Dr. Laza Lazarević"). In addition, there are 46 psychiatric departments in general hospitals as well as outpatient services in 71 municipal health centres. There are about 6,000 beds, of which 3,000 are the so-called bad beds because they are located in large hospitals. The average treatment duration is 31 days (in Belgrade) and 153 days in special psychiatric hospitals. In Serbia there are 947 psychiatrists, of whom 336 are

working in Belgrade. This number is quite sufficient, but it should be noted that many of them work as neurologists, especially in the provincial areas.

c) What are the measures taken to support mental health and well-being of children and adolescents in the educational settings?

Mental health diseases without significant disorders of the children and youth are carried out at the primary health centers by general practitioners and psychiatrists on the primary health care level (in the ambulances of the 71 primary health centers). If there is need for consultation on the higher level of the health care or hospitalization, there are 46 specialized psychiatry departments within the general hospitals and Clinic for neurology and children and youth psychiatry in Belgrade.

d) Do you provide a community based services for people with mental health problems?

Community based services are not provided in the whole country. However, there is community mental health centre at the Southern part of Serbia (Nis). In addition to that, in most of health centers in Serbia there is a mental health team (psychiatrist, social worker, psychologist) which provides mental health care.

60. With specific reference to access to health care system, do you have specific measures in place to allow the poorest people, minorities and people living in rural and remote areas to have equal access to the health care system in your country?

Healthcare in Serbia is provided pursuant to the availability and equality principle, meaning that healthcare is physically, geographically and economically available to all population groups, including those exposed to the highest risk of diseases and vulnerable groups, with an emphasis on primary healthcare.

Primary healthcare is basic, active and belongs to the first level of contact with patient (covers from 2000-50000 of citizens). Healthcare service of primary level is organized in the following manner: health centre, pharmacy and specialized health centers (student health center, occupational health center, emergency care unit, dental clinic, clinic for lung disease and TB, clinic for dermatology and venereal disease).

The first contact with patient is made in health centers, health stations and primary health centre. In the Republic of Serbia there are 158 health centers, 838 (771+67) primary health centers and 401 (377+24) health stations. In 19 health centers there are 370 beds organized into stationeries and birth centers. People living in the most remote areas can satisfy their needs for healthcare at the distance less than ten kilometers.

With the aim of availability of healthcare to the old and the disabled all doctors are obliged to provide home healthcare. Users make appointments with their chosen doctor and if necessary, at their own home so the healthcare is fully available to them. In the case of urgent healthcare need, the patients have right to urgent care at the spot.

With reference to healthcare system users, namely healthcare insurants, it is important to underline that the system does not cover only uninsured individuals older than 26 and foreigners who do not need urgent care.

Right to healthcare covered by mandatory healthcare insurance:

- Prevention and early detection of disease measures
- Physical examination and treatment in the case of disease and injury
- Physical examination and treatment in the case of disease and injury
- Examination and treatment of mouth and teeth
- Medical rehabilitation in the case of disease and injury
- Drugs and medical aids
- Medical- technical aids

Thus, healthcare also covers:

- Economically deprived people who receive social fund payment pursuant to regulations on social protection and protection of veterans and war military and civil disabled people and members of their family if they are not healthcare insured
- Beneficiaries of regular social fund payments pursuant to regulations social protection and provision of accommodation in social protection institutions or in other families;
- Unemployed and other categories of socially deprived persons whose monthly incomes are below limit laid down by law stipulating health insurance

Serbia was faced with a flow of refugees and displaced people during past events in the region. To implement complete healthcare for all, the budget of Serbia provides resources for treatment of refugees and displaced people in public healthcare institutions at the territory of Serbia, under the same conditions as for other insurants of Healthcare Insurance Fund.

Health of Roma population is directly conditioned by degree of education, level of poverty and living and accommodation conditions. The problem is additionally deepened by the fact that significant number of Roma population members does not own personal identification documents. To overcome these problems of the Roma population, after registering in Serbia, they were granted the rights to services in the field of healthcare at all levels.

As a part of The Action Plan for Health Improvement of Roma Population in 2008 through 164 projects in 60 primary health centers has been included 41 908 Roma. There was also made the software for monitoring of indicators related to health status of Roma and the situation in Roma settlements. During 2009, 29 projects was approved and financed by Ministry of Health.

During 2010, 16 projects have been implemented together by Institute of Public Health and Roma NGOs. For Roma NGO projects were approved in the competition which is financed by the Ministry of Health.

The project "Health Mediator from 2008 - 2010 employed 60 women - mothers, involved 34,479 families, were recorded 120,708 Roma, has done 80 824 visits, were provided identity documents and health care cards for the 7347 Roma, 7366 children were vaccinated, systematic review of the 4318 women were made, health control for 2691 pregnant women, 593 mammograms were performed, 1 207 children were enrolled in school, 12 370 Roma chose their doctor and 4563 women chose their gynecologist. In 2011, it is planned to employ 15 mediators within the Project of the Fund for Open Society "Employment of Roma health mediators".

The fundamental objectives of healthcare policy regarding healthcare of the poorest part of population in Serbia are:

- Reduction of impact of poverty and low education to health and healthcare, especially preventive, of vulnerable groups of population
- Protection and improvement of health and prevention of disease of Roma and other vulnerable groups of population, namely improvement of general quality of healthcare of this population

61. With specific reference to infant mortality, what measure are you taking in the field of reproductive health care and infant health care to decrease the infant mortality rate?

The Government of the Republic of Serbia adopted (Official Gazette 28/09) and the Ministry of Health is implementing National program health care of children, women and youth.

We refer to preventive measures including control and systematic screenings of visiting-nurse service and pediatrics service during the age of 0-12 months.

Visiting-nurse service makes five visits to infant and mother during the first month. During the first year, visiting-nurse service is obligated to make two visits for infants who are not at risk, and four for infants at risk.

Control screenings are performed before each vaccination, three examinations in total, and six systematic screenings are performed at the age of 3, 6, 9 and 12 months, namely 2 screenings during the first two months of life.

62. With specific reference to alcohol abuse, control and prevention, how is the sale of alcoholic beverages regulated in your country?

Age limit for prohibition of sale of alcoholic beverages was moved from the age of 16 to the age of 18 in 2005. Prohibition of sale to minors is regulated by the Law on Consumer Protection.

Prohibition of advertising of alcoholic beverages in Serbia entered into force in 2005, including prohibition to show use or simulation of use of alcoholic beverages in advertisements. Prohibition of advertising partially concerns advertising of beer and vine, i.e. advertising of these products is allowed in the period from 6 pm to 6 am within the programs not directly aiming children and youth. The same law bans manufacturers of alcoholic beverages (including vine manufacturers) from sponsoring athletes and sport events, minors and individuals whose audience is mainly consisted of minors. It is forbidden to advertise beer and vine at open space near institutions devoted to children and youth at the distance less than 100 meters.

63. With specific reference to non-communicable disease, as their burden is increasing, what measures are you taking to promote a healthy lifestyle (quit smoking, promote sports, healthy nutrition, fight alcohol abuse) and prevent this type diseases?

The following activities are in place in Serbia with specific reference to health promotion and disease prevention:

- Developing, participating in and monitoring the implementation of national emergency health promotion programmes in the community such as:
 - Health promotion programme in primary healthcare institutions and
 - Health promotion programme in polyvalent Visiting Nurse Service.

- Developing, implementation, co-ordination, monitoring and evaluation of health promotion programs, including national campaigns, in view of acquiring knowledge and attitudes in relation to healthy life style and reducing risk factors for communicable and non-communicable diseases.
- Developing, co-ordination and building on partnerships between governmental, private and civil sector for resolving public health community issues.
- Implementation of education and vocational training of health professionals and associates in the sphere of health education.
- Development and implementation of the programme for the health promotion of special and vulnerable population groups (children, pregnant women, nursing mothers, aged persons, marginalised groups), such as:
- The Programme of improving health of pupils in primary schools, the Programme of health promotion for students in secondary schools, the Programme of preserving and improving oral health for children and youth in the Republic of Serbia, the Programme of education for the health of children in preschool institutions "Healthy Kindergarten".
- Health information of the Serbian population through a continuous work with the media.
- Implementation of the programme for the protection of population from communicable diseases for part of health education.

Activities in the area of prevention and control of disease include: organisation, implementation and control of epidemiological surveillance of communicable diseases, surveillance of nosocomial infections.

The immunisation programme includes:

- surveillance over mandatory active immunisation of persons of a particular age,
- mandatory immunisation of persons exposed to particular communicable diseases,
- active immunisation based on clinical indications, and
- active immunisation of passengers in international traffic through the application of measures prescribed by the law with the purpose of protecting the population from communicable diseases, their prevention, suppression, removal and eradication.

The activities implemented in the sphere of prevention and control of leading chronic non-communicable diseases include:

- The assessment of the prevailing risk factors responsible for the incidence of the leading chronic non-communicable diseases (CND) on the basis of the results of population, targeted and other researches.
- The activities prescribed under the action plan of the National Strategy for CND Prevention and Control are currently in place. Based on the conducted research it is possible to identify the risk population groups for the intervention regarding the promotion of healthy life styles.

The programme activities in the sphere of prevention and control of the leading CND have been regulated in more detail through the following:

- The National programme "Serbia Against Cancer" whose integral parts are the National programme for the prevention of colorectal cancer, the National programme for the prevention of breast cancer and the National programme for the prevention of cervical cancer.

- The National programme for the prevention and control of cardio-vascular diseases in the Republic of Serbia until 2020 – “Serbia for a Healthy Heart”.

The Rulebook on the contents and scope of healthcare rights under mandatory health insurance coverage and on co-payment for 2010, clearly defines the prevention activities in accordance with the national programmes.

The first systematic medical examination has been envisaged for persons between 19 and 35 years of age and it includes a general clinical examination and systematic examination, basic laboratory analyses and other examinations depending on the present risk factors. A systematic examination for persons aged 35 and over has been envisaged to take place every second year, with additional examinations as appropriate, while the tests for the presence of fecal occult blood, digital rectal examination (DRE) and prostate examination by palpation have been envisaged to take place once a year for persons aged 50 and over. Colonoscopy of high risk patients has been envisaged to take place once in three years.

The first preventive gynaecological examination has been envisaged for women aged 15 and over, the re-examination once in three years, with breasts examination by palpation once in five years. Women aged between 25 and 69 should undergo the annual targeted examination in view of early detection of cervical and breast cancer, while women aged between 30 and 69 are given recommendations and instructions for self-examination of breasts. Women aged 40 and over should undergo the annual clinical examination of breasts, while women aged between 45 and 69 should undergo mammographic examination once in two years.

64. With specific reference to rare diseases, do you foresee the implementation of a national Plan/Strategy/Integrated set of actions in the field Rare Diseases?

The Ministry of Health is considering the possibility of amending the Law on Health Insurance to enable the provision of financial means for diagnosis and treatment of rare diseases.