

## **Chapter 1: Free movement of goods**

### GENERAL PRINCIPLES

*These questions are of a general nature and do not refer to the industrial sectors specified in Chapter 15.*

#### **A. Legislative alignment**

##### **1. What is the basis for product conformity regulation and to what extent has your legislation moved towards the principles applied in European harmonised legislation, i.e. minimum requirements, absence of mandatory standards, self certification and the presumption of conformity?**

The new Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of RS, No. 36/09) (Annex 1.1) represents a basic legal framework for regulating conformity of products with technical requirements. Article 21 of this Law prescribes that the product is placed on the market, i.e. delivered on the market only if it is in conformity with the prescribed technical requirements, if its conformity is assessed in accordance with the prescribed procedure, and if it is marked in accordance with the regulations and accompanied by prescribed documents of conformity and other required documentation.

This law provides a legal framework for transposition of European directives, both, the New Approach (Global) and the Old Approach, in case that stipulation of technical requirements and the performing of conformity assessment procedure for products is not prescribed by specific laws, but it also provides the legal framework for the stipulation of national technical regulations for products not comprised by the harmonised legal acts at the EU level.

While drafting this Law, recent versions of the EU reference legal acts concerning trade of goods (the so-called “new good's package”) have been taken into account, as follows:

- Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008, on a common framework for the marketing of products and repealing Council Decision 93/465/EEC.
- Regulation (EC) 765/2008/EC of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) No 339/93 and
- Regulation (EC) 764/2008/EC of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules for products lawfully marketed in another Member State, and repealing Decision 3052/95/EC.

Depending on groups of products and potential hazards posed by the product, this Law sets out different subjects which may perform conformity assessment procedures, such as:

- 1) The manufacturer,
- 2) Designated conformity assessment body (laboratory, inspection body and certification body),
- 3) Public administration body for products posing major risks.

Hence, this Law prescribes that in accordance with the technical requirements the manufacturer may individually perform the conformity assessment of its own product with the requirements laid down in the technical regulation, and issue a relevant declaration on conformity.

Technical regulation sets out a manner of conformity assessment which may comprise the application of a single procedure, a number of procedures or a combination of different

conformity assessment procedures. Article 19 of this Regulation on the Manner of Conformity Assessment, Content of Document of Conformity and Shape, Appearance and Content of Mark of Conformity (Official Gazette of RS, No. 98/09) (Annex 1.2) sets out that the conformity assessment shall perform in accordance with procedures (modules) laid down by the technical regulation, pursuant to Decision 768/2008/EC, thus in full compliance with self-certification which is applied, as conformity assessment procedure, individually or in combination with other procedures (in accordance with the technical regulation for specific product).

Articles 4 to 8 of this Law establish the manner of technical requirements stipulation, as the most important element of the technical regulation, which makes the product a part of the regulated area in the market, in regard to safety. Namely, technical requirements for a single product, i.e. groups of products, are set out by the technical regulation either directly, by specifying such requirements in the text of the regulation, or indirectly, by referring the technical regulation to the standard in force in Serbia, i.e. technical specification.

Article 7, paragraph 1, point 2) of this Law lays down that technical regulation may set out that one of the possible manners for achieving conformity with the requirements of such provision refers to full compliance with the standard in force in Serbia, referred to by the technical regulation. If the technical regulations refer to transposing of the New Approach directives into the legal system of the Republic of Serbia, in such case these are Serbian standards transposing harmonised European standards. In such a way a presumption of conformity with the requirements from the specific technical regulation is ensured, which represents one of the basic principles of the European technical legislation of the New Approach.

By entering into force of the new Law on Standardisation (Official Gazette of RS, No. 36/09) (Annex 1.3) conditions for more rapid and efficient adoption of the EU standards are ensured. This Law has abolished mandatory application of over 8000 standards, and the application of all standards adopted by the Institute for Standardisation of Serbia (ISS) is made voluntary. Thus, one of the basic requirements of the Agreement on Technical Barriers to Trade TBT, of the World Trade Organisation (WTO) is met. This Law has also defined a status of the Institute for Standardisation of Serbia, in accordance with the EU standardisation requirements.

In respect of ensuring market regulation in regard to safety of products for which there are no specific technical regulations, the Law on General Product Safety was adopted (Official Gazette of RS, No. 41/09). The Law on General Product Safety is fully harmonised with the principles and basic requirements of Directive on General Product Safety (2001/95/EC), whereas it fully transposes Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers.

Law on Technical Requirements for Products and Conformity Assessment, and the Law on General Product Safety introduce a presumption of conformity with the prescribed requirements, provided the product is in compliance with the standard requirements referred to in the technical regulation.

## **2. Please specify whether you have a general strategy on Quality Infrastructure.**

General Quality Infrastructure Improvement Strategy has not been adopted yet. Preliminary elaboration of the Quality Infrastructure Improvement Strategy of the Republic of Serbia is

envisaged in 2011. The Strategy aims at improving the competitiveness of the Serbian economy by defining general objectives, i.e. development orientation, and activities aimed at:

- Standardisation (full membership in the EU organisations for standardisation, sales volume rise and application of Serbian standards, as well as promotion of industry share in the standards development).
- Accreditation (upgrade of ATS capacity and fulfilment of requirements for EA MLA signing),
- Metrology (further development of the national Metrology organisation and upgrade of calibration capacities and verification of measuring instruments in the Republic of Serbia, etc.) and
- Conformity assessment (through upgrade of research capacities and certification, in accordance with the needs of the Serbian economy, and increase scope of activities of economic operators and conformity assessment bodies in the field of voluntary certification).

In the field of market surveillance, the Government has adopted a Market Surveillance Strategy (Official Gazette of RS, No. 86/10) in September 2010, aimed at establishing efficient market surveillance for ensuring product safety with minimum burden to the economy.

**3. Please assess the overall compliance of your legislation with the general framework provided by the EU *acquis*. What is still missing and what are your plans for rectifying the situation?**

By revision of the horizontal legislative framework (launched in 2009 and continued in 2010) four framework legal acts have been adopted:

- Law on Technical Requirements for Products and Conformity Assessment
- Law on Standardisation
- Law on Metrology (Official Gazette of RS, No. 30/10) (Annex 1.4)
- Law on Accreditation (Official Gazette of RS, No. 73/10) (Annex 1.5)

With the adoption of the Law on General Product Safety full harmonisation with the EU horizontal technical legislation was achieved, comprising a new framework for marketing of products, adopted in the EU in 2008. This conformity process will be completed in 2011, by adopting bylaws of the Law on Metrology and the Law on Accreditation.

The above mentioned legislation with bylaws (referred to in the answer to the question No. 5) transposes all EU principles in the horizontal sense, whilst vertical legislation referring to specific groups of products shall be gradually conformed in the competent ministries, by using the prescribed principles within the competence of certain ministries.

**4. Please specify how the self-certification principle is addressed in your legislation?**

Article 11 of the Law on Technical Requirements for Products and Conformity Assessment refers to the conformity assessment performed by the manufacturer itself. In accordance with these provisions, in cases when a technical regulation establishes that conformity assessment is performed by the manufacturer such regulation also establishes the requirements concerning internal production control. The internal production control encompasses all measures required for the production process and monitoring of such process to ensure the product compliance with

the technical regulation. The same article requires that the manufacturer, upon performing the conformity assessment procedure, issues a declaration of conformity with the prescribed requirements.

Article 19 of this Regulation on the Manner of Conformity Assessment, Content of the Document of Conformity and the Shape, Appearance and Content of Conformity Mark sets out that the conformity assessment is performed in accordance with the procedures (modules) laid down by the technical regulation, pursuant to Decision 768/2008/EC, thus in full compliance with the self-certification which is applied, as conformity assessment procedure, individually or in combination with other procedures (in accordance with the technical regulation for specific product).

Article 19 of this Law also stipulates the self-certification principle, establishing that a technical regulation may lay down that in the conformity assessment procedure specific activities (under prescribed conditions) are carried out by the accredited body within the manufacturer's system, instead by the designated body.

### ***B. Implementation capacity, including administrative capacity***

#### **5. What is the legal basis and administrative structure for technical regulations, standards, conformity assessment, accreditation, certification, metrology and market surveillance?**

Legal basis in the field of technical legislation and market surveillance is made of the following laws:

- Law on Technical Requirements for Products and Conformity Assessment
- Law on Standardisation
- Law on Metrology
- Law on Accreditation
- Law on General Product Safety
- Law on Trade (Official Gazette of RS, No. 53/10), Law on Public Administration - Articles 22-37 and Article 92 (Official Gazette of RS, No. 20/92, 6/93, 48/93, 53/93, 67/93, 48/94 and 49/99).

Technical legislation field is closely regulated by the following bylaws:

- Regulation on the Manner of Recognition of Foreign Documents and Marks of Conformity (Official Gazette of RS, No. 98/09) (Annex 1.6)
- Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity
- Regulation on the Manner of Designation and Authorization of Conformity Assessment Bodies (Official Gazette of RS, No. 98/09) (Annex 1.7)
- Decision on the Amendments of the Constituent Act of the Institute for Standardisation of Serbia a (Official Gazette of RS, No. 88/09)
- Decision on the Establishment of the Serbian Accreditation Body (Official Gazette of Serbia and Montenegro, No. 44/05)
- Regulation on Legal Units of Measurement (Official Gazette of Serbia and Montenegro, No. 10/06)
- Regulation on Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standards (Official Gazette of RS, No. 45/10) (Annex 1.8)

- Rulebook on Manner of Affixing Marks of Conformity on Products, and Use of Marks of Conformity (Official Gazette of RS, No. 25/10) (Annex 1.9) (Rulebook on the Content of the Form Issuing a List of Serbian Standards Referred to in the Technical Regulation (Official Gazette of RS, No. 110/09);
- Rulebook on Content and Manner of Keeping Registers referring to Technical Regulations (Official Gazette of RS, No. 33/10) (Annex 1.10)
- Regulation on the Manner of Establishment and Functioning of the Rapid Information Exchange System on Dangerous Products (Official Gazette of RS, No. 89/09). 89/09).
- Rules of Procedure on the Form and Content of Information on Dangerous Product (Official Gazette of RS, No. 112/09). 112/09).

Law on Technical Requirements for Products and Conformity Assessment (Article 6, paragraph 1) stipulates that each ministry, within its competence, is responsible for promulgating technical regulations, which is in accordance with Article 29 of the Law on Ministries (Official Gazette of RS, No. 65/08, 36/09 – other law and 73/10 – other law) requesting that ministries within their competence perform public administration activities referring to the preparation, adoption, and proposal of technical regulations.

The Ministry of Economy and Regional Development is responsible for all horizontal questions in the field of standardisation, accreditation, metrology, technical regulations of conformity assessment. Its coordination role, in the field of technical regulations and quality infrastructure (standardisation, accreditation, metrology, and conformity assessment), arises from Article 9 of the Law on Ministries.

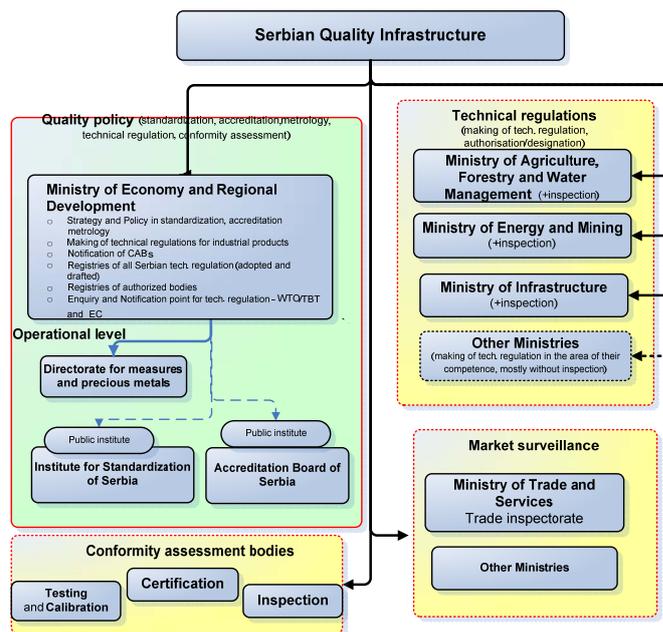
## **6. How are these functions organised, implemented and co-ordinated?**

In order to perform activities relating to strategy and policy in the field of free movement of goods, more efficiently i.e. coordination in the field of standardisation, technical regulations, accreditation, metrology, and obligations under Article 77 of the Stabilisation and Association Agreement, in middle of 2008 Department for Quality Infrastructure was established at the Ministry of Economy and Regional Development. The Department currently has 21 employees, with the following organisational structure:

- Section responsible for the creation and implementation of the strategy and policy of standardisation, accreditation and metrology development,
- Section responsible for the preparation and implementation of technical regulations and conformity assessment for industrial products from the scope of the Ministry,
- Group acting as the Enquiry point for technical regulations and conformity assessment procedures. This organisational unit will also act a centre for notification of draft technical regulations towards the WTO and EC, and as a single-point centre for notification of the authorised and designated bodies for the conformity assessment. The Group is also responsible for the preparation and monitoring of development aid projects in the field of quality infrastructure.

Pursuant to the Law on Standardisation, at the end of October 2009 the Government adopted a Decision on the Amendments of the Constituent Act of the Institute for Standardisation of Serbia

(ISS). Pursuant to this legal act, of 4 January 2010, the ISS has a public institution status operating in accordance with regulations laying down the legal status of public services. In accordance with the Law on Technical Requirements for Products and Conformity Assessment, an approach regarding preparation and adoption of technical regulations has been decentralised. However, the Ministry of Economy and Regional Development, acting as a coordinator in the field of free movement of goods, carries out specific activities in a centralised manner (regulations of the Law on Technical Requirements for Products and Conformity Assessment governing the application of the designated, and authorised body for conformity assessment, keeping the registers referring to technical regulations and notification of draft technical regulation



The Directorate of Measures and Precious Metals was established in 2007, as an authority within the Ministry of Economy and Regional Development, which continued carrying out all activities of the former Institute for Measures and Precious Metals, organisation with an over 130-years long tradition.

Pursuant to the Law on Accreditation, the Serbian Accreditation Body is established as a public institution. Amendment to the Establishment Act of the Serbian Accreditation Body shall be carried out in 2011, aiming at aligning its status with the new Law.

Market Surveillance Strategy, *inter alia*, contains an analysis of the institutional framework for market surveillance, development directions and planned coordination modalities.

Competent authorities for inspection with regard to product safety on the market:

<i>Ministry/competent authority</i>	<i>Inspection/field of surveillance</i>
<b>Ministry of Trade and Services</b>	Trade inspection
Ministry of Economy and Regional Development/ DM DM	Measurement instruments
Ministry of Labour and Social Policy	Labour Inspectorate
Ministry of Infrastructure	Road transport Railway safety Water transport Air transport
Ministry of Health	Sanitary inspection Products of deceptive appearance Pharmaceutical products and medical equipment Toys
Ministry of Mining and Energy	Vessels and equipment under pressure
Ministry of Telecommunications and Information Society	Telecommunications
Ministry of Environment and Spatial Planning	Civil Engineering inspection
Ministry of Interior	Fire protection explosives
Ministry of Finance/Customs Head Office	Customs inspection

Further explanations on the market surveillance coordination are comprised within the answer to the questions 33 and 34.

**7. Do the relevant ministries and technical organisations have sufficient numbers of adequately trained staff to master the technicalities of law-making and to ensure adequate co-ordination and enforcement of the law? Please specify.**

Ministry of Economy and Regional Development (MoERD) in the past few years gradually increased its capacity, but in some ministries there is still insufficient number of competent experts who would perform only activities related to the technical legislation for products. In a few ministries there are organisational units responsible for enacting technical requirements, and their conformity with EU directives, and in certain ministries there are no employees who would be solely responsible for such issues.

New phase, expecting more intensified engagement of the vertical legislation harmonisation with the EU Acquis Communautaire, is envisaged in 2011 and 2012, and it requires a larger number of public servants. Furthermore, based on the experiences of other neighbouring countries, Serbia is aware of the necessity to establish a flexible and modifiable system, from the transposing EU directives to implementing new regulations and market surveillance in terms of placement of product on the market.

Moreover, a necessity of coordination upgrading between the above mentioned institutions is assessed, as well as in regard to market surveillance where further strengthening of cooperation and coordination among all participants in market surveillance on the market of the Republic of Serbia is required. Due to the above mentioned, further education and capacity building within all ministries is required, for the technical requirements establishment and technical regulations

implementation, as well as further qualifying and development of the national conformity assessment bodies, aiming at preparation for the full implementation of the EU regulations.

**8. Please indicate in details your resources and systems to contribute to elaboration and implementation of law.**

As specified in the answer to question num. 6 Infrastructure Quality Department within MoERD, as the coordinator in the area of the free movement of goods, currently has 21 employees (together with the Deputy Minister – Head of Department). Organizational structure of the Department is as follows:

- 8 employees in the Division responsible for the creation and implementation of the strategy and policy of standardisation, accreditation and metrology development. This Division is responsible for the preparation, passing and implementation of all horizontal regulations in the area of standardization, accreditation and metrology.

- 8 employees in the Division responsible for the preparation and implementation of laws and regulations which create the legal framework for defining the technical requirements and conformity assessment, as well as drafting, adoption and implementation of technical regulations on industrial products from the Ministry (machinery, low voltage equipment, electromagnetic compatibility, personal protection equipment, elevators, glass, textiles, wood, furniture etc.).

- 4 employees in the Group acting as the Enquiry point for technical regulations and conformity assessment procedures. This organizational unit acts as an Information center, i.e. the contact point for the application of technical regulations to the WTO and the EC and is responsible for preparing and implementing regulations relating to the provision of information application of technical regulations in preparation (Directive 98/34 EC).

Professional structure of employees in the Sector is as follows:

lawyers	7
engineers	8
economists	3
translators	1
administrative staff:	2
TOTAL	21

Planning of activities on the development and implementation of the regulations is carried out as part of an integrated system of planning and budgeting, preparation of the annual work plan of the Ministry (program budget in the MoERD is not yet fully implemented), which is the basis for drafting the budget for this Department. Within the budget determined for Quality Infrastructure Improvement Strategy, concrete activities on developing regulations in accordance with NPI are being planned and implemented, including funds for the procurement of harmonized standards, training, campaigns and other activities aimed at raising the awareness of entrepreneurs, consumers and other interested parties.

Activities of employees on preparation of legislative acts are not additionally funded, and payment of other experts outside the ranks of public administration is possible under existing regulations, but is rarely used in practice because of restrictive and limited budget.

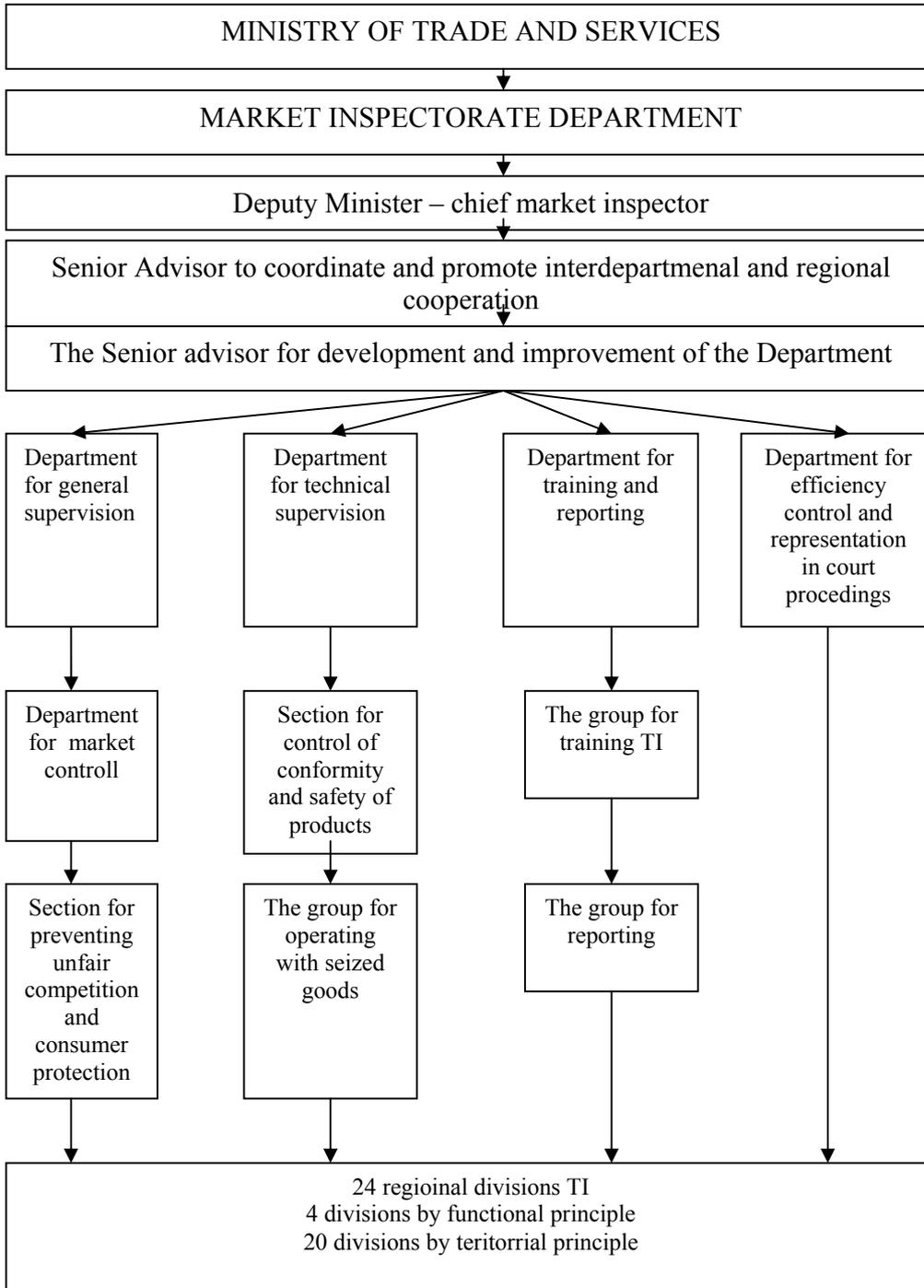
Drafting of legislation is carried out within the framework of Working Group, which in addition to employees from authorities competent for preparation of regulations, involves experts in this area, representatives of companies and associations, universities, engineering and chambers of commerce, conformity assessment bodies, as well as other Ministries. The operating version of provisions prepared by Working Group shall be for a public consultations mostly through the internet site MoERD, and commercial and engineering chambers, and final public hearing is usually organized in the form of round tables. Participants at the roundtable were primarily from the ranks of companies and conformity assessment bodies to which the regulation applies, and other interested subjects and experts.

When it comes to drafting technical regulations, before reaching relevant technical regulation, subject who prepares legislation is obliged to submit the draft regulations to MoERD, together with the notice, and in accordance with the Regulation on Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standards (Official Gazette of RS, No. 45/10), in order to report a technical regulation to the World Trade Organization according to the rules of TBT Agreement and the EC, after its accession to the WTO and to the EU.

For the implementation of technical regulations prepared by MoERD, resources of the Group for conformity assessment and recognition of foreign documents are used, within the Department for technical regulations and conformity assessment. This group performs tasks related to appointment of conformity assessment bodies, and supervision of the appointed bodies, and activities related to recognition of international documents on conformity. The above group provides professional, administrative and technical support to the commissions formed for appointment of conformity assessment bodies and the recognition of foreign documents, for every single area within the framework of MoERD. The commissions, besides having employees from MoERD, engages experts from Serbian Accreditation Body, Institute for Standardization of Serbia, as well as other experts outside the Ministry if necessary.

In terms of implementation of technical regulations on market surveillance, i.e. control of whether the products placed in the market are safe or whether the products are complied with regulated technical requirements, main body and coordinator of market supervision is the Department for inspectorate of the Ministry of Trade and Services.

Scheme 1 shows the organization of this Department:



According to the attached organizational scheme of the Sector for market inspectorate, the sector has been organized to perform market surveillance on the territory of Serbia across 24 regional units. The four divisions in the headquarters coordinate the work of regional units, including the coordination of technical supervision, which is done through the Division of Technical Supervision, where the working position of contact point has been systematized and determined. Planning of activities on the market surveillance is conducted as a part of integrated system of planning and budgeting, by making the Annual operative plan of the Ministry of Trade and Services (programme budget), which is the basis for developing the budget for this department. Within the budget determined for Program of control and surveillance of the market, concrete activities of market surveillance are being planned and implemented, including the resources required for sampling products on the market, training the inspectors, campaigns and other activities aimed at raising the awareness of entrepreneurs, consumers and other interested parties. Within the Plan for market surveillance, the priorities for 2011 have been set. Works on this document are still in progress within the project funded by EU and which is a preparation for the start of IPA 2010 project "Strengthening the capacity of market surveillance in the area of non-food and food products".

The Sector for market inspectorate employs 485 inspectors. The system of fast exchange of information on dangerous products contributes to more efficient law enforcement in the area of market surveillance.

Significant progress on improving the cooperation between the various organs of market surveillance was achieved by adopting the Regulation on the establishment and operation of system for fast exchange of information on dangerous products by the Government. The work of this system aims to create an integrated system approach of all relevant authorities of market surveillance in gathering and dissemination of information on dangerous products and to further develop regional and international cooperation in the area, including the accession of the Republic of Serbia to the RAPEX system and notifying the European Commission.

The most important elements of the Regulation on establishment and operation of fast exchange of information on dangerous products are:

1) Contact point (Ministry of Trade and Services – Market inspectorate) has been established with the purpose of assembling, integrating and forwarding the information on dangerous products. It is in charge for central register on dangerous products and measures taken/proceedings. It alerts the public on dangerous products presenting a serious risk and informs the Government about the functioning of the system for fast exchange of information on dangerous products in which all authorities in market surveillance are involved, including Customs Administration which carries customs inspections.

2) Authorities of market surveillance and Customs Administration are obliged to inform the contact point when they detect a dangerous product on the market and to act in accordance with its powers.

3) The contact point forwards the information to all relevant authorities of the market surveillance to ensure the intensive check for presence of a dangerous product on entire territory and on points of entry (to prevent further placement on the market).

4) Authorities of market surveillance inform the contact point on their findings and proceedings.

5) Contact point follows the available international databases on dangerous products in trade. If there is a suspicion that some product from this database could be on the Serbian

market, all relevant authorities of market surveillance are informed in order to perform an intensive check for presence of dangerous product throughout the territory and at points of entry to prevent placing on the market, i.e. withdrawal from the market and recall from the consumers and other users.

6) Authorities of market surveillance inform the contact point on their findings and proceedings.

Establishing a system of fast exchange of information on dangerous products in the Republic of Serbia is a systematic approach for the further successful integration into EU RAPEX system established by the Directive on general product safety and improved by Regulation EC 765/2008.

### ***HORIZONTAL MEASURES***

**These questions are of a general nature and do not refer to the industrial sectors specified in Chapter 15.**

**9. What mutual recognition or co-operation agreements in the field of standards, testing, certification and conformity assessment has your country signed? Do such agreements use international standards as a basis? Please provide translated copies (in English) of the relevant agreements.**

#### **CEFTA Agreement Provisions**

Article 13 of the CEFTA Agreement stipulates that the Signatories shall undertake measures for identifying and eliminating unnecessary obstacles to trade, within the meaning of WTO TBT, and shall cooperate on the alignment of technical regulations, standards and mandatory conformity assessment procedures. Paragraph 4 of Article 13 prescribes that the Parties shall initiate negotiations by the end of 2010, on the stipulation of agreement on technical regulations and standards alignment, and mutual recognition of conformity assessment procedures.

Within the CEFTA Agreement, which implementation was fully put in place on 22 November 2007, following a decision of the Joint Committee No 5/2007, a Sub-Committee for Technical Barriers to Trade and Non-Tariff Barriers was established. The Sub-Committee's objective is to identify, examine and propose measures for eliminating technical barriers to trade and non-tariff barriers. In point 2.2 of Decision No 5/2007, it was defined that the Sub-Committee for Technical Barriers to Trade and Non-Tariff Barriers shall:

- Encourage the alignment of technical regulations, standards and mandatory conformity assessment procedures with the WTO regulations and procedures;
- Encourage where appropriate, the alignment of technical regulations, standards and conformity assessment procedures with those applied in the EU;
- Encourage the recognition of documents on conformity assessment created by authorised conformity assessment bodies;
- Encourage negotiations for the conclusion of multilateral agreements among the Parties.

Within this Sub-Committee, in the first half of 2010 a Working Group for Technical Barriers to Trade was established, aiming at accelerating the full implementation of Article 13 of the Agreement on the Elimination of Barriers to Trade.

Agreements among the bodies for standardisation, accreditation, metrology, and conformity assessment bodies of the countries signatories to the CEFTA Agreement shall encourage further trade development and elimination of trade barriers.

### **UN/ECE – Agreement on Vehicles Approval**

In the field of approval of vehicles, equipment and parts, Serbia is a signatory to the UN/ECE Agreement on the Adoption of Uniform Technical Prescriptions and Reciprocal Recognition of Approval for Equipment and Motor Vehicle Parts, adopted at Geneva on 20<sup>th</sup> March 1958 („Official Gazette of the FPRY” – International Agreements, No. 5/62). This Agreement shall apply on new types of vehicles, equipment and parts manufactured in Serbia for which the Traffic Safety Agency issues appropriate statements on approval of vehicles. The Agreement also applies to vehicles, equipment and parts from import that do not require further testing if they possess adequate approval certificate. In accordance with this Agreement, Traffic Safety Agency only confirms the alignment with UN/ECE Rulebooks and/or appropriate EU directives/rulebooks and issues proper approval certificates.

### **IEC CB Scheme**

ISS has been a member of the Conformity Assessment and Electrical Equipment Certification System within the International Electrotechnical Commission - IEC (IECEE) since 1985. Recognition of the Report on electrotechnical products testing may be carried out through two recognized conformity assessment bodies based in Serbia ("Kvalitet" AD Nis and “Vinca” Institute of Nuclear Sciences – Laboratory for radiation physics and chemistry “Gamma”), which are part of this international scheme, and may issue national certificates based on research reports elaborated abroad (without additional testing).

### **Field of standardisation**

ISS has concluded commercial agreements with the following institutions (Annex 1.11 – ISS Agreements):

- German Institute for Standardisation (DIN) in Berlin;
- British Standards Institution (BSI) in London;
- Russian Scientific and Technical Centre of Information on Standardisation, Metrology and Conformity Assessment - FGUP „Standartinform”, operating on behalf of the Russian Federal Agency on Technical Regulation and Metrology - GOST R in Moscow;
- American Society for Testing and Materials (ASTM), leading US organisation for standardisation.

In accordance with these agreements, ISS has the right to sell national standards and other publications published by the above mentioned organisations, and moreover to adopt some of those (e.g. DIN and ASTM standards) as Serbian standards or related documents.

Furthermore, in the framework of bilateral cooperation, ISS concluded in 2007 Agreement on Business and Technical Cooperation with the Institute for Standardisation of Montenegro (ISME), and in 2008 an agreement with the Institute for Standardisation of Bosnia and Herzegovina (BAS).

## **Field of Accreditation**

Serbian Accreditation Body (SAB) represents the Republic of Serbia in the European and international organisations for accreditation and takes part in their work.

All agreements from the field of accreditation are listed in the answer to the question No 27.

## **Field of Metrology (Annex 1.12 – DMDM Agreements)**

- On 24 June 2008 Serbia became an affiliate member of the European Cooperation in Legal Metrology (WELMEC).
- Bureau of Measures and Precious Metals became a member-founder of EURAMET e.V., on 11 January 2007, in Berlin.
- Bureau of Measures and Precious Metals signed on 7 September 2006 Statements of Mutual Confidence (DoMC) for P60 measurement transformers and P76 non-automatic weighing devices, and took part in the Mutual Recognition Arrangement of Research of the International Organisation of Legal Metrology OIML (MLA).
- Bureau of Measures and Precious Metals on 25 May 2005 became a member of EURAMET e.V.
- Federal Bureau of Measures and Precious Metals on 16 January 2003 signed a Protocol of Understanding and became a member of Euro-Mediterranean Legal Metrology Forum (EMLMF).
- On 5 December 2002, Federal Bureau of Measures and Precious Metals, as a national metrology institute of the member state of the Meter Convention, signed a Mutual Recognition Arrangement of National Standards, Standards Certificate and Measurement, issued by the national metrology institutes - the Mutual Recognition Arrangement of the International Committee of Weights and Measures (CIPM).
- Federal Bureau of Measures and Precious Metals signed on 12 June 2002 a Memorandum of Understanding and became a member of the Association of European Analysis Organisations (AEAO) and International Association of Assay Offices-IAAO) for objects made from precious metals.
- Since 1955, Serbia (Yugoslavia) has been a signatory to the International Convention on Establishing the International Organisation of Legal Metrology (OIML).
- 1879. In 1879 the Kingdom of Serbia was granted membership in the Metre Convention.

### ***A. Standardisation***

**10. Is the Standardisation Institute able to implement European and international standards? Has the Standardisation Institute made a needs assessment for investment and technical expertise required to participate in the European standards system? Please explain.**

Rights, liabilities and responsibilities of the Institute for Standardisation of Serbia (ISS) are established by the following acts:

- Law on Standardisation
- Decision on the Amendments and Modifications of the Foundation Act of the Institute for Standardisation of Serbia (Official Gazette of RS, No. 88/09), and

- Statute of the Institute (Official Gazette of RS, No. 79/07).

ISS is ready and able to take active participation in the European and international standardisation, and to transpose the international and European standards into Serbian. The legal framework for adopting Serbian standards and related documents is comprised in Article 7 of the Law on Standardisation. During elaboration of the ISS annual work plans and annual plans for adopting Serbian standards and related documents, priorities ensuing from the association process of Serbia to the World Trade Organisation (WTO) and the Stabilisation and Association Agreement (SAA), i.e. requests made by the competent ministries in accordance with the National Integration Plan with the EU, for acquiring candidate status of EU membership, have been taken into account.

In the accession process to the WTO, the Republic of Serbia, besides other documents, is required to accept the Agreement on Technical Barriers to Trade, which contains in Annex 3 the Code of Good Practice for the Preparation, Adoption and Application of Standards. As the national organisation for standardisation, the ISS officially informed in early 1998 the ISO/IEC Information Centre in Geneva on its voluntary adoption of this Code, stating it would operate in compliance with the Code.

The plan for national implementation of European standards in Serbia in the period 2008-2012 is presented in Table 1.

**Table 1 – Plan for  
national implementation of European standards  
in Serbia in the period 2008-2012**

<b>Year</b>	<b>Number of EN standards which will be implemented/transposed as Serbian standards</b>
2008	3 000
2009	3 200
2010	4 000
2011	4 500
2012	4 500

ISS has made an assessment of its capacities, expertise and technical know-how required for participating in the European standardisation system, based on which a necessity for upgrading and modernisation of the information system was identified, aimed at facilitating document monitoring and document operation, copyright and intellectual property protection related to the national and other standards, specialisation and training of employees engaged in the transposition of European and international standards into the ISS.

#### **Institutional framework**

MoERD, as a coordinator in the field of free movement of goods, is responsible for public administration operations related to standardisation. Within its area of competence, MERD prepares the standardisation national strategy and development policy in cooperation with ISS, coordinates activities related to needs identification of the state bodies in terms of EU standards transposition into Serbian standardisation, in the context of their legislative activities and pursuant to Article 20 of the Law on Standardisation monitors the ISS operations relating to standardisation from Article 7 of this Law.

In establishing the Standardisation National Strategy and Development Policy, strategic interests of all stakeholders in Serbia are taken into account (economy, scientific and educational institutions, ministries and other public administration bodies, non-governmental organisations and citizens).

The ISS is able to implement the European and international standards, i.e. to transpose them as Serbian standards. Serbian standards and related documents are adopted and published in accordance with the Law on Standardisation and the internal rules of the ISS, which are in compliance with the rules of the European and international organisations for standardisation, and the Code of Good Practice for the Preparation, Adoption and Application of Standards from the World Trade Organisation's Agreement on Technical Barriers to Trade.

In accordance with Article 12 of the Law on Standardisation, international standards and related documents shall be used as a basis for adoption of Serbian standards and related documents. In case no international publication exists in a specific field, or the international publication in force is inadequate, European publication or national publication of other countries in force may serve as the basis.

In accordance with Article 15 of the Law on Standardisation, Serbian standards and related documents are adopted and published in Serbian language and alphabet, pursuant to the Law on the official use of language and alphabet.

By way of exception, in cases when international, European or national standard of another country, and/or related document, is used as the basis for adoption of the Serbian standard or related document, the Serbian standard or related document may be published in one of the official languages of the European organisations for standardisation (in English, French or German). In accordance with the ISS internal rules, in such cases the Serbian standards and related document are published in English language, by method of endorsement and method of reprinting.

The most important elements in the Capacity Building Strategy of the ISS are the upgrading of expertise and technical know-how in specific fields of standardisation and the upgrading of membership status of the ISS in CEN and CENELEC. The role of technical committees has to be emphasized, as professional bodies made of experts for specific fields, who had taken part, in the capacity of observers, in sessions of certain CEN and CENELEC technical committees.

Until 30 September 2008, ISS had a status of a public administration body; from 1 October 2008 to 3 January 2010 it had a status of an independent non-profit organisation, and since 4 January 2010 ISS is an institution operating in accordance with regulations governing the legal status of public services.

#### **11. Are staff numbers and financing adequate? Please provide figures.**

Strengthening of the ISS is necessary for the achievement of these priorities, both in terms of staffing and financing.

Primary source of ISS financing is subvention from the budget of the Republic of Serbia. Funding is approved based on the Annual Work Plan and Plan for the Adoption of Serbian Standards and Related Documents for each fiscal year. ISS is financed in smaller part through sale of standards, membership fee collection, etc. These funds are used for covering only the basic operational needs of the ISS. For further upgrading of information and communications equipment and accompanying programmatic support, and for long-term capacity building and motivation of employees, substantial funding is required for financing the operational needs of the ISS.

Upgrading of the ISS operations requires a stable financing from the budget of the Republic of Serbia. Furthermore, ISS will at the same time develop its operations and new activities, aiming at increasing the share of its own resources in the total financing, since at present approximately 20 % only of the overall needs is covered from its financing.

Planned ISS expenditures in 2009 and 2010 by sources of financing are presented in Table 2, whereas ISS expenditure projections for the period 2011-2013 and required funds for its financing, by sources of financing, are presented in Table 3.

**Table 2 – Comparative overview of ISS planned expenditures in 2009 and 2010, by sources of financing**

Source of funding for covering expenditures	Planned expenditures (in EUR) 2009	Planned expenditures (in EUR) 2010
Subvention from the budget of the Republic of Serbia	841,954.43	765,264.24
ISS sources (direct revenues)	246,097.89	255,928,53
Surplus of revenues and income from previous year (earmarked for the next year)	39,649.77	0
<b>TOTAL:</b>	<b>1,127,702.09</b>	<b>1,021,192.77</b>

**Table 3 - ISS expenditure projections for the period 2011-2013, by sources of financing**

Source of funding for covering expenditures	Expenditure projections by years (in EUR)		
	2011	2012	2013
Subvention from the budget of the Republic of Serbia	721,092.87	828,203.70	875,768.50
ISS sources (direct revenues)	324,185.93	339,342.28	373,466.09
<b>TOTAL:</b>	<b>1,069,885.55</b>	<b>1,167,545.99</b>	<b>1,249,234.59</b>

ISS Financial Plan for 2011 foresees sources for salaries and social security benefits born by the employer for 68 employees, including the Managing Director.

**12. What percentage of your standards is in conformity with European standards (give separate percentages for CEN, CENELEC and ETSI standards)?**

Until 31 December 2010, ISS has adopted (taken over) 10.214 European standards and related documents in total, out of which 7.104 (or about 50.5 %) non-electrotechnical European standards published by CEN and 3.110 (or about 50.4 %) European electrotechnical standards published by CENELEC.

## **Standards Adoption Plan – from 2010 to 2012**

In 2010, the ISS planned activities related to the preparation of 4.085 Serbian standards and related documents, out of which 255 shall be in Serbian, and 3.830 in English. Out of 4.085 standards and related documents in total, 394 were transferred from 2009 (in preparatory phases), while 3.691 were introduced for first time into the Plan.

In accordance with envisaged categories applied, elaboration of 4.005 drafts standards and 3.910 final draft standards is envisaged in 2010, as well as publication of 3.988 Serbian standards and related documents in total.

Publication of 3.624 standards and related documents introduced into the Plan is envisaged in 2010, out of which 197 shall be in Serbian, and 3.427 in English language. Since 364 standards shall be transferred from 2009, the total number of Serbian standards and related documents in the publication phase is 3.988.

Out of the total envisaged number of Serbian standards and related documents published (3.988), 3.807 shall be harmonised with European standards and related documents, 181 with international standards and related documents (out of which 137 with ISO, 4 with IEC, and 50 with ISO/IEC acts), whilst elaboration of pure national standards and related documents is not envisaged.

In 2010 ISS published 3.780 Serbian standards and related documents (out of which 284 in Serbian and 3.496 in English), whereas 3.668 out of these publications are identical to the European standards (2.158 CEN and 1.510 CENELEC). At the same time, 609 Serbian standards conflicting with the transposed European standards were withdrawn.

Competent ministries presented to ISS their proposals for the elaboration of Serbian standards relevant for the implementation of technical regulations envisaged for adoption in 2010, which shall ensure transposition of the “New Approach” directives into the Serbian legal system. In this regard, the Plan envisages elaboration and adoption of 924 Serbian standards presenting national implementations of harmonised European standards for 28 New Approach and other directives.

Dynamics of the European standards implementation in Serbia, in the period from 1 January 2007 to 31 December 2010, is presented in Table 4.

Table 4 – Number of published and withdrawn Serbian standards and related documents in the period from 1 January 2007 to 31 December 2010

Year	Number of published Serbian standards and related documents			Number of withdrawn conflict Serbian standards and related documents	Number of published Serbian standards and related documents representing national implementations of European standards and related documents
	In Serbian language	In English language	In total		
<i>Before 2007</i>	300	–	300	–	300
<b>2007</b>	65	393	458	128	277
<b>2008</b>	512	2 314	2 826	344	2 688
2009	252	3 257	3 509	386	3 281
2010	284	3 496	3 780	609	3 668
<b>TOTAL:</b>	<b>1 413</b>	<b>9 460</b>	<b>10 873</b>	<b>1 467</b>	<b>10 214</b>

**13. Please indicate if you are a member (or working towards membership) of any European and international standards organisations (CEN, CENELEC, ETSI, others). Is there a timetable for achievement of full membership of CEN and CENELEC? What is the relationship with the international (IEC and ISO) standards bodies?**

The ISS has been an affiliate member of the European Committee for Standardisation (CEN) since 1 January 2008 (where from 1998 to 2004 it had a correspondent member status, whilst from 1 January 2005 to 31 December 2007 it had a status of partner standardisation body), as well as affiliate member of the European Committee for Electrotechnical Standardisation (CENELEC) since 1 October 2005.

ISS is not a member of the European Telecommunications Standards Institute (ETSI). Unlike CEN and CENELEC, whose members may be national standardisation organisations exclusively (such as ISS), several organisations from each country may become members of ETSI. The national standardisation organisation may be an ETSI member, but it is not obligatory. The only ETSI member from Serbia, for the time being, is the Republic Telecommunications Agency (RATEL) which has a full member status in ETSI. Besides, RATEL applied with ETSI as "the national standardisation organisation" which has specific liabilities in terms of transposing EU standards in the telecommunications field and other publications published by ETSI, in accordance with Article 13.2 prescribing its rules of procedure. During the next period, ISS and RATEL shall agree upon cooperation regarding transposition of the ETSI standards in Serbia.

ISS strategic goal is to complete the harmonization of Serbian standards with the European standards (EN) and harmonisation documents (HD) by the end of 2012, i.e. to transpose a minimum of 80 % of all EU standards and harmonisation documents in the set of Serbian standards and fulfil all other formal requirements (i.e. fulfilment of legislative, organisational, technical and technological requirements) necessary for obtaining full-member status in CEN and CENELEC.

ISS has been a full member of the International Organisation for Standardisation (ISO) since 1950 and a full member of the International Electrotechnical Commission (IEC) since 1953.

Furthermore, ISS acts as a Codex Contact Point for Serbia, in the framework of cooperation with Codex Alimentarius Commission.

## ***B. Conformity assessment***

### **14. Please describe the legal framework (laws, bylaws etc) for conformity assessment and report on the current implementation.**

Legal framework defining conformity assessment in Serbia is laid down by the following laws:

- Law on Technical Requirements for Products and Conformity Assessment
- Law on Standardisation
- Law on Metrology
- Law on Accreditation

Bylaws of the Law on Technical Requirements for Products and Conformity Assessment, closely governing the matter of conformity assessment, are the following:

1. Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity
2. Regulation on the Manner of Designation and Authorisation of Conformity Assessment Bodies (Official Gazette of RS, No. 98/09);
3. Regulation on the Manner of Recognition of Foreign Documents and Marks of Conformity (Official Gazette of RS, No. 98/09).
4. Rulebook on Manner of Affixing Marks of Conformity on Products, and Use of Conformity Marks (Official Gazette of RS, No. 25/10).
5. Regulation on the Regulation on Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standards

The aforementioned bylaws are substantially in compliance with Decision 768/2008/EC.

In accordance with the Law on Technical Requirements for Products and Conformity Assessment, and the above mentioned bylaws, it is foreseen that conformity assessment, in accordance with the requirements laid down in the technical regulation, may be performed by the manufacturer, conformity assessment body or public authority. .

Technical regulations prescribe the conditions that have to be fulfilled by the conformity assessment bodies. The Law on Technical Requirements for Products and Conformity Assessment, the Regulation on the Manner of Designation and Authorisation of Conformity Assessment Bodies, and the Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity prescribe monitoring over the operations of the Designated Conformity Assessment

Bodies. Conformity assessment bodies must fulfil the requirements concerning professional competences, necessary equipment, independence and impartiality in the conformity assessment procedure, business confidentiality protection, and liability insurance against potential damage referring to the operations performed. Possession of accreditation certificate is a presumption that the conformity assessment body meets the requirements for designation to the extent covered by the accreditation scope.

The laws and bylaws have followed the principles of the “new good’s package” for marketing of products, and the EU practice defining that the accreditation act for specific area is the best instrument for the conformity assessment bodies to prove the level of required competence and fulfilment of minimum requirements.

In Serbia, an authorisation system for conformity assessment bodies was in place, transposed from the State Union of Serbia and Montenegro, whilst these authorisations referred to the application of over 50 ordinances and rulebooks on mandatory attestation. Through alignment of legislation with the EU, the Republic of Serbia will gradually innovate the system and introduce new designations/authorisations where envisaged by the EU harmonised regulations. Designation committees have been established at the Ministry of Economy and Regional Development, in accordance with new technical regulations which transposed directives referring to machinery, low voltage electrical equipment and electromagnetic compatibility. Designation committees' work is under way, and the first decisions on designation have been enacted.

### **Priorities for 2011-2012**

Education and capacity building are required within all ministries responsible for adoption and implementation of technical regulations, in particular in the part referring to the designation and authorisation, recognition of document of conformity issued by foreign conformity assessment bodies. Moreover, for the full implementation of the EU regulations development of a continuous monitoring system over designated conformity assessment bodies is required, and their further capacity building and development.

Further capacity building of designated conformity assessment bodies is also required, for enabling them to perform testing and certifications in accordance with relevant EU legislation, and signing of EA/MLA required for recognising systems and products designed for export to the EU market.

Ministry of Economy and Regional Development, upon completed harmonisation of technical regulations in specific industrial sectors shall initiate and coordinate activities referring to the ACAA Agreements signing, which shall enable Serbia to become part of the common market even before obtaining a full EU membership status. Thus the access of products to the common EU market will be enabled without additional testing and certification, provided their conformity is recognised by national designated and notified conformity assessment bodies.

### **15. Are procedures applying to conformity assessment in line with Decision No 768/2008/EC?**

Conformity assessment procedures are regulated by the Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity, which are prescribed in a specific technical regulation, are in line with the procedures defined in Decision 768/2008. Namely, Article 18 of this Regulation sets

out that conformity assessment is performed in accordance with procedures (modules) prescribed by the technical regulation, in accordance with Decision 768/2008/EC.

The same Article also defines modules that may be prescribed by the technical regulation (modules from A-H), which represent different phases of the conformity assessment procedure, as follows:

- 1) Module A - internal production control;
- 2) Module B – type examination;
- 3) Module C –conformity to type based on the internal production control;
- 4) Module D - conformity to type based on quality assurance of the production process – production quality assurance;
- 5) Module E - conformity to type based on the product quality assurance – product quality assurance;
- 6) Module F –conformity to type based on the product verification;
- 7) Module G – conformity based on the unit product verification;
- 8) Module H - conformity based on the full quality assurance - full quality assurance.

The above mentioned modules may be applied individually or combined, in accordance with specific technical regulation.

#### **16. Are foreign test reports recognised? If yes, in which conditions?**

Article 28 of the Law on Technical Requirements for Products and Conformity Assessment sets out that documents of conformity issued by a foreign conformity assessment body and marks of conformity issued in foreign country are valid in the Republic of Serbia, provided they are issued in accordance with the ratified international agreements signed by the Republic of Serbia.

Moreover, the competent minister may recognise the validity of the documents of conformity and marks of conformity issued in foreign countries, provided that the requirements from such regulation ensure at least the same level of safety, human life and health, protection of animals and plants, environment protection, protection of consumers and other users and protection of property, that are established by the Serbian technical regulation requirement.

Regulation on the Manner of Recognition of Foreign Documents and Marks of Conformity lays down detailed conditions for the recognition of documents of conformity issued in foreign countries.

Besides, Article 10 of the Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity provides a possibility of recognising foreign test reports. This Article lays down that designated conformity assessment body may create and issue a relevant national document of conformity for foreign products accompanied by document of conformity, without repeating the conformity assessment procedure, under the following conditions:

In case the designated body and the conformity assessment body that issued foreign conformity licence are:

- 1) signatories to the Agreement on Mutual Recognition of Conformity Assessment Results, or
- 2) members of the international Conformity Assessment System.

In case an agreement on mutual recognition of technical competences of conformity assessment bodies is signed at the level of accreditation bodies.

**17. Who is responsible for designating conformity assessment bodies (CABs) and are the criteria for ascertaining their competences defined in the sectoral legislation? Are ISO standards used in this respect? If yes, which ones?**

Competent ministries, within their respective scope of work, are responsible for issuing authorisations (Old Approach) and designation (New Approach) of conformity assessment bodies. Ministry of Economy and Regional Development is responsible for notification of designated conformity assessment bodies. Law on Technical Requirements for Products and Conformity Assessment also recognises the EU practice prescribing that the certificate of accreditation for specific area is the best instrument used by the conformity assessment body for ascertaining the competences for performing conformity assessment activities. Technical regulations lay down the requirements for designated and authorised bodies; accreditation certificate is one of the documents acknowledged in designation and authorisation procedure.

Serbian standardisation transposed the ISO 17000 series standards, such as ISO 17025, ISO 17020, ISO 17021 and EN 4501, and these standards are applied in Serbia. Serbian Accreditation Body issues an accreditation certificate upon carrying out the procedure of ascertaining the competence of the body and its capacity to fulfil the requirements of these standards.

All principles and requirements of the ISO 17011 standards have also been taken into account during elaboration of the Law on Accreditation, and the Serbian Accreditation Body is organised in compliance with the SRPS ISO 17011 standards requirements.

**18. How many CABs are active at present in the Country per EU Directive transposed?**

At present, there are three designated conformity assessment bodies, in accordance with the EU directives, although designated conformity assessment bodies are accredited in accordance with the requirements of specific harmonised standards. Processing of requests, preparation and operation of the committees for designation of ten conformity assessment bodies are under way, for three Rulebooks transposing directives for machinery, low voltage electrical equipment and electromagnetic compatibility.

**19. Has the enquiry point for technical regulations been appointed? Is it already operational? Which is its endowment with material and human resources?**

Yes, it has been established. In accordance with the Law on Technical Requirements for Products and Conformity Assessment (Articles 31-33) Department for Quality Infrastructure, within the Ministry of Economy and Regional Development, has established the Enquiry point responsible for providing information on technical regulations and related conformity assessment procedures, and for notification of draft technical regulations in accordance with the World Trade Organisation and CEFTA regulations, and Directive 98/34/EC. The Enquiry point shall become fully operational on the day of entering in WTO and EU, in regard to the notification of draft technical regulations.

One employee within the Group for Registers and Cooperation with International Organisations of this Department is responsible for the Enquiry point activities, i.e. providing information and notification processes. Upon accession of Serbia to the WTO and the EU, it is foreseen that one employee shall be responsible for notification of technical regulations towards WTO, and one for Directive 98/34/EC.

In mid 2010, through Regulation on Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standards, Directive 98/34/EC was transposed. In the second half of the same year, an application software TEHNIS was developed, comprising electronic database and Internet portal ([www.tehnis.merr.gov.rs](http://www.tehnis.merr.gov.rs)) that will upgrade the Enquiry point operations related to technical regulations, both in terms of information dissemination and notification of draft technical regulations.

#### **20. Has the register for technical regulation been established?**

Ministry of Economy and Regional Development is responsible for keeping the Register of technical regulations, in accordance with the Law on Technical Requirements for Products and Conformity Assessment. During 2009, the Action Plan for the elaboration of technical regulations with measures for their application was implemented; within its framework, relevant data was collected from competent ministries for the establishment of the Register of all valid technical regulations in the Republic of Serbia. Technical regulations are currently classified within the Register according to the competent ministries, and the following data are registered:

- Title and number of the official gazette where such technical regulation was published
- Legal framework for its adoption
- Marks of the Serbian standards the technical regulation is referring to

In May 2010, Regulation on the Content and Manner of Keeping Registers Referring to Technical Regulations (Official Gazette of RS, No. 33/10). 33/10). In accordance with the Regulation, the Register of technical regulations is kept in electronic format, and it will be made available as a public book on the MERD web page.

Final phase of development of the application software and electronic database (TEHNIS) is underway, which will enable the publishing of all prescribed data from registers, via web portal of the Ministry. Completion of entering of the existing data on the current technical regulations is foreseen during the first quarter of 2011.

#### **21. How many, and which, technical regulations have been adopted/registered up to date?**

The Register of current technical regulations in the Republic of Serbia contains 821 regulations, including technical regulations not referring to products only, but to the production of processing as well, and sectoral regulations in the field of rail, water and air transport. Table 2 presents the number and distribution of registered regulations by competent ministries, and their respective fields of work.

Table 2

Competent ministry	No. of technical regulations
<u>Ministry of Economy and Regional Development</u> Technical requirements for industrial products and processes	69
<u>Directorate of Measures and Precious Metals</u> Technical requirements for measuring instruments and pre-packed products	251
<u>Ministry of Energy and Mining</u> <u>Technical requirements in the fields of:</u> -Electrical energy -Oil and gas -Mining and geology	58
<u>Ministry of Agriculture, Forestry and Water Management</u> Technical requirements for agricultural products and animal food <u>Technical requirements in the field of forestry</u>	57
<u>Ministry of Health</u> -- Technical requirements for quality, sampling and testing methods of specific agricultural products -- Technical requirements for medical devices	31
<u>Ministry of Infrastructure</u> <u>Technical requirements for transportation means and infrastructure in the fields of:</u> -- Road transport -- Rail transport -- Water transport -- Air transport	316
<u>Ministry of Telecommunications and Information Society</u> -Technical requirements for products and systems in the field of telecommunications	7
<u>Ministry of Environment and Spatial Planning</u> -- Technical requirements in the field of environmental protection -- Technical requirements in the field of civil engineering	52
<u>Ministry of the Interior</u> -- Technical requirements in the field of protection against fire and explosion -- Technical requirements for technical inspection of vehicles	41
<u>Ministry of Defence</u>	7

-- Technical requirements for shelters and dual-use facilities	
WITHIN THE COMPETENCE OF SEVERAL MINISTRIES	1

List of all current technical regulations will be available on the web portal [www.tehnis.merr.gov.rs](http://www.tehnis.merr.gov.rs).

**22. Please describe your marking system and perspective for the introduction of the CE marking.**

Article 24 of the Law on Technical Requirements for Products and Conformity Assessment prescribes that the manufacturer affixes a mark of conformity on the product compliant with the technical regulation, if it is determined by the technical regulation.

Mark of conformity may not be put on a product not aligned with the prescribed requirements, or on a product for which the mark of conformity placement is not prescribed.

Form, shape and content of the Serbian mark of conformity is governed by the Regulation on the Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content of Mark of Conformity (Articles 30-33), while the manner and use of the marks of conformity are prescribed by the Rulebook on Manner of Affixing Marks of Conformity on Products, and Use of Marks of Conformity.

Article 31 of the Regulation prescribes that the Serbian mark of conformity is the only mark recognising that the product which is placed on the market or put into use in the Republic of Serbia is in line with the requirements of the Serbian technical regulation, if such regulation foresees its affixing.

This provision shall cease to apply as from the date of entering into force of a ratified international Agreement on Conformity Assessment and Acceptance of Industrial Products with EU (ACAA Agreement), for the products the Agreement is referring to, whereas for the products the Agreement is not referring to, the provision of Article 31 of this Regulation shall cease to apply as from the date of accession of the Republic of Serbia to the EU. By way of exception from this provision, the CE mark shall be valid in the Republic of Serbia even prior to the signing of the ACAA Agreement in case the recognition of the document of conformity, and the related mark of conformity, was made, in accordance with the provisions of Articles 28-30 of the Law on Technical Requirements for Products and Conformity Assessment.

As of the date of the ACAA Agreement signing, and not later than the date of the EU accession, the CE mark shall be applied solely (Article 37 relating to Article 32 of the Regulation), whose content and form are prescribed by the above mentioned Regulation (in accordance with Regulation 765/2008/EC).

**23. Does the legislation contain a safeguard clause foreseeing the withdrawal of compliant products that are nonetheless found to endanger health and safety?**

The safeguard clause is foreseen in two laws, as follows:

- In the Law on Technical Requirements for Products and Conformity Assessment– in Article 22 which reads as follows:

“The competent inspector shall undertake appropriate measures restricting the making available on the market, prohibiting the placement of products on the market or making available on the market, withdrawing or recalling the products in accordance with the law, if it is found that a product conforming with the technical regulation may endanger public interest, and particularly if it endangers safety, human life and health, safety and health of animals and plants, environment, safety of consumers and other users and property

and

- In the Law on General Product Safety – in Article 9, with the wording:

“Authority responsible for undertaking appropriate measures in accordance with the authorisations established by this Law and other legal acts (hereinafter referred to as: “the competent authority”) may undertake adequate measures in case there is evidence on the risks posed by the product, although such product fulfils safety requirements established by specific regulations from Article 2 of this Law, and fulfils conformity assessment criteria from Articles 7 and 8 of this Law”.

Thus, if due to certain circumstances during market surveillance the competent inspectorate assesses that the product is dangerous, it may undertake measures of withdrawal or recall of the subject product from the market, even in cases when the manufacturer fulfilled and approved the fulfillment of all prescribed technical regulations. Such procedure, besides regular measures prescribed through these two laws and related technical regulations, has provided for a legal framework banning such dangerous product placement on the market of the Republic of Serbia.

#### **24. Please describe how your legislation defines the manufacturer's and importer's responsibilities and the manufacturer's general product liability.**

In accordance with the Law on Technical Requirements for Products and Conformity Assessment (Articles 23-26) liabilities of manufacturers, importers and distributors are defined, in line with the new EU legal framework (in particular with Decision 768/2008) from 2008:

##### **Manufacturer's liabilities (defined in Articles 23 and 24):**

###### **Article 23**

The manufacturer shall:

- 1) ensure that the product is manufactured in accordance with the prescribed requirements;
- 2) draw up the required technical documentation and keep it in the prescribed period;
- 3) ensure the implementation of the prescribed conformity assessment procedure, prepare the declaration of conformity and keep it in the prescribed period, and affix a prescribed mark of conformity on the product;
- 4) when prescribed so, test the samples of products on the market, process data, keep a complaints register and inform distributors on non-conforming products, as well as on corrective measures undertaken on its own initiative, upon request or in cooperation with competent authorities, aiming at avoiding risks posed by the non-conforming product;
- 5) perform other activities defined in the technical regulation for specific products.

The manufacturer may authorise a representative to perform its obligations by granting it a written authorisation, which must at least provide the representative with the possibility to:

- 1) keep the declaration of conformity and the technical documentation within the prescribed period;
- 2) provide the competent authorities with all information and documentation necessary to demonstrate the product conformity;
- 3) cooperate with competent authorities in all corrective measures undertaken for avoiding risks posed by the product.

The manufacturer may not transfer to the authorised representative either its liabilities from paragraph 1, point 1) of this Article, or the drawing up of technical documentation.

#### Article 24

The manufacturer shall affix the mark of conformity on the product in conformity with the technical regulation if it is specified in the technical regulation.

It shall be prohibited to affix the mark of conformity on a product that is not in conformity with the prescribed requirements, or on a product for which affixing of the mark of conformity is not prescribed.

It shall be prohibited to affix on a product any other mark that is not the mark of conformity but is of similar content or form, which might either create a misperception of a consumer or other user that it actually represents the mark of conformity, or a affixing of another mark on the product might affect visibility and legibility of the mark of conformity.

Form, appearance and content of the mark of conformity shall be governed by a regulation adopted by the Government.

#### **Importer's liabilities** (defined in Article 25):

##### Article 25

The importer shall:

- 1) check whether a declaration of conformity was issued for the product, and whether the product is accompanied by other prescribed document of conformity, whether it is marked by a prescribed mark of conformity, whether it is labelled in a manner providing for identification of the product and its manufacturer, and whether it is accompanied by the prescribed documentation;
- 2) keep a copy of the declaration of conformity and technical documentation within the prescribed period, and make them available to the competent authorities upon their request;
- 3) if there is reason to believe that a product is not in conformity with the prescribed requirements, place the product on the market only after the manufacturer brings the product in conformity with such requirements with such requirements, and inform the competent authority thereto, in case the product is dangerous;
- 4) ensure that, before placing the product on the market, the conditions of storage and transportation do not affect the conformity with the prescribed requirements;
- 5) perform other activities prescribed in the technical regulation for specific products.

The importer shall be deemed to be the manufacturer and assume its obligations upon placing the product on the market under its own name or trademark, and/or in case it modifies the product that was already placed on the market, to the extent affecting its conformity with the prescribed regulations.

#### **Distributor's liabilities** (defined in Article 26):

## Article 26

The distributor shall:

- 1) check whether a prescribed mark of conformity was affixed on the product, and whether the product is accompanied by the prescribed documentation;
- 2) if there is reason to believe that a product is not in conformity with the prescribed requirements, make the product available on the market only after the manufacturer brings the product in conformity with such requirements, and inform the manufacturer or the importer and competent authorities thereto, in case the product is dangerous;
- 3) ensure that, prior to making the product available on the market, the conditions of storage and transportation do not affect the conformity of products with the prescribed requirements;
- 4) perform other activities defined in the technical regulation for specific products.

The distributor shall be deemed to be the manufacturer and assume its obligations upon placing the product on the market under its own name or trademark, and/or in case it modifies the product that was already placed on the market, to the extent affecting its conformity with the prescribed requirements.

### ***C. Accreditation***

**Please provide detailed information on the question below:**

**25. Does your country have an accreditation system and an accreditation body? Is the accreditation system aligned to the rules in Regulation (EC) 765/2008? Please describe the legal framework (laws, bylaws etc) for accreditation and report on the current implementation.**

**Does your country have an accreditation system and an accreditation body?**

Yes, Serbia has a legally established system of accreditation and the Accreditation Board of Serbia (hereinafter referred to as: ATS) as the only national accreditation body. The accreditation system in Serbia includes, in addition to the Accreditation Board of Serbia, accredited conformity assessment bodies (CABs), authorised and designated conformity assessment bodies, accreditation rules and procedures, and the Ministry of Economy and Regional Development (MoERD) that is responsible for the development and implementation of accreditation development policy and strategy. Rights, obligations and responsibilities of the Accreditation Board of Serbia are laid down in the Law on Accreditation, Act on Establishment and Statute.

**Is the accreditation system aligned to the rules in Regulation (EC) 765/2008?**

Yes.

The accreditation system is in full compliance with the requirements of Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products. This could be achieved by applying documented quality management system (QMS) that is conformed to the

requirements of ISO IEC 17011 *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment*.

On 12<sup>th</sup> October 2010 the new Law on Accreditation entered into force and it was adopted to achieve harmonisation with Regulation (EC) 765/2008. In addition to establishment, activities, bodies and financing, this law stipulates accreditation of conformity assessment bodies (CABs) performing testing, calibration, inspection and certification of products, processes, management systems and persons.

Basic aspects of harmonisation of the Serbian accreditation system with the requirements of Regulation 765/2008 are primarily reflected in the role of accreditation in the field of the CAB designation. Furthermore, cross-border accreditation principles are observed in the field of accreditation, including the relation of the Accreditation Board towards the state.

**Please describe the legal framework (laws, bylaws etc) for conformity assessment and report on the current implementation.**

The Accreditation Board of Serbia was established as an institution in accordance with the new Law on Accreditation. The Serbian Government is legally obliged to adopt the new Act of Establishment of the Accreditation Board of Serbia within six months following the adoption of the Law on Accreditation. As a consequence, the new Statute of the Accreditation Board of Serbia must be adopted, while a large number of ATS rules and procedures must be amended.

**26. Does the accreditation body fulfil the requirements of Regulation (EC) 765/2008? Is it independent? Is it a non-commercial body? Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting conformity assessment bodies in line with the European system?**

**Does the accreditation body fulfil the requirements of Regulation (EC) 765/2008?**

The Accreditation Board of Serbia is in full compliance with the requirements of Regulation (EC) 765/2008 that was confirmed by the EU experts during the pre-evaluation visit performed by the assessment team of the European Cooperation for Accreditation (EA) in the period between 2<sup>nd</sup> and 5<sup>th</sup> March 2010. Pursuant to the findings of the assessment team of the European Cooperation for Accreditation, the Accreditation Board of Serbia undertook all necessary corrective actions aiming at full conformity of the accreditation system of the Republic of Serbia to that of the EU.

**Is it independent?**

The Accreditation Board of Serbia ensures its independence through equal participation of all interested parties in the work of ATS bodies, whereas no party, including the Founder, is predominant. Impartiality and objectivity of the accreditation system managed by the Accreditation Board of Serbia is ensured by means of the ATS strategy, policy and procedures implemented during the assessment process and accreditation decision-making.

**Is the ATS a non-commercial body?**

Yes. The Accreditation Board of Serbia is a non-commercial body as laid down in the Law on Accreditation, Article 5 (“The ATS shall not perform profit-making activities”).

**Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting conformity assessment bodies in line with the European system?**

Yes, the Accreditation Board of Serbia has the full range of technical and administrative competency necessary for the purpose of performing accreditation activities.

Bodies of the Accreditation Board of Serbia are as follows: Managing Board, Director and Supervisory Board, and in addition to the said bodies the ATS has the Accreditation Council.

ATS strategy and policy are determined by the Managing Board that also enacts, when approved by the Founder, the Statute, adopts financial reports, annual plans and annual work programmes.

The Accreditation Council is a professional advisory body that provides professional opinions in terms of development of the accreditation system, takes the initiative for the extension of the ATS scope of activities and takes position on other technical issues.

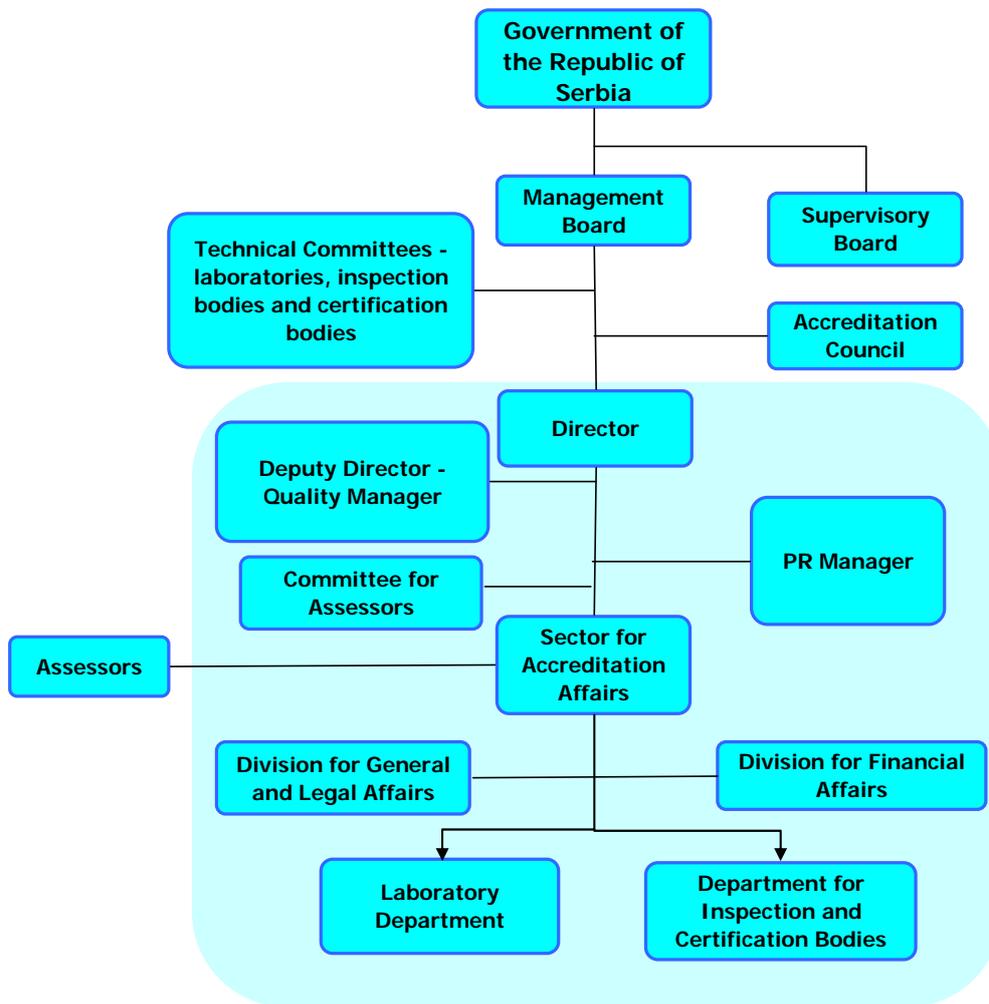
Renowned experts and scientists from the fields of relevance to the performance of activities falling under the ATS competences are selected as members of the Council, as well as representatives of the parties interested in accreditation (Safeguarding Committee).

The Accreditation Board of Serbia has established three technical committees for certain types of accreditation (laboratories, inspection bodies and certification bodies), while ad hoc technical committees can be established, as needed. Tasks of the technical committees are as follows: interpretation of requirements and documents of international organisations for certain types and fields of conformity assessment and accreditation, revision of the EA proposals, ILAC/IAF documents, provision of assistance to the Accreditation Board of Serbia in extending the scope of its activities, participation in assessor competence criteria definition for certain fields of conformity assessment, identification of potential assessors and provision of assistance to the Accreditation Board of Serbia on the occasion of recognition of schemes of inter-laboratory comparisons and PT schemes.

The Supervising Board conducts surveillance into the legitimacy of the work of Accreditation Board and its bodies, reviews business and financial reports to determine whether they have been produced in accordance with legal requirements and controls their authenticity and compliance with laws and other regulations.

The Director is appointed by the Founder.

Internal organisation of the Accreditation Board is stipulated in the Act on Internal Organisation and Functional Titles and Job Descriptions.



The ATS has 30 permanent staff members, and it hires, for the purpose of assessment, assessors and technical experts from the Register of Assessors and Technical Experts of the Accreditation Board of Serbia (The Register comprises 38 lead assessors, 57 technical assessors and 95 technical experts for different fields of accreditation).

**27. Does it have agreements with European or other international organisations?**

In 2002, the Accreditation Board of Serbia, as an associate member, i.e. signatory to cooperation agreements, started participating in the work of the European Cooperation for Accreditation. ATS representatives participate in the work of the General Assembly, technical committees and task forces of the European Cooperation for Accreditation.

On 12<sup>th</sup> February 2009, the Accreditation Board of Serbia submitted the peer evaluation application to the European Cooperation for Accreditation in order to be able to sign bilateral agreements (BLA) and multilateral agreements (MLA). In the first half of 2011 the assessment team members of the European Cooperation for Accreditation will perform the peer evaluation (see answer to Question 26)

The ATS entered into accreditation bilateral agreements with the following countries in the region (Anexx 1.13 – ATS Agreements):

- Hungarian Accreditation Board (NAT), 3<sup>rd</sup> April 2003
- Institute for Accreditation of Bosnia & Herzegovina (BATA), first signed on 22<sup>nd</sup> December 2004; the agreement was renewed on 24<sup>th</sup> February 2010
- Accreditation Body of Montenegro, 13<sup>th</sup> December 2007
- Institute of Accreditation of the Former Yugoslav Republic of Macedonia, first signed on 20<sup>th</sup> December 2005; the agreement was renewed on 29<sup>th</sup> January 2009.

In addition to the agreements that had already been signed, already prepared agreements on bilateral cooperation will be signed in 2011 with the Croatian Accreditation Agency (HAA) and Accreditation Body of Greece (ESYD).

All of these agreements pertain to mutual cooperation in the field of accreditation, but not to mutual recognition of reports and certificates of accredited CABs.

### **28. Is it a member or working towards membership of any such organisations?**

Apart from having extremely intensive cooperation with the countries in the region and Europe, the Accreditation Board of Serbia became an associate member of the International Laboratory Accreditation Cooperation (ILAC) on 17<sup>th</sup> February 2009.

The Accreditation Board of Serbia is currently preparing and completing an application for the membership in the International Accreditation Forum (IAF). The application will be sent in 2011.

### **29. How many conformity assessment bodies have been accredited so far and how many have applied for accreditation?**

403 conformity assessment bodies have been accredited so far:

- 291 testing laboratories,
- 3 medical laboratories,
- 35 calibration laboratories,
- 49 inspection bodies,
- 18 certification bodies certifying products,
- 7 certification bodies certifying management systems

Currently, there are additional 50 applications waiting to be processed.

## ***D. Metrology***

### **30. What is the present metrology structure in your country?**

The basic framework for organising the metrology system in the Republic of Serbia is represented by the Law on Metrology (Official Gazette of RS, No. 30/10).

During the new law elaboration, acts of the International Organization of Legal Metrology have been taken into account – OIML D1 and OIML D9, and EU regulations referring to metrology (the *acquis* of the European Union under the management of DG Enterprise and Industry, chapter 5, legal metrology and pre-packaging). Moreover, this Law transposes terms and definitions of the

International Vocabulary of Terms in Legal Metrology, and terms and definitions of the International Vocabulary of Basic and General Terms in Metrology.

Metrology system in the Republic of Serbia has been established in accordance with international and EU trends, and it consists of the following subjects: The Ministry responsible for metrology activities which is Ministry of Economy and Regional Development (MoERD); Directorate of Measures and Precious Metals (DMPM); Metrology Council; designated conformity assessment bodies, authorised bodies for measuring instruments verification, and accredited calibration laboratories.

Ministry of Economy and Regional Development is responsible for carrying out activities referring to strategy for development of metrology; DMPM is responsible for carrying out specialised activities from the field of scientific and legal metrology and acts as the National Metrology Institute (NMI), while the Metrology Council represents a specialised advisory body comprising renowned experts and stakeholders' representatives.

In accordance with Article 7 of the Law on Metrology, DMPM carries out the following activities:

- 1) Takes care of the legal system of measurement units in the Republic of Serbia;
- 2) Develops, implements, proclaims, keeps, maintains and improves the standards of the Republic of Serbia;
- 3) Ensures metrology traceability;
- 4) Carries out metrology expertise activities;
- 5) Carries out testing of pre-packed products, for the compliance check of metrology requirements;
- 6) Represents the Republic of Serbia in international and regional metrology organisations, and establishes cooperation in the metrology field;
- 7) Performs metrology surveillance;
- 8) Performs conformity assessment of the measuring instruments;
- 9) Decides in administrative procedures from the metrology field;
- 10) Takes part in drafting regulations from the metrology field;
- 11) Keeps a register of the measuring instruments subject to legal control;
- 12) Ensures metrology information and publishes an official bulletin;
- 13) Carries out time distribution;
- 14) Carries out other activities from the metrology field in accordance with the law.

Besides the above mentioned activities, the Directorate carries out verification of measuring instruments for which no other authorised bodies exist.

Having in mind the above mentioned, DMPM is responsible for carrying out activities in the fields of both industrial and legal metrology.

DMPM's role, as the National Metrology Institute of the Republic of Serbia, is to carry out research aiming at SI units' improvement, apply SI units through implementation of new measuring instruments and improvement of the existing national ones, and provide their traceability to the international level, develop and improve calibration methods, calibrate the measuring equipment for accredited calibration laboratories and other organisations and beneficiaries, and provide them with the necessary technical assistance, liaise with regional and

international metrology institutions and take part in relevant mutual recognition arrangements (MRA).

The Directorate is also responsible, in accordance with the Law on Metrology, for carrying out activities from the legal metrology field, which comprises in particular conformity assessment of measuring instruments with metrology requirements, such as, for example, requirements prescribed in MID and NAWI directives, and type approval and verification of measuring instruments, testing of pre-packed products, metrological surveillance etc.

The Directorate has aligned its organisational structure with the competences vested in it by the Law on Metrology. Key units of the Directorate's organisational structure are as follows: Sector for Development of Metrology, Control and Surveillance Sector, Certification Group, and General Administration, Legal and Financial Affairs Department. *Metrology Development Sector* is responsible for carrying out NMI's activities, while *Control and Surveillance Sector* is responsible for activities relating to legal metrology.

Metrology Development Sector consists of seven organisational units comprising national laboratories which carry out development, implementation, maintenance and improvement of the national standards of the Republic of Serbia. In these laboratories the following national standards are kept and applied: National (primary) standard of length unit-meter based on two frequency stabilised Helium Neon (He-Ne) lasers on 633 nm wavelength; national standard for angle in a plane; national standard for sound pressure based on six standard microphones; national standard for mass represented by a standard of kilogramme No. 33 made of Nical D steel and two sets of weights of E1 precision class in a measurement range from 1 mg to 10 kg; national standard for pressure unit based on pressure balance – deadweight tester with weights in the range of up to 1 000 bar; national standards for liquid volume – metal dropper standard of the title volumes 10 L, 50 L and 100 L, and glass dropper standard of the title volumes 1 L, 2 L, 5 L and 10 L; national (primary) standard for time unit and frequency unit, whose substantial part is a Cesium fountain atomic clock, and national time scale UTC(DMDM); national standard for DC electrical voltage (electromotor power) – group of standard cells and group of electronic standards ems; national standard for electrical resistance unit made of four standard Thomas-type resistors of the title value 1  $\Omega$ ; national standards for alternating voltage and current (AC-DC transfer standard and AC-DC thermal converters); national standards for electric power, phase angle, electric current harmonics, voltage and flickers; national standard for electrical energy unit – three-phase comparator; standard electric transformer with electronic error compensation; national (primary) standard for light power unit and national standards for light flux, luminosity, luminance, temperature, colour, spectral permeability, spectral sensitivity, and chromatic coordinates; national standard for density; national (primary) standards in the field of ionizing radiation dosimetry – kerma unit in air and unit of the water absorbed dose; national (primary) standard for thermodynamic temperature – group of three triple-point water cells and a series of temperature fixed points (He, H<sub>2</sub>, Ne, O<sub>2</sub>, Ar, Hg, H<sub>2</sub>O, Ga, In, Sn, Zn, Al, Ag, Cu) implemented for the International Temperature Scale (ITS-90). Beside the national standards, the most precise calibration methods for transposing SI units values to the end-users are implemented in these laboratories, as well as establishing links with international standards.

Within the metrology laboratory in chemistry, equipment is available for implementing the most advanced instrumental analytical methods: Gas chromatograph with FID and ECD detector (GC-FID and GC-ECD), gas chromatograph with mass detector (GC-MS), spectrophotometer UV-VIS, and a number of verified reference materials providing the basis for quality analysis and

implementation of wide-range reference materials, with an option of organising inter-laboratory comparisons for a large number of laboratories from different industrial fields, and in particular alimentary, health and environmental protection. Traceability of measurement results in the metrology field in chemistry, primarily for laboratories performing analytical research for the needs of chemical, alimentary and pharmaceutical industry, in the field of medicine and environmental protection, is carried out through certified reference materials (specific for different fields). These reference materials are produced by renowned foreign manufacturers (BAM, MERKLE, NIST etc.). It may be said that this particular field of metrology has not been sufficiently developed yet; thus its more intense evolution shall be encompassed by a development programme in the following five years.

A substantial part of the equipment supporting calibration and measurements in these laboratories for national standards was donated to Serbia by the EU in the framework of projects providing support to development of the quality infrastructure institutions (CARDS projects).

In the laboratories of this sector specific type testing of measuring instruments, primarily type testing of weighing instruments, electricity meters, pressure meters, etc are also carried out.

Control and Surveillance Sector consists of: Metrology Surveillance Department, six Control and Surveillance Sections, and Department for Precious Metals Product Testing. Control and Surveillance Sections carry out measuring instruments verification, for which mandatory verification is prescribed. These sections are not equipped for verification of all measuring instruments. In most cases, they possess standards and equipment used for verifications of mass and liquid volume measures, while for verification of other measures equipment of other laboratories is used, which frequently causes problems in functioning of these sections.

In accordance with the Law on Metrology (Official Gazette of RS, No. 30/10), verification of measuring instruments (first, regular, periodical or extraordinary), and conformity assessment of measuring instruments with the prescribed requirements, shall be carried out exclusively by entrepreneurship subjects and other legal persons that are, in accordance with relevant procedures, authorised and designated for carrying out verification/conformity assessment of measurement standards (authorised/designated bodies). Verification of measurement standards, for the verification of which no authorised bodies exist, is carried out by the Directorate. Manner of authorisation and conditions that have to be fulfilled by the authorised body are prescribed by the Rules of Procedure on Conditions for Performing Verification of Measurement Standards (Official Gazette of RS, No. 89/10) and the Rules of Procedure on the Manner of Authorisation of Entrepreneurship Subjects and Other Legal Persons for Performing Verification of Measuring Instruments and on Keeping the Register of Authorised Bodies (Official Gazette of RS, No. 89/10), respectively.

In accordance with the Law on Metrology and the above mentioned regulations, accreditation is a prerequisite for the authorisation of measuring instruments verification activities. Namely, entrepreneurs and other legal entities may carry out measuring instruments verification activities if they were previously accredited for the scope and types of measuring instruments which are being verified.

Types of measuring instruments for which control and verification are mandatory are prescribed by the Rules of Procedure on the Types of Measurements Standards Entailing Verification and Timetables of their Periodical Verification (Official Gazette of RS, No. 49/2010) (Annex to the Questionnaire). In accordance with these Rules of Procedure, 38 different types of measuring instruments are subject to the mandatory verification.

Verifications are carried out in accordance with the current metrological regulations and procedures, which for a certain number of measuring instruments are not complied with international and EU requirements. The table presents a list of regulations based on which verification of specific types of measuring instruments is carried out (Annex to the Questionnaire). Alignment of these regulations and transposing of relevant directives (in particular MID and NAWI) is planned for 2011 and for some of them procedures of elaboration and adoptions are already under way.

New organisational unit within the Directorate structure is the Certification Group. *Certification Group* currently carries out type approvals for specific types of measuring instruments, conformity assessment and certification issuance, and activities relating to the quality management system. In accordance with the new Law on Metrology, the Certification Group is preparing for the future Notified Body for conformity assessment of specific types of measurements standards comprised within MID and NAWI, in particular those for which domestic manufacturers exist (non-automatic and automatic weighing instruments, electricity meters, taximeters, water meters, etc.).

The Directorate's headquarters is located in Belgrade, and it also possesses facilities where Control and Surveillance Sections mainly carry out their activities, and these are located in Subotica, Novi Sad, Zrenjanin, Krusevac and Nis. The facility in Belgrade accommodates the National standards laboratories, Certification Group, General Administration, Legal and Financial Affairs Department, Management and Belgrade-based Control and Surveillance Section. In the previous years, refurbishments of several laboratories were made, aimed at improving conditions required for performing measurements, but nonetheless the laboratory space is currently insufficient and in some cases inadequate (e.g. in case of ionising radiation, physical-chemical measurements, etc.). The total number of employees in the Directorate is 120.

**31. Is there a national programme for the development of the metrology structure? Please provide details.**

In the Republic of Serbia currently a draft of a five-year Metrology System Development Strategy is under way. During elaboration of this Strategy, special care is taken of the needs regarding industry, economy, health, safety, environmental protection, and citizens of the Republic of Serbia. Metrology Development Strategy in Serbia is only one of a number of strategic documents that will represent the Overall Quality Infrastructure Development Strategy in Serbia, which will be drafted during 2011.

At the moment, only a Regulation Adoption Strategy is in place, adopted by the Government of the Republic of Serbia. In accordance with the new Law on Metrology, all bylaws for the full implementation of this Law shall be adopted within two years from the date of entering into force of this Law. Adoption of six bylaws is foreseen in 2010, in accordance with this Law, whilst other regulations shall be adopted by the end of 2012. Transposition of two directives referring

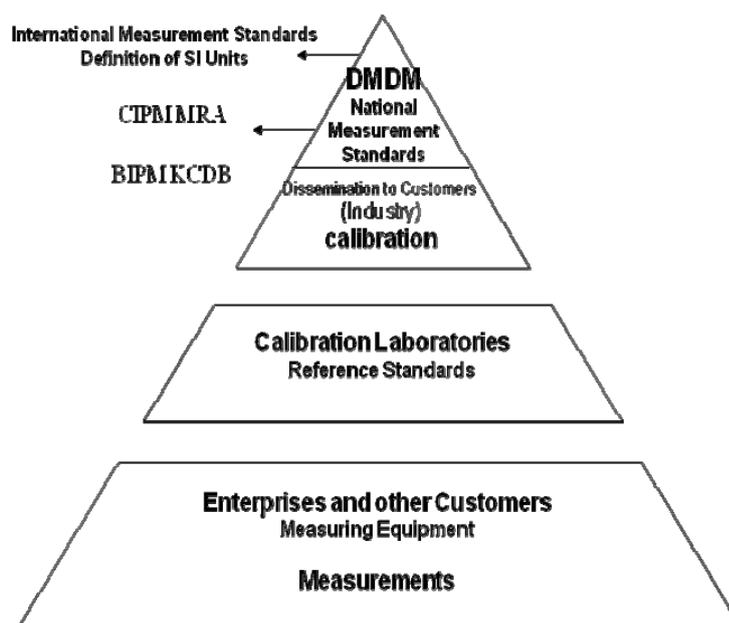
to measuring instruments, MID and NAWI, is foreseen in 2011, while EU Directives referring to packed products shall be transposed in 2012.

The mission of the Ministry of Economy and Regional Development and the Directorate of Measures and Precious Metals, that is especially enabled by the Law on Metrology from 2010, is a contribution of the Republic of Serbia to the fulfilment of requirements for the accession to the World Trade Organisation and the EU, by providing for the unique measurement system in the Republic of Serbia through ensuring correct and comparable measurements, use of measuring instruments whose requirements are aligned with internationally established requirements, use of SI measurement units, and through ensuring traceability of all measurement results to the national, and international standards.

### 32. How is traceability to international measurement standards ensured?

Directorate of Measures and Precious Metals, as the National Metrology Institute (NMI) of Serbia and signatory to the CIPM MPA, for specific calibration and measurement capabilities (CMC) published in BIPM (Bureau International des Poids et Mesures) database (BIPM KCDB) ensures traceability by calibration to international standards of SI units for all customers in the Republic of Serbia (economy, industry, calibration laboratories, conformity assessment bodies, etc.). In a continuous traceability chain, directly under the Directorate calibration laboratories are accredited (accredited by the Serbian Accreditation Body) which through calibration ensure to their beneficiaries traceability to the national standards of SI units. Beneficiaries from Serbia may, for the purposes of ensuring traceability, address NMIs of other states whose CMCs are placed in BIPM KCDB database, or accredited calibration laboratories, accredited by Accreditation bodies of other states, which are signatories to EA MLA and ILAC MPA.

A need for ensuring relevant traceability of measurements to SI units is particularly expressed in the field of industrial metrology. The image displays a manner in which the traceability chain to the national and international standards is currently implemented in Serbia.



Display of the national standards to which traceability is ensured up to SI units, and the manner of ensuring traceability in the field of chemical measurements is given in the answer to the question 30, in the part describing activities of the Metrology Development Sector.

Measurement and calibration capabilities (CMC) of the Directorate of Measures and Precious Metals which are stored in the KCDB BIPM database of key comparisons are provided in the table below. The Directorate publishes its CMC in KCDB through EURAMET (its RMO-Regional Metrology Organisation).

Measurement fields and relevant EURAMET Technical Committee		CMCs published in BIPM KCDB	CMCs in check-up procedure	Key and additional comparisons
TC-EM	ELECTRICITY AND MAGNETISM	YES		YES
TC-L	DIMENSIONAL QUANTITIES	YES		YES
TC-M	MASS	YES		YES
	PHOTOMETRY	YES		YES
TC-T	TEMPERATURE	YES		YES
TC-TF	TIME AND FREQUENCY	YES		YES

The Directorate has published 149 CMCs in KCDB, in the fields of: Electricity and magnetism - 93; dimension sizes and laser radiation frequency- 9; mass – 10; photometry – 11; temperature – 13; time and frequency – 12. In these fields, in accordance with CIPM MRA, Serbian national standards, certificates of calibration and measurements issued by the Directorate of Measures and Precious Metals are reciprocally recognised on a global scale, by all NMI signatories to this Agreement.

### *E. Market surveillance*

**33. How does your country ensure that products on the market throughout the country meet standard requirements? (Alternatively, do you have a reliable and standardised system of pre-marketing authorisation?) What are the available resources, infrastructure (e.g. alert the users, follow up of complaints/accidents etc.) and general principles (e.g. risk assessment) allowing to take the appropriate corrective actions? What penalties apply to infringements? How is coordination ensured between sectors? How is market surveillance coordinated between market surveillance authorities and customs as regards product conformity and safety checks at external borders? Does your country have a national programme on market surveillance? What information exchange network exists between the various authorities? In which way independence and impartiality of market surveillance authorities are ensured? How often testing is done? Please provide statistics for the last year.**

Market surveillance in the Republic of Serbia is carried out by competent Republic authorities, authorised for performing activities and undertaking measures for ensuring that products placed

on the market are in compliance with the prescribed technical regulations and are posing no hazard to health, safety and other aspects of public interest.

Legal framework relevant for market surveillance is represented by the following laws:

1. Law on Technical Requirements for Products and Conformity Assessment
2. Law on Standardisation
3. Law on Metrology
4. Law on Accreditation
5. Law on General Product Safety with the following bylaws: Regulation on the Method of Setting Up and Operation of the Rapid Information Exchange System on Dangerous Products (Official Gazette of RS, No. 89/2009) and Rules of Procedure on the Form and Content of Notification on Dangerous Product (Official Gazette of RS, No. 112/2010);
6. Law on Trade
7. Law on Consumer Protection (Official Gazette of RS, No. 73/10)
8. Law on Chemicals (Official Gazette of RS, No. 36/09, 88/10);
9. Law on Biocidal Products (Official Gazette of RS, No. 36/10, 88/10);
10. Law on Electrical Energy and Civil Engineering Inspection and Steam Heating Boilers Inspection (Official Gazette of RS, No. 5/83, 15/83-correction, 24/85-other law, 45/85, 12/96-other law and 6/89-other law (Official Gazette of RS, No. 53/93-other law, 67/93-other law, 48/94-other law and 44/95-other law);
11. Law on Energy (Official Gazette of RS, No. 84/04);
12. Law on Mining (Official Gazette of RS, No. 44/95, 85/05-other law, 101/05-other law, 34/06 and 104/09);
13. Law on Electronic Communications (Official Gazette of RS, No. 44/10);
14. Law on Sanitary Surveillance (Official Gazette of RS, No. 125/04);
15. Law on Veterinary Practice (Official Gazette of RS, No. 91/05 and 20/10);
16. Law on Medicines and Medical Devices (Official Gazette of RS, No. 30/10);
17. Customs Law (Official Gazette of RS, No. 18/10).

Law on General Product Safety, besides voluntary and corrective measures for manufacturers and distributors, also prescribes mandatory measures, and sanctions. Sanctions (fines) are prescribed in accordance with Articles 22-24 of the Law on General Product Safety, in the following amounts:

- For economic offenses from 500.000 (4,740 EUR) to 3.000.000 (28, 437 EUR) dinars for the manufacturer, legal person and from 50.000 to 200.000 (447 – 1,856 EUR) for the manufacturer's responsible person;
- For economic offenses from 300.000 (2,844 EUR) to 3.000.000 (28, 437 EUR) dinars for the distributor, and from 50.000 to 200.000 (447 – 1,856 EUR) for the distributor's responsible person;
- For offenses from 100.000 (948 EUR) to 1.000.000 (9,479 EUR) dinars for the manufacturer and distributor, for legal person, and from 20.000 (190 EUR) to 50.000 (474 EUR) for the manufacturer's and distributor's responsible person;
- For offenses from 100.000 to 500.000 (948 – 4,740 EUR) dinars for entrepreneurs, and from 10.000 to 50.000 (95 - 474 EUR) for natural persons.

Cooperation among the competent authorities in carrying out surveillance is mandatory in accordance with Article 21 of the Law on General Product Safety.

Coordination among sectors is aligned through agreements/protocols on cooperation. Protocol on Cooperation has been agreed among the Ministry of Economy and Regional Development, Ministry of Finance – Customs Administration and Ministry of Trade and Services – Market Inspection Sector.

Beside the role of market surveillance authority and customs surveillance authority, market surveillance principles have also been defined. Primary responsibility has been established of the authorities for the application of each individual principle providing for the consumer protection, assistance to economic operators in competition development and activities the efficiency of which is based on consultations among all stakeholders. Moreover, development projection refers to the market surveillance measures application, products posing serious risks, restrictive measures and CE mark. Proposal for schedule of responsibilities of the competent authorities has been provided, for transposing of relevant directives and competent authorities for market surveillance, in accordance with the New Approach directives referring to the CE marking, and in accordance with the Old Approach directives referring to specific product groups.

Method of market surveillance coordination has also been determined, as well as cooperation improvement in this field at the national and cross-border level (international cooperation). Priorities for market surveillance improvement in the period from 2010 to 2014 have been defined. Besides further alignment of technical legislation, Law on Market Surveillance was set as a priority (planned in 2011). In accordance with the Market Surveillance Strategy, authority for coordination of such surveillance shall be institutionalised. Coordination shall be carried out by a Government authority, which shall be established in the first phase as a Commission, and upon adopting the Law on Market Surveillance a Product Safety Committee shall be established, also as a Government authority.

Coordination has been established in the Rapid Information Exchange System on Dangerous Products, in accordance with the Law on General Product Safety and the Regulation on the Manner of Establishment and Operation of the Rapid Information Exchange System on Dangerous Products. Coordination in this system shall be carried out by the Ministry of Trade and Services – Market Inspection Sector. Competent authorities in the Rapid Information Exchange System use NEPRO application with procedures identical to RAPEX system. EU experts have completed the evaluation of the elaboration and implementation process of the NEPRO application. Information on dangerous products and measures undertaken by the competent authorities are available on the website [www.nepro.gov.rs](http://www.nepro.gov.rs).

Orientation towards cooperation of the competent authorities for market surveillance with economic operators also contains the Rules of Procedure on the Form and Content of Notification on Dangerous Product (Official Gazette of RS, No. 112/2010), adopted by the Minister of Trade and Services in accordance with the authorities vested by the Law on General Product Safety. Competent authorities and economic operators have joint meetings with educational purpose, and meetings aimed at exchanging experiences regarding risk assessment procedures, elaboration of instructions, application of corrective measures for product conformity with the prescribed requirements and for decision making on specific information and instructions for consumers

regarding consumer products, and for specialised products users. Furthermore, an inter-sectoral cooperation is in place for the exchange of experiences, in particular regarding product risk assessment in terms of safety.

Information of the Consumer Protection Centre, which provides advice and assistance to consumers in addressing their consumers' problems, monitoring and processing system of consumer complaints available to the Market Inspection Sector, information obtained from conformity assessment bodies and rapid information exchange system on dangerous products and risk assessment represent a basis for undertaking market surveillance measures.

Systemic and sectoral regulations provide for authorisations and obligation of the competent authorities for carrying out continuous control and undertaking corrective measures according to the current situation. Besides formal conformity assessment control (requesting documentation and product marking) market inspectors carry out product sampling checks from the market, for testing purposes. These checks have accounted for 10% out of the total number of checks in 2010, aimed at establishing and checking general safety conditions prescribed by the technical regulations. Surveillance in terms of general product safety is also carried out for products not covered by the technical regulations.

In 2010, the inspectors carried out 861 conformity assessment checks and 431 general product safety checks, whilst 135 samples were taken from the market.

The Market Surveillance Strategy, in the part establishing development directions, has defined that market surveillance authorities in the Republic of Serbia carry out their tasks independently, impartially and objectively, which represents a fundamental principle on which these authorities have based their activities.

**34. Please describe how coordination is ensured between the product sectors and between the market surveillance authorities and the customs authorities.**

Coordination in the part of information exchange is ensured within the Ministry of Trade and Services, in accordance with the Regulation on the Method of Setting Up and Operation of the Rapid Information Exchange System on Dangerous Products, adopted in the framework of the Law on General Product Safety.

Envisaged forms of coordination improvement are presented in the answer to the question No. 33.

***OLD APPROACH PRODUCT LEGISLATION***

**For each sector and sub-sector as listed below, please provide the following information:**

***A. Harmonisation of laws including technical regulations***

**35. Please provide information regarding the:**

**a) present status, including a description of the present type of approval system for each sub-sector as listed below;**

**b) forecast (date of adoption and implementation of the EU directives and regulations).**

***B. Calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance***

**36. Please provide information on the relevant regimes for the products:**

- a) short description and**
- b) further evolution.**

**The answers to these two questions above should cover the following sectors and sub-sectors:**

**Motor vehicles**

**35. a) present status**

In the field of wheeled vehicles, the Republic of Serbia applies the international Agreement Concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these Prescriptions (hereinafter referred to as The 1958 Agreement) (former title of the Agreement: Agreement Concerning the Adoption of Uniform Conditions of Approval and Reciprocal Recognition of Approval for Motor Vehicle Equipment and Parts, done at Geneva on 20 March 1958), ratified by the Regulation on Ratification (Official Gazette of the FPRY, No. 5/62 - international agreements). As the tenth Contracting Party, the Republic of Serbia (legal successor of Yugoslavia) has the E10 mark. Up to date 57 UN/ECE Regulations have been adopted and 39 have been notified for adoption. There are 8 authorised laboratories within the approval system.

In accordance with Decision of the Government of Republic of Serbia, the Road Traffic Safety Agency was established, which became operational on 1 September 2010, and afterwards was notified at the UN General Secretary for implementation the 1958 Agreement as Approval Authority.

In the field of wheeled vehicles, the following regulations are applied in the Republic of Serbia:

- Law on Road Traffic Safety (Official Gazette of RS, No. 41/09 and 53/10);
- Regulation on the Classification of Motor Vehicles and Trailers, and Technical Conditions for Vehicles in Road Traffic (Official Gazette of RS, No. 64/10 and 69/10);
- Decision on Classification of Goods for the Import, Export and Transit of which Specific Licences shall be Provided (Official Gazette of RS, No. 7/10), refers to the import of new wheeled vehicles;
- Regulation on the Import of Motor Vehicles (Official Gazette of RS, No23/10), refers to the import of used motor vehicle of category M and N.

**Regulations on Approval, making an integral part of the 1958 Agreement, are the following:**

- Uniform provisions concerning the approval of motor vehicle headlamps emitting an asymmetrical passing beam and/or a driving beam and equipped with filament lamps of categories R2 and/or HS1 (UN/ECE R. 1) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
  - Uniform provisions concerning the approval of incandescent electric lamps for headlamps emitting an asymmetrical passing beam or a driving beam or both (UN/ECE R. 2) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761); The prescriptions of Regulation No. 2 have been superseded by those of Regulation No 37.
  - Uniform provisions concerning the approval of retro-reflecting devices for power-driven vehicles and their trailers (UN/ECE R. 3) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/757);
  - Uniform provisions concerning the approval of devices for the illumination of rear registration plates of power-driven vehicles and their trailers (UN/ECE R. 4) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/760);
  - Uniform provisions concerning the approval of power-driven vehicle's "sealed beam" headlamps (SB) emitting a European asymmetrical passing beam or a driving beam or both (UN/ECE R. 5), (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
  - Uniform provisions concerning the approval of direction indicators for power-driven vehicles and their trailers (UN/ECE R. 6) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/759);
  - Uniform provisions concerning the approval of front and rear position (side) lamps, stop-lamps and end-outline marker lamps for power-driven vehicles and their trailers (UN/ECE R. 7) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/758);
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- Uniform provisions concerning the approval of motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both and equipped with halogen filament lamps (H1, H2, H3, HB3, HB4, H7, H8, H9, HIR1, HIR2 and/or H11), (UN/ECE R. 8) (Official Gazette of SFRY – Annex: International agreements and other agreements, No. 2/69), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
- Uniform provisions concerning the approval of category L2, L4 and L5, vehicles with regard to noise (UN/ECE R. 9) (Official Gazette of SFRY – No. 16/72 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 97/24);
- Uniform provisions concerning the approval of vehicles with regard to electromagnetic compatibility (UN/ECE R. 10) (Official Gazette of SFRY – No.16/72 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 72/245 and 97/24);
- Uniform provisions concerning the approval of vehicles with regard door latches and door retention components (UN/ECE R. 11) (Official Gazette of SFRY, No. 59/90 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/387);
- Uniform provisions concerning the approval of vehicles of categories M, N and O with regard to braking (UN/ECE R. 13) (Official Gazette of SFRY, No. 54/85 and 26/89), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 71/320);
- Uniform provisions concerning the approval of vehicles with regard to safety-belt anchorages, ISOFIX anchorages systems and ISOFIX top tether anchorages (UN/ECE R. 14) (Official Gazette of SFRY, No. 4/85), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/115);
- Uniform provisions concerning the approval of vehicles equipped with a positive-ignition engine or with a compression-ignition engine with regard to the emission of gaseous pollutants by the engine - method of measuring the power of positive-ignition engines - method of measuring the fuel consumption of vehicles (UN/ECE R. 15). (Official Gazette of SFRY, No. 57/75 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/220);
- Uniform provisions concerning the approval of:
  - I Safety-belts, restraint systems, child restraint systems and ISOFIX child restraint systems for occupants of power-driven vehicles
  - II Vehicles equipped with safety-belts, safety-belt reminders, restraint systems, child restraint systems and ISOFIX child restraint systems (UN/ECE R. 16) (Official Gazette of SFRY – No. 47/74 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 77/451);
- Uniform provisions concerning the approval of vehicles with regard to the seats, their anchorages and any head restraints (UN/ECE R. 17) (Official Gazette of SFRY, No. 47/74 -

International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/408);

- Uniform provisions concerning the approval of motor vehicles with regard to their protection against unauthorized use (UN/ECE R. 18) (Official Gazette of SFRY, No. 11/85, 1/87 and 23/88), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/61);

- Uniform provisions concerning the approval of power-driven vehicle front fog lamps (UN/ECE R. 19) (Official Gazette of SFRY – No. 14/75 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/762);

- Uniform provisions concerning the approval of motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both and equipped with halogen filament lamps (H4 lamps) (UN/ECE R. 20) (Official Gazette of SFRY, No. 14/75 - International agreements and other agreements), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);

- Uniform provisions concerning the approval of vehicles with regard to their interior fittings (UN/ECE R. 21) (Official Gazette of SFRY, No. 70/90), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/60);

- Uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motor cycles and mopeds (UN/ECE R. 22) (Official Gazette of SFRY, No. 18/88);

- Uniform provisions concerning the approval of reversing lights for power-driven vehicles and their trailers (UN/ECE R. 23) (Official Gazette of SFRY, No. 59/90), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 77/539);

- Uniform provisions concerning:

I The approval of compression ignition (C.I.) engines with regard to the emission of visible pollutants

II. The approval of motor vehicles with regard to the installation of C.I. engines of an approved type

III. The approval of motor vehicles equipped with C.I. engines with regard to the emission of visible pollutants by the engine

IV. The measurement of power of C.I. engine (UN/ECE R. 24) (Official Gazette of SFRY, No. 11/85 and 1/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 72/306);

- Uniform provisions concerning the approval of head restraints (headrests), whether or not incorporated in vehicle seats (UN/ECE R. 25) (Official Gazette of SFRY, No. 59/90), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 78/932);

- Uniform provisions concerning the approval of vehicles with regard to their external projections (UN/ECE R. 26) (Official Gazette of SFRY, No. 70/90), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/483);
- Uniform provisions concerning the approval of audible warning devices and of motor vehicles with regard to their audible signals (UN/ECE R. 28) (Official Gazette of SFRY, No. 60/86), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/388);
- Uniform provisions concerning the approval of pneumatic tyres for motor vehicles and their trailers (UN/ECE R. 30) (Official Gazette of SFRY, No. 43/83), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/23);
- Uniform provisions concerning the approval of vehicles with regard to the arrangement of foot controls (UN/ECE R. 35) (Official Gazette of SFRY, No. 59/90);
- Uniform provisions concerning the approval of filament lamps for use in approved lamp units of power-driven vehicles and of their trailers (UN/ECE R. 37) (Official Gazette of SFRY, No. 4/85), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
- Uniform provisions concerning the approval of rear fog lamps for power-driven vehicles and their trailers (UN/ECE R. 38) (In accordance with Order on mandatory approval, Official Gazette of SFRY, No. 59/90), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 77/538);
- Uniform provisions concerning the approval of vehicles with regard to the speedometer equipment including its installation (UN/ECE R. 39) (Official Gazette of SFRY, No. 11/85 and 1/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 75/443);
- Uniform provisions concerning the approval of motor cycles equipped with a positive-ignition engine with regard to the emission of gaseous pollutants by the engine (UN/ECE R. 40) (Official Gazette of SFRY, No. 60/86), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 97/24);
- Uniform provisions concerning the approval of motor cycles with regard to noise (UN/ECE R. 41) (Official Gazette of SFRY, No. 60/86), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 97/24);
- Uniform provisions concerning the approval of safety glazing materials and their installation on vehicles (UN/ECE R. 43) (Official Gazette of SFRY, No. 68/85), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/22);
- Uniform provisions concerning the approval of mopeds equipped with a positive-ignition engine with regard to the emission of gaseous pollutants by the engine (UN/ECE R. 47) (Official

Gazette of SFRY, No. 60/86), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/24);

- Uniform provisions concerning the approval of vehicles with regard to the installation of lighting and light-signalling devices (UN/ECE R. 48) (Official Gazette of SFRY, No. 68/85, 1/87 and 46/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/756);

- Uniform provisions concerning the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (UN/ECE R. 49) (Official Gazette of FRY, No. 60/02 and 64/02), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 88/77, 2005/55 and 595/2009);

- Uniform provisions concerning the approval of front position lamps, rear position lamps, stop lamps, direction indicators and rear-registration-plate illuminating devices for vehicles of category L (UN/ECE R. 50) (Official Gazette of SFRY, No. 67/86);

- Uniform provisions concerning the approval of motor vehicles having at least four wheels with regard to their noise emissions (UN/ECE R. 51) (Official Gazette of SFRY, No. 48/84 and 1/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/157);

- Uniform provisions concerning the approval of category L3 vehicles with regard to the installation of lighting and light-signalling devices (UN/ECE R. 53) (Official Gazette of SFRY, No. 68/85), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 93/92);

- Uniform provisions concerning the approval of pneumatic tyres for commercial vehicles and their trailers (UN/ECE R. 54) (Official Gazette of SFRY, No. 11/85), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/93);

- Uniform provisions concerning the approval of mechanical coupling components of combinations of vehicles (UN/ECE R. 55) (Official Gazette of SFRY, No. 63/89), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 94/20);

- Uniform provisions concerning the approval of headlamps for mopeds and vehicles treated as such (UN/ECE R. 56) (Official Gazette of SFRY, No. 67/86);

- Uniform provisions concerning the approval of headlamps for motor cycles and vehicles treated as such (UN/ECE R. 57) (Official Gazette of SFRY, No. 68/85);

**- Uniform provisions concerning the approval of :**

I. Rear underrun protective devices (RUPDs)

II. Vehicles with regard to the installation of an RUPD of an approved type  
III. Vehicles with regard to their rear underrun protection (RUP), (UN/ECE R. 58) (Official Gazette of SFRY, No. 85/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/221);

- Uniform provisions concerning the approval of replacement silencing systems (UN/ECE R. 59) (Official Gazette of SFRY, No. 43/92), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/157 and 81/334);

- Uniform provisions concerning the approval of two-wheeled mopeds with regard to noise (UN/ECE R. 63) (Official Gazette of SFRY, No. 73/87), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 97/24);

- Uniform provisions concerning the approval of power-driven vehicles including pure electric vehicles with regard to the measurement of the maximum speed (UN/ECE R. 68) (Official Gazette of SFRY, No. 17/92);

- Uniform provisions concerning the approval of rear marking plates for slow-moving vehicles (by construction) and their trailers (UN/ECE R. 69) (Official Gazette of SFRY, No. 24/90);

- Uniform provisions concerning the approval of rear marking plates for heavy and long vehicles (UN/ECE R. 70) (Official Gazette of SFRY, No. 24/90);

- Uniform provisions concerning the approval of goods vehicles, trailers and semi-trailers with regard to their lateral protection (UN/ECE R. 73) (Official Gazette of SFRY, No. 43/92), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 89/297);

- Uniform provisions concerning the approval of vehicles of, categories L<sub>1</sub>, L<sub>2</sub>, L<sub>3</sub>, L<sub>4</sub> and L<sub>5</sub>, with regard to braking (UN/ECE R. 78) (Official Gazette of SFRY, No. 17/89), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 93/14);

- Uniform provisions concerning the approval of vehicles with regard to the emission of pollutants according to engine fuel requirements (UN/ECE R. 83) (Official Gazette of SFRY, No. 61/02), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/220 and 715/2007);

- Uniform provisions concerning the approval of power-driven vehicles equipped with internal combustion engines with regard to the measurement of fuel consumption (UN/ECE R. 84) (Official Gazette of SFRY, No. 24/92), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 80/1268);

- Uniform provisions concerning the approval of internal combustion engines or electric drive trains intended for the propulsion of motor vehicles of categories M and N with regard to the measurement of the net power and the maximum 30 minutes power of electric drive trains (UN/ECE R. 85) (Official Gazette of SFRY, No. 12/92), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 80/1269);

- Uniform provisions concerning the approval of vehicles intended for the carriage of dangerous goods with regard to their specific construction features (UN/ECE R. 105) (Official Gazette of FRY, No. 48/02), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 98/91);

- Uniform provisions concerning the approval of motor vehicle headlamps emitting an asymmetrical passing beam or a driving beam or both and equipped with filament lamps and/or LED modules (UN/ECE R. 112) (Official Gazette of FRY, No. 46/02), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);

**The following UN/ECE Regulations (ECE/TPANS/WP.29/343/Rev. 18) were notified:**

- Uniform provisions concerning the approval of passenger cars with regard to braking (UN/ECE R. 13-H);

- Uniform provisions concerning the approval of advance-warning triangles (UN/ECE R. 27);

- Uniform provisions concerning the approval of large passenger vehicles with regard to their general construction (UN/ECE R. 36).

- Uniform provisions concerning the approval of restraining devices for child occupants of power-driven vehicles ("child restraint system") (UN/ECE R. 44);

- Uniform provisions concerning the approval of devices for indirect vision and of motor vehicles with regard to the installation of these devices (UN/ECE R. 46).

- Uniform provisions concerning the approval of M<sub>2</sub> and M<sub>3</sub> small capacity vehicles with regard to their general construction (UN/ECE R. 52);

- Uniform provisions concerning the approval of commercial vehicles with regard to their external projections forward of the car's rear panel (UN/ECE R. 61);

- Uniform provisions concerning the approval of vehicles with regard to their equipment which may include a temporary-use spare wheel and tyre unit, run-flat tyres and/or a run-flat system (UN/ECE R. 64); (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/23);

- Uniform provisions concerning the approval of special warning lamps for power-driven vehicles and their trailers (UN/ECE R. 65);

- Uniform provisions concerning the approval of large passenger vehicles with regard to the strength of their superstructure (UN/ECE R. 66).

- Uniform provisions concerning the approval of: I) Specific equipment of motor vehicles using liquefied petroleum gases in their propulsion system; II) A vehicle fitted with specific

equipment for the use of liquefied petroleum gases in its propulsion system with regard to the installation of such equipment (UN/ECE R. 67);

- Uniform provisions concerning the approval of agricultural tractors with regard to the driver's field of vision (UN/ECE R. 71), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/347);

- Uniform provisions concerning the approval of category L1 vehicles with regard to the installation of lighting and light-signalling devices (UN/ECE R. 74), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 93/92);

- Uniform provisions concerning the approval of pneumatic tyres for motor cycles and mopeds (UN/ECE R. 75);

- Uniform provisions concerning the approval of parking lamps for power-driven vehicles (UN/ECE R. 77), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/540);

- Uniform provisions concerning the approval of vehicles with regard to steering equipment (UN/ECE R. 79), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/311);

- Uniform provisions concerning the approval of seats of large passenger vehicles and of these vehicles with regard to the strength of the seats and their anchorages (UN/ECE R. 80), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/408);

- Uniform provisions concerning the approval of agricultural or forestry tractors with regard to the installation of lighting and light-signalling devices (UN/ECE R. 86), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 2009/61);

- Uniform provisions concerning the approval of: I) Vehicles with regard to limitation of their maximum speed or their adjustable speed limitation function; II) Vehicles with regard to the installation of a speed limiting device (SLD) or adjustable speed limitation device (ASLD) of an approved type III. Speed limitation devices (SLD) and adjustable speed limitation device (ASLD), (UN/ECE R. 89), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 92/24);

- Uniform provisions concerning the approval of replacement brake lining assemblies and drum-brake linings for power-driven vehicles and their trailers (UN/ECE R. 90);

- Uniform provisions concerning the approval of side-marker lamps for motor vehicles and their trailers (UN/ECE R. 91), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/758);

- Uniform provisions concerning the approval of non-original replacement exhaust silencing systems (RESS) for motorcycles, mopeds and three-wheeled vehicles (UN/ECE R. 92);

- Uniform provisions concerning the approval of compression ignition (C.I.) engines to be installed in agricultural and forestry tractors and in non-road mobile machinery with regard to the emissions of pollutants by the engine (UN/ECE R. 96), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 97/68);
- Uniform provisions concerning the approval of vehicle alarm systems (VAS) and of motor vehicles with regard to their alarm systems (AS) (UN/ECE R. 97), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/61);
- Uniform provisions concerning the approval of motor vehicle headlamps equipped with gas-discharge light sources (UN/ECE R. 98), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
- Uniform provisions concerning the approval of gas-discharge light sources for use in approved gas-discharge lamp units of power-driven vehicles (UN/ECE R. 99), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);
- Uniform provisions concerning the approval of battery electric vehicles with regard to specific requirements for the construction, functional safety and hydrogen emission (UN/ECE R. 100);
- Uniform provisions concerning the approval of passenger cars powered by an internal combustion engine only, or powered by a hybrid electric power train with regard to the measurement of the emission of carbon dioxide and fuel consumption and/or the measurement of electric energy consumption and electric range, and of categories M<sub>1</sub> and N<sub>1</sub> vehicles powered by an electric power train only with regard to the measurement of electric energy consumption and electric range (UN/ECE R. 101), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 80/1268);
- Uniform provisions concerning the approval of replacement catalytic converters for power-driven vehicles (UN/ECE R. 103), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 70/220 and 715/2007);
- Uniform provisions concerning the approval of retro-reflective markings for vehicles of category M, N and O (UN/ECE R. 104).
- Uniform provisions concerning the approval of pneumatic tyres for agricultural vehicles and their trailers (UN/ECE R. 106);
- Uniform provisions concerning the approval for the production of retreaded pneumatic tyres for motor vehicles and their trailers (UN/ECE R. 108);
- Uniform provisions concerning the approval for the production of retreaded pneumatic tyres for commercial vehicles and their trailers (UN/ECE R. 109);
- Uniform provisions concerning the approval of: I) Specific components of motor vehicles using compressed natural gas (CNG) in their propulsion system; II) Vehicles with regard to the

installation of specific components of an approved type for the use of compressed natural gas (CNG) in their propulsion system (UN/ECE R. 110);

- Uniform provisions concerning the approval of motor vehicle headlamps emitting a symmetrical passing beam or a driving beam or both and equipped with filament lamps (UN/ECE R. 113) (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 76/761);

- Uniform provisions concerning the approval of: I) Specific LPG (liquefied petroleum gases) retrofit systems to be installed in motor vehicles for the use of LPG in their propulsion system; II) Specific CNG (compressed natural gas) retrofit systems to be installed in motor vehicles for the use of CNG in their propulsion system (UN/ECE R. 115);

- Uniform provisions concerning the protection of motor vehicles against unauthorized use (UN/ECE R. 116), (corresponding to the EU Directive/Regulation with relevant amendments and modifications: 74/61);

- Uniform provisions concerning the approval of tyres with regard to rolling sound emissions and to adhesion on wet surfaces (UN/ECE R. 117);

- Uniform provisions concerning the approval of internal combustion engines to be installed in agricultural and forestry tractors and in non-road mobile machinery, with regard to the measurement of the net power (UN/ECE R. 120).

It has to be taken into account that in the Republic of Serbia certificates of approval are adopted in accordance with the EU Directives/Regulations corresponding to UN/ECE Regulations applied in the Republic of Serbia.

### **35. b) forecast**

The Road Traffic Safety Agency shall, in accordance with notifications from UN/ECE Regulations from previous point a) initiate the implementation procedure in 2011.

Implementation Plan for EU Directives/Regulations from the field of wheeled vehicles shall be adopted in 2011, taking into account the dates when specific EU directives shall cease to have effect, which comprises the following:

- 70/157/EEC,
- 715/2007/EC,
- 72/306/EEC,
- 80/1268/EEC,
- 2005/64/EC,
- 2006/40/EC,
- 78/2009/EC,
- 79/2009/EC,
- 661/2009/EC,

- 595/2009/EC, and
- Directive for L and T category.

In this regard, it is necessary to stipulate agreements with the competent EC authorities (Directorate – General for Mobility and Transport) concerning a possibility of issuing certificates of approval relating to the Implementation Plan for EU Directives/Regulations by the Road Traffic Safety Agency, as the State authority for carrying out the approval system, conformity control, and authorisations of organisations for approval testing in the Republic of Serbia, having in mind the experience gained so far in active implementation of the approval system in over 35 years.

The Implementation Plan for EU directives (2002/24/EC, 2003/37/EC and 2007/46/EC), referring to the approval of the overall vehicle type, shall also be adopted in 2011.

**36. a) short description: calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Law on Road Traffic Safety, Law on International Road Transport and the ratified international Agreement Concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these Prescriptions make a legal framework for governing the field of wheeled vehicles. In accordance with this Law, upon proposal by the minister responsible for traffic matters, the Government has established the Road Traffic Safety Agency, under the competence of which lies the field of wheeled vehicles.

**36. b) further evolution**

In the next period, further monitoring and alignment of legislation with the EU Acquis is envisaged in the field of wheeled vehicles.

Since the Road Traffic Safety Agency became operational, on 1 September 2010, as the competent authority of the Republic of Serbia in the field of wheeled vehicles, the following drafts have been prepared:

Regulation on vehicles testing;

Regulation on training and testing of competence of the inspectors of technical inspection of vehicles

Regulation on the conditions for issuing licences to workshops manufacturing tachographs.

The following is also envisaged:

Adoption of the Regulation on the approval of vehicles and the implementation of notified UN/ECE Regulations from point 35. a) (The following UN/ECE Regulations (ECE/TPANS/WP.29/343/Rev. 18) were notified)

Establishing a database on wheeled vehicles, and

Authorisation of organisations responsible for testing and supervision.

The Road Traffic Safety Agency has published a tender for the manufacturing of memory cards for digital tachographs; thus in 2011 the implementation of digital tachographs system in the Republic of Serbia is expected.

All above mentioned activities require further strengthening of the Road Traffic Safety Agency in regard to human and material resources.

Preparation and implementation of a multi-sectorial pilot study on traffic safety is under way (the study will be financed by the World Bank). Projects directly related to the modernisation of the vehicle pool refer to a vehicle database establishment, digital tachographs introduction, vehicle pool modernisation, and a vehicle approval system.

## **Chemicals**

### **Restrictions, classification, packaging and labelling (REACH, CLP)**

#### **35. a) present status**

Legal basis for restrictions and bans on production, placing on the market and use of particularly hazardous chemicals are laid down in Articles 49 and 50 of the Law on Chemicals (Official Gazette of RS No 36/09)

The Rulebook on Restrictions and Bans of Production, Placing on the Market and Use of Chemicals that Pose an Unacceptable Risk for Humans and the Environment (Official Gazette of RS No 89/10) has been harmonized with the Annex XVII of the Regulation 1907/2006/EC Concerning Registration, Evaluation and Authorization of Chemicals (REACH), Regulation 552/2009/EC amending Regulation 1907/2006/EC, Annex XVII (REACH), Regulation 276/2010/EC amending Regulation 1907/2006/EC , Annex XVII (REACH), Regulation 850/2004/EC on Persistent Organic Pollutants (POPs) and the Directive 2004/42/EC on the Limitation of Emissions of Volatile Organic Compounds Due to the Use of Organic Solvents in Certain paints and Varnishes and Vehicle Refinishing Products.

The Rulebook on Restrictions and Bans of Production, Placing on the Market and Use of Chemicals that Pose an Unacceptable Risk for Humans and the Environment, which entered into force, introduced into the national legislation bans and restrictions regarding production, placing on the market and use of chemicals, in compliance with the EU requirements. Bearing in mind that certain provisions of the Rulebook lay down the requirements for change of technological facilities or the production technology (ban on asbestos fibres and products containing asbestos fibres, restrictions on chromium quantities in cement and other), the Chemicals Agency, following negotiations with the representatives of the industry, defined the interim time frames for entry into force of those provisions. This however is subject to strict control of the MESP inspectorate or the bodies responsible for safety and health at work.

The Law on Chemicals (Official Gazette of the Republic of Serbia, No 36/09) in Articles 9 to 20 stipulates that the chemicals in Serbia shall be classified, labelled and packed in compliance with method and the criteria fully harmonized with the EU legislation (Regulation 1272/2008 and/or the Directives 67/548 and 99/45). Pursuant to these provisions, the manufacturer, importer or downstream user that places chemicals and particular products on the market shall classify the chemicals while the supplier of the chemicals shall label and pack the chemicals in compliance

with the Law and the legal acts adopted on the basis of the Law. In addition, these provisions lay down legal basis for adoption of by-laws that more specifically define the manner of classification, packaging and labelling of the chemicals and particular products. Pursuant to these provisions, the following by-laws have been adopted:

1. The Rulebook on Classification, Packaging, Labelling and Advertising of Chemicals and Particular Products (Official Gazette of RS No 59/10). The Rulebook has been fully harmonized with the Directives 67/548/EEC and 99/45/EC.

2. The Rulebook on Classification, Packaging, Labelling and Advertising Chemicals and Particular Products in Compliance with the Globally Harmonized System of Classification and Labelling UN (Official Gazette of RS No 64/10). 64/10). The Rulebook has been fully harmonized with the Regulation 1272/2008/EC of the European Parliament and the Council and it introduces UN Globally Harmonized System of Classification and Labelling of chemicals (GHS) into the legal system of the Republic of Serbia.

3. The List of Classified Substances (Official Gazette of the RS No 82/10) has been adopted. This list is transposed from Annex 6 to the Regulation 1272/2008, including the amendments stipulated in the Regulation 790/2009/EC (1<sup>st</sup> ATP).

In the transitional period, similar to what had been done in the EU, both Rulebooks governing classification and labelling shall be simultaneously used. The transitional periods for full implementation of the GHS are also similar to those in the EU; full application of the GHS shall be required for the substances as of October 1st 2011 and for mixtures as of June 1st 2015.

The national legislation regarding classification, packaging and labelling of the chemicals referred to shall be applied to all chemicals; the additional specific requirements for labelling and packaging of particular chemicals for specific use, such as biocidal products and detergents are governed by other legal acts.

The Law on Biocidal Products (Official Gazette of the Republic of Serbia, No 36/09) that has been harmonized with the EU Directive 98/8/EC, gives legal basis to adopt, inter alia, specific requirements for packaging, labelling and advertising biocidal products. In accordance with this legal basis, the Rulebook on Specific Requirements for Labelling, Packaging and Advertising Biocidal Products (Official Gazette of RS No 59/10) was adopted. It was harmonized with the Article 20 of the Directive 98/8/EC, to ensure that specific requirements for labelling, packaging and advertising of biocidal products in national legislation is also in compliance with the EU requirements.

Application of these regulations provides that the chemicals in Serbia are classified in compliance with the procedure and criteria stipulated in the EU legislation; the users of the chemicals shall be appropriately informed on the dangerous properties of the chemicals as indicated on the label and the chemicals shall be packed in appropriate packaging, in compliance with the requirements that have been harmonized with the EU requirements.

### **35. b) forecast**

In the following period, the Chemicals Agency shall take activities required to enhance the implementation of the provisions pertaining to the restrictions and bans of production, placing on the market and use of chemicals. The activities shall comprise offering information and also preparation of professional instructions for legal entities and the inspectors responsible for supervision and control of provisions mentioned, on behalf of the Chemicals Agency.

Since the national legislation governing classification, packaging and labelling of the chemicals has been harmonized with the EU legislation and has entered into force, legal entities are required

to align their activities with the aforementioned regulations, within the foreseen time frame. Therefore, starting as of October 1st 2011, the substances shall be classified and packed in compliance with the national legislation that has been harmonized with the Regulation 1272/2008/EC and the same shall apply to the mixtures as of June 1st 2015.

### **36.a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

All assessments methods and/or standards recommended in Annex XVII (REACH) regarding limitations or control of hazardous substances levels in particular mixtures and products are included in the Rulebook on Restrictions and Ban on Production, Placing on the Market and Use of Chemicals that Pose Unacceptable Risk for Humans and the Environment.

The standards have been adopted by the Standardization Institute of Serbia and applied at national level.

The accreditation body of the Republic of Serbia is authorized to perform accreditation of the laboratories in compliance with the adopted standards. The Ministry of Health is responsible for providing conditions for issuing the GLP certificates.

Supervision of the application of the provisions governing the area of restrictions and bans both in the production and the wholesale is carried out by the Ministry of Environment and Spatial Planning Inspectorate while the Ministry of Trade and Services Inspectorate as stipulated in Article 86 of the Law on Chemicals is responsible for supervision in the retails

The standards (ISO, EN, DIN, ASTM and other) required by the mentioned EU legislation regulating classification, packaging and labelling of the chemicals have been adopted at national level. Since this national legislation entered into force in the third quarter of 2010, in the following period, accreditation of laboratories for these standards may be expected. The process of adopting the standards at national level was carried out by the Standardization Institute and the accreditation of the laboratories in compliance with the standards shall be carried out by the Accreditation Body of the Republic of Serbia. The Ministry of Health is responsible for providing conditions for issuing the GLP certificates.

In addition, the Rulebook on test methods for evaluation of Dangerous Properties of Chemicals, which shall be harmonized with the Regulation 440/2008 and the Regulation 761/2009 amending the Regulation 440/2008, is under preparation. The Rulebook shall define in detail the test methods that may be used for classification of chemicals and it shall set standards of testing in compliance with those applicable in the EU.

The Ministry responsible for environmental protection with its environmental protection inspectors is responsible for the supervision of the application of the Law on Chemicals and the by-laws adopted on the basis of the Law. Supervision in retails, on classification, packaging, labelling of the chemicals and particular products, restrictions and bans of production, placing on the market and use of chemicals as well as of the conditions of sales and storing the chemicals, is carried out by the ministry responsible for trade with its trade inspectors.

### **36. b) further evolution**

The development activities planned in the field of restrictions and bans are aimed in first place at building capacities for implementation of the provisions through various training programmes

that are being organized for the employees of the Agency, the inspectorates, customs authorities and the legal entities and also at encouraging use of safer alternatives and safer technologies and the cooperation in development of inspector supervision methodology.

The development planned in the field of classification, packaging and labelling is aimed at capacity building for application of rules and conditions laid down in the corresponding legislation, first of all through preparation of detailed instructions appropriate for various target groups or entities implementing the regulations and for the bodies of the inspectorate responsible for supervision and control. In addition, there are ongoing activities aimed at building administrative capacities through various training programmes organized for the employees of the Chemicals Agency as well as for the inspectors, representatives of customs institutions and other.

Also, there is an ongoing campaign regarding the new legislation and in particular new regulations of classification, packaging, labelling, test methods and standards that have been harmonized with the EU. The goal of the campaign is to prepare the industry and the scientific and educational sectors for implementation of the regulations.

It is planned to improve the national information system (including the Chemicals Registry); to provide conditions for the Chemicals Agency to participate in the work of the European Chemicals Agency as an observer for the purpose of monitoring the centralized EU procedures.

With regard to the future development of the legislation, the amendments to the relevant EU legislation are being monitored with a view to appropriately harmonize the adopted national legislation.

## **Detergents**

### **35. a) present status**

Provisions of the Law on Chemicals (Official Gazette of RS No 36/09), Articles 73 to 81 lay down conditions for placing the detergents on the market, from point of view of biodegradability of surfactants. The provisions of the Law on Chemicals are further developed in the Rulebook on detergents (Official Gazette of RS No 40/10). Provisions of the Law on Chemicals regarding detergents and provisions of the Rulebook on detergents have been harmonized with the provisions of the Regulations 648/2004/EC on Detergents, Regulation 907/2006/EC amending Regulation 648/2004/EC Annex III and VII and the Regulation 551/2009/EC amending Regulation 648/2004/EC Annex V and VI.

Pursuant to these provisions, all surfactants used in detergents shall fulfill the criteria of ultimate aerobic biodegradability. A surfactant not fulfilling the aforementioned criteria may only be used in detergents for industrial or professional use if the approval had been issued by the Chemicals Agency or by the EU competent authorities. In that case, the Agency shall issue the approval to use a surfactant in detergents based upon the technical dossier of the surfactant and in compliance with the criteria laid down; it also may accept a legal act approving the use of such surfactant in detergent in the EU.

The Agency may ban use of a particular surfactant in a detergent and may order withdrawal of the detergent containing the surfactant from the market.

In addition to the labelling elements that are in compliance with the legislation on classification, packaging and labelling of chemicals, for the purpose of consumer protection, the labels or

packages of detergents aimed at general public shall comprise the elements in compliance with the specific labelling requirements given in Rulebook on detergents (Official Gazette of RS No 40/10).

The Chemicals Agency has adopted the List of the surfactants for which the approval has been issued or for which a legal act approving use of the surfactants in detergents in EU has been adopted and the List of Surfactants for which the request for approval was rejected and surfactants are banned in EU.

### **35. b) forecast**

The Rulebook on detergents entered into force in April 2010; transitional provisions regarding labelling the detergents have been adopted and they that shall enter into force in April 2011. In the future, activities aimed at implementation of the provisions regarding the detergents shall encourage use of safer alternatives for surfactants by informing legal entities on surfactants that do not fulfil the criteria laid down and by control carried out by MESP inspectors. The Chemicals Agency will prepare guidance for legal entities and the inspectors responsible for control and supervision of the aforementioned provisions, in order to achieve a more efficient implementation of the provisions.

### **36. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The methods for testing of the biodegradability of surfactants in the detergents or the standards stipulated in the Regulation 684/2004 on Detergents, Regulation 907 /2006 amending Regulation 684/2004 Annexes III and VII and the Regulation 551/2009 amending Regulation 684/2004 Annex V and VI on Detergents have been transposed to national legislation and are laid down in the Rulebook on Detergents (Official Gazette of RS No 41/10)

In Serbia, presently there are no laboratories accredited for testing of biodegradability of surfactants.

The standards have been adopted by the Standardization Institute of Serbia and applied at national level.

The Accreditation body of the Republic of Serbia is authorized to perform accreditation of the laboratories in compliances with the standards regarding surfactants biodegradability. The Ministry of Health is responsible for providing conditions for issuing the GLP certificates.

Supervision of the application of the provisions governing placing detergents on the market and the labelling both in the production and the wholesale is carried out by the Ministry of Environment and Spatial Planning Inspectorate, while Ministry of Trade and Services Inspectorate, as stipulated in Article 86 of the Law on Chemicals, is responsible for supervision in retails.

### **36. b) further evolution**

Capacity building through various training programmes for the employees of the Chemicals Agency, inspectorates and the legal entities followed by raising awareness of safer alternatives use for detergents ingredients.

## Fertilizers

### 35. a) present status

#### 1. Legal Framework (current/future)

The Law on Plant Nutrition Products and Soil Enhancers (Official Gazette of RS No 41/09) (See Chapter 12) governs classification, quality, labelling, phytosanitary control, and sampling in the placing on the market, importation and use of plant nutrition products and soil enhancers and testing of plant nutrition products and soil enhancers, as well as other issues relevant for plant nutrition products and soil enhancers.

The Law on Plant Nutrition Products and Soil Enhancers has been harmonized with the Regulation 2003/2003 of the European Parliament and the Council concerning mineral fertilizers and partially with the Directive 91/676/EEC concerning protection of waters from the pollution caused by nitrates of agricultural origin.

The Law stipulates the following:

- Plant nutrition products shall be fertilizers and substrates;
- Fertilizer shall be a chemical compound of mineral and organic origin and mixtures of such compounds regardless of the state of matter and the micro organisms whose main purpose is to provide nutrient elements for plant nutrition;
- Substrate shall be a product of organic or inorganic origin or a mixture of organic and inorganic substances, with different chemical and mechanical composition, which is used for direct sowing or planting;
- Soil enhancer shall be a product for improvement of physical, chemical, and biological properties of soil, which has a low content of primary and/or micronutrient and biological properties of soil, which has a low content of primary and/or micronutrient elements or does not contain them at all, and which is therefore not deemed to be a fertilizer;
- Ammonium nitrate fertilizer with high nitrogen content shall be an ammonium nitrate based product manufactured for use as a fertilizer, containing 28 or more percent of nitrogen by weight of fertilizer in relation to the ammonium nitrate and which may contain inorganic or inert substances;

This means that this Law does not only related to mineral fertilizers but also to organic, organic-mineral, microbiological, other fertilizers and special products, substrates as well as the field of soil enhancers in terms of registration (approval), classification (in terms of type), quality, testing, conditions for placing on the market, its control and use.

In addition to the provisions of this Law, organic fertilizers shall fulfil the conditions regarding by-products of animal origins which are not used for human nutrition (in compliance with the Regulation 1774/2002/EC) while the products for plant nutrition and the soil enhancers used in

organic production are subject to the provisions of the Law on Organic Production and Organic Products.

The plant nutrition products and the soil enhancers may be produced, placed on the market, and used in the territory of the Republic of Serbia if they are classified, packaged and labelled in accordance with the Law and if they do not pose risk to safety or health of humans, animals or plants, or a risk to soil fertility and the environment.

Plant nutrition products may be classified in a specific class and type if:

- They provide the plants with nutrient substances;
- Relevant sampling and testing methods are applied when such methods are necessary;
- During the practical use, they do not have a harmful effect on the health of humans, animals, plants, soil fertility, and the environment.

The following plant nutrition products and soil enhancers shall not be entered into the Register of Plant Nutrition Products and Soil Enhancers:

- Plant nutrition products that are produced for exports;
- Plant nutrition products that are used for scientific and research purposes and in the quantities required for such purposes;
- Quantities remaining from the exports;
- Plant nutrition products that are placed in circulation for the reasons of trial production, in a specific quantity and for a specific period of time;
- Manure and slurry.

The documentation and the procedure required for to approve placing on the market the aforementioned plant nutrition products and soil fertilisers in the territory of the Republic of Serbia, are stipulated in the Article 20 of the Law.

If in accordance with the new scientific and technical knowledge there is a reason for the plant nutrition products and the soil fertilizers of a specific class and type pose a risk to the safety or health of humans, animals or risk to soil fertility and the environment, the Plant Protection Directorate may take the following actions regarding such plant nutrition products and soil fertilizers:

- Temporarily or permanently ban the production and placing on the market of such products or
- Specify the conditions under which such products may be produced, placed on the market and used.

Plant nutrition products and soil enhancers which also contain the plant protection products, namely the chemicals, may be produced, placed on the market and used in the territory of the Republic of Serbia if they are classified, packed and labelled in compliance with this Law and the regulations adopted based on this Law and the regulations governing the plant protection products, namely the chemicals.

A mineral fertilizer which meets the requirements for placing on the market in the territory of the member states of the European Union shall be designated with the mark „EC FERTILISER”.

The mark „EC FERTILISER” shall not be used if a mineral fertilizer does not comply with the prescribed requirements with respect to the quality and placing on the market in the territory of the member states of the European Union.

The documents of the responsible authority or a laboratory of the European Union verifying that a mineral fertilizer may be designated with the mark „EC FERTILISER” must be submitted upon entry in the Register for Plant Nutrition and Soil Fertilizers and must be available to the phytosanitary inspection.

Before placing ammonium nitrate fertilizer with high nitrogen content (an ammonium nitrate based product manufactured for use as a fertilizer, containing 28 or more percent of nitrogen by weight of fertilizer in relation to the ammonium nitrate) on the market, the manufacturer shall test its resistance to detonation and present evidence that resistance to detonation of such fertilizer has been tested. The manufacturer shall submit the results of the testing to the Ministry of Agriculture, Forestry and Water Management at least five days before placing the product on the market or, in the case of importation, at least five days before the arrival of the shipment to the border crossing.

In addition to the provisions of the Law on Plant Nutrition Products and the Soil Enhancers, fertilizer containing ammonium nitrite are also subject to the provision of the Law on Chemicals (Official Gazette of RS No 39/09) and the Rulebook on Restrictions, Ban of Production, Placing on the Market and Use of Chemical that Pose Unacceptable Risk to the Health of Humans and the Environment (Official Gazette of RS No 89/10) that has been harmonized with the Addendum (point 58) of the Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII).

The exception to this rule is that it is forbidden to place on the market ammonium nitrate as a substance or in mixtures containing 20% of nitrite in relation to the ammonium nitrate after July 14th 2014 (in EU after December 27<sup>th</sup> 2010) and after July 14<sup>th</sup> 2014, the nitrite content shall not be equal to or higher than 16 percent (m/m).

All regulations adopted on the basis of the Law on Plant Protection Products and Soil Enhancers have been harmonized with the Regulation of the European Parliament and the Council 2003/2003

Present status of harmonization with the EU Acquis (Annex 1.14).

In addition to the regulations that have been harmonized with the EU Acquis, the following legislation has been adopted on the basis of the Law on Plant Protection Products:

- The Rulebook on the Contents of the Request for the Entry into the Register of the Plant Nutrition Products and Soil Enhancers and the Content and the Method of Keeping the Registry, Content of the Request and the Documentation to be Submitted with the

Request for Use of Plant Nutrition Products and Soil Enhancers that are used for Science and Research and Placing in the Market for a Specific time and in a Specific Quantity (Official Gazette of RS No 104/09) 104/09),

- The Rulebook on the Form and the Contents of the Request for Entry into the Register of the Distributors and the Importers of Plant Nutrition Products and Soil Enhancers and the Content and Method of Keeping the Register (Official Gazette of RS No 66/09) 66/09),
- The Rulebook on Conditions Regarding the Facilities for Storing the Plant Nutrition Products and Soil Enhancers and the Premises for the Sale of the Plant Nutrition Products and Soil Enhancers (Official Gazette of RS No 78/09) 78/09),
- The Rulebook on Conditions for Classification and Determining Quality of the Plant Nutrition Products, Derogations from the Nutrients Quality and Minimum and Maximum Values of Allowed Nutrient Derogations and on the Contents of the Declaration and the Method of Labelling Plant Nutrition Products (Official Gazette of RS No 78/09) 78/09),
- The Rulebook on the Methods for Placing on the Market the Plant Nutrition Products in Bulk Form (Official Gazette of RS No 106/09) 106/09),
- The Rulebook on Methods of Packaging the Plant Nutrition Products and Soil Enhancers (Official Gazette of RS No 13/2010) 13/2010),
- The Rulebook on the Methods of Submitting Data on Produced Plant Nutrition Products that are Placed on Market (Official Gazette of RS No 56/2010) 56/2010).

It is foreseen that in the first quarter of 2011 the additional three national legal acts shall be adopted on the basis of the Law on Plant Nutrition Products and Soil Enhancers, namely:

- The Rulebook on the Elements of a Good Agriculture Practise that shall prescribe specific, environmentally acceptable but technologically not too high criteria, the application of which shall prevent, as much as possible, adverse impact that agricultural production may have on the environment.
- The Rulebook on the Annual Programme of Post-registration Control of the Plant Nutrition Products, which shall prescribe the sampling plan, type and number of samples; sampling and testing method; measures to be taken in event that chemical and physical qualities of the plant nutrition products are not in compliance with the registration issued or to check compliance of the tested plant nutrition products with the prescribed conditions and the international standards with regard to the type, content of the nutrients and harmful substances and the biologically nutrient values and
- The Decision of the fees in the sector of the plant nutrition products and soil enhancers.

## 2. Responsible bodies/responsibilities, authorized institutions

The body responsible for the sector of plant nutrition products and soil enhancers is the Ministry of Agriculture, Forestry and Water Management (MAFWM) and with the MAFWM, the following bodies perform activities with regard to the plant nutrition product and soil enhancers:

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

The MAFWM is responsible for supervision of the compliance with the Law and the operations of its bodies.

### 2.1. The Plant Protection Directorate;

The Plant Protection Directorate was established in 2004 as a body of the MAFWM, in compliance with the Law on Ministries governing founding of the ministries and other public administration bodies, their method of work and other issues relevant for the public administration operations.

In the area of plant nutrition products and soil enhancers the Plant Protection Directorate performs the following duties:

- Policy creating in the sector of plant nutrition and soil enhancers through preparation of professional background for drafting legislation; monitoring of conditions in the area of plant nutrition and soil enhancers; preparation of reports, analysis, information and other material and also implementation of international conventions and contracts and information exchange.
- Registration of the plant nutrition products and soil enhancers (entry into the Register of Plant Nutrition Products and Soil Enhancers);
- Placing on the market of the plant nutrition products and the soil enhancers (determining conditions for entry in the Register and entry of distributors and the importers in the Register of Distributors and Importers);
- Keeping records of the production, circulation and use of the plant nutrition products and soil enhancers;
- Defining the Annual Plan for examining the plant nutrition products and soil enhancers that have been entered into the Plant Nutrition and Soil Enhancers Registry (sampling plan, number and type of samples; facilities from which samples are taken; sampling frequency; measures to be taken in event that chemical and physical qualities of the plant nutrition products do not meet the requirements of the Decision to be entered in the Register);
- Introducing the principle of a good agriculture practice;
- Participation in international bodies and organizations.

The Sector for Plant Nutrition Products and Soil Enhancers of the Plant Nutrition Directorate performs these activities.

The activities of the internal organizational units of the Plant Nutrition Directorate, the organizational chart of the Plant Nutrition Directorate (current and foreseen), the flow chart – levels of authority – management lines of the units responsible for phytosanitary policy are presented in the answer to the question No 3, point 1.2, Subchapter I – General, Chapter 12.

### 2.2. The General Inspectorate;

The General Inspectorate was founded in 2008 in compliance with the Law on Ministries as a body of the MAFWM. The Phytosanitary Inspectorate of the General Inspectorate is responsible for control in the sector of plant nutrition products and soil enhancers. The phytosanitary inspectorate shall exercise its authorities in compliance with the following legislation: The Law on General Administrative Procedures, Law on Public Administration, Law on Plant Nutrition

Products and Soil Enhancers, Rulebooks, Ordinances, Decrees, Programmes, Instructions and other.

The Activities of internal organizational units of the General Inspectorate and the organizational charts are presented in the answer to the question No 3, point 1.3, Subchapter I – General, Chapter 12.

### **Supervision of the inspectorate in foreign trade**

The Division of the Border Phytosanitary Inspectorate of the General Inspectorate is responsible for control of import and transit of plant nutrition products and soil enhancers.

Import of the plant nutrition products and soil enhancers may be realized on the border crossing at which phytosanitary inspection is organized. Customs bodies may not start the duty process before the phytosanitary inspector has carried out the examination. Importers, transporters and their authorized representatives shall announce the shipment to the phytosanitary inspector within the prescribed time frame and shall submit the request for inspection of the shipment. The request shall be submitted in a written form and shall comprise all documents accompanying the shipment.

The control procedure carried out by the inspectors for plant nutrition products and soil enhancer shipments at the border crossing shall comprise the following:

- Checking the following documentation (documents) accompanying the shipment in order to identify the marks on packaging and the defined content of the shipment and verification of the conditions stipulated by the law.
  - Quality certificate;
  - Bill of lading
  - Decision on entry in the Register of Distributors and Importers;
  - Decision on entry in the Register of Plant Nutrition Products;
  - Invoices, bills of lading and other documents accompanying the shipment;
- Physical examination of the shipment:
  - Visual inspection;
  - Inspection of the means of transport;
  - Packaging and all marks (labels, stamps and other);
- Sampling.

Samples shall be sent to the institutions authorized by the MAFWM to examine their physical and chemical qualities.

The sampling procedure is governed by the Rulebook on Conditions and the Method of Examining and Sampling the Shipment During the Importation, the Method of Announcing Arrival of the Shipment and the Conditions the Importer Must Provide for the Purpose of the Phytosanitary Examination and the Method of Samples Delivery, Number and Size of the Samples for the Purpose of Testing and the Method of Handling the Seized Shipment (Official Gazette of RS No 86/2010) which has been harmonized with the Addendum IV of the Regulation 2003/2003 of the European Parliament and Council.

The shipments undergoing sampling by the phytosanitary inspector shall be under customs supervision and shall not be placed on the market before the testing results have been obtained.

In event that plant nutrition product and soil enhancer:

- As a result of the laboratory testing fails to meet the quality designated in a declaration, the phytosanitary inspector shall issue Decision to ban import and order that the shipment is returned to the sender;
- As a result of the laboratory testing proves to be compliance with the quality indicated in the declaration, the phytosanitary inspector shall approve its import.

If the shipment that is being imported in containers and on the border crossing at which there is no examination of the containers, the phytosanitary inspector shall only check the accompanying documents. In event that the shipment in the container has all required documents the phytosanitary inspector shall approve the transport of the containers, under customs supervision, to a specific location for examination of the container where opening of the containers is secured.

The shipments that are being transported by railway shall be examined at the railway stations designated by the MAFWM. The airplane, piece based shipments and postal shipments shall be examined in the customs storage in a designated location where conditions for examination are provided.

Shipments in transit over the territory of the Republic of Serbia and which are re-loaded or divided, must be examined at the border crossing.

### **Supervision of the inspectorate in domestic trade**

Control in domestic trade is carried out by the Department of Phytosanitary inspection.

The phytosanitary inspector shall perform the following control activities:

- Check whether the plant nutrition product and soil enhancer are produced or placed on the market contrary to an interim or permanent ban on production and placing on the market;
- Check whether the plant nutrition product and the soil enhancer that pose risk to the safety or health of humans, animals or plants or risk to the soil fertility or the environment is being produced, placed on the market or used in compliance with the prescribed conditions;
- Check whether the producer is carrying out the control of each lot of the manufactured plant nutrition products and soil enhancer and whether the producer keeps records on the quality control before the products are placed on the market;
- Checks whether a distributor or an importer is entered in the Register of the distributors and importers and whether the conditions for entry in the Register of distributors and importers are met;
- Checks whether the manufacturer and a distributor submit data on production and placing on the market of the plant nutrition products and soil enhancers in designated time frames;
- Checks fulfilment of contractual obligations of a Legal Entity that performs activities of public interest;
- Checks whether the plant nutrition products and soil enhancers are entered into the Register of Plant Nutrition Products and Soil Enhancers:

- Checks use of the plant nutrition products and soil enhancers for scientific and research purposes;
- Checks the quality of the plant nutrition products and soil enhancers in production, placing on the market and use;
- Checks declaration and labelling of the plant nutrition products and soil enhancers in production, placing on the market and use;
- Checks packaging method;
- Checks circulation of bulk plant nutrition products;
- Checks whether the plant nutrition products are used in compliance with the good agriculture practice;
- Checks whether the plant manufacturer keeps and submits records of use of plant nutrition products and soil enhancers in designated time frames;
- Checks whether advertising of the plant nutrition products is carried out in compliance with the prescribed conditions;
- Checks whether the manufacturer had, before placing the product on the market, carried out testing of resistance to detonations of the ammonium nitrite fertilizers with high nitrogen content;
- Performs sampling of the plant nutrition products and soil enhancers in production, plants and soil with no remuneration of their value;

The sampling method is governed by the Rulebook on Conditions and the Method of Examining the Plant Nutrition Products and the Soil Fertilizers, Method of Sampling and Samples Delivery and the Number and Size of Samples for the Purpose of Testing in Circulation and Use (Official Gazette of RS No 86/2010), which has been harmonized with the Addendum IV of the Regulation 2003/2003 of the European Parliament and Council.

### 2.3. The Directorate for National Reference Laboratories.

The DNRL was founded in 2009, in compliance with the Law on Food Safety (Official Gazette of RS No 41/09) as a body within the MAFWM responsible for laboratory activities in the food chain.

The Activities of internal organizational units of the DNRL, the organizational chart (current and foreseen) are presented in the answer to the question No 3, point 1.4, Subchapter I – General, Chapter 12.

Pursuant to the Article 35 of the Law on Plant Nutrition Products and Soil Enhancers, the DNRL performs testing of the plant nutrition products and soil enhancers that have been entered in the Register of Plant Nutrition Products and Soil Enhancers, in compliance with the Annual Testing Plan. Since the DNRL has not been operational, testing of the plant nutrition products and soil enhancers in compliance with the Annual Testing Plan shall be carried out by the institutions (laboratories) authorized by the MAFWM.

### 2.4. Authorized institutions

The MAFWM has authorized certain professional and scientific institutions to carry out physical and chemical and biological nutrition value testing in the process of registration of plant nutrition products (entry in the Registry).

The authorities granted by the MAFWM comprise definition of the activities and the conditions for entrusting activities, in compliance with the Article 51 of the Law on Plant Protection. However, in since this part of the Law n Plant Protection has been repealed, these institutions shall, in compliance with the Article 49 of the Law on Plant Nutrition Products and Soil Enhancers, perform activities for which they had been authorized until the tender for performing activities of public interest has been completed, in compliance with this Law.

Legal entities to which, based upon the tender, performing the activities of public interest is entrusted, shall be performing the following:

- Testing of physical and chemical and biological nutrition value of the plant nutrition products and soil enhancers for the purpose of the entry in the Registry.
- Laboratory testing of the plant nutrition products and soil enhancers samples taken in the process of inspectorate control for the purpose of checking chemical and physical qualities.

In compliance with the Article 14 of the Law on Plant Protection, one of the criteria for the selection of a legal entity to perform the activities of public interest, in this case testing for the purpose of entry in the Registry and laboratory testing of the samples taken in the process of the inspectorate control, is a proof that the conditions regarding the technical and professional competence or accreditation in compliance with EN/ISO/IEC 17025 (Serbian standard SRPS/ISO/IEC 17025:2006) are fulfilled. This criterion has been harmonized with Part B) of the Addendum V of the Regulation 2003/2003 of the European Parliament and Council.

The institutions authorized, which until the tender has been launched, will be performing testing of physical and chemical qualities and biological nutrition value of the plant nutrition products and soil enhancers for the purpose of the entry in the Registry and laboratory testing of the plant nutrition products and soil enhancers samples taken in the process of inspectorate control for the purpose of testing chemical and physical qualities are the following:

Type of testing	Institution	Accreditation
Chemical and physical qualities and biological nutrition value of inorganic, organic, organic-inorganic and microbiological plant nutrition products and soil enhancers	Institute for Land, Belgrade	SRPS/ISO/IEC 17025:2006 (certificate ATC)
	The Faculty of Agriculture, Department for Field and Vegetable Crops, Novi Sad	SRPS/ISO/IEC 17025:2006 (certificate ATC)
	The Faculty of Agriculture, Zemun	In the accreditation process in compliance with SRPS/ISO/IEC 17025:2006
Chemical and physical qualities and biological nutrition value of inorganic, organic, organic-inorganic nutrition products and soil enhancers	The Institute for Plant Protection and Environment, Belgrade	In the accreditation process in compliance with SRPS/ISO/IEC 17025:2006
Chemical and physical qualities of inorganic, organic and organic-inorganic nutrition products and soil enhancers	Zorka – Research Canter, Sabac	SRPS/ISO/IEC 17025:2006 (certificate ATC)
	The Institute for Use of Nuclear Energy – INEP, Zemun	SRPS/ISO/IEC 17025:2006 (certificate ATC)
Testing of organic and organic – inorganic plant nutrition products by bio-assay methods (special products)	The Institute for Biological Research Dr Sinisa Stankovic, Belgrade	-
Chemical and physical qualities of inorganic, organic, organic-inorganic and chemical and physical qualities of microbiological plant nutrition products and soil enhancers	The Institute for Pesticides and Environmental Protection, Belgrade	SRPS/ISO/IEC 17025:2006 (certificate ATC)
	Institute of Field and Vegetable Crops, Novi Sad	SRPS/ISO/IEC 17025:2006 (certificate ATC) BS EN ISO 14001:2004 (BSI certificate) ISO 9001:2000 (BSI certificate)

The methods of testing the chemical and physical qualities and biological nutrition value of the plant nutrition products and soil enhancers shall be governed by the Rulebook on the Methods of Testing Plant Nutrition Products and Soil Enhancers (Official Gazette of RS 71/2010) that has been harmonized with the Addendum IV of the Regulation 2003/2003 of the European Parliament and Council.

### **35. b) forecast**

The answer has been given within the sub-point a) of the question No 35, under 1. Legal framework (current/foreseen). Current status of harmonization with the EU Acquis.

### **36. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Standards, Testing, certification, compliance assessment and accreditation have been presented in the answer to the sub-point a) of the question No 35, under 2. Responsible bodies/responsibilities, authorized institutions, 2.4 Authorized institutions

The issue of market surveillance has been presented in the answer to the sub-point a) of the question No 35, under 2. Responsible bodies/responsibilities, authorized institutions, 2.2 The General Inspectorate;

### **Drug precursors**

#### **35. a) present status**

Legislation in force comprises the following:

- The Law on the Substances Used in the Illegal Production of Narcotics and Psychotropic Substances;
- Accompanying Rulebooks;
- The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988) that has been ratified.

The Law on the Substances Used in the Illegal Production of Narcotics and Psychotropic Substances has been harmonized with the ratified international conventions and with the following EU legislation governing the sector of precursors:

- 111/2005/EC
- 1277/2005/EC
- 273/2004/EC
- 3677/90/EEC

The following Rulebooks have been adopted to date:

- The Rulebook on the Form and Contents of the Import, Export or Transit of First, Second or Third Category Precursors;
- The Rulebook on Defining the List of Substances Used in Illegal Production of Narcotic Drugs and Psychotropic Substances.

Pursuant to the present Law, permits shall be issued for production or placing on the market of the precursors.

our system of import/export of first, second and the third category precursors comprises:

1. Issuing import/export permit for precursors in compliance with the Law, relevant Rulebooks and the ratified Conventions of the United Nations.
2. Collecting the feedback information on implementation of each permit issued for import/export.

The Division for Narcotic Drugs and Precursors of the Ministry of Health is responsible for the aforementioned activities.

The permit shall be issued for one-off import/export. The permit shall be issued for the period of four months. The importer/exporter shall, when the import/export has been completed, submit to the Division the proof on the completed import/export, within 15 days.

The Division shall, once in a year, prepare and send reports on the imported quantities of precursors to the International Narcotics Control Board (INCB) In addition, the Division shall prepare and submit interim reports to the INCB.

### **35. b) forecast**

The following relevant Rulebooks are being prepared on the basis of the Law on the Substances Used in the Illegal Production of Narcotics and Psychotropic Substances (Official Gazette No 107/05):

- The Rulebook on the Form, Content and Method of Keeping Records on Precursors and Other Substances That May be Used for Illegal Production of Narcotics and Psychotropic Substances;
- The Rulebook on Meeting Specific Criteria for Production or Circulation of the First Category Precursors;
- The Rulebook on the Contents of the Request for Issuing Permit for Production or Circulation of First, Second or Third Category Precursors;
- The Rulebook on Meeting the Criteria for the Chemical Analysis of First, Second or Third Category Precursors;
- The Rulebook on Form and Content of the Identity Document of the Inspector for Narcotics and Precursors.

### **36. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The system of import/export of first, second and the third category precursors in the Republic of Serbia comprises the following:

1. Issuing the import/export permit for precursors in compliance with the Law on the Substances Used in the Illegal Production of Narcotics and Psychotropic Substances (Official Gazette No 107/05), the legislation adopted for the purpose of implementation of this Law and the ratified United Nations Conventions;

2. Collecting the feedback information of implementation of each permit issued for import/export.

The Division for Narcotic Drugs and Precursors of the Ministry of Health is responsible for the aforementioned activities.

The permit shall be issued for one-off import/export. The permit shall be issued for the period of four months. The importer/exporter shall, when the import/export has been completed, submit to the Division the proof on the completed import/export, within 15 days.

The Division shall, once in a year, prepare and send reports on the imported quantities of precursors to the International Narcotics Control Board (INCB) In addition, the Division shall prepare and submit interim reports to the INCB.

### **36. b) further evolution**

The relevant Rulebooks are being prepared in compliance with the Law on the Substances Used in the Illegal Production of Narcotics and Psychotropic Substances (Official Gazette No 107/05).

The working sub-group 28 for Consumer and Health Protection, within the framework of responsibilities of the Ministry of Health, planned to adopt a new Rulebook on the Conditions Regarding Health Safety of the Items for General Use that may be placed on the market by the end of 2010 (not later than first quarter of 2011). The Rulebook shall be harmonized with the European legislations (Directive 76/68/EC and Directive 907/2006 on DETERGENTS and not on cosmetics products COMMISSION REGULATION (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII.

The following legislation shall be adopted:

1. The Law on Items for General Use that shall be harmonized with the following Directives: (89/109/EEC, 78/142/EEC, 81/432/EEC, 82/711/EEC, 85/572/EEC, 2002/72/EC, 90/128/EEC, 2004/1/EC, 2004/19/EC, 84/500/EEC, 93/10/EEC, 93/111/EEC, 93/11/EEC, 2002/16/EC, 2004/13/EC, 80/590/EEC, 1935/2004, Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on Materials and Articles Intended to Come into Contact with Food and Repealing Directives 80/590/EEC and 89/109/EEC 1935/2004)
2. The Rulebook on Cosmetics (Directive 76/768/EEC, presently only the Rulebook on Health Safety of the Items for General Use is planned).

### **Explosives for Civilian Use (the New Approach Directive)**

#### **35. a) present status**

The area of explosives for civilian use is governed by the following legislation in Serbia: The Law on Explosive Substances, Flammable Liquids and Gases (Official Gazette of FRS, No 44/77), comprising the following:

- Classification of explosive substances;

- Production of explosive substances in accordance with this Law is defined as storage of the explosive raw materials, production, refinement, processing, internal transport and storage of final explosive products with the manufacturer;
- Placement of the explosive substances on the market in accordance with this Law is defined as purchase and sales of explosive substances and storing the explosive substances in the warehouses and stores;
- Issuing approval for construction of facilities for production and storing the explosives and the provisions pertaining to the inspection supervision of implementation of fire protection measures and explosives protection measures in all facilities;
- The Law does not govern the area of determining technical requirements for explosive substances or the method of compliance assessment.

The Law on Placing Explosive Substances on the Market (Official Gazette of SFRY, No 30/85), comprising the following:

- Placing the explosive substances on the market in accordance with this Law is defined as purchase, sales and use of explosive substances and storage of the explosive substances in the warehouses, temporary storages and stores of legal entities that perform purchase, storing or sales of these substances;
- Defines the procedure for obtaining permit to perform the activities of placing the explosive substances on the market;
- Stipulates that the explosive substances may only be purchased and used if they are included in the List of explosive substances allowed to be placed on the market;
- Stipulates the conditions to be fulfilled prior to including the explosive substances in the List of explosive substances allowed to be placed on the market; An expert opinion of the institution that performed the testing is required for each explosive substance and for each explosive substance manufactured abroad, the importer shall also submit the expert opinion of the foreign manufacturer, proving its characteristics; Testing may be performed by the institution that has obtained the approval of the Ministry of Interior of the Republic of Serbia to perform such activities; In addition to the expert opinion, the entity performing the activities of placing the explosive substances on the market shall issue a declaration; There are no particular provisions pertaining to compliance assessment procedure.

The Rulebook on Safety at Work during the Explosives and Gunpowder Production and Handling (Official Gazette of SFRY No 55/59), stipulates the following:

- Measures for fire and explosion protection in the process of explosives production and storing in terms of defining the safety zones for the facilities in which the aforementioned activities are performed; the construction of the facilities and the requirements for safety of installations in these facilities (electric and thermo-technical installations).
- The Rulebook does not define technical conditions for explosive substances.

### **35. b) forecast**

The Ministry of Interior – Sector for Emergency Management is responsible for preparation of a new Law on Explosive Substances that shall be harmonized with the EU Directive 93/15/EEC – on the Harmonization of the Provisions Relating to the Placing on the Market and Supervision of Explosives for Civil Uses. The time frame for adopting this Law is the second quarter of 2011.

The time frame for adopting the Rulebook on Technical Requirements for Explosives for Civilian Use implementing the Directive 93/15/EEC is the third quarter of 2011.

**36. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

There is production of explosives in Serbia for civilian use. These explosives are used in mining (ground and underground exploitation), construction (construction of infrastructure facilities), exploitation of mineral resources, pharmaceutical industry, manufacturing of anti – hail rockets, production of hunting and sports ammunition. Also, the imported explosives are placed on the market.

The Ministry of Interior is responsible for implementation of fire and explosion protection measures in the process of production, storing and transport. The activities of calibration, testing and conformity assessment are not performed by the Ministry of Interior.

**36. b) further evolution**

Simultaneously with the transposition of relevant requirements of the Directive 93/15/EEC, though a technical legal act, the harmonized EN standards in this sector shall be adopted—The Rulebook on Technical Requirements for Explosives for Civilian Use. This will resolve the issue of compliance assessment. The Ministry responsible, in accordance with its authorities, shall decide on the need to notify the bodies for compliance assessment. The Rulebooks governing the safety measures in the process of production, storing and use and the supervision process and keeping records of the explosives for civilian use shall also be adopted.

**Pyrotechnic Products (New Approach Directive)**

**35. a) present status**

The answer to this question is identical to the one related to the explosives for civilian use, bearing in mind that there are no particular stipulations pertaining to conditions for pyrotechnic products.

**35. b) forecast**

The Ministry of Interior – Sector for Emergency Management – Department for Prevention is responsible for preparation of a new Law on Explosive Substances that shall be harmonized with the Directive 2007/23/EC – Placing Pyrotechnic Products on the Market. The time frame for adopting this Law is the second quarter of 2011. The time frame for adopting the Rulebook on Technical Requirements for Pyrotechnic Products, implementing the Directive 2007/23/EC is the third quarter of 2011.

**36. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

There is production of pyrotechnic products in Serbia. The Ministry of Interior is responsible for inspection supervision of implementation of fire and explosion protection measures in the process

of production, storage and transport. The activities of calibration, testing and conformity assessment are not performed by the Ministry.

### **36. b) further evolution**

Simultaneously with the transposition of relevant requirements of the Directive 2007/23/EC, through a technical legal act, the harmonized EN standards in this sector shall be adopted — The Rulebook on Technical Requirements for Pyrotechnic Product. The Ministry responsible, in compliance with its authorities, shall decide on the need to notify the bodies for compliance assessment. The Rulebooks governing the safety measures in the process of production, storage and use and the supervision process and keeping records of the pyrotechnic products shall be adopted.

## **Good Laboratory Practice (GLP)**

### **35. a) present status**

The Law on Medicines and Medical Devices stipulates that pre-clinical trials of medicinal products for human use or for veterinary use and safety testing of substances present in medicinal products, pesticides, cosmetic products, food supplements, animal feed supplements and industrial chemicals are conducted in conformity with the Good Laboratory Practice Guidelines. Results of these laboratory tests, which allow assessment of potential threats to human and animal health and environment, are used in procedures for the authorisation of medicinal products and in administrative procedures required for placing pesticides, cosmetic or similar products, food supplements, animal feed supplements and industrial chemicals on the market, in conformity with specific laws governing the placement of these products on the market.

The Law on Medicines and Medical Devices stipulates that, for the purposes of procedures for the authorisation of medicinal products and administrative procedures for placing other products on the market in conformity with specific laws governing their placement on the market, a laboratory that has conducted laboratory tests in conformity with the Good Laboratory Practice Guidelines must provide, with test results, a certificate of good laboratory practice to the applicant and to the competent ministries and organisations holding public powers in the field of chemicals management.

Laboratories conducting pre-clinical trials must bring their work into conformity with the Good Laboratory Practice Guidelines. The Law also stipulates that a laboratory that has conducted laboratory tests in conformity with the Good Laboratory Practice Guidelines must provide, with laboratory test results, a certificate of good laboratory practice issued by the ministry competent for health affairs pursuant to this Law, or a corresponding certificate issued by the competent authority of another country that assesses the conformity of laboratories with good laboratory practice guidelines.

The assessment and control of the conformity of laboratory tests with the Good Laboratory Practice Guidelines are organised and conducted by the ministry competent for health affairs and conformity is assessed by responsible inspectors of the Ministry of Health as part of the inspection procedure.

The procedure for assessing conformity with the Good Laboratory Practice Guidelines is conducted as part of:

1) Inspection conducted for the purpose of issuing a certificate of good laboratory practice, in response to an application by a laboratory,

- 2) Periodic inspection conducted two years after the day of issuing the certificate of good laboratory practice for the purpose of verifying the conformity with the Good Laboratory Practice Guidelines,
- 3) Targeted inspection conducted on request of competent authorities or organisations to which the certificate of good laboratory practice is submitted in the procedure for the authorisation of medicinal products, registration, application for or issuing of marketing authorisation and use of chemicals,
- 4) Extraordinary inspection.

The Good Laboratory Practice Guidelines (Official Gazette of RS No. 28/08) is fully harmonised with Directive 2004/9/EC and Directive 2004/10/EC.

### **35. b) forecast**

Under the Law on Medicines and Medical Devices bylaws should be adopted by May 2011, which shall regulate:

- The modality of entry into the Registry of Laboratories conducting laboratory tests in conformity with the Good Laboratory Practice Guidelines,
- The contents of the form of the Good Laboratory Practice certificate,
- The modality of entry into the Registry of Issued Certificates of Good Laboratory Practice, all of which will be harmonised with Directive 2004/9/EC and Directive 2004/10/EC.

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Good laboratory practice is regulated by the Good Laboratory Practice Guidelines (Official Gazette of RS No. 28/08). Good laboratory practice principles apply to all pre-clinical safety tests of substances present in medicinal products for human use, plant protection products, cosmetic products, medicinal products for veterinary use, food supplements, animal feed supplements and industrial chemicals.

The Law on Medicines and Medical Devices, stipulates that, for the purposes of procedures for the authorisation of medicinal products and administrative procedures for placing other products on the market in conformity with specific laws governing their placement on the market, the laboratory that has conducted laboratory tests in conformity with the Good Laboratory Practice Guidelines must provide, along with test results, a certificate of good laboratory practice to the applicant and to the competent ministries and organisations holding public powers in the field of chemicals management.

Laboratories conducting pre-clinical trials must bring their work into conformity with the Good Laboratory Practice Guidelines. The Law also stipulates that a laboratory that has conducted laboratory tests in conformity with the Good Laboratory Practice Guidelines must provide, with laboratory test results, a certificate of good laboratory practice issued by the ministry competent for health affairs pursuant to this Law, or a corresponding certificate issued by the competent authority of another country that assesses the conformity of laboratories with good laboratory practice guidelines.

The assessment and control of the conformity of laboratory tests with the Good Laboratory Practice Guidelines are organised and conducted by the ministry competent for health affairs and conformity is assessed by responsible inspectors of the Ministry of Health as part of the inspection procedure.

The procedure for assessing conformity with the Good Laboratory Practice Guidelines is conducted as part of:

- 1) Inspection conducted for the purpose of issuing a certificate of good laboratory practice, in response to an application by a laboratory,
- 2) Periodic inspection conducted two years after the day of issuing the certificate of good laboratory practice for the purpose of verifying the conformity with the Good Laboratory Practice Guidelines,
- 3) Targeted inspection conducted on request of competent authorities or organisations to which the certificate of good laboratory practice is submitted in the procedure for the authorisation of medicinal products, registration, application for or issuing of marketing authorisation and use of chemicals,
- 4) Extraordinary inspection.

### **36. b) further evolution**

Under the Law on Medicines and Medical Devices, bylaws should be adopted by May 2011, which shall regulate in detail the modality of entry into the Registry of Laboratories conducting laboratory tests in conformity with the Good Laboratory Practice Guidelines, the contents of the form of the Good Laboratory Practice certificate and the modality of entry into the Registry of Issued Certificates of Good Laboratory Practice, all of which will be harmonised with Directive 2004/9/EC and Directive 2004/10/EC.

## **Pharmaceuticals**

### **35. a) present status**

The Law on Medicines and Medical Devices, stipulates the conditions and procedure for marketing authorisation for medical products, entry of medicinal products into registries kept by the Medicines and Medical Devices Agency of Serbia, production and marketing of medicinal products and medical devices and supervision in these matters, the work of the Medicines and Medical Devices Agency of Serbia and other matters relevant to the field of medicinal products and medical devices.

With a view to further harmonisation with EU legislation in this field, the Law is also harmonised with:

– Directive 2001/83/EC, amended by Directives (EC) 2002/98, 2003/63, 2004/24, 2004/27, 2008/29, 2009/53 and 2009/120 and by Regulations (EC) 726/2004 and 1394/2007 – on medicinal products for human use,

- Directive 2001/82/EC, amended by Directives 2004/28, 2009/9 and 2009/53 and by Regulations 726/2004 and 2377/90 – on medicinal products for veterinary use,
- Directives 2003/94/EC and 91/412/EEC – on manufacturing medicinal products and good manufacturing practice,
- Directives 2004/9/EC and 2004/10/EC – on pre-clinical trials of medicinal products,
- Directives 2001/20/EC and 2005/28/EC – on clinical trials of medicinal products and good clinical practice,
- Directives 92/25/EEC and 63/03/EC – on good distribution practice,
- new approach Directives 93/42/EC, 98/79/EC and 90/385/EC – on medical devices,
- Directive 89/105/EC – on pricing and reimbursement of medicinal products.

### **35. b) forecast**

Under the Law on Medicines and Medical Devices, its implementing bylaws should be adopted by May 2011 and will stipulate:

- The contents of authorisation of a medicinal product and the modality of obtaining it;
- Specific requirements and modality of entry into the Registry of Traditional Herbal Medicinal Products, and of issuing authorisation for traditional herbal medicinal products;
- Specific requirements and modality of entry into the Registry of Homeopathic Medicinal Products, and of issuing authorisation for homeopathic medicinal products;
- Requirements relating to space, equipment and staff, other requirements for the preparation of galenic medicinal products and good practice in the preparation of galenic medicinal products;
- The modality of obtaining authorisation for medicinal products with reduced documentation,
- Requirements, documentation contents and modality of authorisation of variations;
- Requirements, documentation contents and modality of transferring authorisations of medicinal products;
- The modality of renewing authorisations of medicinal products;
- Prescription form and contents for prescription-only medicinal products and modality of prescribing and dispensing medicinal products;
- Contents of an application for the authorisation of a clinical trial of a medicinal product and the modality of conducting a clinical trial of a medicinal product;
- Requirements relating to space, equipment, staff and other requirements for manufacturing medicinal products;
- The programme and modality of obtaining a licence and the modality of revoking a licence of a qualified pharmacist responsible for marketing a medicinal product batch;
- The form of certificate of good manufacturing practice for medicinal products for human use,
- Requirements relating to space, equipment, staff and other requirements for wholesale trade in medicinal products and medical devices;
- The modality of importing unauthorised medicinal products;
- The modality of quality control of medicinal products and medical devices;
- The modality of labelling the outer and inner packaging of medicinal products, additional labelling of medicinal products and contents of package leaflets;
- The modality of reporting, collecting and monitoring adverse reactions to medicinal products and medical devices;
- The modality of advertising medicinal products and medical devices;

all of which will be harmonised with Directive 2001/83/EC as amended by Directives (EC) 2002/98, 2003/63, 2004/24, 2004/27, 2008/29, 2009/53 and 2009/120 and Regulations (EC) No

726/2004 and 1394/2007 – on medicinal products for human use; Directive 2001/82/EC as amended by Directives 2004/28, 2009/9 and 2009/53 and Regulations 726/2004 and 2377/90 – on medicinal products for veterinary use; Directives 2003/94/EC and 91/412/EEC – on manufacturing medicinal products and good manufacturing practice; Directives 2001/20/EC and 2005/28/EC – on clinical trials of medicinal products and good clinical practice; Directives 92/25/EEC and 63/03/EC – on good distribution practice.

**36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

In the Republic of Serbia, a medicinal product may only be marketed under a marketing authorisation issued by the Medicines and Medical Devices Agency of Serbia.

Under the Law on Medicines and Medical Devices, the Medicines and Medicinal Devices Agency of Serbia issues an authorisation for the use of promotional materials and other documentation for advertising medicinal products, including in the media, and to promotion of medicinal products among health and veterinary professionals who prescribe medicinal products, notably at industry conventions, in industry publications and by other means of promotion.

Under the Law on Medicines and Medical Devices, medicinal products may only be manufactured by a legal person that has a manufacturing authorisation issued by the competent ministry. A medicinal product manufacturer that has been issued a manufacturing authorisation by the competent ministry must manufacture medicinal products in accordance with the manufacturing authorisation, the Good Manufacturing Practice Guidelines and the Guidelines on Good Distribution Practice of Medicinal Products, and use, in the manufacture of medicinal products, only those active substances and certain auxiliary substances that have been manufactured in conformity with the Good Manufacturing Practice Guidelines for active substances. The assessment and control of conformity of the manufacture of medicinal products or active substances, as appropriate, with the Good Manufacturing Practice Guidelines are organised and conducted by the ministry competent for health affairs.

Under the Law on Medicines and Medical Devices, only legal persons that have a permit issued by the competent ministry and meet the requirements stipulated by the Law and its implementing regulations may engage in wholesale trade in medicinal products (imports, exports, procurement, storage and distribution). Also, under the Law, only medicinal products with a marketing authorisation may be the subject of wholesale trade, unless the Agency approves the import of a medicinal product without a marketing authorisation. At the request of health or veterinary institutions, the Agency may approve the import of medicinal products without a marketing authorisation which are intended for the treatment of a particular patient or group of patients, with the proviso that it must be delivered or dispensed, as appropriate, by the legal person that holds a wholesale permit and the pharmacy. Application for permit to import medicinal products without a marketing authorisation, if they are intended for scientific or medical research, is submitted to the Agency. A holder of a permit for wholesale trade in medicinal products may import or export medicinal products in conformity with law.

Under the Law, a legal person engaging solely in imports or exports of medicinal products may conduct these affairs provided that it conducts the affairs of import and customs clearance of medicinal products in the name and on behalf of the holder of a permit for wholesale trade in medicinal products to the place of release for free circulation, in conformity with customs regulations.

A legal person engaging solely in imports or exports of medicinal products need not have a permit for wholesale trade in medicinal products issued by the competent ministry and is not considered a holder of a permit for wholesale trade in medicinal products within the meaning of this Law.

A manufacturer of medicinal products may import or export medicinal products within its own product range, starting materials for manufacture, intermediate products and substances, in conformity with law.

Under the Law on Medicines and Medical Devices, the Medicines and Medical Devices Agency of Serbia, which is a member of the OMCL Network (Official Medicines Control Laboratory Network), controls the quality of medicinal products and issues certificates of analysis.

Under the Law on Medicines and Medical Devices, before marketing an imported medicinal product batch, a holder of a permit for wholesale trade in medicinal products must submit samples of the imported medicinal product batch, accompanied by the manufacturer's certificate of analysis or certificate of analysis from a qualified institution for quality control from another state, to the Medicines and Medical Devices Agency of Serbia for the purpose of quality control of the medicinal product concerned. The Agency conducts only quality control based on documentation check if the certificate of analysis of medicinal product quality is issued by the manufacturer or a qualified institution for quality control of medicinal products from a European Union Member State or another country which imposes the same or similar requirements for authorisation of medicinal products. This quality control of medicinal products is quality control on the basis of documentation check in the procedure for issuing certificates of analysis and constitutes the acceptance of technical requirements for products and conformity assessment, in conformity with law.

Under the Law on Medicines and Medical Devices, a holder of a medicinal product authorisation must keep records of all adverse reactions to the medicinal product reported in the Republic of Serbia, European Union Member States or a third country and forward them to the Medicines and Medical Devices Agency of Serbia. The Medicines and Medical Devices Agency of Serbia organises and monitors the modality of collection and assessment of adverse reactions to medicinal products, and processing and assessment of the data obtained. The Medicines and Medical Devices Agency of Serbia must collect and exchange pharmacovigilance data with the authorised pharmacovigilance centre of the World Health Organisation and with other agencies and institutions.

Under the Law on Medicines and Medical Devices, the Medicines and Medical Devices Agency of Serbia issues authorisations of clinical trials of medicinal products and decides on amendments to the authorisation and clinical trial protocol. Clinical trial progress is controlled by the Medicines and Medical Devices Agency of Serbia in conformity with the Law on Medicines and Medical Devices, its implementing regulations, clinical trial protocol and Good Clinical Practice Guidelines.

The enforcement of the Law on Medicines and Medical Devices and its implementing regulations is supervised by the competent ministry (the ministry competent for health affairs or the ministry competent for veterinary affairs, as appropriate), i.e. by its inspectors.

### **36. b) further evolution**

All implementing bylaws of this Law will be adopted by May 2011, in conformity with the Law.

### **Transparency in the Context of Pricing and Reimbursement of Medicinal Products**

### **35. a) present status**

Provisions of Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems have been in force in the Republic of Serbia since 2004, i.e. since the entry into force of the Law on Medicines and Medical Devices and the Regulation on the Criteria for the Pricing of Medicinal Products (Official Gazette of RS Nos 37/08, 84/08, 88/08, 113/08, 18/09, 72/09 and 13/10).

The Law on Health Insurance (Official Gazette of RS No. 107/05 and 109/05) stipulates that the Republic Institute for Health Insurance adopts an instrument setting the Medicinal Product Reimbursement List. This Reimbursement List contains medicinal products that cover all required indication fields, rather than all medicinal products registered in the market of the Republic of Serbia.

The number of medicinal products on the Medicinal Product Reimbursement List has been on the increase year after year as a result of the increase in funding earmarked for medicinal products.

### **35. b) forecast**

The Law on Medicines and Medical Devices provides for setting the criteria for the pricing of authorised prescription-only medicinal products for human use. This has ensured price liberalisation of over-the-counter medicinal products, i.e. the prices of these medicinal products will be set freely by holders of medicinal product authorisations.

### **36. a) short description**

Under Article 58 of the Law on Medicines and Medical Devices, the Government of the Republic of Serbia adopts a decision setting criteria for the pricing of authorised prescription-only medicinal products for human use and price caps for these medicinal products, on the basis of a joint proposal by the Minister competent for health affairs and the Minister competent for trade affairs. Following this, the Government adopts the Regulation on the Criteria for the Pricing of Medicinal Products and, pursuant to this Regulation, the Decision on the Prices of Prescription-Only Medicinal Products for Human Use.

A holder of a medicinal product authorisation sets prices of over-the-counter medicinal products for human use and must submit the data on the prices of these medicinal products to the ministry competent for health affairs at least once in a calendar year.

The Regulation on the Criteria for the Pricing of Medicinal Products sets the following criteria:

- 1) Comparable wholesale price of the medicinal product concerned in reference countries,
- 2) Average comparable wholesale price of the medicinal product concerned in reference countries,
- 3) The ratio of the wholesale price of the medicinal product concerned in the Republic of Serbia to the average comparable wholesale price of the medicinal product concerned in reference countries,
- 4) Current wholesale price of the medicinal product concerned,
- 5) Pharmacoeconomic study indicators,
- 6) Cost of wholesale trade.

On the basis of these criteria, the holder of the medicinal product authorisation submits the relevant documentation to the competent ministries (Ministry of Health and the ministry competent for trade affairs). Following the analysis of the submitted documentation, the competent ministries develop a proposal for the medicinal product price and submit it to the Government for approval.

Therefore, prices of medicinal products are set on the basis of prescribed criteria, which are made public (the principle of accessibility and transparency), and the documentation that all interested parties must provide during analysis.

The procedure for setting prices of medicinal products is conducted for all medicinal products authorised by the Medicines and Medical Devices Agency of Serbia, irrespective of the country of manufacture, i.e. the same criteria apply to both domestically-manufactured and imported medicinal products.

The method used for setting wholesale prices of medicinal products in the Republic of Serbia is based on comparing the wholesale price of the medicinal product concerned in the Republic of Serbia with the average comparable price of the medicinal product concerned in reference countries (Republic of Slovenia, Republic of Croatia and Italian Republic). If the comparable price cannot be ascertained in any of these three countries, the reference country is the EU Member State in which the medicinal product concerned is manufactured and a marketing authorisation has been obtained; if a marketing authorisation has not been obtained in the country of manufacture, reference countries are the EU Member States in which marketing authorisations have been obtained.

The criteria for including medicinal products on the Medicinal Product Reimbursement List are stipulated by the Rulebook on the Criteria, Modality and Procedure for Inclusion of Medicinal Products on and Removal from the Medicinal Product Reimbursement List (Official Gazette of RS No. 95/08 and 7/10). This Rulebook stipulates the criteria for the procedure of including medicinal products on the Reimbursement List; the criteria define conditions regarding proposed medicinal product prices, the maximum number of medicinal products of the same INN or the same or similar pharmaceutical form that may be included on the Reimbursement List, setting specific indications and usage notes, and the requirements to be fulfilled by the applicant for inclusion of a medicinal product on the Reimbursement List. The number and types of medicinal products on the Reimbursement List are determined in accordance with the criteria from the Rulebook, in line with the financial capacity of the Republic Institute for Health Insurance.

As regards the restriction on the number of medicinal products that may be included on the Reimbursement List, the applicable Rulebook stipulates that, in the same or similar pharmaceutical form, a minimum of two (if there is more than one registered medicinal product for which an application has been filed for inclusion on the Reimbursement List) and a maximum of six medicinal products of different manufacturers; of these, a maximum of five medicinal products may be generic; this includes both domestic and foreign manufacturers, since this number is considered to satisfy the needs and provide security to insured persons in the Republic of Serbia.

### **36. b) further evolution**

Since the Law on Medicines and Medical Devices, prices of over-the-counter medicinal products have been liberalised, i.e. the prices of these medicinal products will be set freely by holders of medicinal product authorisations.

## **Cosmetic products**

### **35. a) present status**

List of applicable regulations relating to cosmetic products:

Law on Ministries (Official Gazette of RS Nos 65/2008, 36/2009),

Law on Sanitary Surveillance (Official Gazette of RS No. 125/2004),

Law on Health Surveillance of Foodstuffs and General Consumer Products (Official Gazette of SRS Nos 48/77, 29/88, 44/91. and Official Gazette of RS No. 8/94), where it concerns general consumer products,

Law on Health Surveillance of Foodstuffs and General Consumer Products (Official Gazette of SRS Nos 53/91 and Official Journal of FRY Nos 24/94, 28/96 and 37/2002), where it concerns general consumer products, and bylaws adopted pursuant to these laws:

– Rulebook on Health Safety Requirements for General Consumer Products That May Be Marketed (Official Journal of SFRY No. 18/91),

– Rulebook on Staff, Space and Equipment Requirements for Health Organisations and Other Organisations Performing Analyses and Superanalyses of Foodstuffs and General Consumer Products (Official Journal of FRY No. 60/02),

– Guidelines on the Sampling Method for Analyses and Superanalyses of Foodstuffs and General Consumer Products (Official Journal of SFRY No. 60/1978),

– Rulebook on the Methods for Determining pH Values and Quantities of Toxic Metals and Non-metals in Personal Hygiene Products and Face and Body Care and Beauty Products and for Assessing Microbiological Safety of Those Products (Official Journal of SFRY No. 46/83).

The current law in this field is not fully harmonised with that of the EU.

### **35. b) forecast**

Within the competence of the Ministry of Health, the Working Sub-group 28 – Consumer Protection and Health Care plans to adopt a new rulebook on health safety requirements for general consumer products that may be marketed, which will be harmonised with the European law (Directive 76/768/EC and Regulation (EC) 907/2006 on cosmetic products).

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

This field is now governed by two laws and a rulebook:

1. Law on Safety of Foodstuffs and Products of General Use (Official Journal of SFRY No. 53/91) and

2. Law on Health Surveillance of Foodstuffs and Products of General Use (Official Gazette of SRS No 48/77, 44/91, 48/94)

3. Rulebook on the Requirements with respect to Health Safety of Products of General Use that may be circulated (Official Journal of SFRY No 26/83 and 18/91)

Laboratory tests are done by certified and authorized laboratories/ health and non-health laboratories. Supervision of health safety in production and circulation is carried out by sanitary inspection.

### **36. b) further development**

Draft law on products of general use (cosmetics are in this category) according to EU legislation is planned.

## **Legal Metrology, Pre-packaging and Units of Measurement (Old Approach Directive)**

### **35. a) present status**

The Rulebook on Metrological Requirements for Non-automatic Weighing Instruments is harmonised with the OIML International Recommendation R76, whereby the technical requirements of Directive 90/384/EEC (NAWI) are fulfilled. Requirements concerning the values of the force of gravity are not in force.

The Measuring Instruments Directive (MID) has not been transposed. The measuring instruments covered by these directives are subject to measuring instrument type approval and/or to initial verification of measuring instruments.

The field of legal metrology is regulated by the Law on Metrology and the Rulebook on the Measuring Instruments Subject to Mandatory Verification and Time Intervals of Periodic Re-verification (Official Gazette of RS No. 49/10). The Rulebook stipulates that, in the Republic of Serbia, 38 different kinds of measuring instruments are subject to mandatory verification; prior type approval is required for 27 of these.

Pre-packaged products are a new field regulated by the Law on Metrology.

Legal units of measurement are stipulated by the Regulation on Legal Units of Measurement, which transposes in full the old approach directive on units of measurements, Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC.

Measuring instrument type approval is mandatory only for those measuring instruments as prescribed by the Rulebook on the Measuring Instruments Subject to Mandatory Verification and Time Intervals of Periodic Re-verification. The Directorate for Measures and Precious Metals performs measuring instrument type tests at the request of a domestic manufacturer, authorised importer or authorised distributor of a foreign manufacturer of measuring instruments and, on the basis of those tests, issues certificates of measuring instrument type approval, certifying that the measuring instrument type in question conforms to the prescribed technical and metrological requirements. Measuring instruments subject to mandatory type testing may be verified only if a certificate of measuring instrument type approval has been issued for the measuring instrument in question. New measuring instruments are subject to initial verification prior to being placed on the market, while measuring instruments in use are subject to periodic re-verification.

A table is enclosed indicating the 38 kinds of measuring instruments subject to mandatory verification and the existing metrological regulations pursuant to which they are verified and type-approved.

Old approach directives on measuring instruments (the *acquis* of the European Union under the management of DG Enterprise and Industry, chapter 5. legal metrology and pre-packaging) have not been transposed; therefore, the current metrological regulations (rulebooks on metrological requirements and metrological guidelines) referred to in the table are, for the most part, obsolete and only some parts are harmonised with the relevant OIML recommendations.

Since no rulebook on pre-packaged products has been adopted so far, approval of marketing of pre-packaged products is not in place.

### **35. b) forecast**

Directive 2009/23/EC on non-automatic weighing instruments will be transposed in a new rulebook on metrological requirements for non-automatic weighing instruments. Directive 2004/22/EC on measuring instruments will be transposed in a new rulebook on metrological requirements for measuring instruments. Measuring instruments covered by these directives are subject to measuring instrument type approval and/or to verification of measuring instruments by modules.

A new regulation on legal units of measurement should be adopted in 2011, whereby the Government will regulate legal units of measurement and their use in RS; this regulation will be harmonised with Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009 amending Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement.

In addition, in 2011 and 2012, all metrological regulations should be harmonised with the relevant OIML recommendations and WELMEC guidelines, where they concern those measuring instruments (38 kinds referred to in the table) that are not covered by the new approach directives (in particular MID and NAWI).

Pre-packaged products are a new field regulated by the Law on Metrology. The rulebooks that will stipulate the following procedures and metrological requirements will be harmonised with the relevant European Union directives on pre-packaged products by 2012.

1. The rulebook on the procedure for testing pre-packaged products marked with weight and volume will transpose part of Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products. This rulebook should be adopted in 2011.
2. The rulebook on metrological requirements for pre-packaged products marked with weight and volume will transpose the remainder of Directive 76/211/EC and DIRECTIVE 2007/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 laying down rules on nominal quantities for pre-packaged products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC. This rulebook should be adopted in 2012.
3. The rulebook on metrological requirements for measuring bottle containers and method of testing measuring bottle containers will transpose Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers. This rulebook should be adopted in 2012.

Implementation of EU directives on pre-packaged products will start after their transposition by these rulebooks. Since such a rulebook has not been adopted so far, approval of marketing of pre-packaged products is not in place.

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

In the Republic of Serbia, calibrated working standards or certified reference materials are used for verification of measuring instruments.

The modality of ensuring traceability is described in the answer to question 32.

Measuring instrument type approval is mandatory only for those measuring instruments for which it is prescribed by the Rulebook on the Measuring Instruments Subject to Mandatory Verification and Time Intervals of Periodic Re-verification. The Directorate for Measures and Precious Metals performs measuring instrument type testing, on the basis of which it issues certificates of measuring instrument type approval, certifying that the measuring instrument type concerned conforms to the prescribed technical and metrological requirements. New measuring instruments are subject to initial verification prior to being placed on the market, while measuring instruments in use are subject to periodic re-verification.

Authorised bodies verifying measuring instruments must obtain prior accreditation for the verification tasks performed by them.

Metrological surveillance includes surveillance of the manufacturing, marketing, import, installation, use, maintenance and repair of measuring instruments. Metrological surveillance is performed to verify the conformity of measuring instruments with the stipulated requirements, the conformity of their use with law and other regulations in the field of metrology and the accuracy of quantities indicated on and contained in pre-packaged products.

Pursuant to the Law on Metrology, metrological surveillance of measuring instruments and pre-packaged products and surveillance of the use of legal units of measurement are performed by the Directorate, through persons authorised for metrological surveillance. Ongoing metrological surveillance is performed on measuring instruments placed on the market and put into use. In surveillance, the Directorate cooperates with the Trade Inspection and other inspection and customs authorities.

As the rulebooks have not been adopted yet, market surveillance of pre-packaged products is not in place at present.

Part of the equipment required for checks as part of surveillance was procured by the Directorate in 2010.

### **36. b) further evolution**

The development programme for the next five years foresees more intensive development of metrology in chemistry with a view to ensuring traceability and comparability of measurement results in this area. Development will focus in particular on reference methods and use of reference materials to ensure traceability to the international level for the purposes of chemical, food and pharmaceutical industries, medicine and environmental protection.

A further evolution of methods for testing the amounts labelled and contained in pre-packaged products is planned. The evolution includes the acquisition of equipment required for measuring and standards for calibration of said equipment, as well as the development of testing procedures for the amounts of packaged products and the procedures for calibrating the equipment in order to provide traceability. Since mass measuring instruments (weighing instruments) and volume

measuring instruments are predominantly used for testing the amounts labelled and contained in pre-packaged products, the development shall encompass the procedures for calibration in these areas. The development of the field of pre-packaged products of the Directorate was initiated in 2009 and should be completed in 2012.

The Regulation on the Modality of Performing Metrological Surveillance (Official Gazette of RS No. 88/10) provides a basis for elaborating the procedure and modality of performing metrological surveillance of measuring instruments and pre-packaged products.

### **Emissions of gaseous and particulate pollutants from non-road mobile machinery engines**

#### **35. a) present status**

There is currently no law or bylaw in the Republic of Serbia defining the permitted emission levels for gaseous or particulate pollutants of non-road mobile machinery engines. Notification of the UN/ECE Regulations No. 96 has been undertaken.

#### **35. b) forecast**

The Road Traffic Safety Agency shall initiate the implementation procedure in 2011 in accordance with the UN/ECE Regulations No. 96 notification mentioned in the previous point 35. a).

#### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

See: A. Harmonization of laws including technical regulations, motor vehicles section, under 35 a).

#### **36. b) further evolution**

See: A. Harmonization of laws including technical regulations, motor vehicles section, under b).

### **Aerosol Dispensers (ADD)**

#### **35. a) present status**

Pre-packaged products (including aerosols) represent a new field regulated by the Law on Metrology. This field is currently regulated only through Chapter VIII – Packaged Products of the Law on Metrology. No bylaws have been adopted. Since no rulebooks have been adopted, the authorization of aerosols marketing is not implemented.

#### **35. b) forecast**

A rulebook for pre-packaged products (including aerosol dispensers) shall be prescribed, in line with the relevant European Union directive. The rulebook shall prescribe the procedure for testing aerosols in their packaging to check their compliance with metrological requirements, requirements for equipment used for monitoring aerosol amounts, metrological requirements to

be fulfilled by the amounts of aerosols in the packaging, methods for labelling the amounts and the allowed deviation of the real amounts from the labelled nominal amounts. The adoption of all regulations relating to packaged products is planned in 2012.

The Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers will be transposed by the end of 2012.

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Pre-packaged products, including aerosol dispensers, represent a new field currently regulated only through Chapter VIII – Packaged Products of the Law on Metrology. The Law on Metrology envisages that the Minister competent for metrology issues shall further prescribe the procedure for testing pre-packaged products (including ADD) in order to test compliance with metrological requirements, requirements for equipment used in monitoring the amounts of pre-packaged products, metrological requirements relating to the amounts of pre-packaged products, methods for labelling the amounts and allowed deviation of the real amounts from the labelled nominal amounts.

The equipment used for testing the amounts of pre-packaged products must be calibrated in order to achieve result traceability. Since mostly volume measuring instruments are used in testing the amounts in aerosol dispensers (ADD), the calibration of the measuring instruments may be performed in laboratories accredited for calibrating measuring instruments for liquid volumes using the gravimetric or volumetric method.

Metrological inspection, in addition to inspection of measuring instruments, includes inspection of pre-packaged products, including aerosol dispensers.

Since this regulation has not been adopted, the authorization of aerosols marketing is not implemented.

### **36. b) further evolution**

A further evolution of methods for testing the amounts labelled and contained in pre-packaged products is planned. The evolution includes the acquisition of equipment required for measuring and standards for calibration of said equipment, as well as the development of testing procedures for the amounts of packaged products and the procedures for calibrating the equipment in order to provide traceability. Since mass measuring instruments (weighing instruments) and volume measuring instruments are predominantly used for testing the amounts labelled and contained in pre-packaged products, the development shall encompass the procedures for calibration in these areas. The development of the field of pre-packaged products of the Directorate was initiated in 2009 and should be completed in 2012.

## **Crystal Glass**

### **35. a) present status**

There are currently no specific technical regulations prescribing technical requirements for the composition and labelling of crystal glass products, and no methods for determining chemical and physical properties of types of crystal glass for this group of products – crystal glass products in the Republic of Serbia.

Since there are no specific technical regulations for this group of products, market regulation regarding safety and product labelling is undertaken through the application of:

- Law on General Product Safety
- Law on Consumer Protection and
- Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of RS No. 36/09).

Crystal glass products are not subject to mandatory product certification, nor is there an obligation for manufacturers or importers to issue certificates on the quality of crystal glass products (determining that crystal glass products meet the marketing requirements as determined by Serbian standards), since there are no specific technical regulations prescribing the obligation.

### **35. b) forecast**

Rulebook on Technical and Other Requirements shall be adopted in 2012. The legal basis for the adoption of the rulebook is contained in Article 6, paragraph 1 of the Law on Technical Requirements for Products and Conformity Assessment, prescribing those technical regulations shall be prepared and adopted by the competent ministry.

This Rulebook shall transpose Directive 69/493/EEC on crystal glass products into the legislation of Serbia.

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Crystal glass products are not subject to mandatory product certification, nor is there an obligation for manufacturers or importers to issue certificates on the quality of crystal glass products (determining that crystal glass products meet the marketing requirements as determined by Serbian standards), since there are no specific technical regulations prescribing the obligation.

The Institute for Standardization of Serbia adopted a standard in 1991 defining the classification and labelling of crystal glass products SRPS B.E5.250 – Crystal Glass – Classification and Labelling, in line with Directive 69/493/EEC. The implementation of the standard is voluntary.

The Ministry of Trade and Services – Department for Market Inspection conducts market surveillance in line with the provisions of the Law on General Product Safety, the Law on Technical Requirements for Products and Conformity Assessment and the Law on Consumer Protection.

### **36. b) further evolution**

Transposition of Directive – 69/493/EEC on crystal glass products is planned for the fourth quarter of 2012, i.e. the transposition of the relevant European standards in the field of products made of crystal glass, activities shall be undertaken for the improvement of the infrastructure for compliance assessment, i.e. surveillance over the implementation of the new framework for marketing these products.

## **Textiles**

### **35 a) present status**

This field is currently regulated through the following regulations:

- Law on Technical Requirements for Products and Conformity Assessment,
- Decree on Textile Products with Mandatory Quality Certificates for Market Placement (Official Gazette of FRY No. 14/92),
- Rulebook on Technical and Other Requirements for Textile Products Labelling, Marking and Packaging (Official Gazette of RS No. 56/09),
- Decree on the Mandatory Certification of Cotton (Official Gazette of SFRY Nos 65/84, 44/88),
- Decree on the Mandatory Certification of Wool (Official Gazette of SFRY No. 65/84),
- Rulebook on the Mandatory Certification of Jute and Conditions for Cooperative Organizations Authorized to Certify Jute Products (Official Gazette of SFRY No. 8/91).

The Regulation on Textile Products with Mandatory Quality Certificates for Market Placement prescribes the issuing of quality certificates for textile products determining whether textile products meet the marketing requirements as determined by relevant Serbian standards or the contracted product properties where no Serbian standards have been adopted.

The testing of textile products with the purpose of issuing Quality Certificates is performed in accordance with unified quality testing and sampling methods, as determined by the relevant Serbian standards the specific decree relates to, i.e. methods determined by stakeholders if there are no applicable Serbian standards for the products.

### **35 b) forecast**

This rulebook shall transpose the following directives relating to textiles into Serbian legislation:

- Directive 2008/121/EC on textile names, revoking Directive 96/74/EC and its successive amendments: 97/37/EC, 2004/34/EC, 2006/3/EC, 2006/96/EC, 2007/37/EC,
- Directive 2006/2/EC amending, for the purposes of its adaptation to technical progress Annex II to Directive 96/73/EC ,
- Directive 2007/4/EC amending, for the purposes of its adaptation to technical progress Annex II to Directive 96/73/EC ,
- Directive 96/73/EC on certain methods for the quantitative analysis of binary textile fibre mixtures and
- Directive 73/44/EEC on the approximation of the laws of the Member States relating to the quantitative analysis of ternary fibre mixtures.

### **36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The Regulation on Textile Products with Mandatory Quality Certificates for Market Placement prescribes the issuing of quality certificates for textile products by local manufacturers in case of textile products manufactured locally, and importers or representatives of foreign companies in case of imported products. Quality certificates are used to determine whether textile products meet marketing requirements prescribed by relevant Serbian standards, or the contracted properties for products where no Serbian standards have been adopted. The testing of textile products with the purpose of issuing Quality Certificates is performed in accordance with unified quality testing and sampling methods, as determined by the relevant Serbian standards the specific decree relates to, i.e. methods determined by stakeholders if there are no applicable Serbian standards for the products. Local textile product manufacturers and/or companies importing textile products issue a Quality Certificate with data obtained through testing in their own laboratories and through technical preparation or data obtained from suppliers, companies or other legal persons registered in Serbia for testing the quality of textile products.

There are three regulations among positive regulations in the field of textiles envisaging mandatory testing of the following textile products: cotton, jute and wool. Tests must verify specific properties of the textile products (as defined in the regulations) in order to pass mandatory certification, whose values are determined by the relevant Serbian standards. Samples for testing the prescribed quality properties of these textile products are obtained using methods prescribed by Serbian standards, those being: wool - standard SRPS ISO 105-A02:2001 (identical to ISO 105-A02:1993 + Cor. 1:1997), cotton - standard SRPS ISO 1130:2003 (identical to ISO 1130:1975) and jute - standard SRPS F.S2.501. The competent certification authority issues the certificate, with the attached testing report, for textile products verified to meet the prescribed requirements through the testing procedure. The manufacturer or importer labels the certified textile products with the compliance label.

The latest in the line of regulations adopted in this field is the rulebook prescribing technical and other requirements for labelling, marking and packaging textile products, as determined by the Serbian standard SRPS F.A0.011 Textile – Textile Products Labelling Marking and Packaging.

The number of organizations accredited in the Republic of Serbia for the following activities, according to standard SRPS ISO/IEC 17021:2007 is:

- Quality certification of management systems in line with the SRPS ISO 9001 standard (textiles and textile products manufacture) - six,
- Certification of management systems in environment protection in line with the SRPS ISO 14001 standard (textiles and textile products manufacture) - two,
- Certification of occupational health and safety management systems in line with the SRPS OHSAS 18001 standard - one.

Furthermore, there are ten laboratories in Serbia for testing textiles as accredited by the SRPS ISO/IEC 17025:2006 standard.

There are four control organizations accredited in line with the SRPS ISO/IEC 17020:2002, type A standard (control of textile products), while there is one accredited in line with the SRPS ISO/IEC 17020:2002, type C (sampling and quality control of chemical fibres).

There are currently no certification bodies for the certification of textile products in the Republic of Serbia.

The Ministry of Trade and Services – Department for Market Inspection is undertaking market surveillance in line with the provisions of the Law on Technical Requirements for Products and Conformity Assessment, the Decree on Textile Products with Mandatory Quality Certificates for Market Placement, the Rulebook on Technical and Other Requirements for Labelling, Marking and Packaging of Textile Products, the Decree on the Mandatory Certification of Cotton, the Decree on the Mandatory Certification of Wool, the Rulebook on the Mandatory Certification of Jute and the requirements to be met by cooperative organizations authorized to certify said products and the Law on Consumer Protection.

### **36. b) further evolution**

There are currently 1541 companies engaged in the manufacture of textiles and textile products in the Republic of Serbia (2009 data). This branch of the industry recorded exports totalling 340,708,398 USD in 2009 and imports totalling 386,405,695 USD. There is interest for Serbian economy to invest in this branch of the industry.

Following the harmonization of national legislation with directives in the field of textiles, planned for the fourth quarter of 2012, and the adoption of the relevant European standards, activities shall be undertaken to improve the infrastructure to assess compliance and conduct surveillance over the implementation of the new framework for placing textile products in the market of the Republic of Serbia.

## **Footwear**

### **35. a) present status**

This area is regulated by:

- Law on Technical Requirements for Products and Conformity Assessment,
- Rulebook on Technical and Other Requirements for Labelling, Declaration and Packaging of Leather and Fur, Natural and Artificial Leather Products (Official Gazette of RS No. 56/09).

In line with the abovementioned rulebook, products under the jurisdiction of the rulebook must meet the requirements as established by Serbian standard SRPS G.B1.035 – Leather, Fur, Natural and Artificial Leather Products - Labelling, Declaration and Packaging, in addition to the requirements prescribed by specific technical regulations, during market placement or use.

### **35. b) forecast**

Rulebook on Technical and Other Requirements for Footwear shall be adopted in 2012. The legal basis for the adoption of the Rulebook is contained in Article 6, paragraph 1 of the Law on Technical Requirements for Products and Conformity Assessment, prescribing that technical regulations are prepared and adopted by the competent ministry.

This Rulebook shall transpose Directive 94/11/EC relating to labelling the materials used for the main components of footwear intended for sale to the consumer.

**36. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The regulation prescribing technical and other requirements for labelling, declaration and packaging of leather and fur, natural and artificial leather products, which also applies to footwear, envisages that products, during market placement or use, shall meet the requirements set out by the Serbian standard SRPS G.B1.035.

There is one organization accredited in line with the standard SRPS ISO/IEC 17021:2007 for issuing certificates – quality management systems in line with the SRPS ISO 9001:2001 standard, certification of environment protection management in line with the SRPS ISO 14001:2005 standard and occupational health and safety management systems in line with the SRPS OHSAS 18001:2008 standard.

There are four laboratories in the Republic of Serbia for performing chemical and physical testing of footwear accredited in line with the SRPS ISO/IEC 17025:2006 standard.

There are three control organizations accredited in line with the SRPS ISO/IEC 17020:2002, type A standard (sampling, control of sizes, labelling, marking and packaging), and one accredited in line with the SRPS ISO/IEC 17020:2002, type C standard (quality control and control of packaging, labelling and declaration of leather, fur and fur products, as well as the quality control of rubber and plastic materials for footwear and rubber footwear).

There are currently no certification bodies for the certification of this type of products and processes in the Republic of Serbia.

The Ministry of Trade and Services – Department for Market Inspection undertakes market surveillance in line with the provisions of the Law on Technical Requirements for Products and Conformity Assessment and the Rulebook on Technical and Other Requirements for Labelling, Declaration and Packaging of Leather and Fur, Products made of Natural and Artificial Leather, whereas market surveillance is undertaken in line with the provisions of the Law on General Product Safety regarding the placement of safe products on the market.

**36. b) further evolution**

Following the transposition of Directive 94/11/EC into the national legislation, planned for the fourth quarter of 2012, i.e. the adoption of relevant European standards, activities shall be undertaken to improve the infrastructure for conformity assessment and surveillance over the implementation of the new framework for marketing the products.

***LEGISLATION OF THE NEW AND GLOBAL APPROACH AS APPLIED TO PRODUCTS***

**Please provide the following data for every sector and subsector listed in the following text:**

***A. Harmonization of laws, including mechanical regulations***

**37. Please provide the following data:**

- a) present status, including a description of the present type of approval system for each of the subsectors listed below**
- b) forecast (date of adoption and implementation of the EU directives).**

***B. Calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance***

**38. Please provide data on the relevant modes for the products:**

- a) short description and**
- b) further evolution.**

**The answers to the above two questions should encompass the following sectors and subsectors:**

**Legal metrology: non-automatic weighing instruments, measuring instruments**

**37. a) present status**

The field of legal metrology is defined by the Law on Metrology and the Rulebook on the Measuring Instruments Subject to Mandatory Verification and Time Intervals of Periodic Re-verification.

The new approach directives relating to non-automatic weighing instruments (Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments) and measuring instruments (Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments) have not been transposed.

The Rulebook on Metrological Requirements for Instruments Measuring Mass – Non-automatic Weighing Instruments, is harmonized with international recommendation OIML P76. Thus only the metrological requirements set out in Directive 90/384/EEC (NAWI) are prescribed and adopted. Requirements concerning the values of the force of gravity are not in force.

The measuring instruments covered by these directives are subject to measuring instrument type approval and/or to initial verification of measuring instruments.

**37. b) forecast**

The directive relating to non-automatic weighing instruments, Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments will be transposed into the new rulebook on the metrological requirements for mass measuring instruments – non-automatic weighing instruments by the end of 2011. The implementation of the directive shall begin immediately upon its transposition into the rulebook. Non-automatic weighing instruments represent a type of measuring instruments that are subject to type approval,

wherefore the Directorate for Measures and Precious Metals performs measuring instruments type testing and issues of measuring instrument type approval.

The Measuring Instruments Directive - MID Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments will be transposed into the new rulebook on metrological requirements for measuring instruments by the end of 2011. The implementation of the directive shall begin upon its transposition into the rulebook. Мерила обухваћена овом директивом се сада налазе у Правилнику о врстама мерила за која је обавезно оверавање и временским интервалима њиховог периодичног оверавања (Сл. Гласник РС, 49/10), па ће се, у току 2011. и 2012., и за ове појединачне всте мерила донети нови прописи усклађени са међународним и европским захтевима.

The full implementation of these directives is expected after 2012.

**38. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

See the answer under question No. 36 - Legal Metrology, Pre-packaged Products and Measuring Units (Old Approach Directives), under a).

Non-automatic weighing instruments represent a type of measuring instruments requiring, in addition to type certification, mandatory verification and periodic re-certification. The Directorate for Measures and Precious Metals approves the type of non-automatic weighing instruments.

The measuring instruments encompassed by the Measuring Instruments Directive – MID are found in the Rulebook on the Measuring Instruments Subject to Mandatory Verification and Time Intervals of Periodic Re-verification, wherefore these types of measuring instruments are subject to mandatory initial verification and periodic re-verification. The Directorate for Measures and Precious Metals approves the type of these measuring instruments.

**38. b) further evolution**

Conformity assessment with the prescribed requirements relating to measuring instruments encompassed by these directives shall be performed following the transposition of the relevant directives (MID and NAWI). The conformity assessment procedure shall be harmonized with the possibility that the manufacturer of the measuring instrument may choose, in line with the modules likewise prescribed by these directives, one of the listed module combinations: B + F, B + D or H1. More precisely, in addition to the combination of modules B and F (type testing and initial certification of the measuring instrument), conformity assessment shall be conducted through module H1 (full quality control and prototype testing) and the combination of modules B + D (type testing and quality control of the measuring instrument production process).

Conformity assessment, under the Law on Metrology, shall be conducted by the nominated bodies and the Directorate. To this end, the Directorate is planning capacity building and advancement of its resources (staff training and development of conformity assessment processes and procedures).

## **Low Voltage Equipment (LVD)**

### **37. a) present status**

Rulebook on Electrical Equipment Designed for Use within Certain Voltage Limits (Official Gazette of RS No. 13/10) (Annex 1.15) is harmonized with all the principles and relevant requirements of Directive 2006/95/EC. In addition to the EU Directive, provisions from reference EU regulations in the field of technical legislation were also considered in the course of development of the Rulebook, in particular those from Decision No. 768/2008/EC of the European Parliament and Council of 9 July 2008 on a common framework for the marketing of products. Since a number of local electrical equipment manufacturers will not be able to apply this Rulebook or the Serbian standards the Rulebook refers to (these being, primarily, manufacturers that have not exported electrical equipment to the European Union markets and have not harmonized their equipment with the relevant EU Directive), this Rulebook envisages a transitional period lasting until 1 January 2012. Manufacturers, representatives and importers can market and put into use electrical equipment whose compliance has been assessed in line with the requirements of regulations which ceased to be in effect during this period of so-called double implementation, primarily aiming to enable the manufacturers to conduct internal production control.

The following regulations were repealed with the day this Rulebook came into force:

- 1) Rulebook on Technical and Other Requirements for Electric Accumulation Water Heaters (Official Gazette of FRY No. 5/99);
- 2) Rulebook on Technical and Other Requirements for Electric Light Sources (Official Gazette of SCG No. 44/05);
- 3) Decree on Mandatory Certification of Electric Appliances for Households and Similar Uses (Official Gazette of SFRY No. 8/87);
- 4) Decree on Mandatory Certification of Screw Base Light Bulb Sockets (Official Gazette of SFRY No. 43/88);
- 5) Decree on Mandatory Certification of Electric Household Appliances (Official Gazette of SFRY No. 43/88);
- 6) Decree on Mandatory Certification of Isolation Transformers and Safety Isolation Transformers (Official Gazette of SFRY No. 43/88);
- 7) Decree on Mandatory Certification of Isolated Electrical Energy Conductors and Cables (Official Gazette of SFRY No. 43/88);
- 8) Decree on Mandatory Certification of Device Assemblies (Official Gazette of SFRY No. 43/88).

Therefore, even though the rulebooks and orders were repealed, the provisions of these regulations relating to technical and other requirements for electrical equipment, assessment of their conformity with the prescribed requirements and the type of certificates on conformity issued for the equipment may be applied until 1 January 2012.

This Rulebook is accompanied with a list of Serbian standards in the field of electrical equipment designed for use within certain voltage limits (adopting the European harmonized standards) published on 21 April 2010 in the Official Gazette of RS No. 25/10.

The application of these standards ensures harmonization with relevant requirements set forth in this Rulebook.

### **37. b) forecast**

The rulebook regulating this field is harmonized with all the principles and relevant requirements set forth in Directive 2006/95/EC, as well as Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (*Decision No 768/2008 of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC*).

The activities of the Commission for nominating the bodies authorized to assess compliance for products this Rulebook applies to are under way.

The development of the Guide on the Application of the Rulebook is planned for 2011, modelled after the Guide on the Application of Directive 2006/95/EC, aimed to facilitate its application for manufacturers, importers, conformity assessment bodies and consumers.

### **38. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Rulebook on Electrical Equipment Designed for Use within Certain Voltage Limits is harmonized with all principles and relevant requirements from Directive 2006/95/EC (LVD). In line with the Directive and the Law on Technical Requirements for Products and Conformity Assessment, this Rulebook prescribes significantly novel solutions in the field of electrical equipment, new provisions regarding the types of entities implementing or partaking in assessing conformity and the types of conformity certificates, including the voluntary application of Serbian standards adopting the harmonized European standards in the field.

A significant novelty of this Rulebook implies that the electrical equipment the Rulebook applies to is no longer subject to mandatory certification by the bodies nominated to perform conformity assessment.

This Rulebook, in line with the transposed Directive, prescribes only relevant requirements for the safety of electrical equipment before its placing on the market and/or for use. Manufacturers hold exclusive and full responsibility for ensuring that the electrical equipment marketed in the Republic of Serbia meets relevant safety requirements from this Rulebook, which is achieved by conformity assessment undertaken by manufacturers during the internal production control process. Manufacturers or their representatives must compose and issue an Electrical Equipment Conformity Declaration for confirming that the equipment meets the relevant safety requirements set forth in the Rulebook. However, the Electrical Equipment Conformity Declaration is not sufficient for marketing the equipment in the Republic of Serbia. Namely, before placing the electrical equipment in the Republic of Serbia, the manufacturer or their representative or importer in case the manufacturer is not registered on the territory of the Republic of Serbia, is obliged to submit a copy of the Conformity Declaration or a certified copy with the relevant testing report to the Nominated Body in order to confirm the conformity of the equipment with the requirements set forth in the Rulebook. Based on the submitted documents and if they verify the conformity of the electrical equipment (based on the documents submitted), the Nominated Body issues a Certificate of Conformity of the equipment with the relevant requirements set forth in the Rulebook. The Nominated Body keeps a record of the conformity certificates issued and

publishes the record on its official Internet website and issues an extract from the record on demand of the manufacturer, their representative or importer in case of a new delivery of the electrical equipment from the same manufacturer and the same type of equipment that a certificate has already been issued for. The manufacturer, their representative or importer place the Serbian Mark of Conformity on the electrical equipment based on the Conformity Certificate or the extract from the record issued by the Nominated Body. The acquisition of the certificate of conformity does not apply to manufacturers of electrical equipment manufactured in the Republic of Serbia and for which the conformity assessment was undertaken by the Nominated Body. This solution, introducing the Certificate of Conformity as a type of conformity document is of transitional nature and will be valid until the ratified international agreement on assessing conformity and acceptance of industrial products with the European Union for electrical equipment this Rulebook applies to come into force, not later than the EU accession of the Republic of Serbia.

This Rulebook envisages the possibility that manufacturers, their representatives or importers may place and/or put into use electrical equipment manufactured and assessed for conformity in line with the requirements set forth in regulations envisaging mandatory product certification in the course of the transitional period, i.e. until 1 January 2012, whereas certificates of conformity issued based on those regulations shall be valid until 1 January 2012. The product certification process is conducted in the same way for local and imported products and includes product types certification (a product by a manufacturer of the same technical-construction properties and intended for the same use). All product properties established in relevant Serbian standards that the regulations refer to are subject to product testing during the certification procedure. The certification organization issues certificates for products meeting the prescribed requirements as determined through testing, with an attached testing report. The certified product is labelled by the manufacturer or importer using the mark of conformity.

The Rulebook on Electrical Equipment Designed for Use within Certain Voltage Limits is accompanied with a list of Serbian standards in the field of electrical equipment accepting the harmonized (European) standards in the field of electrical equipment, whose application ensures harmonization with relevant requirements set forth in this Rulebook, published on 21 April 2010 in the Official Gazette of RS No. 25/10. The list contains 367 standards and 188 amendments (114 of those adopted as individual documents, 74 as consolidated editions). The list is harmonized with the list of LVD harmonized standards from the Official Journal of the European Union as of 5 June 2009. In line with the list, of the total number of documents on the LVD list – 1085 (the total number of standards is 603, while the total number of amendments is 482), the Standardization Institute envisaged a plan of acceptance or adoption of 530 standards (the total of 73 previous standard editions that will not be adopted), and 401 amendments (the total of 81 amendments to the previous editions of standards), while 367 standards and 188 amendments had been adopted by the time the list of Serbian standards was published. Since a new list of standards was published in the Official Journal of the European Union in March 2010, the adoption of all harmonized standards on this list is envisaged by the end of 2010 according to the ISS plan and thus a new list of Serbian standards will be revised and published.

Monitoring the application of regulations in the field of low-voltage electrical equipment is conducted by the Ministry of Trade and Services through the Department for Market Inspection.

### **38. b) further evolution.**

Further evolution in this field will be directed towards establishing continuous cooperation between the competent ministry adopting regulations, the ministry implementing the regulations, ISS, ABS, the conformity assessment body and the companies and consumers the regulations apply to, aiming to conduct activities for improving the conformity assessment infrastructure and/or monitoring the implementation of the new framework for placing these products.

Furthermore, national legislation will be further monitored and harmonized with the EU legislation in the field of electrical equipment designed for use within certain voltage limits.

Furthermore, the full implementation of the Rulebook necessitates the adoption of all harmonized standards and training.

## **Electromagnetic Compatibility (EMC)**

### **37. a) present status**

Rulebook on Electromagnetic Compatibility (Official Gazette of RS No. 13/10) (Annex 1.16) is harmonized with all the principles and relevant requirements of Directive 2004/108/EC. In addition to the EU Directive, provisions from reference EU regulations in the field of technical legislation were also considered in the course of development of the Rulebook, in particular those from Decision No. 768/2008/EC of the European Parliament and Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC.

Since a number of local device manufacturers will not be able to apply this Rulebook or the Serbian standards the Rulebook refers to, this Rulebook envisages a transitional period lasting until 1 January 2012. Manufacturers, representatives and importers can market and put into use electrical equipment whose compliance has been assessed in line with the requirements of regulations which ceased to be in effect during this period of so-called double implementation, primarily aiming to enable the manufacturers to conduct internal production control.

The following regulations ceased to be in effect on the date of this Rulebook coming into effect:

1) Rulebook on the Mandatory Certification of the Cable Distribution and Common Antenna System (Official Gazette of SFRY No. 37/87) and

2) Rulebook on the Mandatory Certification of Products Causing Radio-Frequency Interference and the Conditions to be fulfilled by Companies and Other Legal Persons Authorized for Certification of These Products (Official Gazette of SFRY No. 30/91).

Therefore, even though the rulebooks and orders were repealed, the provisions of these regulations relating to technical and other requirements for electrical equipment, assessment of their conformity with the prescribed requirements and the type of certificates on compliance issued for the equipment may be applied until 1 January 2012.

This Rulebook is accompanied with a list of Serbian standards in the field of electromagnetic compatibility (adopting the European harmonized standards) published on 21 April 2010 in the Official Gazette of RS No. 25/10.

The application of these standards ensures harmonization with relevant requirements set forth in this Rulebook.

### **37. b) forecast**

The Rulebook regulating this field is harmonized with all principles and relevant requirements from Directive 2004/108/EC and Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

The activities of the Commission for nominating the bodies authorized to assess compliance for products this Rulebook applies to are under way.

The development of the Guide on the Application of the Rulebook is planned for 2011, modelled after the Guide for the EMC Directive 2004/108/EC aimed to facilitate its application for manufacturers, importers, conformity assessment bodies and consumers.

### **38. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Rulebook on Electromagnetic Compatibility is harmonized with all principles and relevant requirements from Directive 2004/108/EC (EMC). In line with the Directive and the Law on Technical Requirements for Products and Conformity Assessment, this Rulebook prescribes significantly novel solutions in the field of electromagnetic compatibility of equipment that could cause electromagnetic interference and/or equipment that could be affected negatively by interference regarding its operating properties, new solutions regarding the types of entities implementing or partaking in assessing conformity and the types of conformity certificates, including the voluntary application of Serbian standards adopting the harmonized European standards in the field. A significant novelty of this Rulebook implies that the equipment-devices the Rulebook applies to are no longer subject to mandatory certification by the bodies nominated to perform conformity assessment. This Rulebook, in line with the transposed Directive, prescribes only relevant requirements for the safety of the equipment before its placing on the market and/or for use. Manufacturers hold exclusive and full responsibility for ensuring that the equipment-devices marketed in the Republic of Serbia meets relevant safety requirements from this Rulebook, which is achieved by conformity assessment undertaken by manufacturers during the internal production control process. Manufacturers or their representatives must fill in and issue a Device Conformity Declaration confirming that the device meets the relevant safety requirements relating to electromagnetic compatibility set forth in the Rulebook. However, the Device Conformity Declaration is not sufficient for marketing the equipment in the Republic of Serbia. Namely, before marketing the device in the Republic of Serbia, the manufacturer or their representative or importer in case the manufacturer is not registered on the territory of the Republic of Serbia, is obliged to submit a copy of the Conformity Declaration or a certified copy with the relevant testing report to the Nominated Body in order to confirm the conformity of the device with the requirements set forth in the Rulebook. Based on the submitted documents and if they verify the conformity of the device (based on the documents submitted), the Nominated Body issues a Certificate of Conformity of the device with the relevant requirements set forth in the Rulebook. The Nominated Body keeps a record of the conformity certificates issued and publishes the record on its official Internet website and issues an extract from the record on demand of the manufacturer, their representative or importer in case of a new delivery of the device from the same manufacturer and the same type of device that a certificate has already been issued for. The manufacturer, their representative or importer place the Serbian Mark of Conformity on the device based on the Conformity Certificate or the extract from the record issued by the Nominated Body. The acquisition of the certificate of conformity does not apply to

manufacturers of devices manufactured in the Republic of Serbia and for which the conformity assessment was undertaken by the Nominated Body. This solution, introducing the Certificate of Conformity as a type of conformity document is of transitional nature and will be valid until the ratified international agreement on assessing conformity and acceptance of industrial products with the European Union for electrical equipment this Rulebook applies to comes into force, not later than the EU accession of the Republic of Serbia.

This Rulebook envisages the possibility that manufacturers, their representatives or importers may place and/or put into use devices manufactured and assessed for conformity in line with the requirements set forth in regulations envisaging mandatory product certification in the course of the transitional period, i.e. until 1 January 2012, whereas certificates of conformity issued based on those regulations shall be valid until 1 January 2012. Mandatory certification of products is undertaken for all types of products causing radio-frequency interference in their operation, with maximum values determined by Serbian standards in the field of radio-communication. The certification organization issues certificates for products meeting the prescribed requirements as determined through testing, with an attached testing report. The certified product is labelled by the manufacturer or importer using the mark of conformity. There are four laboratories for testing RFS interference in the Republic of Serbia accredited in line with the SRPS ISO/IEC 17025:2006 standard, three certification bodies for the certification of products and processes accredited in line with the SRPS EN 45011:2004 standard for certification of products causing radio-frequency interference and one control organization accredited in line with the SRPS ISO/IEC 17020:2002, type A standard for control of radio-frequency interference of products causing radio-frequency interference through their operation.

The Rulebook on Electromagnetic Compatibility is accompanied with a list of Serbian standards in the field of electromagnetic compatibility accepting the harmonized (European) standards in the field of EMC, whose application ensures harmonization with relevant requirements set forth in this Rulebook, published on 21 April 2010 in the Official Gazette of RS No. 25/10. The list contains 107 standards and 32 amendments (5 of those adopted as individual documents, 27 as consolidated editions). This list is harmonized with the list of harmonized standards for EMC taken from the Official Journal of the European Union as of 5 June 2009. In line with the list, of the total number of documents on the list for EMC – 213 (the total number of standards is 144, while the total number of amendments 69), the Standardization Institute envisaged the acceptance or adoption of 122 standards according to their plan (the total of 22 previous standard editions that will not be adopted), and 41 amendments (the total of 28 amendments to the previous editions of the standard), while 107 standards and 32 amendments had been adopted by the time the list of Serbian standards was published. Since a new list of standards was published in the Official Journal of the European Union in April 2010, the adoption of all harmonized standards on this list is envisaged by the end of 2010 according to the ISS plan and thus a new list of Serbian standards will be revised and published.

Monitoring the application of regulations in the field of electromagnetic compatibility is conducted by the Ministry of Trade and Services through the Department for Market Inspection.

### **38. b) further evolution**

Further evolution in this field will be directed towards establishing continuous cooperation between the competent ministry adopting regulations, the ministry implementing the regulations, ISS, ABS, the conformity assessment body and the companies and consumers the regulations

apply to, aiming to conduct activities for improving the conformity assessment infrastructure and/or monitoring the implementation of the new framework for placing these products. Furthermore, national legislation will be further monitored and harmonized with the EU legislation in the field of electromagnetic compatibility. Furthermore, the full implementation of the Rulebook necessitates the adoption of all harmonized standards and training.

## **Toys**

### **37. a) present status**

This field is regulated by the Law on Health Safety of Foodstuffs and General Consumer Products (Official Gazette of SFRY No. 53/91, Official Gazette of FRY Nos 24/94, 28/96, 37/2002, Official Gazette of RS Nos 79/2005, 101/2005) – note – the Law on Food Safety was published in the Official Gazette of RS No. 41/2009 as of 2 June 2009, prescribing in Article 89 that the Health Safety of Foodstuffs and General Consumer Products shall expire in the section relating to foodstuffs on the day of the Law coming into force (on the eighth day from the date of publication thereof).

- Rulebook on Health Safety Requirements for General Consumer Products That May Be Marketed (Official Gazette of FRY Nos 26/83, 61/84, 56/86, 50/89, 18/91)

Under the provisions of the Rulebook, Children's Toys shall meet general and special conditions in order to be marketable.

### **1. General Market Conditions**

#### **Article 84**

Children's toys may only be made of materials meeting the following requirements:

- 1) Not to contain ingredients harmful for health;
- 2) To be completely clean – without mechanical pollutants;
- 3) To be hygienically maintainable (washable).

The manufacture of children's toys from used materials is prohibited.

Hairs from children's toys and hair on dolls may not fall out if shaken, combed, pulled or in any other procedure.

#### **Article 85**

Toys for infants may only be manufactured from materials that may be disinfected, i.e. boiled, without loss of toy quality. The toys shall be designed so that children may not swallow them or place them in their nose or ears.

Toys for infants shall be no shorter than 7 cm. If toys for infants are comprised of multiple parts that may be disassembled easily, their smallest component shall be no shorter than 7 cm.

#### **Article 86**

Regarding construction, children's toys shall meet the following requirements:

- 1) Not to be pointy, or have sharp or jagged edges that could harm infants or small children;
- 2) To be well polished or covered in lacquer or varnish colours (wooden toys or wooden parts of toys);
- 3) That the electrical voltage in toys using electrical power does not exceed 24 V.

#### **Article 87**

Colours used for painting toys shall not transfer from toys to saliva or acetic acid, 3% (v/v) at a temperature of  $20\pm 2^{\circ}\text{C}$  for the duration of 24 hours, and regarding cleanliness shall adhere to the provisions of Article 7 of this Rulebook.

Children's toys shall not be painted using pigments based on cadmium, mercury, selenium, lead, arsenic and chromates or 4-dimethylaminoazobenzene.

Article 88

Colours used for painting children's toys shall firmly adhere to the surface of the toys, have no odour and not be removable due to sweat and saliva, rubbing with dry cotton-balls or cotton-balls moisturized using soap solutions, during play or washed in water using soap solutions or through disinfection.

## **2. Special Market Conditions**

Article 89

Lead, zinc, or any alloy containing more than 1% lead cannot be used for manufacturing children's toys made of metal.

The provision from paragraph 1 of the Article hereof regarding zinc does not apply to model cars – children's toys.

No tin alloys shall be used for soldering children's toys made of metal if it contains more than 10% lead.

Article 90

Children's toys made of artificial substances shall only be manufactured using polymers adhering to the provisions of Articles 25 – 36 of this Rulebook.

Article 91

Only celluloid that is not readily flammable may be used for manufacturing children's toys made of celluloid.

Article 92

Children's toys made of rubber shall, in addition to the general provisions prescribed for the manufacture and marketing, also fulfil the provisions of Articles 25 – 36 of this Rulebook, excluding the tires on cars – children's toys.

Article 93

No textiles processed using compounds containing arsenic may be used for making children's toys made of textiles.

The manufacture of children's toys is prohibited if they are made of:

- 1) Textiles containing more than 0.01 g of antimony, calculated at a surface area of  $100\text{ cm}^2$ ;
- 2) Cloth, threads or knitwear processed using lead or mercury salts;
- 3) Cloth filled with sawdust or wool.

The provisions of the Article hereof also apply to the manufacture of children's toys made of paper, feathers or similar materials.

Article 94

Only leather or fur previously subjected to dry sterilisation at a temperature of  $140^{\circ}\text{C}$  for a duration of three hours or a temperature of  $180^{\circ}\text{C}$  for one hour may be used for the manufacture of children's toys made of leather or fur.

Article 95

The manufacture of children's toys from glass, porcelain, ceramics or clay is prohibited.

Marbles and decorative items (Christmas tree decorations, various figurines, etc.) are exempt from the provisions of paragraph 1 of the Article hereof, if they are made of solid glass which is difficult to break during play.

Article 96

Children's toys made of wax or similar materials used for modelling may not contain solvents or softeners harmful to health, or components that release colour, i.e. materials listed in Article 87 of this Rulebook.

Article 97

No pyrotechnical materials that could harm children during play may be used for the manufacture of children's toys.

The manufacture of children's toys from mercury rhodanide is prohibited.

Article 98

Air rifles, air guns and starter guns are not considered children's toys within the scope of this Rulebook.

Article 99

Children's toys placed into the mouth during play and toys for infants shall be packaged in special, enclosed packaging.

Article 100

The mechanical quality of children's toys made of rubber or artificial compounds filled with air (footballs, animal figures, floatation belts, etc.) may only be tested during manufacture and sale using pneumatic devices intended for the purpose.

**Procedure:**

**Importers of general consumer products are obliged to:**

Notify directly or through their representative (transporter) notify the sanitary inspector in charge of the border area immediately upon the arrival of the shipment, by submitting a written **request for shipment inspection** for every shipment that has arrived.

**The request shall contain the following data:**

- Name and correct address of the sender, importer and user,
- Contents of the shipment and its weight,
- State and type of packaging and number of packaged units,
- ID of the mode of transport (ship, wagon, car, etc.),
- Declaration and purpose of the shipment,
- Any possible accidents during transport,
- Name and address of the organization paying the costs of analysis,
- Time required to prepare the shipment for inspection and place of inspection,
- Number and date of customs application, (unified customs document or similar document for the identification of the shipment).

The request for shipment inspection shall be taxed in line with the Law on Administrative Taxes.

**The importer is obliged to submit the following documents with the request for inspection:**

- Documents from the competent body of the exporting country indicating the shipment of general consumer products is safe for health;

- Product specification, if the invoice indicates that the shipment contains multiple different products;
- Manufacturer's specification for chemical substances, additives and similar products;
- Translation of the declaration for products in their original packaging and other documents potentially required for the procedure for determining the health safety of the products under control.

Copies of the originals and translation into the Serbian language certified by a sworn court interpreter are submitted for all the documents listed.

The following procedures are undertaken as part of the sanitary - inspection control:

- 1 Examination of the documents;
- 2 Determining the hygienic conditions the shipment arrived in;
- 3 Physical examination of the shipment on the vehicle or place of storage;
- 4 Organoleptic control of the shipment;
- 5 Sampling the shipment in question for laboratory testing.

(The amount of contents from the shipment required for sampling, the number of samples and the methods for sampling are prescribed in the Rulebook on the Methods of Sampling for Performing Analyses and Superanalyses of Foodstuffs and General Consumer Products (Official Gazette of SFRY, No. 60/78)) 60/78))

**Upon the conducted laboratory testing:**

- Should the importer disagree with the results of the analyses, they have the right to submit a request for a superanalysis of samples taken at the same time, in the same way, and tested using the same method, within the period of three day from the date of publishing the analysis results.
- Superanalyses of general consumer products are conducted in one of the laboratories nominated in the Decision on Health and Other Cooperative Organizations Meeting the Requirements for Conducting Superanalyses of Foodstuffs and General Consumer Products. The superanalysis cannot be performed in the laboratory performing the first analysis.
- Samples of perishable foodstuffs can be sent for analysis and superanalysis simultaneously at the request of the importer.

The procedure of the sanitary inspector in charge of the border area upon finishing of sanitary – inspection control (first-degree procedure):

If health inspection shows that the shipment meets all the requirements prescribed by positive regulations on health safety of foodstuffs and general consumer products, the inspector shall approve the import of the shipment by issuing a decision through the first-degree administrative procedure.

If it is established during import that the shipment does not meet all the requirements prescribed by positive regulations on health safety of foodstuffs and general consumer products, the inspector shall, aiming to protect the health of people, apply Article 26, paragraph 1 of the Law on Health Safety of Foodstuffs and General Consumer Products to

- Prohibit the marketing and use of general consumer products unsafe for health (this measure applies to products of local origin, exported and then returned to the Republic of Serbia,

should they be proven to be unsafe. These products are subject to mandatory sanitary inspection upon return to the country);

- Prohibit the import of general consumer products unsafe for health and order their return to the sender;

- Order the destruction of general consumer products unsafe for health if they cannot be returned to the sender.

The inspector is obliged to make a written decision on the prohibition of import.

Complaints may be filed against the decision of the sanitary inspector in charge of the border area.

Complaints against the decision of the sanitary inspector in charge of the border area are submitted to the minister competent for health issues (as a second-degree body) within eight days from the day of issuing the decision.

The complaint is:

- Charged administrative taxes;
- Forwarded through the sanitary inspector in charge of the border area making the decision in the first-degree procedure against which the complaint is lodged;

### **37. b) forecast**

The adoption of the Law on General Consumer Products is envisaged. It will be adopted by the Government by 2011/IV.

### **38. a) short description relating to calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance and b) further evolution**

Sanitary inspectorate shall supervise the manufacture and sale of detergents, cosmetic products and toys based on authority prescribed by law.

Laboratory control of the health safety of these products is conducted by public health institutes and institutions and laboratories outside the healthcare system based on authorization issued by the Ministry of Health of the Republic of Serbia. Accreditation of laboratory methods for testing health safety is performed by the Accreditation Body of Serbia, which is outside the domain of the Ministry of Health.

Substances from the CAS No: 117-81-7, 84-74-2, 85-68-7, 28553-12-0, 26761-40-0, 68515-49-1 and 117-84-0 shall not be used in concentrations higher than 0.1% of mass in toys. The requirements regarding limitations provided in the Rulebook on Limitations and Prohibitions of Production, Marketing and Use of Chemicals Representing Unacceptable Health and Environmental Risk are:

- 1 Their use as substances or in compounds in concentrations higher than 0.1% of mass in plasticized materials in toys and products intended for childcare is prohibited.
- 2 The sale of toys and products intended for childcare containing more than 0.1% of said phthalates in mass – in line with Annex XVII (REACH) is prohibited.

### **38. b) further development**

Within the competence of the Ministry of Health, the Working Sub-group 28 – Consumer Protection and Health Care plans to adopt a new rulebook on health safety requirements for general consumer products that may be marketed by the end of 2010, which will be harmonised with the European law (Directive 88/378/EEC on the safety of toys).

## **Machinery**

### **37. a) present status**

Rulebook on Machinery Safety (Official Gazette of RS No. 13/10) (Annex 1.17) is harmonized with all principles and relevant requirements of the Directive 2006/42/EC on machinery. In the process of preparation of the Rulebook, in addition to the aforementioned EU Directive, other solutions included in relevant EU regulations in the area of technical legislation have been taken into consideration, and in particular those stipulated in the Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

Bearing in mind that a number of national machinery manufacturers shall not be able to, as soon as the Rulebook has entered into force, apply the Rulebook and the Serbian standards in compliance with the Rulebook, the Rulebook lays down a transitional period up to January 1<sup>st</sup> 2012. It is foreseen that in the period of dual application the manufacturers, their representatives and the importers may also place on the market and/or use the machinery designed, manufactured, and the machinery whose compliance has been assessed pursuant to the requirements deriving from the repealed legislation, with the aim to enable the manufacturers to implement the internal control of the production process.

The following legislation has been repealed on the day of the entry into force of the Rulebook:

- 1 The Rulebook on Technical Criteria for Static Electricity Protection (Official Gazette of SFRY No. 62/73)
- 2 The Rulebook on Technical Criteria for Iron Foundry Industry (Official Gazette of SFRY, No. 14/79 and 65/91)
- 3 Rulebook on Technical Criteria for Use of Motor Driven Saws in Forestry (Official Gazette of SFRY No. 34/80)
- 4 The Rulebook on Technical Criteria for Facade Electrically Operated Elevators (Official Gazette of SFRY No. 19/86)
- 5 The Rulebook on Technical Criteria for Electrically Operated Hanging Scaffolds (Official Gazette of SFRY No. 19/86)
- 6 The Rulebook on Technical Criteria for Plastic Workings on Non-ferrous Metals (Official Gazette of SRFY No. 25/86)
- 7 The Rulebook on Technical Criteria for Electrically Operated Elevators for Vertical Transport of Goods with Non-accessible Carriers (Official Gazette of SFRY No. 55/87)
- 8 The Rulebook on Mandatory Issuing Certificate of Attestation for Electrically Operated Elevators for Vertical Transport of Goods with a Non-accessible carrier and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 18/91)
- 9 The Rulebook on Technical Criteria for Cranes (Official Gazette of SFRY No. 65/91)

- 10 The Rulebook on Technical Criteria for Escalators (Official Gazette of SFRY No. 83/94)
- 11 The Rulebook on Technical Criteria for Machinery Used in Agriculture (Official Gazette of SFRY No. 34/95)
- 12 The Rulebook on Technical and Other Criteria for Motor Driven Automotive Ladders (Official Gazette of SFRY No. 56/09)
- 13 Ordinance on Mandatory Attestation of Chains and their Components (Official Gazette of SFRY No. 9/83)
- 14 Ordinance on Mandatory Attestation of Steel Ropes For General Use (Official Gazette of SFRY No. 61/83 and 17/88)
- 15 Ordinance on Mandatory Attestation of Mobile Equipment with Electro Motors (Official Gazette of SFRY No. 43/88)

Therefore, although on the day of entry into force of the Rulebook, the aforementioned Rulebooks and Ordinances have been repealed, the provisions of these regulations pertaining to technical and other requirements for machinery, assessment of their compliance with the provisions of those regulations (mandatory certification, testing, control and other) and also the type of the compliance assessment documents that are issued for such machinery, may still be used till 1 January 2012.

An addendum to the Rulebook is the list of Serbian Standards relevant for machinery (by which European harmonized standards have been adopted), published on April 21<sup>st</sup> 2010. 2010 in the Official Gazette of RS, No. 25/10).

The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through application of the standards.

### **37. b) forecast**

The Rulebook governing this area has been harmonized with all principles and relevant requirements of the Directive 2006/42/EC and of the Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

The activities of the Committees responsible for notifying bodies for conformity assessment of products to which this Rulebook applies, are in progress.

It is foreseen that the Guide to application of the Rulebook, similar to the Guide to application of the Machinery Directive 2006/42/EC shall be prepared in 2011, in order to improve the capacity of the manufacturers, importers, compliance assessment bodies and the consumers to apply the Rulebook.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Pursuant to the Directive 2006/42/EC and the Directive of so called New Approach in the area of technical legislation and the Law laying down the provisions for the technical requirements for the products and their compliance assessment, new and considerably different solutions are foreseen with regard to the machinery and the entities implementing or participating in the compliance assessment and also with regard to the type of documentation confirming compliance and also with regard to voluntary application of Serbian standards by which harmonized

(European) standards relevant for this area have been adopted. A very important novelty achieved by this Rulebook is that the machinery excluding the machinery listed in Annex 4 of the Rulebook, shall no longer be subject to mandatory certification by the bodies notified for compliance assessment. Bearing in mind that the Rulebook also stipulates that the producers, their representatives and importers may place on the market and/or use, in the transitional period up to January 1<sup>st</sup> 2012, machines manufactured and machines whose compliance has been assessed in accordance with the requirements of the repealed regulations (stipulating mandatory certification of the products), the compliance certificates issued on the basis of such regulations shall be valid up to January 1<sup>st</sup> 2012.

The Rulebook, in compliance with the adopted Directive, lays down only relevant requirements for safety of machinery which must be met before placing the machinery on the market of the Republic of Serbia.

It is sole and full responsibility of the manufacturers to assure compliance of the machinery placed on the market of the Republic of Serbia with the relevant safety requirements stipulated in the Rulebook. This shall be achieved through compliance assessment, carried out mostly by the manufacturer, in the process of internal control of production and/or in the process of total quality assurance. The manufacturer or its representative shall prepare and issue a Declaration on compliance of the machinery confirming that the machinery is in compliance with the safety requirements stipulated in the Rulebook.

The producer applying internal production control may engage the Notified Body that shall additionally perform the compliance assessment procedure by checking the type. This refers only to certain machinery and in particular to those listed in the Annex 4 of the Rulebook.

However, the Declaration on Compliance for an apparatus is insufficient to place the apparatus on the market of the Republic of Serbia. Before placing certain machinery on the market of the Republic of Serbia, namely: electrically operated elevators for vertical transport of goods with non-accessible carriers; chains and their components; steel ropes for general use and mobile tools with dual polarity electro motors of voltage up to 250V for use in households and similar use, the manufacturer of such machinery, its representative or the importer, in event that the manufacturer or its representative is not registered in the territory of the Republic of Serbia, shall submit to the Notified Body the Declaration on Compliance or its certified copy including the report on testing, in order to confirm compliance of the machinery with the requirements of the Rulebook. In event that the Notified Body, on the basis of the documentation submitted, confirms the compliance of the respective machinery, it shall issue the Confirmation on Compliance of the machinery with the relevant requirements of the Rulebook. The Notified Body shall keep records of the issued Confirmations on Compliance and it shall be published on its official web site. At the request of the manufacturer, its representative or the importer the Notified Body shall issue a copy from the records, in event of a new delivery of the machinery from the same manufacturer and of the same type, in other words for the type of the machine for which the confirmation on compliance had already been issued. Based upon the Confirmation on Compliance or the copy from the records issued by the Notified Body, the manufacturer, its representative or the importer shall place the Serbian compliance mark on the machine. The manufactures of the machinery produced in the Republic of Serbia, for which the Notified Body carried out compliance assessment, are not obliged obtain the Confirmation on Compliance. This solution, that introduces issuing the Confirmation on Compliance as a type of document on compliance, is a transitional measure that shall be applied to the machinery laid down in this Rulebook only until the ratified international Assessment and Acceptance of Industrial Products Agreement signed with the European Union

enters into force, and not later than the date of the accession of the Republic of Serbia to the European Union.

An addendum to the Rulebook is the List of Serbian Standards relevant for machinery, published in the Official Gazette of RS No. 25/10 on April 21<sup>st</sup> 2010, by which European harmonized standards relevant for this area have been adopted. The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through application of the standards. 2010. The list comprises 442 standards and 62 amendments (of which 16 were enacted as separate documents and 46 as consolidated editions). The List is in compliance with the list of harmonized standards for MD which was adopted from the Official Journal of the European Union of June 5<sup>th</sup> 2009. In compliance with the List, out of the total number of 802 MD documents (of which the total number of standards is 686 and the total number of the amendments is 116), the Standardization Institute planned to adopt and enact all 686 standards and 116 amendments and by the date of publishing the List of Serbian Standards, it enacted 442 standards and 62 amendments. Bearing in mind that in May 2010 a new List of Standards was published in the Official Journal of the European Union, the Standardization Institute plans to adopt all harmonized standards from the List by the end of 2010. The List of Serbian Standards shall be amended and published accordingly.

Supervision of the implementation of the legal provisions in the area of safety of machinery is carried out by the Ministry of Trade and Services through its Trade Inspectorate and by the Ministry of Labour and Social Policy through its Labour Inspectorate.

### **38. b) further evolution**

Further development in this area shall be focused on establishing cooperation between the Ministry responsible for enacting legislation, the ministries applying the legislations, ISS, ATS, compliance assessment bodies, the industry and the consumers to which the legislation applies, with the goal to implement the activities aimed at improving the infrastructure for compliance assessment and the supervision of the application of a new framework for placing the products on the market.

In addition, national legislation shall further be monitored and amended in compliance with the EU legislation pertaining to the safety of machinery. It also is necessary to adopt the all harmonized standards and to organize training for full implementation of the Rulebook.

## **Noise emissions by outdoors equipment (Global Approach directive based on New Approach elements)**

### **37. a) present status**

The Article 16 of the Law on Environmental Noise Protection prescribes that machines, equipment and means of transport manufactured in, or imported to the territory of the Republic of Serbia, must be in compliance with the technical regulations related to the noise emission limit value under certain conditions of use which have to be labelled on the products in compliance with the specific regulations.

### **37. b) forecast**

No date has been specified for adoption and implementation of the Directives 2000/14/EC and 2005/88/ EC.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The Law on Technical Requirements for Products and Conformity Assessment lays down rules for conformity assessment carried out by the manufacturer, body notified for compliance assessment, the purpose of accreditation, duties of the product supplier and the owner.

Environmental Noise Measurements may be carried out by the authorized professional organization that meets the criteria for noise measuring, in compliance with the Law on Noise Protection. Noise monitoring is carried out by systematic measurements, assessment or calculation of noise indicators, in compliance with the Law.

A legal entity or person who is the owner or the user of the source of noise shall ensure noise measurements, in a prescribed way, provide a report on it, and shall bear the costs of measuring noise in the zone of impact, in compliance with the Law.

In the process of supervision, the environmental protection inspector is authorized to ban the use of machinery, equipment and devices which do not have data on sound power level.

### **38. b) further evolution**

No date has been specified for adopting and implementation of the Directives 2000/14/EC and 2005/88/ EC.

## **Lifts**

### **37. a) present status**

This area is currently regulated by the following legislation:

- The Law on Technical Requirements for Products and on Conformity Assessment.
- The Law on Standardization.
- Rulebook on Lift Safety ((Official Gazette of RS, No. 108/10). This Rulebook refers to new lifts that are placed on the Serbian market, as well as on the existing ones, for which the provisions of the Rulebook shall apply from 1. January 2014.

Rulebook on Lift Safety repealed following 7 technical regulations:

a) The Rulebook on Technical Criteria for Electrically Operated Elevators for Vertical Transport of Persons and Goods (Official Gazette of SFRY No. 16/86, 28/89 and 22/92 and Official Gazette of SRY No. 47/95 and 14/96)

b) The Rulebook on Mandatory Issuing Certificate of Attestation for Electrically Operated Elevators for Vertical Transport of Persons and Goods and on the Criteria that Must be Met by

the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 27/90)

c) The Rulebook on Technical Criteria for Electric Elevators for Diagonal Transport of Persons and Goods (Official Gazette of SFRY No. 46/86)

d) The Rulebook on Mandatory Issuing Certificate of Attestation for Driving Shaft Locks and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 18/91) 18/91),

e) The Rulebook on Mandatory Issuing Certificate of Attestation for Lift Suspension Devices and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 18/91) 18/91),

f) The Rulebook on Mandatory Issuing Certificate of Attestation of the Maximum Speed Limits of Elevators and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 18/91) 18/91),

g) The Rulebook on Mandatory Issuing Certificate of Attestation for Buffers Used in Lifts and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products (Official Gazette of SFRY No. 18/91) 18/91).

The above mentioned legislation (a-g) related to lifts that prescribe mandatory attestation of lifts as well as certain devices on lifts and the conditions that must be fulfilled by the organizations authorized to perform attestation, have been repealed, but if the manufacturers still want to apply them, it will be possible only till 1. January 2014. .

### **37. b) forecast**

The Guide to application of the Rulebook, similar to the 'Guide to the application of the Lifts Directive 95/16/EC' shall be prepared during 2011, as means of helping the manufacturers, importers, conformity assessment bodies and the consumers to apply the Rulebook.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The attestation of lifts is conducted by attesting each lift manufactured in or imported to Serbia, followed by ad hoc control of conformity with the attested elevator. The specific qualities of the lifts subject to the testing for mandatory attestation are stipulated in the Serbian standard SRPS M.D1.510 – Lifts. Installation of the lifts type I, II and III. Dimensions, maximum load and speed in the Yugoslav standard SRPS M.D1.511 – Lifts. Installation of lifts type IV. Dimensions maximum load and speed. The authorized organization shall issue a certificate of attestation accompanied with a record on examination carried out and a report on testing if the results of the examination demonstrate that the lifts satisfy the stipulated criteria. The authorized organization shall mark the lift for which a certificate of attestation has been issued with a compliance mark. Compliance of the lift with the attested lift shall be controlled once in a year, based upon which the attest shall be either confirmed or withdrawn. Compliance shall be controlled by organizations authorized to perform mandatory attestation that had issued the certificate of attestation.

Until the designation of conformity assessment bodies in accordance with the Rulebook on Safety of Machinery, the accredited and authorized bodies shall continue to operate in accordance with the old regulations.

There are five bodies in Serbia certified for certification of the products and procedures accredited in compliance with the standards SRPS EN 45011:2004 – certification of products on the basis of type examination of the product. Electrically operated lifts for vertical transport of persons and goods, certification of the lifts in compliance with the technical regulations on mandatory certification.

In addition, there are eight control bodies accredited in compliance with the standard SRPS ISO/IEC 17020:2002, Control of electrically operated elevators – control of elevators after before putting them into service, periodic control of elevators, control of completeness of technical documentation, control of repairs and modifications, periodic control, periodic technical control, technical control before they are put into service, technical control of reconstructed elevators and of the elevators in which the equipment has been replaced.

By the end of 2010, the Standardization Institute of the Republic of Serbia enacted Serbian standards transposing all harmonized European standards pertaining to lifts, in compliance with the list of harmonized standards published in the Official Journal EU C 052 on March 2<sup>nd</sup> 2010.

### **38. b) further evolution**

After adopting the Rulebook on Lift Safety, which implemented provisions of the Directive 95/16/EC, it is necessary to publish the list of harmonized standards and to conduct activities regarding improvement of conformity assessment infrastructure that is surveillance over the implementation of new framework for placing these products on the market.

In addition, the national legislation shall further be monitored and harmonized with the EU legislation in the field of lift safety.

## **Personal protective equipment (PPE)**

### **37. a) present status**

In compliance with the National Programme for Integration of Serbia with the EU, the Ministry of Economy and Regional Development is responsible for enacting technical legislation in the area of personal protective equipment.

This area is presently governed by the following legislation:

- The Law on Technical Requirements for Products and on Compliance Assessment
- The Rulebook on Technical and Other Requirements for Personal Protective Equipment (Official Gazette of RS No. 56/09 56/09),
- Ordinance on Mandatory Attestation of Helmets for Protection in Industry (Official Gazette of SFRY No. 4/82 and 43/82).
- Ordinance on Mandatory Attestation of Helmets For Fireman (Official Gazette of SFRY No. 67/86) 67/86)
- Ordinance on Mandatory Attestation of Respiratory Organs Protection Equipment (Official Gazette of SFRY No. 49/87) 49/87)

- The Rulebook on Mandatory Attestation of Protection Belts and on the Criteria that Must be Met by the Organizations Authorized for Issuing Attestation Certificates for Such Products (Official Gazette of SFRY No. 67/89) 67/89)
- The Rulebook on Mandatory Attestation of Brackets for Climbing Wooden Overhead Power Line Poles and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing the Certificates for Such Products(Official Gazette of SFRY No. 67/89) 67/89)

Legislation in force pertaining to personal protective equipment stipulate mandatory attestation of personal protective equipment, including issuing examination report and a certificate on attestation by the organization authorized for attestation, in event that the examination confirms that products satisfy the requirements of Serbian standards that apply to them.

Examination of personal protective equipment for the purpose of issuing a report on examination and a certificate of attestation shall be performed in compliance with the quality assurance examination and sampling method, in compliance with the relevant Serbian standards stipulated in the aforementioned by-laws.

### **37. b) forecast**

The National Programme for Integration of Serbia with the EU foresees preparation and adopting of the Rulebook on Technical Requirements for Personal Protective Equipment in the fourth quarter of 2011. The Rulebook shall be enacted in compliance with the Article 6, paragraph 1 of the Law on Technical Criteria for Products and on Compliance Assessment, which stipulates that technical regulations shall be prepared and enacted by the Ministry, in compliance with its authorities. The Rulebook shall transpose Directives 89/686/EEC, 93/68/EEC, 93/95 EEC and 96/58 EEC concerning personal protective equipment to Serbian legislation.

An addendum to the Rulebook shall be the list of Serbian Standards relevant for personal protective equipment (by which European harmonized standards shall be adopted). The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through application of the standards.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

Legislation in force pertaining to personal protective equipment stipulates mandatory attestation of personal protective equipment. The following is subject to mandatory attestation: respiratory organs protective equipment, fireman helmets, helmets for protection in industry, protective belts and brackets for climbing wooden overhead power line poles. The attestation shall be performed for the following: for domestic products, the product type shall be attested, followed by the compliance control of a manufactured product with the attested type; for imported products, the product type shall be attested, followed by the compliance control of a product from each delivered lot containing products of the same type and origin with the attested type (type of a product shall be defined in relevant Serbian standards). Certain specific qualities of these products shall be subject to mandatory attestation. The qualities shall be examined using the methods stipulated in relevant Serbian standards. Size of the samples to be taken for examination and the requirements pertaining to sampling are stipulated in relevant Serbian standards. Sampling for attestation shall be performed by the organization authorized for attestation. If the

result of the examination demonstrates that the products satisfy the requirements with regard to quality, the organization authorized for attestation shall issue a certificate of attestation accompanied with an examination report. The manufacturer or the importer shall mark the product for which a certificate of attestation has been issued with a compliance mark.

Two examination laboratories in Serbia have been accredited to perform the following examinations in compliance with the standard SRPS ISO/IEC 17025: high voltage examination of products and personal protective equipment and examination by strike, mechanical, thermo and electric examinations of helmets for protection in industry and the fireman helmets; one Certification body is accredited to perform the certification of the following products and processes in compliance with the standard SRPS EN 45011 to perform the following certification: Certification of products based upon the type examination of a product: helmets for protection in industry, fireman helmets, manual and mobile fire extinguishers and protective belts. One organization responsible for control has been accredited in compliance with the standard SRPS ISO/IEC 17020:2002, type A, to perform control activities concerning quality control of personal protective equipment.

Intensified activities of transposing European harmonized standards in the area of personal protective equipment are in process, in order to provide conditions in 2012 and 2011 to fully apply the Rulebook by which Directives concerning personal protective equipment shall be transposed. The Standardization Institute transposed and adopted 222 out of the total number of 274 harmonized standards concerning personal protective equipment (the list was published in the Official Journal of EU on May 6<sup>th</sup> 2010 No. C118/10). It is foreseen that 24 standards and 4 amendments presented in the list shall be adopted by the end of 2010 while the remaining 38 standards and 5 amendments shall be adopted in 2011.

The Ministry of Labour and Social Policy with its Labour Inspectorate is responsible for supervision of the and implementation of provisions pertaining to personal protective equipment.

### **38. b) further evolution**

After transposing the Directive on personal protective equipment to the national legislation which is planned for the fourth quarter of 2011 and adopting relevant European standards, the activities shall be focused on improvement of infrastructure for compliance assessment including supervision of the implementation of a new framework for placing these products on the market.

## **Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)**

### **37. a) present status**

The following legislation is presently in force:

1. The Law on Mining (Official Gazette of RS No. 44/95, 34/06 and 104/2009)
2. The Law on Standardization (Official Gazette of RS No. 36/2009)
3. The Law on Safety and Health at Work (Official Gazette of RS No. 101/05)
4. The Law on Protection Against Fire (Official Gazette of RS No. 111/09)

5. The Rulebook on Technical Criteria for Electrically Operated Plants and Equipment in Mines for Ground Exploitation of Mineral Resources (Official Gazette of SFRY No. 66/87 and 16/92 and Official Gazette of RS No. 37/2009)
6. The Rulebook on Method of Examining and Testing Work Equipment (Official Gazette of RS No. 94/06),
7. The Rulebook on Technical Criteria for Protection of Facilities from Static Electricity (Official Gazette of SFRY, No. 62/73) 62/73);
8. The Rulebook on Technical Criteria for Protection of Facilities Against Atmospheric Discharge, (Official Gazette SRY, No. 11/96) 11/96);
9. All electrically operated equipment used in explosive atmospheres are subject to attesting in compliance with the Ordinance on Mandatory Attestation of Electrically Operated Equipment in Explosive Atmospheres (Official Gazette of SRY No. 35/95  
The process of mandatory attestation shall be performed in compliance with the standard SPPS A.K2.401- Attestation schedules.  
Electrically operated equipment for explosive atmospheres.
10. Decisions on Adopted and Repealed Serbian Standards and Related Documentation (Official Gazette of RS No. 7/09) and other decisions published in the Standardization Institute.

### **37. b) forecast**

The Law on Explosive Substances (proposal was prepared by the Ministry of Interior – Sector for Emergency Management) shall define in detail the protection of facilities in which explosive substances are used or stored.

,In addition it is necessary to adopt by-laws (rulebooks, decrees, decisions, ordinances and other) to define more precisely those requirements that are broadly stipulated in the Law.

In the process of implementation of the aforementioned laws and by-laws, it is necessary to apply technical legislation, technical recommendations, standards that have to be harmonized with the EU legislation (Directives 93/15/EEC and 2007/23/EEC) and also with the international legislation. To achieve this, cooperation of the Division for Emergency Management and the institutions responsible for such activities (the Standardization Institute, the Accreditation Body - ATS, ministries and other) and other organizations operating in the areas to which the aforementioned legislation applies.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The following legislation is presently in force:

1. The Law on Mining (Official Gazette of RS No. 44/95, 34/06 and 104/2009)
2. The Law on Technical Criteria for Products and on Compliance Assessment (Official Gazette of RS No. 36/09)
3. The Law on Standardization (Official Gazette of RS No. 36/2009)
- The Law on Safety and Health at Work (Official Gazette of RS No. 101/05)
5. The Law on Protection Against Fire (Official Gazette of RS No. 111/09)

6. The Rulebook on Technical Criteria for Electrically Operated Facilities and Equipment in Mines for Ground Exploitation of Mineral Resources (Official Gazette of SFRY No. 66/87 and 16/92 and Official Gazette of RS No. 37/2009);
7. Rulebook on Method of Examining and Testing Work Equipment (Official Gazette of RS No. 94/06),
8. The Rulebook on Technical Criteria for Protection of Facilities Against Static Electricity (Official Gazette of SFRY, No. 62/73) 62/73);
9. The Rulebook on Technical Criteria for Protection of Facilities Against Atmospheric Discharge (Official Gazette of SRY, No. 11/96) 11/96);
10. Ordinance on Mandatory Attesting of Electrically Operated Equipment in Explosive Atmospheres (Official Gazette of SRY No. 35/95)  
The process of mandatory attestation shall be performed in compliance with the standard SPPS A.K2.401- Attestation schedules. Electrically operated equipment for explosive atmospheres
11. Decisions on Adopted and Repealed Serbian Standards and Related Documentation (Official Gazette of RS No. 7/09) and decisions published in the Standardization Institute
12. The Rulebook on Technical Criteria for Underground Exploitation of Coal (Official Gazette of SFRY, No. 4/89, 45/89, 3/90 and 54/90)
13. The Rulebook on Technical Criteria for Electrically Operated Plants, Equipment and Installations in Mines for Underground Exploitation (Official Gazette of RS No. 21/88 and 90/91).

#### STANDARDS IN FORCE:

- Equipment and components for use in underground mines in potentially explosive atmospheres - SRPS EN 1710 (en)
- Protection against detonation and protection in underground mines. Protective systems. Part 1: Ventilation channels resistant to 2 bar detonation – SRPS EN 14591-1 (en);
- Protection against detonation and protection in underground mines. Protective systems. Part 1: Ventilation channels resistant to 2 bar detonation – SRPS EN 14591-1 2008/A1 (en);
- Electrically operated equipment for potentially explosive atmospheres Part 0: General requirements - SRPS EN 60079-0 (en);
- Electrically operated equipment for potentially explosive atmospheres. Part 1: Fire resistant box "d" – SRPS EN 60079-1 (en);
- Electrically operated equipment for potentially explosive atmospheres. Part 2 Increased pressure "p" – SRPS EN 60079-2 (en);
- Electrically operated equipment for potentially explosive atmospheres. Part 11 Characteristic safety "i" – SRPS EN 60079-11 (en);
- Electrically operated equipment for potentially explosive atmospheres. Part 18: Encapsulation "m" - SRPS EN 60079-18 (en);
- Electrically operated equipment for potentially explosive atmospheres. Part 25 Characteristic safe electric systems "i" – SRPS EN 60079-25 (en);
- SRPS N S8.910 – Anti- explosive protection Mining helmet lights
- SRPS N S8.911 – Anti- explosive protection. Examination of mine detonation equipment
- Electrically operated equipment for potentially explosive atmospheres. Electrically operated equipment with S type of protection, special type of protection
- SRPS B 31.043 Safety in mines. Petrol powered safety light. Technical criteria

- SRPS N S8.901 Anti- explosive protection. Special requirements for ventilators in facilities with explosive atmospheres hazard
- SRPS MJ5.102 Ventilation of mine facilities – Axial ventilators for separate ventilation of sites- Technical criteria
- SRPS MJ5.103 Ventilation of mine facilities – Ventilators for separate ventilation of sites- noise absorbers
- SRPS N S8.201 – Anti- explosive protection. Increased safety (security)
- IEC 60529 – Level of protection provided by boxes (IP code)
- SRPS B 31.071 Safety in mines Categorization of underground workings and classification of shafts in underground mines
- SRPS B 31.069 Safety in mines Methods for determining methane presence posing security hazard in mines
- Machinery for underground mines Mobile machinery operating underground. Security. Part 1. Rubber wheel vehicles - SRPS EN 1889-1 (en)
- Machinery for underground mines Mobile machinery operating underground. Security. Part 2. Locomotives - SRPS EN 1889-2 (en)
- SRPS BH9.005 Coal sampling methods for testing explosivity of coal powder
- SRPS B 31.063 Coal sampling methods for testing explosivity and level of separation of coal powder
- SRPS B 31.065 Methods for testing explosivity of coal powder
- IEC 60529 – Level of protection provided by boxes (IP code)
- Markings and cable types as presented in Tables 12 and 13 and according to the relevant SRPS cable standards. - SRPS N C5.....

### **38. b) further evolution**

Provisions relevant for handling equipment and protection systems used in potentially explosive atmospheres is governed by the legislation in force to which so far the ATEX Directive has not been transposed. It is foreseen that the Directives shall be implemented by the end of 2012.

## **Medical devices**

### **37. a) present status**

The national legislation in the area of medical devices has been harmonized with the New Approach Directives 93/41/EC, 98/79/EC and 90/385/EC by enacting the Law on Medicines and Medical Devices.

### **37. b) forecast**

By May 2011 the legislation defining specifically the following issues shall enter into force:

- The rules for classification of medical devices
- The method of entering medical devices in the Register of Medical Devices;
- The conditions regarding the facilities, equipment and staff for production of medical devices;

- The method of marking external and internal packaging of medical devices and the contents of instructions for use of medical devices  
The legislation shall be harmonized with the New Approach Directives 93/42, 98/79 and 90/385.

**38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

On the basis of the Law on Medicines and Medical Devices medical devices may be placed on the market in the Republic of Serbia if they are entered in the Registry of Medical Devices that is maintained by the Agency for Medicines and Medical Devices of the Republic of Serbia.

The medical devices shall be entered in the Registry of Medical Devices on the basis on the following:

- 1) A Certificate on Compliance issued by the authorized notifying body or a Statement on Compliance
- 2) A permit to place on the market a medical device that has not been harmonized with the EU Directives on medical devices

Only a legal or a natural person holding a production permit issued by the Ministry responsible may perform the activities of production of medical devices.

On the basis of the Law on Medicines and Medical Devices wholesale of the medical devices (import, export, supply, storing and distribution) shall be performed by legal entities that hold a permit issued by the Ministry responsible provided that they satisfy the conditions stipulated by this Law and the relevant legislation enacted for the purpose of implementing the Law.

In addition, pursuant to the Law, wholesale of medical devices shall be limited to the medical devices entered in the Registry of Medical Devices unless the Agency for Medicines and Medical Devices of Serbia approves the import of medical devices that are not entered in the Registry. The Agency for Medicines and Medical Devices of Serbia, at the request of health or veterinary institutions may issue approval for import of medical devices that for which a permit to be placed on the market has not been issued and which are meant for treatment of a particular patient or group patients if the distribution or prescription delivery is carried out by a legal entity that holds a permit for wholesale or a pharmacy. The request for import of the medical devices that do not hold a permit for placing on the market and which are aimed at use for scientific or medical research shall be submitted to the Agency for Medicines and Medical Devices.

Holder of a permit for wholesale of medical devices may import or export medical devices in compliance with the Law.

On the basis of the Law, a legal entity performing only import or export of medical devices, may perform these activities if the import and customs of medical devices are performed on behalf of and in the name of a holder of a wholesale permit for the medical devices up to the point of placing the goods on free market, in compliance with the customs legislation. . Pursuant to the Law, a legal entity performing only import and export activities is not obliged to hold a permit for wholesale of medical devices issued by the Ministry responsible and shall not be considered a holder of wholesale permit.

The producer of medical devices may import or export medical devices included in its production program, material for production, semi-products of substances, in compliance with the Law.

The Ministry and its Inspectorate (the Ministry responsible for health issues or the Ministry responsible for veterinary issues) is responsible for supervision of implementation of the Law on Medicines and Medical Devices.

### **38. b) further evolution**

By May 2011, all by-laws shall be enacted in compliance with the New Approach Directives, in order to implement the Law on Medicines and Medical Devices. Pursuant to new by-laws, the procedure for placing medical devices on the market shall be harmonized with the EU Directives and the Certificate on Compliance issued by the authorized Notifying Body (CE mark) of the EU countries shall be recognized and applied.

### **Gas appliances (GAD)**

#### **37. a) present status**

In compliance with the National Programme for Integration of Serbia with the EU, the Ministry of Mining and Energy is responsible for enacting technical legislation in the area of gas devices.

This area of gas devices in the Republic of Serbia is presently governed by the following legislation:

- 1 The Law on Technical Requirement for Products and Conformity Assessment (Official Gazette of RS No. 36/2009)
- 2 The Law on Standardization (Official Gazette of RS, No. 36/2009)
- 3 The Rulebook on Technical Criteria for Movable Gas Stoves with no Connection to Chimneys (Official Gazette of SFRY No. 43/80)
- 4 The Ordinance on Mandatory Attestation of Gas Devices (Official Gazette of SFRY No. 58/94)
- 5 The Ordinance on Mandatory Attestation of Movable Gas Stoves with no Connection to Chimneys (Official Gazette of SRFY No. 1/82)

The aforementioned criteria define conditions and methods for manufacturing, testing and attestation of particular gas devices.

The activities pertaining to compliance assessment of gas devices are presently performed by the bodies accredited for certification of the products.

#### **37. b) forecast**

The Directive 90/396/EEC on gas devices shall be transposed to national legislation in the Rulebook on Gas Devices, which shall enable the assessment bodies to take over duties concerning compliance assessment of gas devices, in compliance with the Law on Technical Criteria for Products and on Compliance Assessment. It is foreseen that the Rulebook shall be enacted in the fourth quarter of 2011.

An addendum to the Rulebook shall be the list of Serbian Standards concerning gas devices (by which European harmonized standards shall be adopted). The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through application of the standards.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The legislation in force in the area of gas devices and the relevant Serbian standards stipulate conditions and methods for manufacturing, testing and attestation of particular gas devices.

The activities pertaining to compliance assessment of gas devices are presently performed by the bodies accredited for certification of the products.

By the end of 2010, the Standardization Institute of the Republic of Serbia enacted Serbian standards by which 90% of harmonized European standards in the area of gas devices have been adopted.

### **38. b) further evolution**

The Directive 90/396/EEC on gas devices shall be transposed to national legislation in the Rulebook on Gas Devices, which shall enable the assessment bodies to assume duties concerning compliance assessment of gas devices. The activities shall be focused on improvement of infrastructure for compliance assessment including supervision of the implementation of a new framework for placing these products on the market.

In addition, it is necessary to adopt all harmonized standards.

## **Pressure equipment (PED)**

### **37. a) present status**

The area of pressure equipment in the Republic of Serbia is presently governed by the following legislation:

- 1 The Law on Technical Requirement for Products and Conformity Assessment (Official Gazette of RS No. 36/2009)
- 2 The Law on Standardization (Official Gazette of RS, No. 36/2009)
- 3 The Rulebook on Technical Criteria for Stable Pressure Vessels (Official Gazette of SFRY No. 16/83)
- 4 The Rulebook on Technical and Other Requirements for Boiler Rooms (Official Gazette of RS No. 50/2009) 50/2009);
- 5 The Rulebook on Technical and Other Requirements for Stable Pressure Vessels (Official Gazette of RS No. 50/2009) 50/2009);
- 6 The Rulebook on Technical Criteria for Stable Pressure Vessels for Liquid Atmospheric Gases (Official Gazette of SFRY No. 9/86) and
- 7 The Rulebook on Technical Criteria for Testing and Examination of Stable Pressure Vessels for Liquid Carbon Dioxide (Official Gazette of SFRY No. 76/90)

The aforementioned criteria lay down the technical conditions for manufacturing, installation, use and examination of stable pressure vessels and of the boiler rooms.

The Ministry of Energy and Mining with its Pressure Equipment Inspectorate is responsible for supervision of manufacturing of such equipment and for the compliance assessment.

### **37. b) forecast**

The Directive 97/23/EC on pressure equipment shall be transposed to national legislation in the Rulebook on Pressure Equipment, which shall enable the assessment compliance bodies to take

over duties concerning compliance assessment of pressure equipment, in compliance with the Law on Technical Criteria for Products and on Compliance Assessment. It is foreseen that the Rulebook shall be enacted in the second quarter of 2011.

An addendum to the Rulebook shall be the list of Serbian Standards concerning pressure equipment (by which European harmonized standards shall be adopted). The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through implementation of the standards.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The legislation in force in the area of pressure equipment and the relevant Serbian standards lay down conditions and methods for manufacturing, installation, use and testing of stable pressure vessels and the boiler rooms.

The Pressure Equipment Inspectorate is presently responsible for supervision of manufacturing and examination of all pressure equipment that is in use.

By the end of 2010, the Standardization Institute of the Republic of Serbia enacted Serbian standards by which all harmonized European standards in the area of pressure equipment have been adopted.

### **38. b) further evolution**

The Directive 97/23/EC on pressure equipment shall be transposed to national legislation in the Rulebook on Pressure Equipment, which shall enable the assessment bodies to assume duties concerning compliance assessment of pressure equipment. The activities shall be focused on improvement of infrastructure for compliance assessment including supervision of the implementation of a new framework for placing the pressure equipment on the market.

In addition, the Rulebook on Examination and Testing the Pressure Equipment, stipulating process and time frames for examining and testing the pressure equipment in use and the criteria to be met by the bodies performing the examinations and testing, shall be enacted by the end of the second quarter of 2011.

## **Simple pressure vessels (SPVD)**

### **37. a) present status**

The area of simple pressure vessels in the Republic of Serbia is presently governed by the following legislation:

- 1 The Law on Technical Requirement for Products and Conformity Assessment (Official Gazette of RS No. 36/2009)
- 2 The Law on Standardization (Official Gazette of RS, No. 36/2009)
- 3 The Rulebook on Technical Criteria for Stable Pressure Vessels (Official Gazette of SFRY No. 16/83)
- 4 The Rulebook on Technical and Other Requirements for Stable Pressure Vessels (Official Gazette of RS No. 50/2009) and

5 The Rulebook on Technical Criteria for Stable Pressure Vessels for Liquid Atmospheric Gasses (Official Gazette of SFRY No. 9/86)

The aforementioned legislation lays down the technical conditions for manufacturing, installation, use and testing of simple pressure vessels.

The Ministry of Energy and Mining with its Pressure Equipment Inspectorate is responsible for supervision of manufacturing of simple pressure vessels and for the compliance assessment.

**37. b) forecast**

The Directive 2009/105/EC on simple pressure vessels shall be transposed to national legislation in the Rulebook on Simple Pressure Vessels, which shall enable the assessment compliance bodies to take over duties concerning compliance assessment of simple pressure vessels, in compliance with the Law on Technical Criteria for Products and on Compliance Assessment. It is foreseen that the Rulebook shall be enacted in the second quarter of 2011.

An addendum to the Rulebook shall be the list of Serbian Standards concerning simple pressure vessels (by which European harmonized standards shall be adopted). The assumption of compliance with the relevant requirements of the Rulebook shall be achieved through application of the standards.

**38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The legislation in force in the area of simple pressure vessels and relevant Serbian standards lay down conditions and methods for manufacturing, installation, use and testing of simple pressure vessels.

The Pressure Equipment Inspectorate is presently responsible for supervision of manufacturing and examination of all pressure equipment that is in use.

By the end of 2010, the Standardization Institute of the Republic of Serbia enacted Serbian standards by which all harmonized European standards in the area of simple vessels equipment have been adopted.

**38. b) further evolution**

The Directive 2009/105/EC on simple pressure vessels shall be transposed to national legislation in the Rulebook on Simple Pressure Vessels, which shall enable the assessment bodies to assume duties concerning compliance assessment of simple pressure vessels. The activities shall be focused on improvement of infrastructure for compliance assessment including supervision of the implementation of a new framework for placing the pressure equipment on the market.

In addition, the Rulebook on Examination and Testing the Pressure Equipment, stipulating process and time frames for examining and testing the pressure equipment in use and the criteria to be met by the bodies performing the examinations and testing, shall be enacted by the end of the second quarter of 2011.

**Cableway installations**

### **37. a) present status**

The Law on Railway (Official Gazette of RS No. 18/05) in Article 50 stipulates that the terms and conditions for construction, reconstruction and maintenance, as well as the conditions for organization of transport by cableway shall be governed by a separate law.

The legislation in force for which the Ministry of Infrastructure is responsible still does not govern this area.

### **37. b) forecast**

The EU Directive 2000/9/EC on cableway installations designed to carry persons governs this area. Preparation of the Law on Cableway Installation is a medium term priority and at the moment there is no estimate when the preparation of the Law shall start. It is foreseen that in the following period, the Ministry, in cooperation with the Ministry of Environment and Spatial Planning, shall prepare the activity plan on preparation of the Law on Cableway Installations.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The legislation in force for which the Ministry of Infrastructure is responsible still does not govern this area.

### **38. b) further evolution**

The EU Directive 2000/9/EC on cableway installations designed to carry persons governs this area. Preparation of the Law on Cableway Installations is a medium term priority and at the moment there is no estimate of when the preparation of the Law shall start. It is foreseen that in the following period, the Ministry, in cooperation with the Ministry of Environment and Spatial Planning, shall prepare the activity plan on preparation of the Law on Cableway Installations.

## **Construction products**

### **37. a) present status**

In accordance with the Law on Technical Requirements for Products and Conformity Assessment Article 30, paragraph 2, the Government promulgated Regulation on the Manner of Recognition of Foreign Documents and Marks of Conformity that governs the manner of recognising the validity of the documentation on conformity issued by the international conformity assessment bodies and the marks of conformity issued abroad. The Committee formed by the Minister responsible for construction activities shall decide whether the conditions for recognising validity of an international document for construction products are met. Based upon the submitted request for recognizing validity and the submitted proofs, the Committee shall decide on the following:

- 1) The requirements of the international technical legal act stipulate an equal or higher level of safety and health of human, animal and plant protection and the environmental, consumer and property protection when compared to those stipulated in relevant Serbian technical legal act.
- 2) The requirements of the international technical legal act that the international compliance assessment body must meet in order to implement the process of compliance

assessment of a product, stipulate an equal or higher level of compliance with the requirements when compared to those stipulated in Serbian technical legal act relevant for notified or authorized compliance assessment body. Based upon the submitted request for recognition, the proofs submitted and the established facts, it will be decided whether an international document or the compliance assessment mark meet the requirements stipulated in Article 8 of the Regulation. The Minister responsible, at the proposal of the Committee, shall issue a decision on recognizing the validity of an international document or a conformity mark if it has been confirmed that the international document or conformity mark meet the stipulated requirements.

### **37. b) forecast**

The provisions of the Rulebook on Construction Products would transpose stipulations of CPD (89/106/EEC) by which the assumption of conformity of construction products for their intended use would be achieved. It is foreseen that the Rulebook on Construction Products shall be prepared in 2011 and enacted in December 2011.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The Law on Planning and Construction (Official Gazette of RS No. 72/09, 81/09, 64/10) for which the Ministry of Environment and Spatial Planning is responsible, is a legal basis for preparation of technical legislation laying down relevant requirements for construction and other products used in the process of the construction of facilities or implementation of works (Article 201, point 3). The (licensed) designers and construction companies shall continue to be fully responsible for determining the level and the scope of the requirements until the technical legislation has been enacted.

The technical legislation and mandatory standards in force are as follows:

- POA 34/85 Ordinance on Mandatory Attesting of Cement (Official Gazette of SFRY No. 34/85 and 67/86)
- POA 61/83/1 Ordinance on Mandatory Attestation of Plywood Panels Intended for General Use in Construction Activities (Official Gazette of SFRY No. 61/83/1)
- POA 34/85/1 Ordinance on Mandatory Attestation of Prefabricated Elements of Aerated Concrete (Official Gazette of SFRY No. 34/85) 34/85)
- POA 4/85 Ordinance on Mandatory Attestation of Steel Products for Sealing Openings for Movement in Shelters and Dual-purpose Facilities (Official Gazette of SFRY No. 4/85)
- POA 13/85 Ordinance on Mandatory Attestation of Steel-concrete Products for Sealing Openings for Movement in Shelters and Dual-purpose Facilities (Official Gazette of SFRY No. 13/85)
- POA 34/85/3 Ordinance on Mandatory Attestation of Concrete Sewer pipes Exceeding One Meter in Length (Official Gazette of SFRY No. 34/85)
- POA 34/85/3 Ordinance on Mandatory Attestation of Concrete Sewer Pipes Exceeding One Meter in Length (Official Gazette of SFRY No. 34/85)
- POA 34/85/2 Ordinance on Mandatory Attestation of Additives to Concrete (Official Gazette of SFRY No. 34/85)

- POA 35/86 Ordinance on Mandatory Attestation of Profiled Rubber Sealing Tapes for Doors, Lids and Movable Barriers of Shelters and Dual-purpose Facilities with Airtight Closing of Wings (Official Gazette of SFRY No. 35/86)
- POA 41/87 Ordinance on Mandatory Attestation of Stone Fraction Aggregate for Concrete and Asphalt (Official Gazette of SFRY No. 41/87)
- POA 46/87 Ordinance on Mandatory Attestation of Hydro-insulation Products Impregnated with Bitumen and Bitumen Tapes (Official Gazette of SFRY No. 46/87)
- POA 24/90/2 Ordinance on Mandatory Attestation of Elements of Typical Construction Structures for Resistance to Fire and the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing Attestation for Such Products (Official Gazette of SFRY No. 24/90)
- POA 24/90/1 Ordinance on Mandatory Attestation of Facade Bricks and Clay Blocks and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing Certificates for Such Products (Official Gazette of SFRY No. 24/90)
- POA 24/90 Ordinance on Mandatory Attestation of Clay Tiles and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing Certificates for Such Products (Official Gazette of SFRY No. 24/90)
- POA 24/90/3 Ordinance on Mandatory Attestation of Anti-strike Valves for Shelters and Dual-purpose Facilities and on the Criteria that Must be Met by the Organizations of Associated Labour Authorized for Issuing Certificates for Such Products (Official Gazette of SFRY No. 24/90)
- POA - 61/87 Ordinance on Mandatory Attestation of Ventilation Systems for Shelters and Dual-purpose Facilities (Official Gazette of SFRY No. 61/87)
- POA 61/85 - Ordinance on Mandatory Attestation of Screws, Bolts and Shims for Joints of Main Steel Constructions (Official Gazette of SCG No. 61/85) 61/85);
- The Rulebook on Technical and Other Requirements for Ceramics Sanitary Equipment (Official Gazette of SCG No. 56/09) 62/04);

The Ministry of Environment and Spatial Planning is the institution responsible for this area.

The priority is to strengthen staff and administrative capacity and to implement institutional changes relevant for the area of construction products.

The assumption of conformity of construction products with their intended use would be introduced in the event that the construction products are in compliance with the harmonized standards, European technical approvals or recognized national technical specifications. In compliance with the Law on Ministries, the Minister shall enact the legal act by which the List of Standards shall enter into force and repeal the legislation that is not in compliance with the new legal act. Transitional periods shall also be introduced for each specific element. Since it was unclear which ministry would be responsible for the respective Law, and it has been clarified now that the Ministry of Environment and Spatial Planning shall be responsible, which however did not plan the budget for this purpose; it is required to urgently allocate resources for continuation of work on preparation of the Rulebook on Construction Products. The Rulebook shall stipulate the following:

- 1 The list of regulation that shall remain in force
- 2 The list of regulation that shall be repealed
- 3 Entry into force of the Rulebook
- 4 Applicability of particular provisions

### **38. b) further evolution**

Further evolution in this area is linked to adoption of the Rulebook on Construction Products, which would overtake CPD (89/106/EEC) and introduced a presumption of benefits of construction products for the intended use. It is foreseen that the Rulebook on Construction Products shall be prepared in 2011 and enacted in December 2011.

### **Recreational craft**

#### **37. a) present status**

The Law on Navigation and Ports on Inland Waters (Official Gazette of RS No.73/10) lays down provisions for technical inspection and determination of seaworthiness of inland navigation vessels. The aforementioned Law stipulates that the construction and technical seaworthiness of inland navigation vessels and the safety of their devices, machinery, equipment and materials that serve to maintain the safety of navigation of ships, protection of lives, safety and health at work of crew members and other persons on board the ships and preventing pollution of inland waters from ships shall be laid down in technical regulations. In addition, the Law governs the issue of the technical inspection and of seaworthiness of inland navigation vessels. According to the Law, the Minister of Infrastructure enacts the Technical Rules for inland navigation vessels and the Technical Rules for inland navigation boats. The Authority for determination of the seaworthiness, body within the Ministry of Infrastructure, is responsible for technical inspection of inland navigation vessels. The Authority shall, within three months from the date of entry into force of this Law (which entered into force on November 20<sup>th</sup> 2010), take over the responsibilities of the Federal Public Institution Yugoslav Register of Shipping “Jugoregistar”.

In compliance with the Law on Navigation and Ports on Inland Waters, the provisions of the Law on Maritime and Inland Navigation (Official Gazette of SRY No. 12/98, 44/99, 74/99 and 73/00 and Official Gazette of RS No. 85/05 and 101/05) relating to maritime navigation and the provisions concerning sea-going ships and sea boats shall remain in force. In compliance with the Article 66 of the Law on Maritime and Inland Navigation, the authorized legal entity shall adopt Technical Rules regarding the construction and technical seaworthiness of the vessels and other standards for construction of the vessels. The legislation concerning the technical rules shall be published in Official Gazette of SRY and the technical rules shall be published in a special edition of the authorized legal entity. The authorized legal entity in the Republic of Serbia is the Federal Public Institution Yugoslav Register of Shipping “Jugoregistar” whose responsibilities shall be taken over by the Authority for determination of the seaworthiness, established by the Law on Navigation and Ports on Inland Waters.

The issue of type-approval and recognizing the manufacturer and the assessment institutions is laid down in the Decision on Technical Rules of the “Jugoregistar” –type- approval of the products (Official Gazette of the SFRY No. 60/88), which is consistent with to the Rules on Type Approval and in the Decision on Technical Rules of “Jugoregistar” concerning recognizing the manufactures and the assessment institutions (Official Gazette of SFRY No. 60/88) which is consistent with the Rules on Recognizing Manufacturers and Assessment Institutions. „Jugoregistar” is the legal entity authorized to issue the certificate on recognizing the

manufacturer and the certificate on the type-approval after which the manufacturers are entered in the list of recognized examined manufacturers and in the list of approved types of products and the recognized manufacturers of the recreational vessels.

### **37. b) forecast**

It is foreseen that by 2012, the Directive of the European Parliament and of the Council 94/25/EC concerning harmonization of the laws and other legislation of the member states on recreational vessels and the Directive of the European Parliament and of the Council 2003/44/EC amending the Directive 94/25/EC on harmonization of laws and other legislation of the member states on recreational vessels shall be promulgated into national legislation.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

In compliance with the Law on Maritime and Inland Navigation, whose provisions relating to the maritime navigation remained in force, the authorized legal entity shall enact technical rules regarding the construction and technical seaworthiness of vessels and other standards for construction of the vessels (sea-going ships and sea boats).

The Law on Navigation and Ports on Inland Waters stipulates that the technical rules for inland navigation vessels and boats shall be adopted by the Minister of Infrastructure.

The technical rules for construction of inland navigation vessels stipulate the technical criteria for construction of inland navigation vessels (inspection over construction, hull, equipment, stability, and protection against fire, mechanical devices, systems and pipelines, electrical devices, signalization devices, navigation equipment, safety at work, prevention of pollution from the ships, radio equipment, measurement and the rules for construction of the boats).

The technical rule for construction of sea-going ships stipulate technical criteria for construction of inland navigation vessels (inspection over construction, hull, equipment, measurement, stability, welding material, machinery, pipelines, protection against fire, rearrangements, signalization devices, radio equipment, rescue equipment, prevention of pollution from the ships, safety at work, cargo handling equipment, automated systems and other).

The Authority for determination of the seaworthiness, which shall take over the responsibilities the Federal Public Institution Yugoslav Register of Shipping "Jugoregistar", in compliance with the Article 281 of the Law on Navigation and Ports on Inland Waters, is responsible for inspection on the issued product type-approval of the manufacturers. The Decision on the Technical Rules of "Jugoregistar" concerning the product type-approval and the Decision on the Technical Rules of "Jugoregistar" concerning recognizing the manufacturers and assessment institutions lay down technical rules for recognizing the manufacturers and the assessment institutions and the issue of product type-approval. The designated technical rules stipulate that the Certificate on Recognizing Manufacturers shall be issued for the period of four years and that "Jugoregistar" that issues the certificate may in the period mentioned perform periodic examination with the manufacturers and if it considers that the product is below the required quality or if it receives information on the change of the method of production in event of change of particular requirements, rules specifications, standards or conventions and in event that the

result of examination is negative, the manufacturer shall be deleted from the Registry of Recognized Manufacturers.

The inspection of finished vessels in the market is not governed by the legislation concerning navigation.

### **38. b) further evolution**

It is foreseen that by 2012, the Directive of the European Parliament and of the Council 94/25/EC concerning harmonization of the laws and other legislation of the member states on recreational vessels and the Directive 2003/44/EC of the European Parliament and of the Council amending the Directive 94/25/EC on harmonization of laws and other legislation of the member states on recreational vessels shall be promulgated into national legislation.

## **Eco-design requirements for energy-related products**

### **37. a) present status**

Directive 32/2005/EC, which regulates this field, had not been transposed into Serbian law – it is expected to happen through the adoption of the Law on Rational use of energy in the first half of 2011.

### **37. b) forecast**

Rational use of energy should enable and encourage responsible, efficient and long-term sustainable use of energy; contribute to increase of security of supply and increase of employment and competitiveness and to improvement of environmental issues by establishing a broad market of energy efficiency services, change of attitudes and established behaviour with regard to the use of energy.

Integration of environmental protection conditions in the design of the products that use energy aiming to improve the impact of the products on the environment during the entire product life cycle is of a large importance. The link between the product design and the energy consumption in the process of production, use and end of the life cycle of the product is very important.

These issues are integrated in the Directive 32/2005/EC and Directive 125/2009/EC which will be transposed to our legislation by enacting the Law on Rational Use of Energy. It is foreseen that the Law shall be adopted during 2011. The experts of the Ministry of Mining and Energy, the Ministry of Environment and Spatial Planning and the Agency for Energy Efficiency are preparing the Law. Pursuant to the Draft Law on Rational Use of Energy, detailed conditions of eco-design shall be laid down by the Minister responsible for environment and Minister responsible for energy.

Introduction of the eco-design concept through implementation of this legislation should significantly contribute to improvement of rational energy management and decrease of its adverse effect on environment.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The area of units of measurement and calibration in Republic of Serbia is regulated by the Law on Metrology (Official Gazette of RS No. 30/10), while the issues of standards, testing, certification and accreditation are regulated by the Law on Standardization (Official Gazette of RS No. 36/2009) and the Law on Accreditation (Official Gazette of RS No. 73/2010) in accordance with the European practice and the international standards. In accordance with the Draft Law on Rational Use of Energy, supervision of environmental requirements for the products that use energy and are placed on the market, shall be performed by the **Trade Inspectorate**. It is foreseen that the Ministry of Environment and Spatial Planning, the Ministry of Mining and Energy and the Agency for Energy Efficiency shall prepare enactment of a by-law that would more specifically define the provisions of the Directive 32/2005/EC and shall inform the interested parties on the changes that the by-law shall introduce.

### **38. b) further evolution**

Aspects of measures related to metrology, compliance and market supervision will be regulated by sub-laws regulations for the implementation of the Ecodesign Directive in accordance with the future Law on Rational Use of Energy.

## **Radio and telecommunications terminal equipment (R&TTE)**

### **37. a) present status**

The Law on Electronic Communications (Official Gazette of RS No. 44/10) repealing the Law on Telecommunications (Official Gazette of RS No. 44/03, 36/06 and 50/09) was adopted on 29th June 2010. The Law amended the system of issuing approval for import of goods, which was based upon Article 86 of the Law on Telecommunications.

The system of control of compliance with the stipulated standards and criteria and the issuing of technical permits and certificates was based upon Article 86 of the Law on Telecommunications which was applied by the date of entry into force of the Law on Electronic Communications, stipulating that the telecommunication systems and devices could be placed on the market only if a relevant technical permit or a certificate is issued for them. The system was implemented by the Republic Agency for Electronic Communications (hereinafter: RATEL) in compliance with Article 65, paragraph 3 of the Law on Telecommunications and the Decision on Determining Goods for Import, Export and Transit of which Specific Documentation shall be Issued (Official Gazette of RS No. 07/10). Pursuant to Article 65, paragraph 3 of the Law on Telecommunications, a legal entity registered for the import of radio stations for the purpose of their sale shall obtain a prior approval of RATEL. In addition, in compliance with the point 8 of the Decision, the approval for import of goods listed in Annex 6 of the Decision, shall be issued by RATEL.

RATEL shall issue technical licenses-certificates for placing the telecommunication systems and products on the market, in compliance with Article 86, paragraph 10 of the Law on Telecommunications, which stipulates that the telecommunication systems and products may be placed on the market only if the relevant license-certificate had been granted. The technical licence (certificate) on conformity with the standards and the criteria stipulated for placing the telecommunication systems and products on the market shall be issued in compliance with the Law on Telecommunications, the Rulebook on Control of Compliance of Telecommunication Network Systems and Means with the Stipulated Standards and the Criteria (Official Gazette of

RS No. 29/06) and the Rulebook on Issuing Technical Licenses – Certificates (Official Gazette of RS No. 34/06).

The aforementioned Rulebooks of RATEL are in compliance with Articles 3 and 5 of the Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and the telecommunication and terminal equipment and the mutual recognition of their conformity, and in particular with regard to control of conformity of telecommunication networks, systems and products concerning the following:

- Safety and health of humans
- Electromagnetic compatibility
- Design and construction of radio equipment in a way that it efficiently uses the spectrum allocated to terrestrial and space radio communications so as to avoid harmful interferences
- Other requirements pertaining the interworks via networks with other apparatus and connecting to particular types of interface; protection of telecommunication networks from possible abuse, interference and the unacceptable decrease of quality of services and prevention of abuse, fraud and other
- Application of harmonized European standards.

The aforementioned system of issuing technical licenses-certificates has been changed by entry into force of the Law on Electronic Communications which stipulates in Article 44 that the Ministry of Telecommunications and Information Society, at the proposal of RATEL, shall enact technical legislation that lays down the requirements for particular types of electronic communications, networks, associated facilities, electronic communications equipment and terminal equipment. If the aforementioned legal act stipulates that the compliance assessment shall be performed by the compliance assessment body, the Ministry shall appoint such body in compliance with the Law on Technical Criteria for Products and on Compliance Assessment. Pursuant to the Law on Electronic Communications, RATEL may be designated as the body for compliance assessment.

The technical legislation referred to in Article 44 of the Law on Electronic Communications shall be enacted in accordance with the Law on Technical Requirements for Products and Conformity Assessment.

### **37. b) forecast**

Pursuant to Article 142 of the Law on Electronic Communications and on the basis of authorities stipulated by the Law, the Ministry of Telecommunications and Information Society shall enact general regulations within a year from the date of the entry into force of the Law. Therefore, it is foreseen that the technical legislation referred to in Article 44 of the Law on Electronic Communications shall be adopted by the end on June 2011 and that it shall transpose to national legislation relevant part of P&TTE Directive concerning construction, installation and use of electronic communications networks, associated facilities and electronic communications equipment and terminal equipment.

### **38. a) short description regarding calibration, standards, testing, certification, conformity assessment, accreditation and market surveillance**

The Law on Electronic Communications lays down the system of conformity control of the products that is based upon the Law on Technical Requirements and Compliance Assessment and stipulates that the Ministry of Telecommunications and Information Society shall enact technical legislation laying down requirements for particular types of electronic telecommunication networks, related products, electronic communication and terminal equipment.

Pursuant to Article 34, paragraph 1 of the Law on Technical Requirements for Products and on Conformity Assessment, competent Ministry shall perform inspection supervision of the implementation of the provisions of this Law and legislation based upon the Law and technical legislation. Accordingly, inspection supervision of the implementation of legislation in the area of electronic communication shall be performed by the Ministry of Telecommunications and Information Society (Article 132 of the Law on Electronic Communications). The Republic Agency for Electronic Communications is authorised to perform testing and measurement of electronic communication network and services through monitoring centers for measurement and control (Article 131 of the Law on Electronic Communications).

### **38. b) further development**

The Law on Electronic Communications defines and establishes the framework for control of compliance with the stipulated standards and the criteria for issuing technical licenses while relevant by-law shall define in detail the procedure and the system of compliance assessment control and implementation of relevant EU Directives.

## ***PROCEDURAL MEASURES***

### ***A. Measures having an equivalent effect to quantitative restrictions***

**39. Do measures exist in the laws, regulations or administrative provisions adopted at national or local level on the production, distribution and marketing of food or industrial products:**

**a) Relating to the price of such products (e. g. fixing the prices above or below which the importation or marketing of a product is prohibited or restricted, laying down profit margins or other price components etc.)?**

Law on Trade in Article 46 prescribes the provisional measures of market protection. In order to prevent market disturbances or eliminate harmful consequences of market disturbances in terms of supply of goods and services vital to human life and health and for businesses, institutions and other organisations of public interest, the Government may order provisional measures relating to certain types of goods and services, certain categories of traders or consumers, the necessity to implement the obligations ensuing from international agreement, the prices, and other conditions for trading, except for measures concerning the import and export of goods. Government will decide on provisional measures referred to in paragraph 1 of this Article, as well as the period of application of these measures, the according to purpose and expected results, which shall not be longer than six months from the date of determining the provisional measure, and/or not later than the fulfilment of obligations regarding the implementation of the obligations ensuing from the international agreement.

On the day of entering into force of this Law the following three laws ceased to have effect:

- 1 Law on Trade (Official Gazette of RS, No. 32/93, 50/93, 41/94, 29/96 and 37/02 – other law, and Official Gazette of RS, No. 101/05 – other law and 85/05 – other law);
- 2 Law on Conditions for Performing Trade of Goods, Rendering Services in Trade of Goods and Inspection Surveillance (Official Gazette of RS, No. 39/96, 20/97, 46/98, 34/01 – other law, 80/02 – other law and 101/05 – other law);
- 3 Law on Prices (Official Gazette of RS, No. 79/05);

Law on Trade in Articles 28, 29 and 30 stipulated that in case major disturbances occur in production and trade of certain goods on the common market, and in case such disturbances can not be eliminated by measures of the current economic policy, the Federal Government may prescribe provisional measures to prevent and remedy these disruptions, the types of measures and deadlines to be effective.

Law on Conditions for Performing Trade of Goods, Rendering Services in the Trade of Goods and Inspection Surveillance (Official Gazette of RS, No. 39/96, 20/97, 46/98, 34/01 – other law, 80/02 – other law and 101/05 - other law) in Article 8a, stipulated that in case of market disturbances in production and trade of certain goods, and in case the disturbances can not be eliminated by measures of the current economic policy, the Government of the Republic of Serbia may prescribe provisional measures for the prevention and elimination of disruptions while they last.

Law on Prices (Official Gazette of RS, No. 79/05) in Article 9 stipulated that in order to provide conditions for the regular market supply with certain agricultural-food products, the Government may determine the prices of these products on the basis for their production costs and prices in the domestic and international markets, whilst Articles 10, 11 and 12 stipulated that in case of the event of market disturbances in production, service provision and trade in certain products or services that directly affect the prices of products and services, and if the disturbances can not be eliminated by measures of the current economic policy, the Government may issue interim measures, and a period of validity of these measures.

In order to preserve the standards of the lower social categories, and for a balanced supply of the population with basic types of bread, the Government in October 2010 adopted a Regulation on mandatory production and trade of bread type "T-500" (Official Gazette of RS, No. 75/10) in accordance with Article 8a of the Law on Conditions for Performing Trade of Goods, Rendering Services in Trade of Goods and Inspection Surveillance (Official Gazette of RS, No 39/96, 20/97, 46/98, 34/01-other law, 80/02-other law and 101/05-other law) which was in force at the time. This Regulation regulates the production and marketing of one type of bread "T-500" type, and determines the maximum amount of margin, unsold copies, and terms of payment to economic operators engaged in the production of bread "T-500". This Government measure is of temporary nature. The Regulation was adopted in response to the current market situation and its validity was limited until 31 March 2010, after which it ceased to have effect.

Prices of medicines which obtained licences and which are used in human medicine and issued on prescription are administratively controlled to ensure availability of medicines to all citizens in sufficient quantities and range, and rational use of limited financial resources allocated for medicines that are prescribed and issued at the expense of the compulsory health insurance. The legal basis for controlling medicine prices is contained in the Law on Medicines and Medical Devices under which the Government of the Republic of Serbia establishes criteria for the pricing of medicines that are granted permission for the medicine, which are used in human medicine and

issued on prescription, as well as the highest rates of these medicines, based on the joint proposal of the minister responsible for public health and the minister responsible for trade.

Medicine prices are determined in accordance with the Regulation on criteria for the pricing of medicines for human use which are issued on prescription. The way the price of medicines is established is impartial, since prices are determined on the basis of objective criteria and in a transparent manner and domestic and imported medicines are treated in the same way. For medicine pricing a methodology of international reference prices has been applied. The criteria for the pricing of medicines are mainly based on comparison of prices, using prices of identical medicines in the prescribed benchmark countries (Slovenia, Croatia and the Republic of Italy and European Union countries where the medicine is produced and in which the permission for marketing of such medicine was obtained).

Law on Communal Activities (Official Gazette of RS, No. 16/97 and 42/98) stipulates that the PUC, or another company or entrepreneur involved in communal activities, with the consent of the competent local authorities shall decide on the prices of municipal products and services paid by direct beneficiaries.

In addition, the local authority shall act in accordance with the Regulation on the procedure to temporarily suspend the transfer of transfer funds from the budget of the Republic of Serbia to the local authority, and/or transfer of the related income tax and corporate tax to the Autonomous Province (Official Gazette of RS, No. 6/06 and 108/08), adopted under Article 22b, paragraph 4 of the Law on Public Utilities and performing activities of public interest (Official Gazette of RS, No. 25/00, 25/02, 107/05, 108 / 05 and 123/07). This Regulation restricts the allowed price increase of all PUs, including the PUC, established by the local government, up to the projected rise in prices which the Government determines by the Memorandum on Budget and Economic and Fiscal Policy for each year and shall specify the procedure to temporarily suspend the transfer of funds from the budget of the Republic of Serbia to the local self-government. That basically means that the jurisdiction of the Ministry of Trade and Services is to, based on the model set out in the Regulation, control the alignment of price movements of all companies founded by local self-governments, including those companies that provide utility services, with projected growth of prices for each year. Also, the duty of the Ministry of Trade and Services is to notify the ministry responsible for temporarily suspension of transfer of funds on the results of price controls (for all companies founded by local government), and on notified excess of the allowed framework for increase of (their) prices, in a monthly schedule.

Pursuant to the Law on specific duties on import of agricultural products and foodstuffs (Official Gazette of FRY, No. 90/94), by making appropriate decisions, the Government determines the agricultural and food products for which special taxes (levy) is paid on import, and determines the amount of such duties, in order to stabilize domestic production and its protection from excessive imports, primarily from countries where production of these products is highly subsidized.

Levies are paid by companies, entrepreneurs and natural persons on importation of agricultural and food products, and it is collected during customs clearance, according to the regulations governing the collection of customs duties.

**b) Which require automatic or non-automatic import licences or permits for imported goods (e.g. licence for import of automobiles)?**

Permits are required for import of products listed in Decision on determining the goods for which import, export and/or transit provision of specific licences is prescribed (Official Gazette of RS, No. 7/2010)(Annex 1.18.). This decision was adopted in accordance with Law on Foreign Trade (Official Gazette of RS, No. 36/09) and it includes all import licenses, regardless of the regulation based on which these were introduced, and which authority is responsible for their issuance. The decision contains lists of goods subject to licensing, and it refers to regulations containing these lists, with reference to the competent authority.

All import permits in Serbia are non-automatic.

**c) Which ban certain specific products (foodstuffs, including vitamins and other food supplements, and chemical substances)?**

According to the Law on Genetically Modified Organisms (Official Gazette of Republic of Serbia, No. 41/09) Article 2, "No living modified organism or product of a genetically modified organism shall not be put into circulation, and grown commercially on the territory of the Republic of Serbia." Ministry of Agriculture, Forestry and Water Management of the Republic of Serbia has prepared a new draft Law on Amending and Modifying the Law on Genetically Modified Organisms.

In accordance with the Law on Plant Protection Products and the Law on Plant Nutrition products and Soil Enhancers, plant protection products and plant nutrition product and soil enhancers shall not be put on the market on the territory of the Republic of Serbia, if not registered in accordance with these laws.

Plant protection products and plant nutrition products and soil enhancers that are not registered in the Republic of Serbia may be produced and stored in the Republic of Serbia, and their import and transit through the territory of the Republic of Serbia may be carried out only if these are intended for marketing in the country where are being exported. Testing of unregistered plant protection products, for the purposes of registration, and their import are carried out in accordance with the decision of the Ministry of Agriculture, Forestry and Water Management.

Also, in case of unexpected emergency cases that may be caused by harmful organisms, which is not possible to suppress or reduced properly by registered plant protection products and through other measures, or due to a shortage of registered plant protection products on the market in the Republic of Serbia, the decision approving the import, and their limited and controlled application shall be issued by the Plant Protection Directorate of the Ministry of Agriculture, Forestry and Water Management.

Administrative measures that restrict or limit production, distribution and use of certain hazardous substances are prescribed in the Regulations on restrictions and bans of the production, marketing and use of chemicals that represent an unacceptable risk to human health and the environment (Official Gazette RS, No. 89/10).

**d) Which restrict or prohibit distant selling (mail order, internet sales) of certain products (pharmaceuticals, alcoholic beverages and others)?**

Representatives of the Ministry of Foreign Affairs - Permanent Mission of Serbia to the United Nations and other international organisations in Geneva, in collaboration with inter-sectoral expert team composed of representatives from the Ministry of Finance - Customs Administration and the Administration for Tobacco, the Ministry of Trade and Services – Market Inspection Sector, the Ministry of Justice and the Ministry of the Interior, and with the support of the Ministry of Health - Office of the WHO, and the Council for Tobacco Control, were actively involved in the process of negotiating and agreeing on the text of the Draft Protocol on the elimination of illicit trade in tobacco products. Article 10 of the Protocol contains several alternative proposals relating to the sale of tobacco products over the Internet, telecommunications equipment and other advanced technologies. In the process of harmonizing these issues Serbia has established cooperation with the Member States of the European Union and other European countries.

The Law on Medicines and Medical Devices banned the transport of medicines and medical devices through the Internet and by mail, except for sending medicine samples in accordance with this Law.

**e) Which make access to the domestic market conditional upon having an agent or representative in the territory of your country (e.g. legislation which provides for the sale of certain goods in your country subject to authorisation that may be obtained only by a person established there)?**

There are no measures conditioning the access to the domestic market through power of attorneys or representatives in the territory of Serbia.

**f) Which oblige importers to have storage facilities in the territory of your country (e.g. legislation applying only to imported goods which require these imported goods to be stored for some time before being marketed)?**

Law on Trade prescribed the obligation of the legal person dealing with the activities of trade in explosives to provide for adequate storage space for the storage of these substances, regardless of whether such entity is the importer or not. The new Law on Explosive Substances does not envisage the change of this situation.

When performing transport of explosive substances, legal entities shall meet the requirements prescribed by the Law on Transport of Explosive Materials – which provides that a legal entity must have the storage space - its own or leased, which must meet the requirements of the Law on Transport of Explosive Materials, Flammable Liquids and Gases, and the Rules of Safety in the manufacturing of explosives and gunpowder and manipulation of explosives and gunpowder. “In the process of adopting new legislation, this issue will also be arranged in a new way.”

In accordance with the Law on Medicines and Medical Devices the wholesale of medicinal products (import, export, purchase, storage and distribution), may be dealt with only by legal entities which have a license issued by the Ministry of Health and who meet the requirements of this Law and regulations adopted for its implementation.

However, a legal entity that performs only the activities of import or export of medicines may perform these activities on condition that it performs import and clearance of medicines on behalf of the holder of a wholesale permit for medicinal products to the site of release of goods for free circulation, in accordance with customs regulations. Legal person that performs only the

activities of import or export of medicines is not required to have a permit for wholesale of medicinal products, nor a storage capacity, since it is not considered a holder of a wholesale permit for medicinal products.

**g) Which impose on the marketing of imported products conditions (relating in particular to shape, size, weight, composition, presentation, identification and packaging, labelling) that are different from those imposed on domestic products or which require or encourage the use of certain type of packaging (shape, size, composition) for the marketing of a certain product, whether domestic or imported (e.g. requirement that some goods may only be sold in a package with special form)?**

The list of substances for which the applicable restrictions and limitations given in the Draft Regulation on the limitations and restrictions of manufacturing, marketing and use of chemicals that represent an unacceptable risk to human health and the environment, may have specific requirements pertaining to labelling and packaging only for substances, mixtures or products intended for industrial or professional use.

**h) Which oblige economic operators to label their product with the: “Made in ...” marking (obligatory origin marking)?**

Law on Trade applicable from 1 January 2011, in part regulating the conditions for the retail trade, in Article 40 which regulates the labelling of goods in retail trade, stipulates the obligation of stating the country of origin on the label. In the same article it is stipulated that as the country of origin the European Union (EU) may be stated, in accordance with the rules of origin of goods.

Regulation on the Declaration and Marking of Packed Food (Official Gazette of SAM, No. 04/04, 12/04 and 48/04) prescribes that a declaration on food, among other things, shall contain the name of the country of origin ("Made in ...") and the name of the country from which the food is imported ("Imported from ...").

**i) Which encourage or authorise the purchase (by individuals or public authorities) of domestic products alone or give preference to the purchase of such products in advertising campaigns (e.g. promotion actions with the participation of public authorities applying only to goods produced by producers in your country or from domestic raw materials)?**

Ministry of Trade and Services, Serbian Chamber of Commerce and the daily economic newspaper "Privredni pregled" ("Economic Review"), within "The Best of Serbia" promotional initiative, organise a selection of the best brands and corporate brands operating on the Serbian market, on annual basis. This promotional initiative is aimed at strengthening the image of domestic brands and the perception of products and services produced in Serbia. Competition is open to all entities operating in the Serbian market for the business generated in Serbia, and the initiative is on a voluntary basis. Selection of brands is transparent since a methodology and criteria were developed that are known in advance and are available to all interested parties and the general public. Top-rated brands in categories receive awards in the form of statues and plaques, the best brands in the category of goods of everyday purchases are especially promoted in stores of leading retail chains during one month period, and all the winning brands are promoted during the year.

Ministry of Trade and Services, as part of its operation programme, has for several years carried out activities of different forms of promotion of the economy. Funds for this purpose are provided in the budget.

Exhibitions that have been organised up to date are as follows:

- National exhibition of Serbian economy in Moscow, organised in 2005, under the name "Serbia 05";
- National exhibition of Serbian economy in Krasnodar, Russian Federation, organised in 2008, under the name "Serbia in Krasnodar 2008";
- National exhibition of Serbian economy in Minsk, Belarus, organised in 2009, under the name "Serbia in Minsk 2009".

**j) Which exclude imported products alone, in full or in part, from the possibility of using domestic facilities or equipment or which reserve the use of such facilities or equipment, in full or in part, for domestic products alone?**

There are no such provisions in the legislation of the Republic of Serbia.

**k) Which subject imported products to controls, other than those inherent in customs clearance procedures, which are not carried out on domestic products (e.g. veterinary, sanitary, phytosanitary and other controls)?**

The legislation of the Republic of Serbia has no such provisions in terms of phytosanitary control of plant protection products, plant nutrition products and soil enhancers.

For imported products, the market inspection does not exercise control that is different from those inherent in customs clearance procedures, and those that are not made for domestic products.

In accordance with the Law on Medicines and Medical Devices, the Medicines and Medical Devices Agency of Serbia controls the quality of medicines produced by domestic manufacturers and imported medicines, and issues certificates of analysis.

Holder of the medicines trade licence shall, prior to marketing of the imported batch of medicines, deliver to the Agency, for quality control purposes, samples of such series of imported medicine with a certified analysis of the professional body for quality control of medicines of the EU or other country that has the same or similar requirements for issuing license for such medicines. Such quality control of medicines is considered documentary quality control in the process of issuing certificate of analysis and it represents a procedure for accepting the technical requirements for products and conformity assessment, in accordance with the law.

**l) Which allow only traders holding a production licence or wholesale licence to import some goods (e.g. licensing system for the production and wholesale of some goods, which allow only the licence holder to import these goods)?**

Cases when it is necessary to obtain permits / licenses for the manufacturing, wholesale, marketing (or registration) in order to obtain the right to engage in import of certain products are available for:

- particularly hazardous chemicals - in accordance with the Law on Chemicals (OG RS 36/09)

In accordance with the Law on Chemicals (Official Gazette of Republic of Serbia, No. 36/09) according to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, for import and export of certain substances for which restrictions and bans are established on manufacturing, marketing and use, and certain mixtures and products containing such substance, a procedure of prior notice and prior informed consent procedure shall be applied (hereinafter referred to as PIC procedure). Prior notice procedure is applied to chemicals from the List of chemicals subject to prior notice procedure, whilst the PIC procedure is applied to chemicals from the List of chemicals subject to the PIC procedure.

- plant protection products - in accordance with the Law on Plant Protection Products

In accordance with the Law on Plant Protection Products (Article 39) through distribution of plant protection products such products may be imported and/or sold by legal persons and entrepreneurs registered in the Register of distributors and importers of plant protection products. Distributor and/or importer are registered in the Register provided they meet the requirements in regard to facilities, equipment and professional capacities of staff. The professional competence of staff includes training of personnel employed by legal persons and entrepreneurs engaged in import and distribution of plant protection products.

The application form and manner of entry into the aforementioned Register is prescribed by the Rulebooks on the form and content of requirements for registration into the Register of distributors and importers of plant protection products, and content of the Register of distributors and importers of plant protection products (Official Gazette of RS, No. 5/2010). 5/2010).

Detailed terms that must be met by legal persons and entrepreneurs, in terms of facilities and equipment, to be entered in this Register shall be prescribed by the Rulebooks on the conditions in terms of facilities, equipment and professional capacities of staff to be met by the distributor and/or importer for the registration in the Register of distributors and importers, as well as the conditions regarding facilities, equipment and personnel qualifications to be met by the distributor for trading in particularly dangerous pesticides. This Rulebook has been drafted and is in the process of adoption.

The same Rulebooks shall prescribe training of staff, which will be conducted in accordance with the Programme of training of persons responsible for the storage and distribution of plant protection products, provided by these Rulebooks. The training programme is compliant with Annex I of the Directive 2009/128 of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

- fertilizers - in accordance with the Law on Plant Nutrients and Soil Enhancement Substances

In accordance with the Law on Plant Nutrition Products and Soil Enhancers (Article 7) through distribution of plant nutrition products and soil enhancers such products may be imported and/or sold by legal persons and entrepreneurs registered in the Register of distributors and importers of plant nutrition products and soil enhancers. Legal persons and entrepreneurs are registered in this Register provided they meet the requirements in terms of storage facilities and sales and appropriate education of personnel (higher education for wholesale and import, secondary education for retailers).

The application form and manner of entry into the aforementioned Register is prescribed by the Rulebooks on the form and content of requirements for registration into the Register of distributors and importers of plant nutrition products, and content of the Register of distributors and importers of plant nutrition products (Official Gazette of RS, No. 66/2009).

Detailed terms that must be fulfilled by legal persons and entrepreneurs in order to be registered in the above mentioned Register are prescribed by the Rulebooks on conditions related to facilities for storage of fertilizers and premises for the sale and storage of plant nutrition products (Official Gazette of RS, No. 78/2009).

- narcotic medicines and psychotropic substances - in accordance with the Law on Manufacturing and Sale of Narcotic Drugs (OJ FRY 46/96 and 37/02 OG RS 101/05 – other law)

In accordance with the Law on Manufacturing and Sale of Narcotic Medicines, narcotic medicine may be imported and exported by legal persons registered for the manufacturing and sale of narcotics.

In accordance with the Law on Substances Used in Illicit Production of Narcotic Medicine and Psychotropic Substances (Official Gazette of RS, No. 107/2005), the Ministry of Health issues a permit to import, export and transit of precursors of the first, second or third category to legal person that has the license for manufacturing and trade of the precursors of the first, second or third category.

In accordance with the Law on Manufacturing and Sale of Narcotic Medicine, narcotic medicine may be imported and exported by legal persons registered for the manufacturing and sale of narcotics. The new Law on Psychoactive Controlled Substances, which is in a preparatory phase, envisages that the Ministry of Health issues a permit for export and/or import of controlled psychoactive substances to a legal person that has the license for manufacturing and trade of controlled psychoactive substances.

- precursors - in accordance with the Law on Substances Used in Illicit Production of Narcotic Medicines and Psychotropic Substances. In accordance with this Law, the Ministry of Health issues a permit to import, export and transit of precursors of the first, second or third category to legal person that has the license for manufacturing and trade of the precursors of the first, second or third category.

Also, in accordance with the Law on Manufacturing and Sale of Narcotic Medicines, narcotic drugs may be imported and exported by legal persons registered for the manufacturing and sale of narcotics. The new Law on Psychoactive Controlled Substances, which is in a preparatory phase, envisages that the Ministry of Health issues a permit for export and/or import of controlled psychoactive substances to a legal person that has the license for manufacturing and trade of controlled psychoactive substances.

- medical products - in accordance with the Law on Medicines and Medical Devices In accordance with this Law, the wholesale of medicinal products (import, export, purchase, storage and distribution) may be dealt with only by legal entities which have a wholesale license issued by the Ministry of Health and who meet the requirements prescribed by this Law and regulations adopted for its implementation.

However, a legal entity that performs only the activities of import or export of drugs may perform these activities on condition that it performs import and clearance of medicines on behalf of the holder of a wholesale permit for medicinal products to the site of release of goods for free circulation, in accordance with customs regulations. Legal person that performs only the activities of import or export of medicines is not required to have a permit for wholesale of medicinal products, nor a storage capacity, since it is not considered a holder of a wholesale permit for medicinal products.

Drug manufacturer based in the Republic of Serbia may import or export medicines from its product range, the starting materials for production, intermediate products and ingredients, in accordance with the law.

In addition, cases when it is necessary to obtain permits / licenses for the manufacturing, wholesale, marketing (or registration) in order to obtain the right to engage in import of certain products are also identified in other sectors:

- sources of ionizing radiation, radioactive and nuclear materials - in accordance with the Law on Protection against Ionizing Radiation and Nuclear Safety (OG RS 36/09)
- sporting and hunting weapons and ammunition - the Law on Weapons and Ammunition (OG RS 9/92, 53/93, 67/93, 48/94, 44/98, 39/2003, 101/2005 – other law and 85/2005 – other law law).
- weapons, military equipment and dual-use goods - in accordance with the Law on Foreign Trade in Weapons, Military Equipment and Dual-Use (OJ SAM 7/05 and 8/05-correction)
- tobacco, processed tobacco and tobacco products - in accordance with the Law on Tobacco (OG RS 101/05 and 90/07)
- waste - in accordance with the Law on Waste Management (OG RS, 36/09, 88/2010)
- protected animal and plant species - in accordance with the Law on Nature Protection (OG RS 36/09, 91/2010 update)
- substances that deplete the ozone layer - in accordance with the Law on Air Protection (OG RS 36/09)
- seeds and seedlings - the Seed Law (Official Gazette RS No 45/05 and 30/10-other law), Law on Seedlings of fruit trees, vines and hops (Official Gazette RS No. 18/05 and 30/10).

**m) Which create monopolies of sale of some goods (e.g. tobacco products, alcohol products etc)?**

There are no such provisions in the legislation of the Republic of Serbia.

**n) Which reserve certain trade names for domestic products alone and, if so, on what conditions (e.g. rules which reserve the use of a certain description to products prepared in your country from domestic raw materials)?**

Article 57, paragraph 1 of the Law on Appellations of Origin prescribes which actions related to the use of the registered geographical indication are considered illegal.

Persons who do not have the status of authorised users of geographical indications may not:

- 1) use the registered name of origin and/or registered geographical indications for marking products to which the appellations of origin does not apply, if the products are similar to products that are marked by registered geographical indications, or if such use violates the reputation of the protected geographical indication;
- 2) copy or support the registered appellations of origin, and use translation, transcription or transliteration of a registered geographical indication, even if to the designation of geographic origin are added the words "kind", "type", "style", "imitation" and if the mentioned geographical origin of products is true;

3) use in packaging, marketing materials or documents, false or deceptive indication of geographical origin, nature or quality of products, which may create confusion regarding the origin of product;

4) perform any other activities which may create confusion in the trade as to the actual origin of the product.

Article 84, paragraph 1 of the above mentioned Law prescribes that in respect of geographical indications that are registered in the European Community in accordance with regulations of the European Union, which represent common phrases in common use for certain products in the Republic of Serbia, the provision of Article 57, paragraph 1, shall be implemented three years from the date of entry into force of the Interim Agreement on Trade and Trade Related Matters between the European Community and the Republic of Serbia.

Consequently, local manufacturers which are using in trade the label registered as geographical indications in the European Community, which in the Republic of Serbia represents a common term in general use, shall be obliged to remove this tag from their products during the transitional period of three years from the entry into force of the Interim Agreement on Trade and Trade Related Matters between the European Community and the Republic of Serbia.

**40. Do you have any information on the number of times your authorities intervened to prohibit the marketing of products or withdraw products from the market for any reason over the last 2 years, e.g. health risk, incomplete labelling, inadequate consumer information, failure to comply with compulsory standards etc?**

Statistical data of Market Inspection Sector related to incomplete labelling, inadequate information for customers and non-compliance with certain standards designated by certain groups of products are given in Annex 1.19.

Veterinary inspectors, while carrying out official controls in the cultivation, production and trade of animals, animal products and foods of animal origin, animal feed, medicines and medical products for use in veterinary medicine and related subjects, prepare reports on the current situation, prohibit sales of defective products (for health reasons, poor quality, improper labelling, etc.), make decisions on the procedure of established non conformity and file complaints for economic offences, infractions and criminal charges.

The monthly and annual reports on the work of veterinary inspectors provide information on the withdrawal and cancellation of goods that are under veterinary and sanitary surveillance. As one of these tables, enclosed is an Excel table for 2008 and 2009 (Annex 1.20).

The work of Border Veterinary Inspection in the international trade of goods, for 2008 eliminated from the market a total of 84 defective items - of which eight consignments of animals, 65 product packages and 11 packages of food for animals. In 2009, out of the total of 61 defective shipments there were 3 consignments of animals, 48 product packages and 10 packages of food for animals.

During the past two years the Border phytosanitary inspection conducted the interception of shipments of plants, plant nutrition and plant protection products, as well as food for animals and feed of plant origin that are subject to the Law on Food Safety (Table 1).

Table 1

Year	Treated	Destroyed	Returned	Returned (food safety)	Total No. of shipments
2008	39	36	189	-	264

2009	19	19	69	24	131
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During this period the main reasons for the interception were: incomplete documentation (inadequately completed phytosanitary certificate), presence of harmful organisms, and/or quality none complied with the prescribed.

#### Phytosanitary Inspection

In domestic trade, in the past two years withdrawal from circulation and appropriation of seeds, seedlings, plant protection products and plant nutrition products was carried out, as well as adoption of certain measures as in Table 2.

Table 2

Year	Decision on measures ordered	Complaint filed with the Offence Court	Complaint filed for economic offence	Criminal charges
2008	2932	382	142	65
2009	1268	293	101	24

The main reasons for these measures refer to declarations with exceeded expiration date, expired duration of the declaration, inadequate quality.

#### **41. What are the general rules applicable in your country to non-food products? For example, is the marketing of products with a label and instructions written in a foreign language allowed? What particulars must be mentioned on the label of any industrial product intended for sale to consumers?**

The Law on Trade in Article 40 stipulates that the goods in retail trade (goods intended for consumers and natural persons who buy goods in order to meet personal needs or the needs of the household) must have a declaration containing information about the name and type of goods, content and quantity, as well as other information in accordance with special regulations and the nature of goods, especially information about the manufacturer, country of origin, production date and expiration date, the importer, the quality (class), and warning of potential hazard or harm posed by the goods.

The declaration shall be placed on goods and/or on its packaging (including the pendant, label, ring, cover) or directly next to the goods at the point of sale (e.g. goods in bulk) in accordance with the particular characteristics of goods, featured prominently, and in the catalogue or other material with the offer of the goods which is freely available to consumers at the point of sale, before purchasing. This information must be provided in a clear, easily visible and legible manner, in the Serbian language, in Cyrillic or Latin alphabet.

The declaration may also contain information in foreign languages, as well as trademark, GTIN identification (bar code) and other data more closely identifying the goods and its properties. In the same article it is stipulated that as the country of origin the European Union (EU) may be stated, in accordance with the rules of origin of goods.

The Law on Consumer Protection in Article 16 prescribes the duty of informing the consumer, and/or natural person who obtains goods or services on the market for purposes not intended for

its business or other commercial activities, before concluding the contract. Trader - legal or natural person acting in the market as part of its business or other commercial purposes, shall, before the conclusion of a contract of sale of goods or provision of services, inform the consumer in a clear and comprehensible manner of all important elements for making a decision on purchase:

- 1 basic characteristics of goods or services;
- 2 address and other data relevant to establishing the identity of the trader, such as the name of the trader or the name of another trader in whose name the trader acts;
- 3 sale price or the manner in which the sales price shall be calculated if due to the product's nature the sale price can not be determined, as well as on any additional shipment, transport and delivery costs and the possibility that these costs may be made at the expense of consumer;
- 4 payment method, manner and deadline of delivery, method of enforcement of other contractual obligations, and procedure in case of consumer complaints;
- 5 existence of consumers' rights to unilaterally terminate the contract under the conditions prescribed by this Law;
- 6 support that the trader provides to the consumer after the sale, by contractual guarantees and conditions under which the consumer is entitled to the contractual guarantee;
- 7 period of validity of the contract if it was concluded for a limited period of time, and if the contract is concluded for an indefinite period on the terms and conditions for terminating the contract;
- 8 minimum duration of the contractual obligation of the consumer if it is necessary to determine its duration;
- 9 obligation of the consumer to provide any form of insurance at the request of the trader and the conditions under which such obligation exists.

Trader is not obliged to inform consumers about the information provided in paragraph 1 of this Article, if these details apparently arise from the circumstances of stipulation of the contract of sale of goods or services.

In the case of public auctions, a trader may, instead of providing information about the data specified in paragraph 1, point 2) of this Article, inform consumers about the address and data which are important for establishing the identity of the auctioneer.

If a trader and a consumer enter into a contract of sale of goods or services, the information specified in paragraph 1 of this Article shall become its integral part.

The burden of proof regarding fulfilment of the obligation to inform consumers of the information referred to in paragraph 1 of this Article lies with the trader.

Trader is obliged to clearly and unambiguously declare a commercial purpose of informing consumers about the information under paragraph 1 of this Article.

If at the conclusion of the consumer contract the trader fails to comply with the obligation of notification under paragraph 1 of this Article, the consumer may request annulment of the contract, regardless of whether the trader intended to induce the customer to conclude the contract by omitting to provide proper information. The right to request annulment of the contract shall cease one year after the date of contract signing.

## ***B. Return of unlawfully removed cultural objects***

### **42. Do you have legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State?**

For the return of cultural property illegally removed from the territory of other countries the Law on Customs (26 March 2010, Official Gazette RS, No. 18/2010) shall be applied. In addition, the Republic of Serbia is a signatory of relevant international conventions, which, inter alia, regulate this area: The 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, ratified by the SFRY Federal Executive Council Regulation No. RS 83 of 31 May 1972 (Official Journal SFRY - International Treaties, No. 50/73) and the Convention for the Protection of Cultural Property in the Event of Armed Conflict, UNESCO 1954, ratified by the Federal National Assembly under No. PR No. 33 of 29 December 1955 (Official Journal of FPRY, Annex No. 4 / 56),

### **43. What are the legal provisions ensuring the return of cultural goods in your country?**

The Convention on the Means of Prohibiting and Preventing the Illicit Import and Transfer of Ownership of Cultural Property provides that States Parties to this Convention - Official Journal of SFRY, International Agreements, No. 50/73 (including Serbia) shall, inter alia, take appropriate measures, on request of the country of origin, member of the Convention, to seize and return any stolen and imported cultural property. Requests for seizure and return shall be addressed to the requested country through diplomatic channels. The requesting Party shall, at its own expense, present the documentation and all evidence necessary to justify its request for seizure and return. The Parties shall impose no customs duties or other charges upon cultural property returned. All expenses incident to the return of cultural property or cultural properties shall be borne by the requesting state. Under Article 8 of the Convention, States Parties to the Convention committed themselves to impose criminal penalties or administrative sanctions on any person responsible for infringing the prohibitions referred to in this Convention. While Article 13 of the Convention provides that States Parties to this Convention under the laws of each State shall prevent by all appropriate means transfers of ownership of cultural property likely to promote the illicit import or export of such property, they shall ensure that their competent services co-operate in order to facilitate the earliest possible restitution of illegally exported cultural property to its rightful owners, etc.

However, the Convention on the Means of Prohibiting and Preventing the Illicit Import and Transfer of Ownership of Cultural Property does not prescribe the manner of return of goods, except the provision that the request for return of goods is sent through diplomatic channels.

Bearing in mind Article 250 of the Law on Customs, the above-mentioned provisions of the Convention on the Means of Prohibiting and Preventing the Illicit Import and Transfer of Ownership of Cultural Property, upon proposal by the Customs Administration, provided that the competent authority / authorities (Ministry of Culture, and others) agree that there are no obstacles to returning the seized cultural goods to the territory from which it was stolen, the Government of the Republic of Serbia, under Article 43 of the Law on Government (Official Gazette of RS, No. 55/05, 71/05- correction, 101/07 and 65/08) shall adopt an act on the restitution of cultural property.

Also, under the provisions of Article 83, paragraph 1 of the Law on Customs, for such goods the customs-approved treatment or use may be determined, regardless of its type or quantity, origin, destination or way of shipping, unless otherwise provided by this Law.

However, paragraph 2 of the same article stipulates, inter alia, that exceptional customs-approved treatment or use of goods shall not be determined if it is in conflict with the measures set out for the protection of natural rarities, cultural heritage, artistic, historical, archaeological, ethnological or technological values, protection of copyright and other related rights.

Also, the provisions of Article 100 of the Law on Customs provide, inter alia, that the customs authority may take necessary measures, including the return of goods abroad, seizure and sale of goods, if goods can not be released to the declarant because the goods are subject to bans or restrictions.

**44. If such legislation exists, what categories of cultural goods are covered?**

All categories are covered by the ratified conventions listed in the questions under No. 42 and 43.

**45. Which is the central authority, if any, responsible for dealing with the return of cultural goods?**

The Government of the Republic of Serbia, under Article 43 of the Law on Government (Official Gazette of RS, No. 55/05, 71/05- correction, 101/07 and 65/08) may adopt an act of restitution of cultural property, in accordance with the Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property.

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

Set of laws that will regulate the protection of cultural heritage will be adopted, according to the plan of the Government of the Republic of Serbia for the harmonisation of legislation with the EU not later than 2014.

The National Programme for Integration (NPI) includes the following EU regulations with which compliance will be made in this field:

- COUNCIL DIRECTIVE 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State
- COUNCIL REGULATION (EEC) N° 3911/92 of 9 December 1992 on the export of cultural goods
- COUNCIL REGULATION (EC) No 2469/96 of 16 December 1996 amending the Annex to Regulation (EEC) No 3911/92 on the export of cultural goods
- COMMISSION REGULATION (EC) No 1526/98 of 16 July 1998 amending Commission Regulation (EEC) No 752/93 laying down provisions for the implementation of Council Regulation (EEC) No 3911/92 on the export of cultural goods
- COUNCIL REGULATION (EC) No 974/2001 of 14 May 2001 amending Regulation (EEC) No 3911/92 on the export of cultural goods

- COMMISSION REGULATION (EC) No 656/2004 of 7 April 2004 amending Regulation (EEC) No 752/93 laying down provisions for the implementation of Council Regulation (EEC) No 3911/92 on the export of cultural goods
- Council Resolution of 21 January 2002 on the Commission report on the implementation of Regulation (EEC) No 3911/92 on the export of cultural goods and Directive 93/7/EEC on the return of cultural objects unlawfully removed from the territory of a Member State
- COMMISSION REGULATION (EEC) No 752/93 of 30 March 1993 laying down provisions for the implementation of Council Regulation (EEC) No 3911/92 on the export of cultural goods
- DIRECTIVE 96/100/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 February 1997 amending the Annex to Directive 93/7/EEC on the return of cultural objects unlawfully removed from the territory of a Member State
- Council Regulation (EC) No 116/2009 of 18 December 2008 on the export of cultural goods (Codified version).

### ***C. Control of the acquisition and possession of weapons***

#### **47. Do you have legislation providing for the control of the acquisition and possession of weapons? Please explain and summarise.**

Republic of Serbia, under its Law on Weapons and Ammunition (Official Gazette of RS, No. 9/92, 53/93, 67/93, 48/94, 44/98, 39/2003, 85/2005 and 101/2005), and the Regulation on detailed conditions of performing, the manner of implementation and training programme for the handling of firearms (Official Gazette of RS, No. 1/99 and 30/2000), Regulation on detailed conditions and manner of storage of weapons and ammunition (Official Gazette of RS, No. 1/99) and the Regulations on the application form, approval, weapon certificate and other documents and records provided by the Law on Weapons and Ammunition (Official Gazette of RS, No. 1/99), regulates the acquisition, holding, carrying, sale, transport, repair and conversion of weapons, parts of weapons and ammunition. Provisions of the Law on Weapons and Ammunition apply also to foreign citizens who have been granted permanent residence or temporary residence of more than one year, if not otherwise provided by an international agreement.

The above mentioned Law on Weapons and Ammunition:

- Defines what is considered a weapon, by the types (firearms, air guns, gas guns, fragmentation weapons, special weapons, weapons with a chord, stabbing weapons). The same law provided for the classification of weapons according to the purpose and specific types (weapon for personal safety, hunting guns, sporting guns, antique guns, antique weapons and combined arms );
- Defines a weapon whose distribution, acquisition, holding, carrying, repair and alteration is prohibited;
- Determines the conditions under which approval for the acquisition will not be issued;
- Determines the conditions under which a permit to carry weapons for personal security is issued;
- Determines the obligation of the Ministry of the Interior to keep records of submitted applications and issued permits to obtain weapons and ammunition, issued weapon documents and permits for holding firearms, seized, found and surrendered weapons, parts for weapons and ammunition, reported old weapons and weapons with tendon.

Law on Weapons and Ammunition regulates in detail the following issues: acquisition, possession, carrying weapons and ammunition, handling of weapons and ammunition, seizure of weapons and ammunition, repair and conversion of weapons, traffic of arms and ammunition, transportation of arms and ammunition, monitoring and recording. This law also stipulates offences and offences for violations of the Law.

Criminal Law of the Republic of Serbia (Official Gazette of RS, No. 85/2005), under Article 347 stipulates a criminal offence of Manufacturing and procurement of weapons and means for the execution of criminal acts, which sanctioned that anyone manufacturing, supplying, or enabling others to procure weapons, explosives, means required for their production or toxin that is known to be intended for committing criminal offence, shall be punished with imprisonment from six months to five years, while Article 348 of the same Law stipulates illicit possession of weapons and explosives as criminal offence. The above mentioned Article of this Law stipulates that anyone who illegally manufactures, sells, purchases, exchanges, or possesses firearms, their parts, ammunition or explosives, shall be punished with imprisonment from three months to three years and a fine. If the subject of criminal offence is firearms, ammunition, explosive substance or product based on these materials, fragmentation or gas weapons whose manufacture, sale, purchase, exchange, or possession is not permitted to citizens, the offender shall be punished with imprisonment from six months to five years or a fine. If the subject of criminal offence is a larger quantity of weapons, ammunition or means, or it is a weapon or other means of great destructive power, or the offence is made contrary to the rules of international law, the offender shall be punished with imprisonment from one to eight years. Whoever unlawfully carries objects pertaining to the offence of this Article shall be punished with imprisonment from two to twelve years. Firearms, their parts and ammunition, and explosive materials, shall be seized.

In the Criminal Police Administration of the Ministry of the Interior of the Republic of Serbia, in the Department for Combatting Organised Crime, a Section for combatting weapons smuggling has been established. While performing operational activities, each police officer who finds, during inspection or search, illegal weapons, shall seize it along with issuing a confirmation of the temporary seizure of objects and shall file a criminal complaint against such person to the competent public prosecutor's office. If it is an organised criminal group, the complaint shall be filed to the Office of the Prosecutor for organised crime.

**48. Is there a legislation laying down the categories of firearms the acquisition and possession of which by private persons is either prohibited or subject to authorisation or declaration?**

Law on Firearms and Ammunition prohibits sales, purchase, possession, carrying, repair and alteration of a firearm with devices for noise suppression, noise suppression devices, telescopic sights with light beam, or a device for the electronic amplification of light or infra-red device, fragmentation and gas weapons and gadgets that are not designed and adapted as a firearm. Moreover, for natural person's acquisition, holding and carrying semi-automatic and combined long shot guns, except for hunting, as well as acquisition, holding and carrying automatic long firearms, automatic and combined short weapons and special weapons are forbidden. It is forbidden to carry weapons for personal security without permit. Wearing of hunting, sporting

and special weapons outside the grounds, facilities of shooting organisations and other special facilities is forbidden.

Firearms for personal safety (pistols and revolvers calibre 5.6 mm and larger calibres), hunting guns (hunting rifles with bordered and non-bordered pipes), sporting firearms (rifles, pistols and revolvers of high-calibre set up for sporting purposes, small-calibre rifles and revolvers and small calibre 5.6 mm pistols, air rifles and air pistols and revolvers and guns with the chord) may be procured only with the approval issued by the Ministry of the Interior. Parts for these weapons and ammunition for the weapons with bordered tubes may be purchased only with the approval of the competent authority, for the type of weapon the weapon certificate was issued for. Ammunition for firearms with non-rounded pipes may be procured on the basis of weapon certificate issued for such weapon.

Old weapons may be procured and kept with the prior registration at the Ministry of the Interior.

#### **49. If the legislation is in force:**

##### **a) Which categories of firearms are covered? Do you make distinctions between “civil” firearms and “military” firearms?**

Firearms, in accordance with the Law on Weapons and Ammunition, comprises all types of rifles, pistols and revolvers, and all types of devices that expel projectile through propulsion of gunpowder or other gases generated as a product of propellants combustion.

Firearms regulated by the Law on Weapons and Ammunition, are the following:

- weapon for personal safety, comprising guns and revolvers, calibre 5.6 mm and larger calibre;
- automatic and semi-automatic short and long arms;
- hunting weapons comprising hunting rifles of various calibres with rounded and non-rounded pipes;
- sporting weapons comprising guns, pistols and revolvers of high-calibre set up for sporting purposes, small-calibre rifles and revolvers, and small calibre 5.6 mm pistols;
- old weapons.

Law on Weapons and Ammunition particularly prescribes conditions for the possession of military weapons, and Article 17 provides that the approval for obtaining and keeping military weapons, both automatic and semiautomatic weapons, except automatic handguns, may be issued to authorities, enterprises, institutions and other legal persons that are directly engaged in activities related to physical security and protection of facilities, for carrying out activities within their scope of work.

Under Article 5 of the Law on Weapons and Ammunition, for natural persons the acquisition, holding and carrying semi-automatic and combined long shot guns, except for hunting, as well as acquisition, holding and carrying automatic long firearms, automatic and combined short weapons and special weapons are forbidden.

##### **b) Which are the conditions necessary to be fulfilled in order to obtain the authorisation?**

Law on Firearms and Ammunition stipulates that the approval for the acquisition of arms, weapon certificate for possession and carrying firearms may be issued to citizens who are of legal age, trained in handling firearms, able to conduct business, not sentenced to unconditional imprisonment for criminal acts with elements of violence, or punished in the past three years from the date of application for violations of the Law on Public Order and the Law on Weapons

and Ammunition, as well as those against whom no criminal proceeding or infringement are instituted.

In the process of issuing approvals for purchase of weapons, the competent authority of the Ministry of the Interior, ex officio, shall verify that all the above conditions are met and shall decide on the application form.

**c) What kind of information must be given in the declaration?**

Regulation on the application forms, approval, weapon certificate and other documents and records prescribed by the Law on Weapons and Ammunition, stipulates that the request form for purchase, possession and carrying of weapons is of 297x210 mm dimensions and consists of two sides.

The first page is filled by the applicant with the following information: identification number, family name and name, name of a parent, birth date, gender, community and place of birth, nationality, occupation, possession of weapon already, residence and address, information on weapons for which the application is submitted, or for which the weapon certificate is issued. Part of the form filled out by an official of the Ministry refers to the outcome of the request for approval for weapon purchase, and to the previously issued weapon certificate and confiscated weapons.

When applying for approval for purchase and possession of weapons, natural persons shall enclose a certificate proving that no criminal proceedings are instituted against them, and a certificate proving they are trained in handling firearms.

**50. Are there any special rules for collectors and bodies concerned with the cultural and historical aspects of weapons? If so must these collectors and bodies be recognised by the local authorities?**

Law on Weapons and Ammunition regulates the matters of antique firearms, comprising shooting and stabbing weapons, which are kept from the times of national uprisings and liberation wars, or represent a personal or family trophy of the owner. Trophy weapons and obsolete weapons that no longer fit for use may be kept under the approval of the Ministry of the Interior.

Law on Weapons and Ammunition stipulates that old weapons comprise rifles, pistols, sabers, swords and other weapons which are no longer in use and has a historical or artistic value. Old weapons may be procured and kept with the prior registration at the Ministry of the Interior.

Law on Cultural Property (Official Gazette of RS, No. 71/94) does not recognise collectibles, but only regulates museum collections and it is referred to in Article 98, which reads as follows: "The museum collection consists of a set of artistic and historical works, of similar nature or comprising different kinds. Museum collection may be held by institutions, enterprises and other organisations and individuals. Museum collection may be open to the public only if previously professionally examined and catalogued, and exhibited under expert supervision. Exhibition of the museum collection is approved by the museum entrusted with the protection of cultural activities and historical works in the specific territory."

**51. Does the legislation, if any, exclude from its scope weapons and ammunition used for hunting or target shooting? If so, what rules are applied?**

Law on Weapons and Ammunition regulates the matter of weapons and ammunition used for hunting and target shooting.

Approval for the purchase of hunting and sporting weapons may be issued to a natural person provided it meets the conditions for the purchase of weapons under the Law on Weapons and Ammunition.

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

Ministry of the Interior will in 2011 engage in the preparation of the Draft Law on Weapons and Ammunition, which will be aligned with the following international regulations:

- United Nations Firearms Protocol;
- European Directive on Firearms, No 477/91 and
- The Schengen Agreement.

**53. Do you have an overall obligation to mark firearms at the time of manufacturing? What kind of marking do you apply?**

Firearms, ammunition, ammunition components, devices as well as refurbished firearms and devices, are prior to, before marketed, testing, labelling and marking, in accordance with the Law on Examining, Labelling and Marking of Firearms and Ammunition (Official Gazette of the Republic of Serbia No. 46/95).

The following firearms, ammunition and ammunition components are not subject to examining, labelling and marking:

- Imported from abroad, and which are determined to be tested, labelled and marked in a manner and under the procedures established by International Agreement on the Establishment of Uniform Procedures for the Mutual Recognition of Official Designation for examined Firearm;
- Imported from abroad exclusively for research and judicial purposes;
- Intended for exclusive use by the Army of Serbia and Ministry of the Interior;
- Which are in transit transport across the territory of the Republic of Serbia and
- For which the regulations on safety at work prescribe an obligation of certificate issuing.

It is forbidden to traffic in firearms, ammunition, ammunition components, devices, and refurbished firearms and devices that are not tested, labelled and marked properly.

Testing, labelling and marking of firearms, ammunition, ammunition components and devices is made for verification or confirmation of their safety and quality according to standards, technical standards and quality norms.

Ammunition and ammunition components, for which the test procedure met the prescribed requirements, are labelled.

Labelling of ammunition and ammunition components is done in such way that in each package of ammunition of the same series that sample testing has shown to have met the requirements, written certificate of survey is inserted, and special label (banderol) is put to each package. Certificate of survey contains a particular character for the tested type of ammunition or ammunition component.

Testing, labelling and marking of firearms, ammunition, ammunition components and devices is entrusted to Institute for testing and labelling of hand firearms and ammunition from Kragujevac. The jobs of testing, labelling and marking the Institute can not entrust to another company, or other legal entity.

Testing of firearms, ammunition, ammunition components and devices as well as refurbished firearms and devices and their labelling and marking, when determined to meet the given requirements, the Institute shall execute within 30 days from the day of receipt.

Companies or stores registered for repairing and alteration of firearms, must submit the altered firearm to Institute within 15 days from the day of alteration, for testing, labelling and marking.

**54. Do you have record-keeping obligations to trace transfers of firearms when manufactured or sold by dealers? Who has this obligation (the State, the dealers)? For how many years?**

Rulebook on application forms, approval, weapon certificate and other documents and records (Official Gazette of RS” No. 1/99) given in Law on Firearms and Ammunition (Official Gazette of RS” No. 9/92, 53/93, 67/93, 48/94, 44/98, 39/2003, 85/2005, and 101/2005), specifies: Application forms, approvals and permit for purchase, possession, carrying and transfer of firearms, parts for firearms and ammunition; forms for the weapon certificate issued for possession and carrying of firearms, or keeping the firearms for personal safety; permit to carry the firearms for personal safety; records on firearm, firearm parts and ammunition trafficking, repaired and refurbished firearms, firearms for state and other agencies, companies, organizations and institutions and other legal entities that possess firearms and ammunition to carry out their activities; records of submitted applications and issued permits to purchase firearms and ammunition, issues weapons certificates and permits for firearm possession, seized and turned firearms, firearm parts and ammunition governed by competent authority.

State and other authorities, companies, organizations, institutions, other legal entities and stores, keep the record in the registers on following formats:

- register of purchased firearm and firearm parts is kept in the form “Form No. 19”;
- register of purchased ammunition is kept in the form “Form No. 20”;
- register of sold firearm and firearm parts is kept in the form “Form No. 21”;
- register of sold ammunition is kept in the form “Form No. 22”;
- register of repaired and refurbished firearm and spent ammunition for testing the safety and accuracy of firearms is kept in the form “Form No. 23”;
- register of firearms and ammunition of the public and other authorities, companies, organizations and other legal entities is kept in the form “Form No. 24” and
- register of persons trained for handling firearms and issued certificates is kept in the form “Form No. 25”;

Ministry of the Interior shall keep proper record in the registers that are made in the following formats:

- register of applications and approvals issued for purchasing the firearms and firearm parts is kept in the form “Form No. 26”;
- register of applications and issued permits for purchasing ammunition is kept in the form “Form No. 27”;
- register of issued weapon certificates, permits for trophy firearms and permits for firearm possession for legal entities is kept in the form “Form No. 28”;

- register of issued permits for carrying firearms for personal safety is kept in the form “Form No. 29”;
- register of seized, found and handed firearms, firearm parts ammunition is kept in the form “Form No. 30”; and
- register of reported antique firearms is kept in the form “Form No. 31”;

All registers shall be kept permanently in both written and electronic form.

**55. How are the firearms tested at the time of manufacturing? Do you have a state proof houses?**

Testing the weapons is not under the Ministry of Interior, but the Institute (Proofhouse) for testing of firearms and ammunition from Kragujevac.

Rulebook on the conditions, manner and procedure for testing, marking and labelling of firearms and ammunition (Official Gazette of RS, No. 28/96) prescribes the manner of testing of weapons and ammunition, which is carried out by the Institute. The test results provided by the Institute, in the period from 1973 to 1992, were internationally recognized by the membership of the former Yugoslavia in the Permanent International Commission for Firearms Testing (C.I.P.), and in accordance with the 'Convention for the Reciprocal Recognition of Proof Marks of Small-Arms, from 1 July 1969'.

In order to re-accede to this Convention, there is an initiative to amend the existing legislation, that is, to adopt new Law on testing of firearms, devices and ammunition.

**56. What are your main requirements to “deactivate/neutralize” a firearm? What techniques do you use?**

The Republic of Serbia, in accordance with law regulations, does not deactivate, but neutralize (destroy) firearms. By doing the control in matters related to stockpile management of firearms in possession of the state, the Republic of Serbia conducts removal of its surpluses.

Based on the project of the Ministry of Interior of the Republic of Serbia and international organizations UNDP (United Nations – Development Programme) and SEESAC (The South Eastern Clearinghouse for the Control of Small Arms and light Weapons), following destructions of firearms and ammunition were taken:

- 2003, total of 11 228 pieces of firearms and 42 000 pieces of ammunition were destroyed.
- 2004 in the old steel plant in Smederevo, 9621 pieces of firearms were destroyed by melting into blast furnace.
- 2005, based on above mentioned cooperation, destruction of at least 7018 pieces of firearms was done in the plant “US STEEL” in Smederevo.
- 2006, destruction of the 7916 pieces of firearms that were in possession of the state was carried out in steel plant “US STEEL
- 2009, on two occasions, this Ministry carried out the destruction of 27000 pieces of firearms in Recycling Centre in Železnik.
- 2010, the destruction of 28285 pieces of firearms was carried out in Recycling Centre Belgrade in Železnik.

The Ministry will continue to carry out such actions.

During 1992, 1997, 1999, 2003, and 2007 the Ministry carried out the procedure for legalization of illegal weapons, and during this period, citizens handed over around 100 000 pieces of various weapons.

**57. Have you statistics about legal holders of firearms in your country (hunters, marksmen, private persons or companies)?**

Ministry of Interior holds the unique database of records of small arms and light weapons in legal possession, which is kept in both written and electronic form. According to the newest statistic data of this Ministry, as of 01.12.2010 a total of 1, 189 522 pieces of firearms were registered, out of which 3, 304 legal entities that have 44, 659 pieces of firearms in possession, and 586, 258 individuals that have 1, 144 863 pieces of firearms in possession, as follows:

- firearms for personal safety of individuals (guns and revolvers) 522 285 pieces;
- firearms for security and protection of facilities of legal entities (automatic weapons, guns and revolvers...) 35, 484 pieces;
- hunting firearms (rifles, carbines, combined firearms) 524, 445 pieces;
- sporting firearms (small arms and air guns) 104, 901 pieces and
- specialized firearms (signalling, starting weapons and other devices) 445 pieces.

The Ministry has accurate data in electronic and written records on amount, type and purpose of a firearm for every individual and legal entity.

***D. Checks for conformity with the rules on product safety in the case of products imported from third countries***

**58. Do you have legislation providing for conformity with the rules on product safety in the case of imported products? If so:**

**a) Since when has it been in force?**

As of 11 December 2009, the Law on General Product Safety is applied (Official Gazette of RS, No. 41/09), which ensures conformity of the product with the general safety requirement and applies to all products, except for products which safety is defined by special regulations. This law makes no distinction regarding the safety requirements of domestic and imported products.

**b) Please describe its broad outlines (which service is responsible for border controls and co-ordination regarding imported products, what is the procedure provided for etc?)**

Customs Administration is responsible for border control.

In accordance with Article 17, paragraph 3 3. of the Law on General Product Safety, it is prescribed that:

"The competent customs authority shall not permit the import of products or product series (group, batch, lot, etc.) not accompanied by required documentation of compliance with the requirements for product safety, or that are not marked with the prescribed conformity mark with the requirements for product safety.

If the competent customs authority establishes that, regardless of the existence of documents and marks referred to in paragraph 4 of this Article, a product raises well-founded doubt in terms of posing a serious risk to health and safety of consumers and other users, it shall immediately inform the competent inspection body thereto."

Competent authorities are obliged to cooperate in order to ensure effective surveillance. Their obligation to cooperate on the matters of market surveillance is based on Article 21 21. Law on General Product Safety, which is binding upon market surveillance authorities to rapidly exchange information on hazardous products, including imported products posing a serious risk and any other risks to health and safety of our customers. Coordination in this system is ensured by the Ministry of Trade and Services through the Market Inspection - Contact Point.