REPUBLIC OF SERBIA
Ministry of Finance and Economy

SERBIAN HORIZONTAL LEGAL FRAMEWORK IN THE FIELD OF QUALITY INFRASTRUCTURE

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Belgrade, 2012.

Content

Foreword

Dear readers,

As a result of completing a legal and institutional framework of the new modern Quality Infrastructure (QI) system in Republic of Serbia, all stakeholders who play a role in this area, will be provided and assisted with guidelines through the serial of handbooks for implementation of specific rulebooks, in all phases of the legal implementation. Three years ago, Ministry of Economy and Regional Development (MoERD)[1], Sector for QI, supported by technical assistance of GTZ (now GIZ - Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH), through PLAC Project, prepared a translation of referent documents published in so called "green book" that had been of enormous significance for the regulator, in the process of drafting new "QI laws"; today, the new serial of handbooks for implementation of specific rulebooks, done in cooperation between GIZ ACCESS (ACCESS - Program for private Sector Development) and MoERD will assist the stakeholders to implement the new "QI laws". Due to the significant support and efforts of GIZ, these activities will help the MoERD in strategic policy making in respected areas.

In last period, MoERD together with QI institutions has been intensively working on establishing a new structure of QI. Due to the efforts of the MoERD - Sector for QI, four crucial laws in this field (*Law on technical requirements for products and conformity assessment, Law on standardization, Law on accreditation and Law on metrology*) are now in place, as four pillars of the new QI structure, as well as more than 40 bylaws for its implementation. We also have transposed New Approach Directives for certain industrial products into Serbian legal system and so we have got, new technical rules for machines, domestic appliances, lifts, personal protective equipment , that are equal to the ones valid for the same products in Europe. In this way, this kind of Serbian products will be safer and more competitive on European and world markets. In addition to that, almost 80% of European standards have been transposed into Serbian standards, a Multilateral Agreement between Serbian and European Accreditation has been signed and that will have an additional positive impact to the competitiveness of Serbian industry.

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1 Establishment of the new Government of the Republic of Serbia brought to a change in the structure of state authorities. Ministry of Economy and Regional Development has changed its name to the Ministry of Finance and Economy.

REPUBLIC OF SERBIA
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and Economy

Thanks to the gradual implementation of the new laws in QI area, today, Serbian industry is faced with new designated conformity assessment bodies for the assessment of industrial products, new authorized bodies for the verification of measuring instruments, new facilitated procedures, as far as imports, exports, production and conformity assessment are concerned. These are the reasons why all stakeholders in this field in the Republic of Serbia (consumer, producer, importer, exporter, the state) could be more relaxed and safe as regards compatible and competitive role of Serbian industry on European and world markets.

All details about the changes in the newly established QI system, you can find here, in this serial of handbooks for implementation of specific rulebooks. So, I wish you a pleasant journey through the lines of the whole serial of handbooks!

Jelena Popovic

Assistant Minister, Ministry of Finance and Economy

Foreword

Dear readers,

Serbia progressing earlier this year to a candidate - status country has already accomplished a significant part regarding the implementation of the Acquis Communautaire. Chapter one of Acquis contains also parts of the National Quality Infrastructure. The setting up of a state of the art Quality Infrastructure in Serbia is crucial for a functioning internal market, a precondition for placing safe goods and services, strengthening consumer protection and enhancing Serbia´s competitiveness and export capabilities. This goal is a logical precondition to GIZ/ACCESS`s (GIZ - Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH; ACCESS - Program for Private Sector Development) overall objective of promoting the competitiveness of Serbian SME´s.

Four new laws introduced in Serbia can be seen as pillars of the QI. *Law on Accreditation, Law on Standardization, Law on Metrology* and the *Law on technical requirements for products and Conformity Assessment*, all recently effected enabling a state of the art operation of major QI Institutions.

Furthermore Ministry of Economy and Regional Development (MoERD) has transposed a significant number of important directives, s.a. *Rulebook on Electrical Equipment Designed for Use within Certain Voltage Limits, Rulebook on Electromagnetic Compatibility, Rulebook on the Safety of Lifts, Rulebook on Personal Protection Equipment, Rulebook on Machinery Safety*, whereas additional explanatory information on these directives was the very purpose when editing the handbooks for implementation of specific rulebooks.

Based on the aforementioned firm legal framework the development of the "National Quality Infrastructure" strategy lead by the MoERD has been started in 2011. In order to involve utmost competence in the developing process MoERD is supported in this endeavor by German Organizations s.a. GIZ, represented by the ACCESS program, PTB (Physikalisch-Technische Bundesanstalt - The German national metrology institute providing scientific and technical services) and many other reputed enterprises within the German NQI-landscape.

The NQI strategy development shall be module-structured leading to a "step by step" establishment of an overall NQI Strategy, adequate for governmental approval and later implementation. Beside the Strategy as the main goal several support measures to major QI institutions are part of the project. The partners in developing the Serbian NQI strategy have signed a MoU including a „concept note" defining partner activities between MoERD, GIZ ACCESS and PTB. The "concept note" however follows a twofold approach, namely a strategy-related and a support-related one. Of course enduring commitment over years is requested from all stakeholders in the process. The "government side" with its endeavor to continue with practicable and economy-friendly legislation as well as with the accessing of EU- financing for equipment in the conformity assessment area. The industry on the other hand shall be determined to permanently improve quality of products and services. GIZ/ACCESS program and its partners are highly committed to contribute on a long term base to the establishment of a functional National Quality Infrastructure and therefore envisages a three-phased program duration till 2019.

Whether you are an innovative industry, a Laboratory, Test-institute, Certification Body or an interested consumer or market inspector, these handbooks for implementation of specific rulebooks will provide you with an informative insight to the Serbian Quality Infrastructure.

Tobias Stolz
Head of GIZ ACCESS Program

SERBIAN HORIZONTAL LEGAL FRAMEWORK IN THE FIELD OF QUALITY INFRASTRUCTURE

Introduction

Three main goals will be achieved in the process of setting up the new and modern Quality Infrastructure system in Republic of Serbia as the key segment of internal market and free movement of goods,: **1. marketing of safe products underpinned by gradual removal of technical barriers to trade, 2. strengthening the consumer protection and 3. enhancing competitiveness of the Serbian economy.** Namely, after the entire Quality Infrastructure system has been put in place, Serbia will be a few steps closer to the EU integrations and its values thus having a direct positive impact on:

- Serbian economic operators who will be able to produce, import and export quality products conforming to the same safety and other technical requirements laid down for the production of EU products thus creating limited or no technical barriers to trade;
- Consumers who will have access only to safe products;
- State that will be able to simplify its control procedures related to the safety of products and to primarily establish adequate cooperation and coordination between Customs administration and Market Inspectorate.

After these goals have been achieved, Serbia will be able to become actively involved in trading with the European Union and world.

This publication is divided into five chapters. Chapter 1 deals with Quality Infrastructure in general terms, Quality Infrastructure components, and purpose of Quality Infrastructure; Chapter 2 provides readers with information about EU legislation in this field; Chapter 3 provides an insight into the novelties in the field of Quality Infrastructure that have been introduced into the Serbian legal system and about the mechanisms for its implementation thereof; Chapter 4 speaks of the implementation and impact of the new legal framework on the industry. Chapter 5 is a conclusion.

CHAPTER 1

1.1. What Is Quality Infrastructure

The system of primarily industrial production is based on the division of labour and international exchange of goods and commodities, demand that materials, components and production processes should conform to specified requirements in order to make a final product safe. Each country has to develop its own Quality Infrastructure system in order to reach the said goal, whereas this system will serve as a framework for upgrading the safety of marketed products.

Quality Infrastructure (hereinafter referred to as: QI) refers to all aspects of metrology, standardization, conformity assessment (testing, certification, inspection) and accreditation. This includes both public and private institutions and the regulatory framework within which they operate. Therefore, IQ requires existence of at least three institutions: National Standards Body, National Metrology Institute and National Accreditation Body, and numerous conformity assessment bodies (hereinafter referred to as: CABs) that are mainly privately-owned c; QI also requires a legal framework composed comprising umbrella laws governing QI and all necessary sub-laws for implementation thereof.

QI system underpins technical competence and compliance with national, European and relevant international safety and technical requirements. Nevertheless, the QI system is designed to be mainly **voluntary** (conformity to standards), but, under certain circumstances, it can be **mandatory** when **technical requirements** are observed given that they are prescribed by the regulatory bodies as mandatory. Thus we can make a distinction between voluntary and mandatory components of QI:

- **Industrial and scientific metrology and assessment of conformity to standards are always voluntary** *since they conform to standards (standards are always voluntary)*
- **Assessment of conformity to essential requirements** of the New Approach Directives **and legal metrology** ***are always mandatory.***

1.2. Components of Quality Infrastructure

QI System is comprised of four elements: standardization, metrology, conformity assessment, and accreditation.

Standardization shall mean a set of coordinated activities aimed at adoption of standards (and related documents)- definition from Article 3, paragraph 1), point 1 of the Law on Standardization.

Standard shall mean a publicly available document, defined by a consensus and adopted by a recognized body, which determines, for general and multiple use, the rules, requirements, characteristics, instructions, recommendations or guidelines for the activities or their results with the aim of achieving the optimal level of regulation in a specific area in relation to the current or potential problems - definition from Article 3, paragraph 1), point 2 of the Law on Standardization.

Metrology is a science that provides accurate and reliable measurements. Measurements have to be defined, described, published and traceable to international measurement standards. Nowadays, these are the tasks of a National Metrology Institute. As far as industrial metrology is concerned, traceability of measurement results is provided on a voluntary basis via a network of calibration laboratories which are accredited and hence proven competent. In the field of legal metrology, this task is performed by verification service that checks measuring instruments subject to legal control for compliance with the regulations.

Conformity assessment aims at prevention of mistakes from occurring and at provision of guarantee of product safety. Conformity assessment can be mandatory when the product must meet essential requirements of the directive/technical regulation that is transposed into the national legislation. Conformity assessment can also be voluntary when the product has to be in conformance with the requirements of standards.

There are several forms of conformity assessment:

Testing is the most common form of conformity assessment. When performing testing, **testing laboratories**, can determine the property values and other characteristics of the products in order to evaluate whether they are in line with the requirements of the standards and thus in line the relevant requirements of technical regulations (if compliance is mandatory) or whether they are only in line with the requirements of standards (if compliance is voluntary); testing laboratories issue **test reports** that do not have the same importance as a certificate.

Certification process is a process during which a products awarded a certificate following the assessment since compliance with the requirements of a standard and hence with the relevant requirements of a technical regulation - Directive (if the compliance is mandatory) has to be confirmed or after proving compliance with the requirements of a standard (if the compliance is voluntary); conformity assessment is performed by a **certification body** issuing a **certificate**.

In addition to testing and certification, conformity assessment also includes ***inspection, quality management system assessment etc.***

In addition to that, there are two main types of conformity assessment:

- **Conformity assessment not requiring third party verification** (first party assessment): in this case assessment of conformity to the requirements of a standard, technical (producer's) specification or regulation is carried out by **the producer organization itself**. This is actually, a type of self-assessment (internal production control) and the result of this assessment is known as **producer's declaration of conformity**.
- **Conformity assessment requiring third party verification** (third party assessment): in this case assessment of conformity to a standard, technical specification or regulation is performed by a **body that is independent of both producer and customer**. The result of this assessment is known as **inspection certificate/ or any other prescribed form of a certificate of conformity.** In case of EU Member States third party assessment is performed by notified bodies (for more information please read Chapter 2- New Approach and Global Approach); if the country is not an EU Member State , conformity assessment is performed by a third party which is a certification body or sometimes even an inspection body.

Accreditation is a formal recognition of technical competence of certification bodies, testing and calibration laboratories and inspection bodies that is performed by a national accreditation body. In other words, accreditation is based on the European and international standards and represents a procedure by which the entire process is deemed reliable and transparent and thus leading to international trade and competitiveness.

1.3. Integration Of The QI Components Into A National Quality Infrastructure System

Standardization, metrology, conformity assessment and accreditation comprise a national QI system. This system should be used for all industrial products and services and it should ensure their conformance with the requirements of regulators, clients, consumers and producers.

Firstly, consumer wants to make sure that a product is conformed to adequate requirements of a **standard**, and therefore conformed to prescribed technical requirements. Thus the product must be accompanied by relevant certificate that proves product compliance with given standards and thereby its compliance with technical requirements. This should be demonstrated by a **certification process**. ***Secondly***, certification process requires products to be **tested** in order to determine their conformance to relevant standards/ requirements of relevant New Approach directives. Product conformance is performed by **testing laboratories**. ***Thirdly***, technical competence of laboratories and certification bodies is confirmed by **accreditation bodies** thus providing a route map for gaining confidence of all involved parties in the results of the entire process. ***Fourthly***, testing laboratories must have capacities that will show that **their measurements** are reliable and hence **traceable to national standards,** and through national standards **to international standards**. Furthermore,

equipment must be properly calibrated if test results are to be trusted as this is one of the tasks in metrology.

The abovementioned paragraph provides an overview of QI components and their integration into a national QI system.

1.4. Why A National Quality Infrastructure System

Establishment of a national QI system in a country strives to attain a number of objectives. National QI system is:

a) a precondition for free movement of goods and removal of technical barriers to trade,

b) a main indicator for marketing of safe products,

c) a structure with a direct impact to innovation and competitiveness,

d) a precondition for the access to international markets,

e) an indicator of a level of consumer protection (health, safety, environmental protection),

f) a support to an economic development in general.

CHAPTER 2

2.1. QUALITY INFRASTRUCTURE AT THE EUROPEAN UNION LEVEL

The Single Market is one of the greatest achievements of our time. This economic space within which goods, services, capital and labour can be circulated freely and with no limitations provides a basis for prosperity in the EU and those countries joining the EU.

On the other side, marketing of safe products in the EU and creation of free trade zone followed by the creation of the EU Customs Union and internal market required development of a QI system at the EU level. It was planned that the QI system in the EU would facilitate trade between Member States. Unfortunately, the process of development of the QI system in the EU was time-consuming and divided into several phases, and was often exposed to the different needs of different EU Member States. Soon, it became obvious that the EU needed specific tool to reconcile all different national interests of the Member States. That is how a "mechanism for adjustment of different needs and interests" by means of harmonization of the laws came into existence.

2.1.1. From Old Approach to the Revision of New Approach - Harmonized Area

From the very beginning when the European Communities were established in 1958, the main goal was creation of the Common Market and removal of all barriers to trade. The plan was to attain this goal within a 12 year period.

However, even at the time of signing of the Treaty establishing the European Communities, the said Treaty contained Article 94 prescribing that the Directive would be the main instrument for harmonization of legal acts of the Member States in order to create a uniform legislation at the EU level. The same article prescribed that the Council should, at the proposal of the Commission, decide on the adoption of Directives **by consensus** which was, in most cases, an endless and exhausting process. This actually meant that the idea of harmonization of different laws existed at the moment of establishment of the European Communities, but the technique of the adoption of directives by the Council made the directive adoption process very slow and uncertain.

Namely, a Member State with different proposals, ideas and rules relating to the directive in question could use its veto; it was concluded that a more efficient tool was needed to avoid any obstruction of the adoption process, especially if we have in mind that the practice of European Court of Justice at the time was the main instigator of the integration process, particularly when non-food laws were concerned (Dassonville case, etc).

Once the Single European Act was agreed among Member States in 1986, certain articles of the Treaty establishing the European Communities were amended. Hence Article 94 of the said Treaty was amended by Article 95 that **introduced new instruments for harmonization of the laws** such as "other measures for legal harmonization", and **qualified majority as a way of decision-making.** Thus, the legal harmonization was facilitated, but still the development of the QI system in the EU in terms of industrial products and technical legislation had to go through several phases.

2.1.2. Old Approach

Until 1985 technical legislation of the Member States was being harmonised through transposition of the so called **Old Approach Directives** which primarily regulate technical requirements for products such as medicines, cosmetic products, chemicals, wood, textile, etc. Today there are around seven hundred directives of this kind. However, the method of legal harmonization of the Old Approach Directives proved to be rather complex due to many reasons:

- Old Approach Directives contain the smallest technical details which makes them over-comprehensive, whereas the agreement between the Member States was difficult to reach;
- technical specifications are very detailed too;
- the process of adopting technical legislation in the form of Old Approach Directives required unanimity in decision-making process and voting in the European Council which presumed a lengthy approval process;
- Old Approach Directives often had a form of a single legal document, but at the same time it was a mixture of different national legal documents which made the adoption process more difficult and complex;
- Old Approach legislation can refer to standards mentioned in the text of annexes to the Directives thus making the standards mandatory;
- Old Approach Directives do not recognize CE marking.

At one stage the Old Approach became very complex and a need for the new legal technique came up,. Yet, the Old Approach has some advantages, and that is why this Old Approach exists even today in some sectors (primarily when medicines, chemical products, wood, textile, motor vehicles are concerned) in parallel with the New Approach. Actually, Old Approach still exists in the most sensitive sectors where the Member States, due to potential threats that such products could pose, had an interest to keep the competence in assessing conformity and inspection of such products.

2.1.3. New Approach and Global Approach

In order to eliminate difficulties related to the final establishment of the internal market by 1992, which was the goal of the Single European Act from 1986, the Council adopted a new Resolution on the New Approach in 1985 (so called – Council Resolution of 1985 on the New Approach). By adopting this new Resolution, a new regulatory technique was introduced in the following sectors: electrical/electronic products, pressure vessels, lifts, machinery, toys, construction products, personal protective equipment, medical devices, etc. In this way legal harmonization was facilitated, and some novelties were introduced into the QI system in the EU:

- For the purpose of adopting technical legislation the Council abandoned unanimity principle and introduced **qualified majority principle** in decision-making and voting process.
- New Approach Directives regulate only **essential requirements** for products instead of all technical details that were then mandatory for all Member States.
- In addition to that, **a European harmonised standard** ***prepared by CEN/CENELEC as per a mandate given by the Commission, with a view to the fulfilment of essential requirements of the New Approach,*** has been introduced; a distinction between standards, European standards and harmonised European standards could be made as follows:

a) It was explained in Chapter 1 (Components of the QI) what **standard** is, i.e. how to define it; a standard represents a document, a model specification, a technical solution against which a market can trade, it codifies the best practice and is of great importance to businesses.

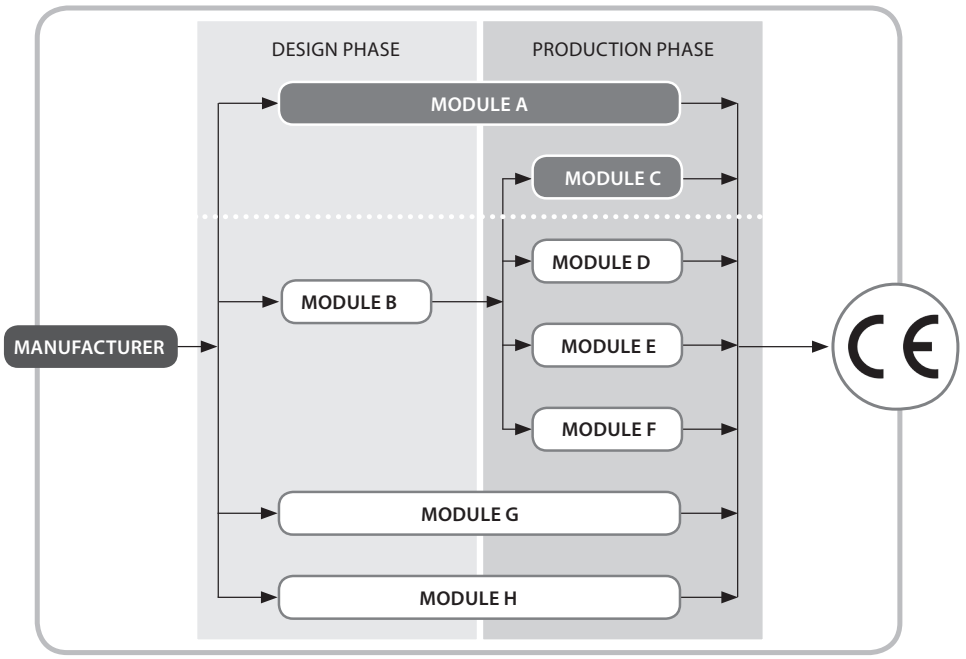
b) **European standard** provides more than this; it has two main characteristics that make it different from the standard:1) European standard (EN) is a standard that has been ratified by the European Standards Organizations (**CEN, CENELEC** or **ETSI**); it is designed and produced by all interested parties through a transparent process.2) European standard must be transposed as a national standard in all Member States; thus the producers can have easier access to the market of all European countries when applying European standards.

c) **European harmonised standard** is a standard prepared by CEN/CENELEC as per a mandate given by the Commission with a view to the fulfilment of the essential requirement of a New Approach Directive; it should be on the list of European harmonized standards and transposed as a national standard in all Member States**;** this definition shows direct connection to the New Approach Directives and creates a presumption of conformity as explained in the text below:

- **Presumption of conformity** that the New Approach introduced as a novelty implies that products meeting the requirements of harmonised European standards will automatically be presumed to conform to the requirements of a European Directive (for example the format of credit cards in line with MSA EN ISO/IEC 7810:1996 defining their dimensions; conformance to the requirements of the standard will be presumed as conformity to the European Directive, and even more, since the European

standard is based on the International one (ISO IEC), these credit cards can be used worldwide.) European standards are not necessarily based on international ones.

- **New conformity assessment procedures** have been introduced as the key segment of the so called **Global Approach**. Conformity assessment is defined as**: "any activity used to determine either directly or indirectly whether the relevant requirements are fulfilled"**. Conformity assessment procedures provide a means of ensuring that the products, services or systems have the required characteristics and that these characteristics are consistent from product to product, service to service, or system to system; conformity assessment procedures relate to the design phase, production phase or both; the said procedures are divided into several modules or represent a combination thereof; conformity assessment procedures lead to safe products and CE marking under the New Approach Directives.



The relevant procedure is chosen on the basis of **a) type of product, b) nature of risks involved, c) economic infrastructure of the given sector, d) types and importance of production, e) principle of proportionality** (all of these issues are included in the respective Directive).

Conformity assessment procedures are based on 1) conformity assessment requiring third party verification or 2) conformity assessment not requiring third party verification depending on the document which accompanying the products; as explained in Chapter 1 (Components of QI) conformity assessment could be performed by **a producer organization itself** and then the product will be accompanied by **declaration on conformity (conformity assessment not requiring third party verification)**; conformity assessment will be performed by a **body independent from a producer or customer** (see above) and in this case a product is accompanied by a certificate issued

by a notified body (**conformity assessment requiring third party verification**). A notified body is an independent body (certification body or rarely inspection body, e. g. assessment as per the Construction Products Directive - CPD) appointed by a Member State under appropriate national regulations to conduct, as laid down in the Directive, a independent conformity assessment of a product or its production processes in order to be CE marked. The procedures vary depending on the Directives, so third part involvement is not mandatory for all products.

– **Notified body** is a novelty introduced by the New Approach ; each Member State notifies to the Commission what bodies will be in charge of:

a) providing relevant information to their notifying authority, market surveillance authorities and other notified bodies;

b) operating in a competent, non-discriminatory, transparent, neutral, independent and impartial manner;

c) employing the necessary personnel with sufficient and relevant knowledge and experience to carry out conformity assessment activities in accordance with the respective Directive.

– One of the novelties introduced by the New Approach Directives is a **safeguard clause** which obliges the Member States to restrict or forbid marketing and using of dangerous or, according to certain directives, otherwise non-compliant products or to have them withdrawn from the market. As a general rule, this safeguard clause procedure is limited to products which are:

a) covered by the New Approach Directives

b) CE marked

c) identified by the Member States as a substantial hazard, even if the products are properly constructed, installed and maintained, or used to serve the intended purpose.

The safeguard clause procedure shall apply as a national measure to:

a) restrict or ban marketing of a product or to have a product withdrawn from the market

b) relate to all products belonging to the same batch or series

c) have legally binding effect

Member States shall notify the European Commission immediately after having taken actions invoking the implementation of the safeguard clause. The necessary information and evidence to justify the action must accompany the information provided thereto.

– Requirements for **CE marking** are also a "New Approach" novelty introduced into the QI system; the CE marking confirms the conformity of a product with all applicable Directive requirements; in other words a CE mark affixed to a product confirms that a) a product conforms to all applicable Community provisions; and b)

appropriate conformity assessment activities have been completed. It is important to highlight that CE marking is not mandatory for all products; namely, CE marking is not demanded for certain products. A CE mark must be affixed by the producer, or by its authorised representative registered in the territory of the Community; a CE mark shall be affixed to a product or to a document containing other information about the product, whereas the CE mark shall be visible, legible, and indelible; however, where this is not possible or not warranted on account of the nature of the product it shall be affixed to the packaging.

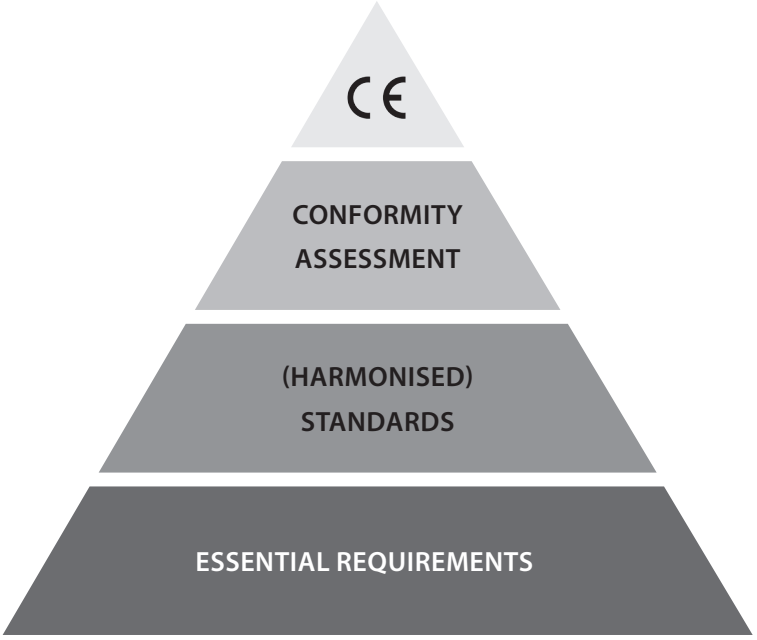
– **Split responsibilities** between a producer and a Member State is another novelty of the New Approach; a producer is responsible for ***pre-market assessment*** (products must fulfil the relevant requirements in order to be CE marked); the competent authority of a Member State shall be responsible for ***post–market*** conformity assessment what means that the **compliance of a marketed product** with relevant requirements of a Directive shall be inspected by market surveillance authorities.

All these novelties introduced into the QI system by the New Approach prompted without doubt:

- the increase of the level of protection of the internal market
- the application of the same rules for EU and imported products
- the increase of the level of product safety
- the reduction of burden on enterprises.

All the aforementioned had a positive impact on the free movement of goods.

The following figure depicts the "New Approach" arrangement:



2.1.4. Revision of the New Approach

The New Approach has been and will remain a regulatory instrument to exercise the duties of the signatories to Treaty establishing the EC. However, certain objectives and provisions of the New Approach Directives were, to some extent, differently interpreted in practice, whereby it became necessary to revise certain aspects of the New Approach in order to achieve:

- improvement in the exchange of information and experience between notified bodies,
- harmonization of the requirements for notified bodies and of the notification procedures,
- improvement of administrative cooperation as regards market surveillance,
- faster response in case of the safeguard clause procedure,
- enhancement of the credibility of the CE mark (it was necessary to understand that the CE mark was no longer an instrument to be used only by producers and market surveillance authorities. It should have also been recognised as an instrument of relevance to consumers, whereas its importance should have been clearly communicated thereto).

The said reasons and a need for the revision of the New Approach led to the adoption of the so-called "**New Package of measures for enhancing trade of products".** The "Package" included:

– **Decision 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on common framework for the marketing of products, and repealing Council Decision 93/465 EEC

– **Regulation (EC) 765/2008** 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** of the European Parliament and of the Council of 9 July2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

The documents from the "Package" are mainly focused on the following points:

– Responsibilities and duties of producers, authorised representatives, importers and distributors are defined to trace the products through the entire chain from production to consumption. This needs to be coupled with efficient market surveillance;

– Strengthening the use of modules related to the conformity assessment procedures aiming at optimum level of safety and quality of products through all the phases of production;

– Conformity assessment bodies are to be notified according to a procedure based

on a formal accreditation; deviation from the procedures is allowed only in well-founded and exceptional cases;

- Furthermore, the exchange of information and experience should be intensified by including the European Commission, notified bodies, authorities, and accreditation bodies;
- Each Member State is obliged to appoint only one national accreditation body; accreditation body is granted public benefit tasks, whereas any commercial competition shall therefore be prohibited.

However, these points and provisions exclusively relate to the scope of the "Old" and "New" Approaches, i.e. to the regulated (mandatory) and not to the voluntary area (non-harmonised).

2.1.5. Non-harmonized Area, GPSD and Mutual Recognition Principle – Cassis de Dijon

Movement of industrial products in the non-harmonized area is somewhat different. Given that technical standards have not been transposed (harmonised) in the entire territory of the European Union each Member State applies its own technical regulations and national standards. This makes the trade in products deficient due to a large number of technical barriers since a standard in one country often creates a barrier in another. The only Directive being applied as a link between the Member States in relation to unsafe products is the General Product Safety Directive. Everything else remains in the domain of direct application of the Treaty establishing the European Economic Community.

a) Mutual Recognition Principle

The first mechanism for the removal of technical barriers in non-harmonized area is implementation of the principle of mutual recognition (Art. 34- 36 of the Treaty establishing the EU deriving from the judicial practice of the Court of Justice of the European Communities (ECJ). Rules and procedures which have to be followed by the competent authorities when making decisions which would hinder the free movement of a product lawfully marketed in another Member State are laid down in Regulation 764/2008.

Principle of mutual recognition came into focus in the case Cassis de Dijon No. 120/78. Namely, the principle has been derived from the attempt of reconciling the two basic principles from Treaty establishing the EC: the principle of free movement of goods and the principle of protection of health and safety.

The principle of mutual recognition is based on the following: products that have been lawfully marketed in one Member State may not be removed from the market in another Member State due to the difference in national rules. The only exception allowed – important public interest such as health, consumer or environment- is

subject to strict conditions stated in Regulation 764/2008.

The following table shows a relationship between harmonized and non-harmonized area:

The table shows that harmonized and non-harmonized areas almost look like an unusual type of chess board. What is important in this "game", as in all other games, is that the "chess players" make appropriate "moves" in accordance with the rules.

Bearing in mind that the harmonized area is governed by harmonized technical legislation, we can conclude that there is far less chance for technical barriers to occur in all Member States having more or less the same legislation; in the non- harmonized area technical legislation and standards are not harmonized, so Member States are in position to apply their own national legislation thus opening the door to technical barriers on a far larger scale due to different national rules; that is why the application of General Product Safety Directive, as well as application of the principle of mutual recognition can reduce the level of risk of producing technical barriers to trade.

b) General Product Safety Directive- GPSD- Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety (OJ L 11, 15.1. 2002)

This Directive imposes a general safety requirement on any product placed on the market for consumers, including all products that provide a service. Second-hand products having antique value are not subject to this requirement, but in some cases the products requiring some repairs or modifications are not subject to this requirement.

According to the Directive a safe product is one which poses no risk or only a reduced level of risk in line with its intended use and as such provides a high level of protection of human health and safety. Furthermore, a product is deemed safe once it conforms to the safety provisions provided in the European safety legislation, or, in the absence of such rules, if it complies with the specific national regulations of the Member State in

which it is being marketed or sold. The product is also deemed safe if it complies with a European standard adopted according to the procedures as laid down in the Directive. In the absence of such regulations or standards, the product conformance to safety requirements is determined in line with the following:

- voluntary national standards used to transpose other relevant European standards
- European Commission's recommendations
- standards of a Member State in which the product is being marketed or sold
- codes of good practice as regards health and safety
- current state of art
- consumers' safety expectations.

When marketing safe products all actors are granted specific roles:

Producers must provide consumers with necessary information in order to assess a product's inherent risk, especially when the risk is not directly obvious, as well as to take the necessary actions to prevent occurrence of such risks (e.g. to withdraw products from the market, to inform consumers, to recall products which had already been supplied to consumers, etc.)

Member states are obliged to ensure that the producers and distributors perform their obligations; in order to reach that goal, Member States have to upgrade the capacities of the institutions responsible for monitoring product compliance with the safety requirements, taking the necessary actions as regards risky products and informing the European Commission of the details.

The European Commission authorises the European standardization organizations and publishes the lists of European standards in the Official Journal of the European Union and those shall conform to the general safety standard.

In order to facilitate the whole process, **RAPEX system** for rapid intervention where products pose a serious risk, has been introduced. According to the Directive, Member States identify products posing a serious risk to health and safety and following that they take rapid actions to protect consumers. In this case they are obliged to immediately inform the European Commission via RAPEX system. This system is a tool for rapid exchange of information between the Member States and European Commission. It enables distribution of dangerous products to be limited or prevented.

Food, pharmaceutical and medical products are governed by other intervention systems.

When using the RAPEX system, Member States must provide the European Commission with at least the following information:

- information enabling the product to be identified,
- a description of the risk inherent to the product, and documents on risk assessment,
- details of actions already taken,

- information on distribution of the product.

The European Commission manages the RAPEX system (Rapid Information System for non-food products posing a serious risk) and can adopt "emergency measures" in cooperation with Member States. Information on the risks presented by products must be provided to the public. Namely, professional secrecy is limited to justified cases.

2.1.6. How Do the Two Main Principles of the Treaty on EU Affect the Industry and Consumers

European structure of QI relies on two basic principles: the principle of free movement of goods and the principle of marketing of safe products (protection of human health and life, public safety, public morality...).

The principle of free movement of goods is based on Article 34-36 Treaty on EU and it primarily reflects the interests of the industry:

"Quantitative restrictions on imports, exports and all measures having equivalent effect shall be prohibited between Member States".

The principle of safety of the product is based on Article 36 of the Treaty on EU and it reflects the interests of the consumers who are guaranteed a safe product:

"Article 34 and 35 shall not represent an obstacle to the bans and restrictions of imports, exports and transit of goods if the bans and restrictions are justified by reasons of public morality, public security, protection of health of humans, animals and plants, protection of national cultural value, protection of industrial and commercial property, etc. However, these derogations must not become means for arbitrary discrimination or disguised restriction on trade among Member States".

A clear conclusion can be made on the basis of the aforementioned paragraphs that these two principles very often confront each other. On one hand, removal of technical barriers is demanded (Article 34), on the other hand, technical barriers should be allowed if this can be justified in terms of health of humans, animals, plants, public morality, etc. (Article 36). In other words, bearing in mind the second sentence of the article 36 of the Treaty on EU, a question could be posed: "how to avoid manipulation of the principle of free movement of goods by recognizing unsafe products thus posing a risk to health?" Judicial practice of the European Court of Justice shows how often court proceedings have been initiated among Member States just because "justified" technical barriers opened the door to different forms of discriminatory imbalances in trade. The only mechanism to "reconcile" these two principles "remains in the hands of the European Court of Justice" that will be able, from case to case, to recognize and make distinction between a case of manipulation of the free trade objective (the measures for limiting or banning the marketing of the product have been undertaken, thus making a technical barrier to trade, although the product is safe and does not pose a risk to life and safety) and a case when the product is indeed unsafe and as such poses a risk, whereby actions for limiting or banning the marketing of the product are justified.

CHAPTER 3

3.1. QUALITY INFRASTRUCTURE IN SERBIA - HORIZONTAL LEGAL FRAMEWORK

After an in-depth analysis of the QI system, its components and their integration into a national QI system, and after "a long walk along the path leading to the impressive edifice of the European Quality Infrastructure", it is time to "come back" to Serbia and take a look at the Serbian legal framework that represents a foundation of the Serbian QI.

After dissolution of the State Union of Serbia and Montenegro in 2006, Republic of Serbia "inherited" an outdated legal and institutional framework governing Quality Infrastructure. It was necessary to set up a new, modern system in this area that would be in line with the new trends in the European Union in order to enable our industry to be more competitive.

In the last three and a half years, a cornerstone of the QI was laid. The system structured around "four pillars" or in other words, the following four umbrella laws**: Law on Technical Requirements for Products and Conformity Assessment, Law on Standardization, Law on Metrology, and Law on Accreditation.** All four laws introduced solutions from the abovementioned "new **Package of the EU measures for enhancing trade of products",** for two reasons *to gradually eliminate technical barriers to trade in accordance with EU and WTO requirements, and to ensure placing of safe products on the Serbian market*. On the other hand, the adopted laws were harmonised with new laws of Republic of Serbia (the Law on Ministries and The Law on Public Administration). Pursuant to these Laws, Ministry of Economy and Regional Development (hereinafter referred to as: MERD) became the main policy maker as far as QI is concerned.

By completing creation of the new, modern QI system in Serbia, the Republic of Serbia will achieve its long-term strategic goal: upgrade of the competitiveness of the Serbian industry in order to make it ready to become a part of European Single Market.

CONFORMITY ASSESSMENT

3.1.1. What Novelties Have Been Introduced into the Serbian Legal System after the Adoption of the new Law on Technical Requirements for Products and Conformity Assessment

The New Law on Technical Requirements for Products and Conformity Assessment was adopted by the Serbian Parliament on 13th May 2009, and published in Official Gazette No. 36/09. Constitutional basis for the adoption of the Law is Article 97 of the Constitution which prescribes that the Republic of Serbia shall define and enable operation of the common market of the Republic of Serbia, legal status of all economic operators and shall determine the mode of performance of certain economic and other activities. The Law on Technical Requirements for Products and Conformity Assessment prescribes technical requirements for products, adoption of technical regulations, assessment of conformity of products to prescribed requirements, obligations of all actors in the chain (producers, importers, distributors), recognition of foreign certificates of conformity, information and dissemination of technical regulations and conformity assessment procedures and enforcement of the Law and all related sub-laws**.** The Law entered into force on the eighth day following its publication in the "Official Gazette of the Republic of Serbia."

In order to ensure marketing of safe products, assessment of conformity of products to prescribed technical requirements shall be performed as a pre-market inspection. **The Law** on Technical Requirements for Products and Conformity Assessment **represents the key legal framework regulating conformity of products to technical requirements.**

Novelties that have been introduced into the Serbian legal system by adopting this Law can be divided into three groups: **a**) novelties based on the harmonization of the new law with the legal system of the Republic of Serbia, as well as novelties arising from the harmonization of technical legislation at EU and international level, **b**) novelties based on the alignment of the Serbian technical legislation with that of the EU ,and **c**) novelties based on WTO/TBT requirements.

a) Novelties based on the harmonization of the new law with the legal system of the Republic of Serbia as well as novelties arising from harmonization of technical legislation at European and international level

1. Legal framework prescribing technical requirements for products and conformity assessment with prescribed requirements that had been be set up at **the level of State Union** was not applicable in the legal system of the Republic of Serbia. Namely, at the State Union level ***centralised model*** had been applied and this meant that only one ministry (Ministry for Internal Economic Relations at the time) was in charge of adoption of technical regulations in all areas, keeping of the registers of technical regulations,

keeping of other types of registers, authorisation of conformity assessment bodies, performance of conformity assessment procedures for products, etc. Such (centralised) an approach was not in compliance with the principles of the Serbian legal system. Serbian Law on Ministries confirmed unsustainability of the centralised approach that had been applied in the State Union of Serbia and Montenegro. Therefore, Article 29 of the Serbian Law on Ministries prescribed that all respective ministries were in charge of preparation and adoption of technical regulations in the area of their competence, whereby **a new model** - ***decentralised model*** **was introduced**. Another argument that underpins such a solution is the fact that only competent ministries have a capacity to assess the need for certain new technical regulations from the area of their competence (e.g. need for technical regulations in the area of medicine, civil engineering, etc.).

On the other hand, according to the Law on Ministries, MERD has been identified, for the purpose of sustainability of such a system, as a coordinator in the field of QI. This precisely means that MERD keeps the registers (of all existing technical regulations, technical regulations in preparation, recognised foreign certificates and designated/authorised conformity assessment bodies.) At the same time, legal provisions oblige other ministries to submit to the MERD their new technical regulations and other information that should be entered into the MERD registers (Sector for QI). MERD is also an Enquiry Point for the notification of technical regulations to the EU and World Trade Organization (WTO). In addition to these technical regulation-related activities, MERD is also in charge of development policy of other QI institutions in Serbia, according to the Law on Ministries (Accreditation Body of Serbia, Institute for Standardization of Serbia, and Directorate of Measures and Precious Metals that is an integral part of the Ministry).

2. Legal QI acts only recognised, at the time of the State Union of Serbia and Montenegro, the term "authorized" conformity assessment bodies" which was typical of the "Old Approach", but they never recognised the term "notified" conformity assessment bodies the term introduced in technical legislations by the "New Approach". In practical terms only "authorisation" of conformity assessment bodies had been applied in terms of the technical assessment of specially sensitive products such as chemicals, medicines, motor vehicles, cosmetics, , given that the state was interested to maintain competence and control of such sensitive products (Old Approach). In other words, only those conformity assessment bodies authorised by the state performed technical assessment of the product in question, and afterwards, the State issued certificates confirming product conformity with technical requirements prescribed by a respective technical regulation. Hence, the laws adopted at the State Union level never recognised the New Approach that had introduced "notification" of conformity assessment bodies to perform conformity assessment of the less sensitive products.

The new Law on Technical Requirements for Products and Conformity Assessment, introduced for the first time the term " notified " and "notification " was introduced into the Serbian legal system. It means that the state designates a number of conformity assessment bodies that operate on the market and a producer can select one of them; the selected notified body performs conformity assessment procedure and issues an adequate certificate of conformity (the most often a certificate) to prove conformity of the product to the technical requirements; (it is valid for less sensitive products such as electric and electronic appliances, toys, lifts, personal protective equipment, etc.) It is typical of the New

Approach and a huge advantage of this solution is increased level of competitiveness among the conformity assessment bodies, and a possibility for the producers to select.

The new Law on Technical requirements for Products and Conformity Assessment **recognised both terms -" authorisation" and "designation" ,or in other words, the new Law accepted both approaches (Old Approach for the most sensitive products where State maintains certification and control and New Approach for the less sensitive products the conformity to the technical requirements of which is assessed and certified by a notified body;** ***less sensitive products are, in this way, more exposed to the market rules, without any kind of control by the State, except market surveillance.***

It can be concluded that both authorization and notification are in keeping with the legal system of the Republic of Serbia, and at the same time this is acceptable from the perspective of harmonization of technical legislation at European and international level.

3. The new Law introduced another novelty into the Serbian legal system. **It is related to the new procedure and conditions for the recognition of foreign certificates and marks of conformity**. When compared with the old Law that prescribed that "the foreign certificates and conformity marks shall be valid in the Republic of Serbia only if they are issued in accordance with ratified international agreements to which the Republic of Serbia is a signatory", while the new Law regulates the new mechanism for the recognition of foreign certificates and conformity marks;

Namely, new Law introduces a possibility for the competent Minister to recognise, under special procedure, the validity of foreign documents and marks of conformity of the foreign product, **under the following two conditions: a) that requirements of foreign technical regulation with which the product in question conforms provide at least the same level of protection of: safety, human life and health, environment, consumers and property as that provided by the requirements of the Serbian technical regulation; b) that the requirements to be met by a foreign conformity assessment body as per a foreign technical regulation in order to perform conformity assessment procedure provide at least the same level of fulfilment of the requirements as defined in the Serbian technical regulation for notified bodies in Serbia.**

This possibility is introduced by the new Law with a view to facilitate the process of recognition of foreign certificates and conformity marks in case when there are no international agreements. In addition to that, **the Republic of Serbia will, by transposing European Directives into the Serbian legal system, put in place technical regulations equal to technical regulations in other European countries. This position will enable the competent Minister to recognize foreign certificates and conformity marks by means of urgent administrative procedure.** (e.g. recognition of foreign certificates and conformity marks for lifts issued by foreign certification bodies from the European Commission list is based on the request of a producer or importer accompanied only by a copy of certificate, since Serbia has transposed the European Lifts Directive and therefore is in a position to have the same rules as those of the EU as far as safety of lifts is concerned).

4. **The new Law** on Technical Requirements for Products and Conformity Assessment is a **legal basis for the transposition of the New and Old Approach Directives into the Serbian legal system** except in cases when technical requirements for products and confor-

mity assessment procedure are prescribed by specific laws. Article 4 of a new Law is a necessary connection to the European Sectoral Directives since it prescribes that the **technical requirements for individual products or groups of products shall be prescribed in *a technical regulation***. This article of the Law made it possible for the transposition of the EU Directives to occur since the Republic of Serbia adopt the solutions from the EU Directives by prescribing requirements for products in *the Serbian technical regulations*.

This Law also provides the legal framework prescribing technical requirements for the product in the national technical regulations if the products in question are not comprised by the harmonised legal acts at the EU level.

According to the new Law, technical regulation is a regulation which prescribes, for individual products or group of products, at least one of the following elements: a) technical requirements to be met by a product in order to be placed on the Serbian market, b) conformity assessment procedures, c) regular and extraordinary inspection of the product, d) documents that accompany product when placed on the market e) marking and manner of marking the product, f) requirements to be met by conformity assessment bodies, g) requirements with regard to packaging and labelling; h) safety requirements for the product during the period of use. Technical regulations are adopted with a view to protect: safety of the life and health of humans, animals and plants, environment, consumers and property.

b) Novelties based on the alignment of Serbian Law with EU technical legislation

While drafting this Law the latest versions of the EU legal acts concerning trade of goods (the so-called "new goods package") have been taken into account, especially **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 (see Chapter 2- Revision of the New Approach). Hence all new solutions from these documents have been transposed into the Serbian legal system:

1. Firstly, **all new definitions** such as "product", "making available on the market", "placing on the market", " producer", "representative", "importer"," distributor", etc.

2. **"presumption of conformity**" principle has been transposed into the new Law. Namely, Articles 4 to 8 of this Law prescribe the manner in which technical requirements are prescribed since this is the most important element of the technical regulation and it makes, in regard to safety, the product a part of the regulated area in the market.

Hence, technical requirements for individual products, i.e. groups of products, are set out by the technical regulation either **directly**, by specifying such requirements in the regulation (typical of Old Approach products since the requirements have to be prescribed in detail in the regulation, e.g. motor vehicles) or **indirectly**, by referring to the Serbian standard in the technical regulation , i.e. technical specification (typical of the New Approach products where only essential requirements for products should be prescribed, e.g., household electronic appliances).

Furthermore, Article 7, paragraph 1, point 2) of this Law lays down that technical regulation may prescribe that one of the possible manners for achieving conformity with the requirements of such a regulation refers to ***full compliance with the requirements of the Serbian standard referred to by the technical regulation*.** If technical regulations are a means to transpose the New Approach Directives into the legal system of the Republic of Serbia these are then identified as 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. In other words, ***the Law on Technical Requirements for Products and Conformity Assessment introduces a presumption of conformity of the product with the prescribed requirements, what means that if the product is in compliance with the standard requirements referred to in the technical regulation, it is automatically in compliance with the technical regulation.***

3. **Assessment of conformity of the product** is fully in compliance with the abovementioned Decision. Depending on the groups of products and potential hazards posed by the product, this Law prescribes that **different operators may perform conformity assessment procedures, such as:**

1) **producer,**
2) **notified conformity assessment body,**
3) **public administration bodies** in case of products posing higher risks.

1) Hence, this Law prescribes that **a producer may perform assessment of conformity of its own product to the requirements laid down in the technical regulation,** what is a h novelty of huge importance transposed into the Serbian legal system. Namely, Article 11 of the Law on Technical Requirements for Products and Conformity Assessment refers to the conformity assessment performed by the producer itself. These provisions prescribe that conformity assessment shall be performed by a producer when laid down in a technical regulation, and such a regulation also prescribes the requirements concerning internal production control. The internal production control encompasses all actions requiring the production process and monitoring of such a process to ensure the product compliance with the technical regulation. The same article requires that **manufacturer producer shall, upon performing the conformity assessment procedure, issue a declaration of conformity with the prescribed requirements.**
2) The new Law prescribes that assessment of conformity of the product with prescribed technical requirements could also be performed by an **"independent third party" - conformity assessment body** that is, in most cases,, privately owned one. In this case, a producer can select one of the conformity assessment bodies designated by the state. In other words, State is responsible only for the designation of the bodies which includes assessment of their competence, while everything else is based on contractual relation between a producer and selected conformity assessment body. The Law also prescribes the possibility of subcontracting another conformity assessment body by selected notified body, but this must be approved by

a producer. In this event, a subcontractor is limited only to the assessments agreed with a producer, whereas the selected body remains responsible for all agreeed assessments and their results. Therefore, **the relation between a producer and a notified conformity assessment body is outside the public authority's area of competence. Conformity assessment performed by a notified conformity assessment body is typical of the New Approach,** as explained above.

The competence of conformity assessment bodies have to be in compliance with the requirements of international standards, whereby the following three types of conformity assessment bodies exist:

a) testing and calibration laboratories - i*nternational standard ISO/IEC 17025;*

b) inspection bodies – ***international standard ISO/IEC 17020,***

c*) certification bodies-** ***European standard EN 45011.

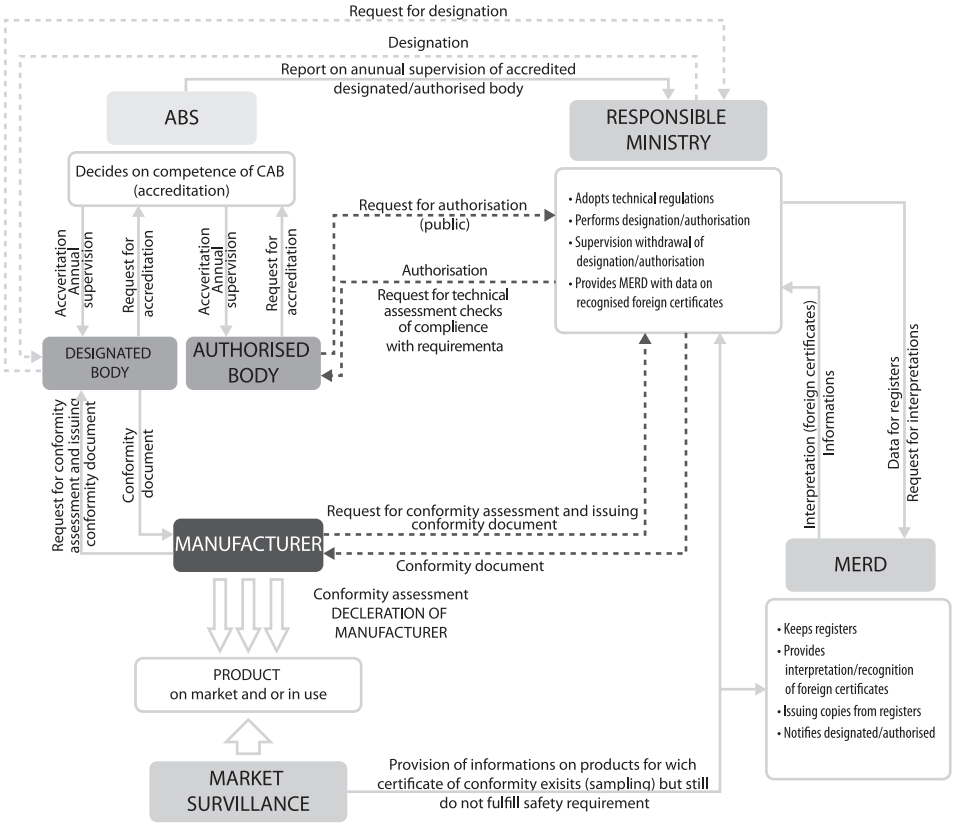
Only a certification body can issue a certificate as a document recognised to have the highest level of certainty confirming the conformity of the product with the prescribed requirements. That is why certification bodies are the most welcome to become notified bodies at EU level. Inspection bodies and testing laboratories should provide a strong support to the certification bodies by carrying out different tests and analyses. They are also mainly „authorised" by the state to perform technical assessment of the product`s compliance with the prescribed requirements, whereas the state issues a certificate of conformity on the basis of the results of the assessment (Old Approach, see paragraph 3).

Accreditation Body of Serbia issues an accreditation certificate upon confirming the **competence of a conformity assessment body** and its capacity to fulfil the requirements of these standards. **Competent ministries**, within their area of competence, perform **notification** (**New Approach**) of conformity assessment bodies. **MERD** is responsible **for the notification of notified conformity assessment bodies**.

The Law on Technical Requirements for Products and Conformity Assessment also recognises the EU practice prescribing that **the accreditation certificate for specific areas is the best instrument used by a conformity assessment body to confirm the competence for performing conformity assessment activities**. However, competence for performing conformity assessment activities could also be confirmed by other relevant documentation.

3) **The State maintained the competence in conformity assessment area in case of the „most sensitive" products** such as medicines, cosmetics, motor vehicles, chemicals... (Old Approach). In this case, public administration (competent ministries) performs the assessment of conformity of products to the prescribed requirements, but if they do not have the capacities for the assessment, other bodies (conformity assessment bodies) are to be engaged for this purpose. Then the state (competent Ministry) **„**authorize**"**„ conformity assessment bodies (hereinafter referred to: CABs) to perform the technical assessment, but due to the risk that the product could pose, the state shall eventually issue the certificate of conformity. As far as authorization is concerned, all requirements of the standards have also to be met in case of the bodies to be authorised.

The following figure shows all those participating in conformity assessment and market surveillance activities:



4. **Provisions of the EC Decision related to the conditions that should be fulfilled by CABs** are transposed through the new Law on Technical Requirements for Products and Conformity Assessment. CABs have to 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 the accreditation certificate is an assumption that the CAB meets the notification requirements to the extent covered by the scope of accreditation.

5. **Conformity assessment procedures** are another novelty transposed into the new Law on Technical Requirements for Products and Conformity Assessment. Article 10 of the Law prescribes that technical regulations shall lay down a mode of performing conformity assessment which may comprise the application of a single procedure, a number of procedures or a combination of different conformity assessment procedures. All details as regards the procedures are regulated by the provisions of the sub-law related to the mode of performing conformity assessment.

6. **Safeguard procedures** (corrective actions such as withdrawal and recall of the product) regulated by the Decision 768/2008 EC also became a part of our technical legislation. Namely, the new 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. **If under certain circumstances occurring during market surveillance, the competent inspectorate assesses that the product is dangerous, it can undertake actions to withdraw the product from the market or recall the product from the consumer. The competent inspectorate may undertake such actions even in cases when the producer has fulfilled and proved that all prescribed technical requirements have been met**.

Such a procedure, in addition to regular actions prescribed in this law and related technical regulations, has provided a legal framework not allowing dangerous products to be placed on the market of the Republic of Serbia.

7. One of the most significant novelties introduced in the Serbian QI system relates to **the obligations and liability of economic operators** (producer, representative, importer, and distributor). Responsibilities and obligations of all those participating in the "chain" are precisely defined in the provisions of the new Law with a view to enabling proper traceability of the products. All those participating therein are delegated different obligations and different levels of liability for the safety of marketed products. So, the producer for e.g. is the most responsible one in terms of placing safe products on the market. In addition to that, a distributor is the least responsible for performing the same task.

1) **A producer** is a person (legal entity, entrepreneur or natural person) responsible for designing and producing products with a view to place them on the market on its own behalf. A producer has an obligation to assess whether a product to be placed on the market is in conformance to relevant requirements in accordance with provisions of the technical regulation concerned; the producer draws up the required technical documentation and keeps it for the prescribed period of time, issues a declaration of conformity and keeps it for the prescribed period of time and affixes the prescribed mark of conformity on the product. All other participants do not have such a level of liability for the safety of products.
2) The producer may appoint any legal entity or entrepreneur registered in the Republic of Serbia, or a natural person resident of the Republic of Serbia to act on behalf of the producer as an authorised **representative**. A producer may delegate certain obligations to the representative such as: preparation of declaration of conformity, keeping it within the prescribed period of time and affixing prescribed mark of conformity to the product. However, a producer can never delegate to the representative to draw up the product technical documentation. Nevertheless, a producer remains responsible for any of the actions carried out by a representative.
3) **An importer** (legal entity or entrepreneur registered in the Republic of Serbia or natural person resident of the Republic of Serbia) shall check whether a declaration of conformity has been issued for the product, and whether the product is accompanied by another prescribed certificate of conformity, whether it is marked by a prescribed mark of conformity, whether it is labelled so that the product and its producer could

be identified , and whether it is accompanied by the prescribed documentation (technical documentation); an importer is also responsible for keeping a copy of the declaration of conformity and technical documentation within the prescribed period of time, and make them available to the competent authorities upon their request.

As we can see, the importer`s level of responsibility for placing safe products on the market is obviously lower than the level of responsibility of the producer and representative since the importer's responsibility for the safety of product is only to check if the producer/representative have done its duties, and to keep a copy of declaration and technical documentation within the prescribed period of time and to make it available to the competent authority.

On the other hand, **an importer has, to some extent, the same duties as a distributor**. These duties include the following:

a) **if there is reason to believe that a product is not in conformity with the prescribed requirements, such a product can be marketed only after the producer has brought the product in conformity with such requirements, and after it has informed the competent authority, in case of dangerous products;**

b) **an importer is also responsible for ensuring that, before placing the product on the market, the conditions of storage and transportation do not affect the product conformity with the prescribed requirements.**

In practice an importer can sometimes be considered as the one assuming the responsibilities placed on a manufacturer. At the same time, **if a foreign producer does not have a representative in the Republic of Serbia, an importer shall assume certain obligations that have originally been granted to the representative;** in practice this means engagement of a third party (notified CAB) to perform conformity assessment and affix the Serbian mark of conformity to the product.

4) In addition to the specific duties shared by the importer and distributor (see the paragraph above), **distributor** (legal entity or entrepreneur registered in the Republic of Serbia or natural person resident of the Republic of Serbia) shall check whether a prescribed mark of conformity has been affixed to the product, and whether the product is accompanied by the prescribed documentation; following the aforementioned it can be concluded that, **when compared with other economic operators, a distributor is granted with the lowest level of responsibility as far as marketing of safe products is concerned.**

8. Provisions of the EC Decision related to the **mark of conformity** have been transposed through Article 24 of the Law on Technical Requirements for Products and Conformity Assessment prescribing that a manufacturer shall affix a mark of conformity to a product if the product is in conformance with the requirements of the technical regulation and if this is determined by the technical regulation.

A mark of conformity cannot be affixed to a product not aligned with the prescribed requirements, or to a product for which the mark of conformity placement is not prescribed.

Form, shape and content of the Serbian mark of conformity, and manner and use of the marks of conformity are governed by the specific sub-laws.

Serbian mark of conformity is the only mark recognising that products placed on the

market or put into use **in the Republic of Serbia** are in line with the requirements of the **Serbian technical regulation** if such a regulation foresees the mark to be affixed.

Such a mark shall cease to apply as from the day of entry 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, application of the Serbian mark of conformity shall cease to apply as from the day of accession of the Republic of Serbia to the EU. Notwithstanding the abovementioned, the **CE mark shall be valid in the Republic of Serbia** even prior to the signing of the ACAA Agreement **in case of the recognition of the foreign documents of conformity, and the related mark of conformity**. On the other hand, CE mark could be used for the **markets outside the Republic of Serbia**.

Only the CE mark shall be applied as of the day of signing the ACAA Agreement, but no later than the day of the EU accession.

9. **Notification Directive 98/34** has been transposed into the Law on Technical Requirements and Conformity Assessment, while the details of the Directive are laid down in the relevant sub-law; by transposing the mentioned Directive into our legal system **notification procedure of the technical regulations towards EU** has been put in place fully in line with Decision EC 768/ 2008 and Directive EC 98/34 (Chapter R4); pursuant to the provisions of these legal documents, the **MERD shall,** as the public administration body, **notify all technical regulations that belong to the non- harmonized area (what includes all national technical regulations), and all technical regulations that are harmonized with the EU Directives (transposed into our legal system), *but they contain some additional national rules in terms of additional technical requirements*.** A typical example of the abovementioned case is the Machinery Directive that has been fully transposed into the Serbian legal system, but which introduced a document not covered by the European Directive, for a few types of machines - "confirmation of conformity" as a transitional solution for proving products conformity with technical requirements; this type of document is issued by a notified conformity assessment body after the documentation accompanying the product has been checked (declaration of producer, test report...).

c) Novelties based on WTO/TBT requirements

1. **Article 6 of the Law** on Technical Requirements and Conformity Assessment **lays down the main principles of the WTO / TBT Agreement**. Namely, when preparing, adopting and applying technical regulations each respective Ministry shall take into account the WTO / TBT principles such as: prevention of unnecessary barriers to trade, non-discrimination between domestic and foreign products on the market, use of the Serbian standards transposing international standards as a basis for the preparation of a technical regulation, specifying the reasonable time line for the commencement of application of a technical regulation, any changes in the circumstances that occurred after the adoption of a technical regulation - for the purpose of its amendment or repealing, fulfilment of the objectives of the technical regulations in the manner that is least trade-restrictive, the requirements that must be met by a product primarily in terms of functionality rather than design or descriptive characteristics thereof.

2. In line with WTO Agreement on Technical Barriers to Trade (TBT) Sector for Quality Infrastructure, within the MERD, has established the **Enquiry Point responsible for the provision of information on technical regulations and related conformity assessment procedures, and for the notification of draft technical regulations in accordance with the WTO rules and Directive 98/34/EC.**

The Law on Technical Requirements for Products and Conformity Assessment has provided a legal base for setting up the Enquiry Point (Articles 31-33).

Pursuant to the WTO / TBT Agreement, the Enquiry Point shall be responsible for notifying technical regulations in preparation in order to make sure:

a) **that they do not create unnecessary barriers to trade;**

b) **that they are based on international standards.**

The Enquiry Point shall become fully operational on the day of accession to the 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 the QI Sector shall be responsible for the Enquiry Point activities, i.e. providing information and notification processes. It has been planned that, upon accession of Serbia to the WTO and EU, one employee shall be responsible for notifying the technical regulations to the WTO, and one for Directive 98/34/EC.

In the second half of 2010, the application software TEHNIS was developed and it comprised electronic database and internet portal (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.

Furthermore, MERD 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 actions for their application was implemented; within its framework, the relevant data were collected from competent ministries in order to establish the Register of all valid technical regulations in the Republic of Serbia. Technical regulations are currently classified within the Register according to the respective ministries, and the following data are registered:

- Title and number of the official gazette where such a technical regulation was published
- Legal framework for its adoption
- Identification of the Serbian standards the technical regulation refers to.

The Register of current technical regulations in the Republic of Serbia contains 821 regulations, including technical regulations not referring only to products, but to the production and processing as well, and sectoral regulations in the field of railway, water and air transport. The following table presents the number and distribution of registered regulations by respective ministries, and their scope of competences: The List of all current technical regulations is available on the web-based portal www.tehnis.merr.gov.rs.

MERD is also responsible for keeping three more registers: Register of technical regulations in preparation, Register of notified and authorised conformity assessment bodies and Register of recognised foreign certificates and conformity marks.

RESPECTIVE MINISTRY	NO. OF TECHNICAL REGULATIONS
Ministry of Economy and Regional Development • Technical requirements for industrial products and processes	**69**
Directorate of Measures and Precious Metals • Technical requirements for measuring instruments and pre-packed products	**251**
Ministry of Energy and Mining • Technical requirements in the fields of: - Electrical energy - Oil and gas - Mining and geology	**58**
Ministry of Agriculture, Forestry and Water Management • Technical requirements for agricultural products and animal feed • Technical requirements in the field of forestry	**57**
Ministry of Health • Technical requirements for quality, sampling and testing methods of specific food products • Technical requirements for medical devices	**31**
Ministry of Infrastructure • Technical requirements for transportation means and traffic infrastructure in the fields of: - Road transport - Railway transport - Water transport - Air transport	**316**
Ministry of Telecommunications and Information Society • Technical requirements for products and systems in the field of telecommunications	**7**
Ministry of Environment and Spatial Planning • Technical requirements in the field of environmental protection • Technical requirements in the field of civil engineering	**52**
Ministry of the Internal Affairs • Technical requirements in the field of protection against fire and explosion • Technical requirements for technical inspection of vehicles	**41**
Ministry of Defence • Technical requirements for shelters and dual-use facilities	**7**
WITHIN THE COMPETENCE OF SEVERAL MINISTRIES	**1**

3.1.2. Law on Technical Requirements for Products and Conformity Assessment
(Official Gazette of the RS No. 36/2009)

I INTRODUCTORY PROVISIONS

Scope

Article 1

This Law shall govern the manner of prescribing technical requirements for products and adoption of technical regulations, assessment of conformity of products with prescribed technical requirements (hereinafter referred to as: conformity assessment), obligations of suppliers of products and owners of products in use, validity of foreign documents of conformity and conformity marks, notification of technical regulations and conformity assessment procedures and enforcement of this Law and regulations adopted on the basis of this Law.

Application

Article 2

This Law shall apply to all products, excluding products for which the technical requirements are governed by specific laws and regulations adopted on the basis of such laws.

If the specific laws and regulations referred to in paragraph 1 of this Article do not govern matters related to the designation and/or authorisation of conformity assessment bodies and validity of foreign documents of conformity and conformity marks, the provisions of this Law shall apply thereto.

The provisions of this Law governing notification of designated and authorised conformity assessment bodies, keeping of registers and notification of technical regulations shall also apply to the products for which technical requirements are governed by specific laws and regulations adopted on the basis of such laws.

Meaning of Terms

Article 3

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

1) *product* shall mean any product which has been, as the result of a certain process, made or in any other manner obtained, regardless of the level of processing, whereas it is intended for placing on the market or making available on the market;

2) *making available on the market* shall mean any activity enabling availability of products on the market of the Republic of Serbia for the purpose of distribution, consumption or use, whether in return for payment or free of charge;

3) *placing on the market* shall mean the first delivery of products on the market of the Republic of Serbia;
4) *producer* shall mean a legal entity, entrepreneur or natural person that produces a product, or a person claiming to be a producer by affixing its business name to the product, name or title, trademark or other distinctive mark or in any other manner;
5) *representative* shall mean a legal entity or entrepreneur that is registered in the Republic of Serbia, or a natural person resident of the Republic of Serbia, that has been authorised by the producer to, on its behalf, undertake actions according to the authorisation and with regard to the placing products on the market of the Republic of Serbia;
6) *importer* shall mean a legal entity or entrepreneur that is registered in the Republic of Serbia, or a natural person resident of the Republic of Serbia that places the product from other countries on the market;
7) *distributor* shall mean a legal entity or entrepreneur that is registered in the Republic of Serbia, or a natural person resident of the Republic of Serbia that is a part of the supply chain and that delivers the product as part of its its business activity, , but is neither a producer nor importer;
8) *supplier* shall mean a producer, representative, importer or distributor;
9) *conformity assessment* shall mean any activity demonstrating that specific technical requirements relating to a product or production process are fulfilled;
10) *conformity assessment body* shall mean a company, institution or another legal entity performing conformity assessment activities, i.e. technical evaluation activities including calibration, testing, certification and inspection ;
11) *certificate of conformity* shall mean a declaration of conformity, test report, certificate, inspection certificate or any other document verifying the conformity of products to the prescribed requirements;
12) *designation* shall mean an approval granted by the competent Minister to a conformity assessment body for performing conformity assessment for the needs of a producer in accordance with the requirements contained in the technical regulation;
13) *authorisation* shall mean an approval granted by the competent Minister to a conformity assessment body for performing the activities of technical valuation for the needs of the state administration authority conducting conformity assessment in accordance with the requirements contained in the technical regulation;
14) *technical valuation* shall mean testing and/or inspection of products aligned with the requirements of the technical regulation, whereas the said testing and/or inspection shall be performed by the authorised conformity assessment body for the needs of state administration authority;
15) *technical specification* shall mean a document that defines technical requirements for products and conformity assessment procedures, and it is prepared by the expert commission established by the competent ministry, whereas it is adopted by the Minister in charge of the competent ministry;
16) *inspection* shall mean an activity of regular or extraordinary control of the fulfilment of the prescribed safety requirements for products throughout their lifecycle;

17) *conformity mark* shall mean a mark affixed to the product by the producer to confirm that the product is in conformance with the prescribed technical requirements.

Other terms used in this Law, other than those defined in paragraph 1 of this Article, shall have the meaning as defined in the laws governing general safety of products, standardization and accreditation.

II TECHNICAL REQUIREMENTS FOR PRODUCTS AND TECHNICAL REGULATIONS

Manner of Prescribing Technical Requirements

Article 4

Technical requirements for individual products or groups of products (hereinafter referred to as: technical requirements) shall be prescribed in a technical regulation directly by specifying such requirements in the text of the regulation, or indirectly by the reference in the technical regulation to the Serbian standard or technical specification.

Technical Regulation

Article 5

Technical regulation shall mean any regulation which, for individual products or groups of products, (hereinafter referred to as the product) governs at least one of the following elements:

1) Technical requirements to be met by a product being made available on the market;

2) Conformity assessment procedures;

3) Safety requirements for products throughout its lifecycle;

4) Regular and extraordinary inspection of products, throughout its lifecycle;

5) Certificates that accompany products when placed on the market or put to use;

6) Marks and manner of marking products;

7) Requirements to be met by conformity assessment bodies;

8) Requirements with regard to packaging and labelling.

Technical regulations and technical requirements contained therein shall be adopted for the purpose of protecting safety, life and health of humans, protecting animals and plants, environment consumers and other users and property.

Adoption of Technical Regulation

Article 6

Technical regulations shall be prepared and adopted by the ministry within its area of competences (hereinafter referred to as: the competent ministry).

When preparing, adopting and applying technical regulations, the competent ministry

shall take into account particularly the following:

1) Preventing creation of unnecessary barriers to trade;

2) Non-discrimination between domestic and foreign products on the market;

3) Use of Serbian standards that incorporate international standards as a basis for the preparation of a technical regulation;

4) Specifying the reasonable period for commencement of application of a technical regulation;

5) Any changes in the circumstances that occurred after the adoption of a technical regulation for the purpose of its amendment or repeal;

6) Fulfilment of the objectives of technical regulations in the manner that is least trade-restrictive and, in that context, it shall amend or repeal technical regulations;

7) The requirements to be met by a product primarily in terms of performance rather than design or descriptive characteristics of the product.

Prescribing Technical Requirements Indirectly

Article 7

A technical regulation may refer to a Serbian standard in two manners:

1) a technical regulation may define that the only manner of ensuring compliance with the requirements of such a regulation is to comply with the requirements of the Serbian standard to which the technical regulation refers;

2) a technical regulation may define that one of the possible manners of ensuring compliance with the requirements of such a regulation is to comply with the requirements of the Serbian standard to which the technical regulation refers.

The Institute for Standardization of Serbia shall, upon request of the competent ministry, submit the information to confirm existence of the relevant Serbian standard for the product being governed by a technical regulation or to confirm that its adoption is pending or to confirm existence of the relevant international or European standard.

The Minister in charge of the competent ministry (hereinafter referred to as: the competent Minister) shall compose the list of standards referred to in paragraph 1, item 2 of this Article to which the technical regulation prepared and adopted by that ministry refers.

The list of standards referred to in paragraph 3 of this Article shall be published in the "Official Gazette of the Republic of Serbia on the form the content of which shall be prescribed by the Minister competent for standardization.

Article 8

A technical regulation may specify that the only manner of achieving compliance with the requirements of such a regulation is to meet the requirements of the technical specification to which the technical regulation refers.

The competent Minister shall specify the list of technical specifications referred to in paragraph 1 of this Article which shall be published in the „Official Gazette of the

Republic of Serbia".

Technical specification shall be published on the website of the competent ministry.

III ASSESSMENT OF CONFORMITY OF PRODUCTS

Prescribing Conformity Assessment

Article 9

The obligation to perform conformity assessment shall be prescribed in a technical regulation.

A technical regulation shall prescribe that, prior to placing a product on the market or in use, conformity assessment may be conducted and/or participated by:

1) producer;
2) designated conformity assessment body;
3) public administration authority.

A technical regulation shall specify the type of the certificate of conformity which a supplier is obliged to issue or provide for a product prior to its placing on the market or in use.

The content of the certificate of conformity shall be governed by the regulation adopted by the Government.

Conformity Assessment Procedures

Article 10

A technical regulation shall define the manner of conformity assessment which may include application of a single procedure, several procedures or a combination of different conformity assessment procedures.

The conformity assessment procedures referred to in paragraph 1 of this Article can also be defined indirectly in a standard or technical specification to which the technical regulation refers.

Conformity Assessment Conducted by the Producer

Article 11

When a technical regulation specifies that conformity assessment shall be conducted by a producer, such a regulation shall also prescribe the requirements with respect to the internal production control.

Internal production control shall include all actions that are necessary for the production process and monitoring of such a process to ensure the conformity of products with a technical regulation.

A producer shall issue a declaration of conformity and provide technical documentation in accordance with the prescribed requirements, whereas the said declaration shall be made available to the competent inspector for the purpose of supervision.

Conformity Assessment Conducted by the Designated Conformity Assessment Body

Article 12

When a technical regulation specifies that conformity assessment shall be conducted by a designated conformity assessment body, such a regulation shall also specify the requirements to be met by such a body, particularly with respect to:

1) professional capacities of the employees and other contracted persons;

2) equipment;

3) independence and impartiality with respect to the persons related to the product which is subject to conformity assessment;

4) handling of complaints with regard to its operations and any decisions made;

5) business secrecy;

6) insurance against liability for damage.

Article 13

When a technical regulation specifies that conformity assessment is conducted by a designated conformity assessment body (hereinafter referred to as: designated body), decision on its designation shall be issued by the competent Minister, in accordance with the law governing general administrative procedure.

The competent Minister shall issue a decision on appointment, provided the conformity assessment body which submitted an application for appointment meets the requirements from the technical regulation in the context of Article 12 of this Law.

When assessing the compliance with the prescribed requirements, the competent Minister shall also take into account the certificate confirming accreditation granting which the conformity assessment body has obtained in the course of the accreditation procedure.

The decision referred to in paragraph 1 of this Article shall be made final.

Article 14

The designated body referred to in Article 13, paragraph 1, of this Law shall, on the basis of the contract concluded with a producer, conduct conformity assessment in accordance with the procedures specified in a technical regulation.

Prior to the issuance of a certificate of conformity, the designated body shall request that the producer that failed to meet the prescribed requirements should undertake appropriate corrective actions.

Where a designated body, during the assessment of conformity and after the document has been issued, finds that a product no longer meets the prescribed requirements, it shall request the producer to undertake appropriate corrective actions and, if necessary, it may temporarily or permanently confiscate the certificate of conformity or limit the

validity of such a document.

The designated body may, with the consent of the producer, delegate, with regard to conformity assessment, certain tasks to the subcontractor, provided the subcontractor meets the requirements from the same technical regulation as the designated body.

The designated body may delegate to the subcontractor only those tasks for which such a body has been designated. The designated body shall retain the responsibility for the tasks delegated to the subcontractor.

The manner of conducting conformity assessment referred to in paragraph 1 of this Article shall be governed by the regulation adopted by the Government.

Article 15

A designated body shall inform the competent Minister of:

1) a refusal to issue, restriction, temporary or permanent confiscation of the certificate of conformity;
2) any changes in the circumstances from the decision on its designation that may affect the scope and requirements of the designation;
3) a request of the competent inspector related to the conformity assessment;
4) delegation of tasks to the subcontractor referred to in Article 14, paragraph 4, of this Law;
5) conducted conformity assessment within the scope of its designation in the country or abroad;
6) other conformity assessment-related activities.

The notices referred to in paragraph 1, points 5 and 6 of this Article shall be submitted upon request of the competent ministry.

Article 16

If the competent Minister finds that the designated body no longer meets the prescribed requirements or no longer performs its duties, he/she shall issue a decision on withdrawal of the approval for conducting conformity assessment in accordance with the law governing general administrative procedure.

Before issuing the decision referred to in paragraph 1 of this Article, the competent Minister may, taking into account the significance of deficiencies with respect to compliance with the requirements or performance of duties, warn the designated body in writing about the deficiencies with respect to the compliance with requirements or performance of duties, and set the deadline for the elimination of such deficiencies which may not exceed 60 days.

The decision referred to in paragraph 1 of this Article shall be made final.

In the event of issuance of the decision on withdrawal of the approval referred to in paragraph 1 of this Article or in the event that the designated body ceases its operations, the competent Minister shall instruct such a body to transfer the conformity assessment-related documentation within the specified period of time to another designated body as chosen by the producer, i.e. to allow the competent authorities access to such documentation.

Conformity Assessment Conducted by the State Administration Authority

Article 17

Where a technical regulation prescribes that conformity assessment shall be conducted by the public administration authority, the competent public administration authority shall, at the request of a producer, conduct conformity assessment in accordance with the procedures prescribed by such a regulation.

Before issuing a certificate of conformity, the public administration authority shall order a producer that failed to meet the prescribed requirements to undertake appropriate corrective actions.

If the public administration authority, during the assessment of conformity and after issuing a certificate of conformity, finds that a product no longer meets the prescribed requirements, it shall instruct a producer to undertake appropriate corrective actions and, if necessary, issue a decision to confiscate the certificate of conformity, temporarily or permanently, or to restrict the validity of such a document.

The decision referred to in paragraph 3 of this Article shall be made final.

The costs of conformity assessment referred to in paragraph 1 of this Article shall be borne by a producer.

The manner of conducting conformity assessment referred to in paragraph 1 of this Article and the manner of determining and covering the costs of conformity assessment referred to in paragraph 5 of this Article shall be governed by a regulation adopted by the Government.

Article 18

Where a technical regulation prescribes that conformity assessment is conducted by the public administration authority, and if a conformity assessment body performs technical valuation for the needs of such an authority, such a body shall meet the requirements from the technical regulation in the context of Article 12 of this Law.

The competent ministry shall invite conformity assessment bodies to submit applications for the purpose of notification and consequent performance of technical evaluation.

The public invitation shall particularly specify the number and type of conformity assessment bodies that the public administration authority needs for the performance of technical evaluation, as well as the requirements from the technical regulation that shall be met by such a body.

The competent Minister shall issue the decision on authorisation of a conformity assessment body referred to in paragraph 1 of this Article in accordance with the law governing general administrative procedure.

Decision referred to in paragraph 4 of this Article shall be made final.

If the competent Minister finds that the authorised body referred to in paragraph 4 of this Article no longer meets the prescribed requirements and/or no longer performs its duties, as well as if there is no longer a need for performing technical evaluation, the competent Minister shall act in accordance with Article 16, paragraphs 1 and 2, of this Law.

Role of Accreditation

Article 19

When issuing the decision referred to in Articles 13 and 18 of this Law, it shall be deemed that a conformity assessment body holding an accreditation certificate meets the prescribed requirements to the extent in which they fall within the scope of accreditation, taking into account the conformity assessment procedures and the products covered by the accreditation.

A technical regulation can prescribe that, during the procedure of conformity assessment, certain activities may be conducted by an accredited body belonging to the producer instead of a designated body.

The body referred to in paragraph 2 of this Article shall be an independent organizational unit of the producer, it shall not take part in the production, delivery, assembly, use or maintenance of the products the conformity of which it is assessing and may provide services only to the producer it belongs to.

Notification of Conformity Assessment Bodies

Article 20

The Ministry competent for issues related to technical regulations (hereinafter referred to as: the Ministry) shall, upon the proposal of the competent ministry, notify the designated or authorized conformity assessment body to the relevant international organization in accordance with the rules of ratified international agreements of which the Republic of Serbia is a signatory.

The manner of designation, authorization, withdrawal of the approval for performing conformity assessment, notification of conformity assessment bodies, as well as the manner of determining the fulfilment of the prescribed requirements for appointment or authorization of conformity assessment bodies shall be governed by a regulation adopted by the Government.

IV OBLIGATIONS OF PRODUCT SUPPLIERS AND OWNERS OF PRODUCTS IN USE

Conformity of Products

Article 21

A product may be placed on the market or made available on the market only if it is in conformity with the prescribed technical requirements, if its conformity was assessed according to the prescribed procedure, if it is marked in accordance with the regulations, and if it accompanied by the prescribed documents of conformity and other prescribed documentation.

Safeguard Clause

Article 22

The competent inspector shall undertake appropriate actions restricting the availability on the market, prohibiting the marketing of products or their availability 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 threaten public interest, and particularly if it threatens safety, human life and health, safety and health of animals and plants, environment, safety of consumers and other users and property.

The competent Minister shall remove a Serbian standard from the list of standards referred to in Article 7 paragraph 3 of this Law, if it is found that non-safety of the product referred to in paragraph 1 of this Article is a result of inadequate technical solutions derived from such a standard.

Obligations of Producers

Article 23

The producer shall:

1) ensure for a product to be made in accordance with the prescribed requirements;
2) draw up the required technical documentation and keep it within the prescribed period of time;
3) ensure implementation of the prescribed conformity assessment procedure, prepare the declaration of conformity and keep it within the prescribed period of time, and affix the prescribed conformity marking to the product;
4) where prescribed, it shall test the samples of products on the market, process the information, keep the register of complaints, and inform distributors about the non-conforming products, and about any corrective actions undertaken on its own initiative, as instructed by or in cooperation with the competent authorities with the purpose of eliminating the risks posed by the non-conforming product;
5) perform other activities prescribed by the technical regulation for specific products.

The producer may authorize a representative to perform its obligations by means of a written authorization which shall enable the representative to at least:

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

A producer shall not transfer to the authorized representative its obligations referred to in paragraph 1, point 1, of this Article or authorise the representative to draw up the technical documentation.

Article 24

A producer shall affix the conformity mark to the product that is in conformity with a

technical regulation if specified in the technical regulation.

It shall be prohibited to affix the conformity mark to a product that is not in conformity with the prescribed requirements or to a product not requiring the prescribed conformity mark.

It shall be prohibited to affix to a product any other mark that is not a conformity mark but is of similar content or form, whereby it could mislead the consumers or other users to believe that it is a conformity mark, or if affixing of other mark to a product would impair the visibility or legibility of the conformity mark.

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

Obligations of Importers

Article 25

An importer shall:

1) check if the declaration of conformity was issued for a product and/or if a product is accompanied by other prescribed certificate of conformity, whether it bears the prescribed conformity mark, whether it is labelled in a manner enabling identification of a product and producer, and whether it is accompanied by the prescribed documentation;
2) keep, within the prescribed period of time, a copy of the declaration of conformity and technical documentation, and make them available to the competent authorities at their request;
3) if there is reason to believe that a product is not in conformity with the prescribed requirements, it shall place the product on the market only after the producer brings the product in conformity with such requirements, and it shall inform the competent authority that the product is unsafe ;
4) ensure that, prior to marketing of the product, the conditions of storage or transportation do not adversely affect the conformity of products with the prescribed requirements;
5) perform other activities prescribed by a technical regulation for specific products.

An importer shall be considered as a producer and assume its obligations when it places a product on the market under its name or trademark, namely if it modifies a product that was already placed on the market to the extent which affects the conformity with the prescribed requirements.

Obligations of Distributors

Article 26

A distributor shall:

1) check whether the prescribed conformity mark is affixed to the product and whether it 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 producer brings

the product in conformity with such requirements, and inform the producer or importer and competent authorities that the product is unsafe;

3) ensure that, prior to making the product available on the market, the conditions of storage and transportation do not adversely affect the conformity of products with the prescribed requirements;

4) perform other activities prescribed by a technical regulation for specific products.

A distributor shall be considered as a producer and assume its obligations when it places on the market a product under its name or trademark, namely if it modifies a product that was already placed on the market to the extent which affects the conformity with the prescribed requirements.

Obligations of the Owner of Product in Use

Article 27

Owner of a technically complex product for which a technical regulation provides for regular or extraordinary inspection with the purpose of confirming the product safety throughout its lifecycle, may put in use such a product, i.e. may enable the use of such a product, only if the prescribed inspections confirming its safety have been performed.

A technical regulation may specify that the prescribed inspection shall be performed by a designated body or public administration authority.

The provisions of Articles 12 through 19 of this Law shall apply mutatis mutandis to the manner of performing the prescribed inspection referred to in paragraph 2 of this Article.

V VALIDITY OF FOREIGN DOCUMENTS AND CONFORMITY MARKS

Article 28

Certificates of conformity issued by a foreign conformity assessment body and conformity marks issued abroad (hereinafter referred to as: foreign documents and conformity marks) shall be valid in the Republic of Serbia if they were issued in accordance with the ratified international agreements to which the Republic of Serbia is a signatory.

The competent Minister may recognize the validity of foreign certificates and conformity marks which confirm the conformity of products with foreign technical regulations under the condition that requirements of such a regulation provide at least the same level of protection of safety, human life and health, protection of animals and plants, environmental protection, protection of consumers and other users, and protection of property as provided by the requirements of a Serbian technical regulation.

Article 29

In the process of recognition of the validity of foreign certificates and conformity marks it shall be determined, in addition to the conditions referred to in Article 28, paragraph 2, of this Law, whether the requirements from a foreign technical regulation to be met by a foreign conformity assessment body in order to perform the product conformity assessment activities provide for at least the same level of fulfilment of the requirements

as that defined in the Serbian technical regulation for an appointed designated body.

Article 30

The document on recognition of the validity of documents and conformity marks referred to in Article 28, paragraph 2, of this Law shall be issued upon previously obtained opinion of the Ministry.

The manner of recognition of documents and conformity marks referred to in Article 28, paragraph 2, of this Law shall be governed by a regulation adopted by the Government.

VI NOTIFICATION

Registers

Article 31

The Ministry shall keep public registers of:

1) current technical regulations and designated and authorized conformity assessment bodies;
2) technical regulations under preparation;
3) foreign certificates and conformity marks valid in the Republic of Serbia.

The registers referred to in paragraph 1 of this Article shall particularly include: name of the competent ministry that has adopted the technical regulation; title of the technical regulation; business name, head office and business activity of the designated or authorized conformity assessment body, and other data relevant to the operation of such bodies; name of the competent ministry that has prepared a technical regulation and title of such a regulation; type of foreign certificates and conformity marks that are valid in the Republic of Serbia, business name and head office of foreign conformity assessment bodies which have issued the certificate of conformity, and other data relevant to the operation of such foreign bodies, and other data relevant to foreign certificates and conformity marks .

The content and manner of keeping the registers referred to in paragraph 1 of this Article shall be prescribed by the Minister competent for activities related to technical regulations.

Notification of Technical Regulations under Preparation

Article 32

The Ministry shall, in accordance with the rules of ratified international agreements to which the Republic of Serbia is a signatory, notify the relevant authorities from such agreements the technical regulations under preparation and related conformity assessment procedures.

The notification procedure of technical regulations referred to in paragraph 1 of this Article shall be governed by a regulation adopted by the Government.

Provision of Information

Article 33

The Ministry shall, upon request of domestic and foreign legal entities and natural persons, provide information and relevant documentation with regard to:

1) current technical regulations or technical regulations under preparation;

2) current conformity assessment procedures or conformity assessment procedures under preparation;

3) membership of the Republic of Serbia in international and regional cooperation programs in the field of conformity assessment, or in bilateral and multilateral agreements related to technical regulations and conformity assessment procedures.

The manner of providing information and documentation referred to in paragraph 1 of this Article shall be governed by a regulation adopted by the Government.

VII INSPECTION SUPERVISION

Article 34

Inspection control over the implementation of the provisions of this Law and regulations adopted on the basis of this Law, and technical regulations applied based on Article 41 of this Law, shall be performed by the competent ministries through the inspectors and in accordance with the law.

In addition to the measures for which they are authorized by virtue of other regulations, the competent inspectors shall, when conducting control, be authorised to:

1) request from suppliers all the necessary information and access to the certificates of conformity and prescribed technical documentation;

2) perform relevant controls, take product samples and forward them for testing to verify the conformity of products with the prescribed technical requirements;

3) check whether the prescribed inspections confirming the safety of products throughout their lifecycle have been performed;

4) instruct elimination of established non-conformity within the specified period of time;

5) request that the products be marked with the prescribed conformity marks, or removal of marks that are not allowed;

6) restrict or prohibit delivery of products to the market and implement additional actions in accordance with law to ensure that the restriction or prohibition is observed;

7) instruct the withdrawal or recall of products that are not in conformity with the prescribed requirements;

8) notify the competent ministry which has adopted the technical regulation related to a particular product for the purpose of undertaking relevant actions;

9) instruct destruction of non-conforming products if they present a serious risk to the safety, life and health of humans, animals and plants, and environmental protection.

When performing inspection control, the competent inspector shall be authorised to inspect the supplier's business premises and facilities.

If the competent inspection authority does not have the necessary technical expertise or equipment for performing the controls or testing referred to in paragraph 2 of this Article, it may delegate control and testing to the relevant conformity assessment body.

Costs of control and testing of the product conformity, and other costs incurred during inspection control shall be borne by a supplier if it is established that a product is not in conformity with the prescribed requirements.

An appeal against the decision by which the inspector instructed undertaking of the actions referred to in paragraph 2 of this Article shall not stay the execution of the decision.

VIII PENAL PROVISIONS

Article 35

A fine of between 100,000 and 1,000,000 RSD shall be imposed for the following offences committed by a legal entity (conformity assessment body) if it:

1) performs conformity assessment and/or performs technical evaluation of products without a decision on appointment or authorisation (Article 13, paragraph 1, and Article 18, paragraph 4);
2) fails to notify the competent Minister in accordance with the obligations referred to in Article 15 of this Law;
3) fails to act as instructed by the competent Minister referred to in Article 16, paragraph 2, of this Law.

A fine of between 20,000 and 50,000 RSD shall be imposed on a responsible person of a legal entity (conformity assessment body) committing the acts referred to in paragraph 1 of this Article. .

Article 36

A fine of between 100,000 and 100,000,000 RSD shall be imposed on a responsible person of a legal entity (supplier) committing the acts referred to in paragraph 1 of this Article if it:

1) places on the market and/or makes available on the market a product that is not in conformity with the prescribed technical requirements, if the product conformity is not assessed in accordance with the prescribed procedure, if a product is not marked in accordance with the regulations or if it is not accompanied by the prescribed certificates of conformity or other prescribed documentation (Article 21).

A fine of between 20,000 and 50,000 RSD shall also be imposed on a responsible person of a legal entity (supplier) committing the acts referred to in paragraph 1 of this Article.

A fine of between 100,000 and 500,000 RSD shall also be imposed on an entrepreneur (supplier) committing the acts referred to in paragraph 1 of this Article.

A fine of between 10,000 and 50,000 RSD shall also be imposed on a natural person (supplier) committing the acts referred to in paragraph 1 of this Article.

Article 37

A fine of between 100,000 and 1,000,000 RSD shall be imposed for the following offences committed by a legal entity (producer) if it:

1) fails to draw up and enable keeping of the necessary technical documentation, fails to prepare and/or keep the declaration of conformity, fails to affix to the product the prescribed conformity mark (Article 23, paragraph 1, points 2 and 3, and paragraph 2, item 1);

2) fails to perform, as prescribed for certain products for which such is, the testing of product samples on the market and if it fails to perform other activities and measures as prescribed for such products , and/or does not cooperate with the competent authorities in terms of undertaking all the corrective actions with the aim of preventing occurrence of the risk posed by the product (Article 23, paragraph 1, point 4 and paragraph 2, point 3);

3) affixes a conformity mark to the product which is not in conformity with the prescribed requirements or affixes a conformity mark to a product to which the conformity mark should not be affixed (Article 24, paragraph 2);

4) affixes to the product a mark that is not a conformity mark, but is of similar content or form thus leading consumers or other users to believe that it is a conformity mark, or if affixing other mark to a product would impair the visibility or legibility of the conformity mark (Article 24, paragraph 3).

A fine of between 20,000 and 50,000 RSD shall also be imposed on a responsible person of a legal entity (producer) or its representative committing the acts referred to in paragraph 1 of this Article.

A fine of between 100,000 and 500,000 RSD shall also be imposed on an entrepreneur (producer) or its representative committing the acts referred to in paragraph 1 of this Article.

Article 38

A fine of between 100,000 and 1,000,000 RSD shall be imposed for the following offences committed by a legal entity (importer) if it:

1) fails to keep, within the prescribed period of time, a copy of the declaration of conformity and technical documentation or fails to make them available to the competent authorities at their request (Article 25, paragraph 1, point 2);

2) places, if there is reason to believe that a product is not conforming with the prescribed requirements, such a product on the market before it is rendered in conformity with such requirements, and if it fails to notify the competent authorities thereof in the event of an unsafe product (Article 25, paragraph 1, point 3).

A fine of between 20,000 and 50,000 RSD shall also be imposed on a responsible person of a legal entity (importer) or its representative committing the acts referred to in paragraph 1 of this Article.

A fine of between 20,000 and 50,000 RSD shall also be imposed on an entrepreneur (importer) committing the acts referred to in paragraph 1 of this Article.

Article 39

A fine of between 100,000 and 1,000,000 RSD shall be imposed for the following offences committed by a legal entity (distributor) if it:

1) markets, if there is reason to believe that a product is not conforming with the prescribed requirements, a product before it is rendered in conformity with such requirements, if it fails to notify a producer or importer thereof, and the competent authorities in the event of an unsafe product (Article 26, paragraph 1, point 2).

A fine of between 20,000 and 50,000 RSD shall also be imposed on a responsible person of a legal entity (distributor) committing the acts referred to in paragraph 1 of this Article.

A fine of between 100,000 and 500,000 RSD shall also be imposed on an entrepreneur (distributor) committing the acts referred to in paragraph 1 of this Article.

A fine of between 10,000 and 50,000 RSD shall also be imposed on a natural person (distributor) committing the acts referred to in paragraph 1 of this Article.

Article 40

A fine of between 50,000 and 500,000 RSD shall be imposed for the following offences committed by a legal entity (owner of the product) if it:

1) places or enables the use of a product for which the prescribed inspections were not performed to confirm its safety throughout its lifecycle (Article 27, paragraph 1).

A fine of between 50,000 and 100,000 RSD shall also be imposed on an entrepreneur (owner) committing the acts referred to in paragraph 1 of this Article. A fine of between 10,000 and 50,000 RSD shall also be imposed on a natural person (owner) committing the acts referred to in paragraph 1 of this Article.

IX TRANSITIONAL AND FINAL PROVISIONS

Article 41

Technical regulations and other regulations adopted on the basis of the Law on Technical Requirements for Products and Conformity Assessment ("Official Journal of the S & M", No. 44/05) shall be applied pending the adoption of the technical regulations and other regulations adopted on the basis of this Law.

Article 42

Conformity assessment shall be performed by the conformity assessment bodies which were authorised or accredited as of the entry into force of this Law pending the adoption of technical regulations prescribing the requirements to be met by designated or authorised conformity assessment bodies as laid down in this Law, i.e. pending the adoption of the regulations referred to in Article 20, paragraph 2, of this Law.

Article 43

Sub-laws adopted on the basis of the Law on Technical Requirements for Products and Conformity Assessment of Products with the Prescribed Requirements ("Official

Journal of Serbia and Montenegro", No. 44/05) shall apply pending the adoption of the following sub-laws prescribed by this Law:

1) Decree on the Manner of Preparing and Adopting Technical Regulations and the Register Thereof („Official Journal of Serbia and Montenegro", No. 17/06);
2) Decree on the Manner of Authorising Conformity Assessment Bodies, Register of Authorised Conformity Assessment Bodies, Records of Certificates of Conformity, Conformity Marks and Conformity Assessment Bodies and on the Conditions for Application of Technical Regulations of Other Countries "Official Journal of Serbia and Montenegro", No. 22/06);
3) Decree on the Manner and Procedures of Conformity Assessment "Official Journal of Serbia and Montenegro", No. 22/06);
4) Decree on the Manner of Providing Information on and Notifications of Technical Regulations, Standards and Conformity Assessment ("Official Gazette of the RS", No. 126/07).

The Government shall adopt the documents referred to in Article 9, paragraph 4, and Articles 14, 17, 20, 24 and 30 of this Law within six months following the entry into force of this Law.

The Government shall adopt the documents referred to in Articles 32 and 33 of this Law within one year following the entry into force of this Law.

The content of the form referred to in Article 7, paragraph 4, of this Law shall be prescribed by the Minister competent for standardization within six months following the entry into force of this Law.

The regulation referred to in Article 31, paragraph 3, of this Law shall be adopted by the Minister competent for the activities related to technical regulations within one year following the entry into force of this Law.

Article 44

The Law on Technical Requirements for Products and Conformity Assessment of Products with the Prescribed Requirements ("Official Journal of Serbia and Montenegro", No. 44/05) shall be repealed with effect from the day of entry into force of this Law.

Article 45

This Law shall enter into force on the eighth day following its publication in the "Official Gazette of the Republic of Serbia".

3.1.3. Mechanisms for the Implementation of the Law on Technical Requirements for Products and Conformity Assessment

Provisions of any law are always elaborated in more details in the sub-laws. In other words, sub-laws serve as mechanism for the implementation of the laws.

The following sub-laws arising from the Law on Technical Requirements for Products and Conformity Assessment prescribe in more details conformity assessment:

1. **Regulation on Manner of Performing Conformity Assessment, Content of the Document of Conformity, and Shape, Appearance and Content Mark of Conformity** (Official Gazette of the RS, No. 98/09);
2. **Regulation on the Manner of Designation and Authorisation of Conformity Assessment Bodies** (Official Gazette of the RS, No. 98/09);
3. **Regulation on the Manner of Recognition of Foreign Documents and Marks of Conformity** (Official Gazette of the RS, No. 98/09) ;
4. **Regulation on Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standard** (Official Gazette of the RS, No. 45/10);
5. **Rulebook on Manner of Affixing Marks of Conformity on Products, and Use of Conformity Marks** (Official Gazette of the RS, No. 25/10);
6. **Rulebook on the Content and Manner of Keeping the Registers referring to Technical Regulations** (Official Gazette of the RS, No.33/10)
7. **Rulebook on the content of the form publishing a list of Serbian standards referred to by the technical regulations** ("Official Gazette of the RS", Nos. 110/09 and 14/12)**.**

1. Conformity assessment procedures that are regulated by the **Regulation on the Manner of Performing Conformity Assessment, Content of the Certificate of Conformity, and Shape, Appearance and Content of Conformity Marks are in line with the procedures defined in Decision EC 768/2008**. Pursuant to this Regulation, conformity assessment procedures are prescribed in a specific technical regulation depending on the area.

Article 18 of this Regulation prescribes that conformity assessment is performed in accordance with the procedures **(modules)** laid down by the technical regulation in accordance with Decision 768/2008/EC.

The same Article defines the modules that can be prescribed by the technical regulation (modules from A to H) and those represent different phases of the conformity assessment process:

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

The above mentioned modules may be applied individually or combined as defined in the technical regulation.

Furthermore, provisions of the above mentioned Regulation provide a legal basis for the CABs to issue a **document proving conformity of the imported product** with prescribed requirements **(certification of conformity),** *whereas it shall be based only on the documentary review (without a need to perform conformity assessment procedure again in the Republic of Serbia*); it is valid for the imported products that are accompanied by the declaration of a producer (in addition to other documentation) or, in other words, it is valid for the products not requiring a "third party" conformity assessment.

On the other hand*, **it is not valid*** **for the imported products accompanied by the certificates of conformity issued by a third party;** in this case a certificate issued by a foreign CAB shall be recognised by the competent Minister by means of a special procedure for the recognition of foreign certificates;

However, there is **an exception** for the imported products accompanied by foreign certificates issued by third parties: they could be subject *only* to *documentary review in order to obtain confirmation of conformity from a domestic notified body without a need to perform conformity assessment procedure again* by *or conduct recognition of foreign certificates under* ***the following three conditions:***

If the notified body in Serbia and the CAB that issued foreign certificate of conformity are:

1) **signatories to the Agreement on Mutual Recognition of Conformity Assessment Results, or**
2) **members of the international Conformity Assessment System**
3) **In case when an agreement on mutual recognition of technical competence is signed by the accreditation bodies.**

This Decree has been adopted with a view to enable efficient, professional and economical performance of conformity assessment, without or with least burden for the economic operators the products of are subject to conformity assessment procedures notwithstanding the origin of the product (domestic or foreign product).

2. The main purpose of the **Decree on the Manner of Notification and Authorisation of Conformity Assessment Bodies** (Official Gazette of the RS, No. 98/09) **is to regulate both CAB notification (New Approach) and authorisation (Old Approach) procedure. Notification** covers *testing laboratories, inspection bodies and certification bodies,* while a producer can select one of them to perform conformity assessment and to issue a certificate on conformity as an independent third party. **Authorisation** covers only *testing laboratories and inspection bodies*, while the state will select a limited number of these bodies to perform technical assessment for the needs of the state, and on the basis of the assessment performed, the state will issue a an adequate certificate of conformity (in most of the cases it will be a certificate). **Both notification and authorisation is performed by the state / competent ministry (depending on the sector).**

The competent Minister shall nominate the Committee to assess if the conformity assessment body meets all notification-related requirements laid down by a technical regulation. The Committee shall be consisted of three members (representative of the competent ministry, representative of the Accreditation Body of Serbia and representa-

tive of the Institute for standardization). The competence of the conformity assessment body (required by a technical regulation) can be proved by an applicant by means of an accreditation certificate or other relevant documentation. Once notification/authorisation has been approved by the competent ministry, it can be withdrawn if it has been found that the requirements for the designation/authorization can no longer be fully met; the only difference in the procedure between notification and authorisation is the manner of initiating the procedure- authorisation procedure is initiated by a public invitation.

Currently, **there are eight conformity assessment bodies that have been designated for different areas: Jugoinspekt ad Beograd** (limited liability company Belgrade) has been designated for conformity assessment of products in accordance with the Regulation on Machinery Safety (Official Gazette of the RS, No. 13/10), Regulation on Electromagnetic Compatibility (Official Gazette of the RS, No.13/10), Regulation on Lift Safety (Official Gazette of the RS, No.101/10); **Institut 1. maj, Niš** is designated for conformity assessment of products in accordance with the Regulation on Machinery Safety (Official Gazette of the RS, No. 13/10); **Institut za nuklearne nauke Vinča**, **Beograd**, is designated for conformity assessment of products in accordance with the Regulation on Electrical Equipment Designed for Use within Certain Voltage Limits (Official Gazette of RS, No. 13/10); **„Kvaliet" ad Niš** (joint stock company) is designated for conformity assessment of products in accordance with the Regulation on Electromagnetic Compatibility (Official Gazette of the RS, No.13/10); the Regulation on Electrical Equipment Designed for Use within Certain Voltage Limits (Official Gazette of the RS, No. 13/10) and the Regulation on Machinery Safety (Official Gazette of the RS, No. 13/10); **Institut za zaštitu na radu, Novi Sad** is designated for conformity assessment of products in accordance with the Regulation on Machinery Safety (Official Gazette of the RS, No. 13/10) and **Regulation on Lift Safety (Official Gazette of the RS, No. 101/10)**; **Sertifikaciono telo RTS Beograd** is designated for conformity assessment of products in accordance with the Regulation on Electromagnetic Compatibility (Official Gazette of the RS, No.13/10); **Tehnički opitni centar (TOC)** is desiganted for conformity assessment of products in accordance with the Regulation on Electromagnetic Compatibility (Official Gazette of the RS, No.13/10); and **Elkont Inženjering Beograd** is designated for conformity assessment of products in accordance with the Regulation on Machinery Safety (Official Gazette of the RS, No. 13/10) and Regulation on Lift Safety (Official Gazette of the RS, No.101/10); all details about these designated bodies can be found on the MERD web page at: www.tehnis.merr.gov.rs.

3. **Regulation on the Manner of Recognition of Foreign Documents and Conformity Marks** (Official Gazette of the RS, No. 98/09) is a step forward in creating the preconditions for free movement of goods and removal of technical barriers in line with the provisions of WTO / TBT Agreement. Namely, **the procedure of recognition of foreign certificates and conformity marks will replace retesting/re-sampling (to be carried out by a Serbian testing laboratory, i.e. certification body) of foreign products** that had already been tested and certified abroad**.** This will however foster higher level of competitiveness of Serbian products when placed on the European and world markets.

The competent Minister shall nominate the Committee that consists of three members: representative of the competent ministry, representative of the Accreditation Body of

Serbia, representative of the Institute for Standardization of Serbia, but it could be extended to include one or more external experts for the subject matter concerned. The Committee shall assess whether the prescribed requirements for the recognition have been met and then the competent Minister shall pass a decision on recognition of the foreign certificate or conformity mark on the basis of the elaborated proposal of the Committee. When determining the fulfilment of the requirements the Committee shall:

- Firstly identify a Serbian technical regulation laying down requirements for the product;
- then determine whether the said Serbian regulation requires a certificate of conformity issued by a "third party";
- if it is the case, the Committee shall determine if the foreign technical regulation, that is valid for the foreign product in question, lays down at least the same level of product safety as that of the Serbian technical regulation; at the same time, the Committee shall determine whether the conformity assessment body who has performed conformity assessment of the product in question meets at least the same degree of requirements as those of the Serbian technical regulation;
- if it is not the case (certificate of conformity by a third party is not required), the Committee shall halt the procedure since the certificate not issued by a third party shall be subject to a different procedure (see the aforementioned – certificate of conformity).

After a decision on the recognition of a foreign certificate has been made by the competent Minister, the decision shall be submitted to the MERD that shall enter the decision in the Register kept by the MERD as a coordinator in this area; for each subsequent supply of the **same imported product**, for the purpose of customs clearance and its marketing, **it will be sufficient to have just an extract from the MERD Register of current foreign certificates and conformity marks**.

4. The **Regulation on the Manner of Notification and Provision of Information about Technical Regulations, Conformity Assessment and Standards** (Official Gazette of the RS, No. 45/10) is adopted with a view to enable efficient implementation of WTO/TBT Agreement by means of the provisions governing notification and information about technical regulations, standards, and conformity assessment procedures in preparation. Additionally, this Regulation is fully in compliance with Directive 98/34 (98/48) that prescribes the notification procedure in terms of technical regulations and rules of information society. Basic provisions of the Regulation prescribe the competences in the area of notification of technical regulations and standards. Therefore, these provisions prescribe that the MERD shall be in charge of notification of technical regulations (Enquiry Point for technical regulations), while the Institute for standardization of Serbia shall be in charge of notification of standards (Enquiry Point for standards).

5. **Rulebook on the Manner of Affixing Conformity Marks to Products, and Use of Conformity Marks** (Official Gazette of the RS, No. 25/10) regulates the manner of affixing the conformity marks to the products conforming to the requirements of technical regulations prior to their being placed on the market and the use of conformity marks. Once the conformity assessment procedure has been completed, a producer or its rep-

resentative, or in some cases an importer, shall affix conformity marks to products in line with the technical regulation. There are three types of conformity marks: a) **Serbian conformity mark** proving the conformity of a product being placed on **the Serbian market** with the requirements of technical regulations, b) **CE mark** affixed to **products to be exported** and c) **other conformity marks** (e.g. E used for homologation).Conformity marks shall be visible, legible, and indelible.

6. The **Rulebook on the Content and Manner of Keeping the Registers Refering to Technical Regulations** (Official Gazette of the RS, No. 33/10) was adopted In May 2010. In accordance with the Rulebook, the Register of technical regulations shall be kept in electronic format, and shall be made publically available on the MERD web page.

7. **Rulebook on the Content of the Form Used for Publishing a List of Serbian Standards Referred to by the Technical Regulation** ("Official Gazette of the RS", Nos. 69/09 and 14/12) was adopted in December 2009 and amended in March 2012. This regulation prescribes the content of the form used for publishing a list of Serbian standards transposing harmonised European standards that refer to any technical regulation transposing the New Approach Directives of the EU into the legal system of the Republic of Serbia.

The aforementioned sub-laws are substantially in compliance with Decision 768/2008/EC and they followed the principles of the "new good's package" for marketing of products.

STANDARDIZATION

3.1.4. What Novelties Have Been Introduced into the Serbian Legal System after the Adoption of the new Law on Standardization

The area of standardization had previously been under the jurisdiction of public administration. Pursuant to the Law on Standardization adopted during the State Union of Serbia and Montenegro, the Federal Biro for Standardization established as a part of the Federal Ministry of Internal Economic Affairs had been in charge not only of the standardization affairs, but also of the technical regulations, conformity assessment, accreditation, certification, and surveillance. After the dissolution of the State Union of Serbia and Montenegro, **Serbian Government adopted the Act on Establishment of the Institute for Standardization** (Official Gazette of the RS, No. 16/07) ***as a body outside the area of state administration's competence***. Additionally, the MERD became responsible for all horizontal questions in the field of standardisation, accreditation, metrology, technical regulations and 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 (Official Gazette of the RS, No. 16/11).

For all these reasons there was an urgent need for harmonising the area of

standardization with the legal system of the Republic of Serbia and with the WTO Agreement on Technical Barriers to Trade and EU requirements. That is why one of the MERD priorities was the adoption of the new Law on Standardization. This new Law was adopted in 2009 (Official Gazette of the RS No. 36/09) and it entered into force on the eighth day following its publication in the "Official Gazette". This **Law governs the principles and objectives of standardization, organisation, and activities of the national standardization body, and the adoption, publication and application of Serbian standards and related documents.**

Novelties that were introduced into the Serbian legal system by adopting this new Law on Standardization **can be divided into two groups**:

a) novelties based on the harmonisation of the new law with the legal system of the Republic of Serbia;

b) novelties based on the alignment of the new Law with WTO /TBT and EU requirements.

a) Novelties based on the harmonisation of the new law with the legal system of the Republic of Serbia

1. By adopting the Act on Establishment of the Institute for Standardization of Serbia, (Official Gazette of the RS, No. 16/07), the governing of the area of standardization was delegated to an independent body, independent non-profit organization" not belonging to the public administration (see the abovementioned). However, **the legal status of the body was not defined in line with the principles of the Serbian legal system** given that the definition of the "independent non-profit organisation" was unclear and imprecise and as such it did not exist in any of law prescribing the legal status of the public administration (public authorities), public services, companies, associations, etc. Hence the new law on Standardization regulated the legal status and position of the Institute for Standardization of Serbia (ISS), in a way that it is now in keeping with the Serbian legal system. Pursuant to the new Law on Standardization (Official Gazette of the RS, No. 36/09) and Decision on Amendments of the Act on Establishment of the Institute for Standardization (Official Gazette of the RS, No. 88/09), the ISS **now has a public institution status** operating in accordance with the Law on Standardization and Law governing the legal status of public services.

Operation of the ISS is partially financed from the budget of the Republic of Serbia (80%), while a smaller portion is provided through selling standards, collecting membership fees, etc. Funding from the budget is approved on the basis of the Annual Work Programme and Plan for the Adoption of Serbian Standards and Related Documents for each fiscal year. **Main business activity of the Institute is adoption and sale of standards**.

Management bodies of the Institute are as follows: Assembly, Management Board, Director and Supervisory Board. Special role has been delegated to the Technical Councils and Committees for standards and related documents as advisory bodies consisting of experts in different fields in the process of adoption and revision of standards.

Strategic interests of all interested parties in Serbia (economy, scientific and civic awareness institutions, ministries and other public administration bodies, non-

governmental organisations and citizens) will be taken into consideration when determining the national policy and standardization development strategy.

2. **Distinction between general and sectoral standardization was made** for the first time through the provisions of the new Law on Standardization. Namely, this Law applies to standards and related documents adopted and published by the Serbian Institute for Standardization (ISS), and to international and European standards and related documents of the recognised international and European organisations for standardization; having said that, these **standards governed by the new Law are related to general standardization**, **and not to, sectoral standardization** in the field of transportation, defence, etc. since these are **governed by special laws**.

b) Novelties based on the alignment of the new Law with the WTO/ TBT and EU requirements.

1. One of the most important novelties introduced by the new Law on Standardization (Official Gazette of the RS, No. 36/09) is **voluntary application of standards** (as of 30th June 2009). **This Law abolished mandatory application of over 8000 standards** and the application of all standards adopted by the Institute for Standardization of Serbia (ISS) is made voluntary. Thus, one of the basic requirements of the WTO Agreement on Technical Barriers to Trade (TBT)) was met. Moreover, entry into force of the new Law on Standardisation enabled more rapid and efficient adoption of the EU standards.

2. **International standards and related documents used as the basis for the adoption of the Serbian standards**. In case when there is no international standard in a particular area or the existing international standard is not suitable, European or national standards and related documents of other countries may be used as a basis for the adoption of the Serbian standards.

3. **Procedure of the adoption and publication of standards was significantly improved** through the provisions of the new Law. Therefore Article 13 of the Law on Standardization prescribes that a standard or related document, document on withdrawal of a Serbian standard or related document shall be adopted in the form of decision by the responsible body of the ISS. This decision shall be published in the Official Gazette of the Republic of Serbia. On the day of publication of the document confirming the adoption of a standard or related document, such a standard or related document becomes publicly available.

4. By adopting the new Law on Standardization, **a procedure for conformity assessment of products, processes and services with a Serbian standard has been introduced** for the first time; given that the application of standards is voluntary, the procedure for conformity assessment is also voluntary; it differs from the procedure for assessment of conformity of products with the requirements of the technical regulation that is mandatory.

Namely, **conformity** of products, processes and services with the Serbian standard **can be confirmed** by the **declaration of conformity** issued by the producer or service provider what means that all the requirements of the standard have been met; however, in addition to the declaration of conformity **the conformity mark**

can be affixed to a product, its packaging or accompanying documentation, when a producer can choose to affix the national conformity mark after it has been approved by the ISS or to affix a conformity mark of the conformity assessment body performing certification and approving the use of its conformity mark**.** However, ***conformity procedure as such is always voluntary*** (non –regulated area). The only way to make the conformity procedure in a non-regulated area mandatory, e.g. introducing SRPS ISO EN 9001-quality management in a company by means of the Law on Public Procurement (when inviting bidders one of the conditions can be mandatory introduction of the requirements of the said standard by the companies applying for bids).

5. **ISS acts as an Enquiry Point for standards** providing information related to standards in line with the requirements of TBT/WTO and Directive 98/34 laying down the procedure for the provision of information in the field of standards and technical regulations.

6. **Standardization in the Republic of Serbia is based on the following TBT/WTO principles**:

1) the right of all interested parties to voluntarily take part in the adoption of Serbian standards;
2) consensus of interested parties;
3) prevention of the precedence of individual interests over the common interest of the interested parties;
4) transparency of the standardization procedure and public availability of Serbian standards and related documents;
5) mutual consistency of Serbian standards and related documents;
6) taking into account development of technology and rules of international and European organizations for standardization and relevant international agreements;
7) non-discriminatory treatment of foreign products or services and same or similar domestic products or services in accordance with ratified international agreements to which the Republic of Serbia is a signatory.

Institute for Standardization transposes international and European standards into Serbian ones and is ready and able to take active participation in the European and international standardization.. The legal framework for the adoption of Serbian standards and related documents is comprised in Article 7 of the Law on Standardization.

ISS has adopted (taken over) 10.214 European standards and related documents in total, as of 31 December 2010, whereas 7,104 of which (or about 50.5 %) are non-electrotechnical European standards published by CEN and 3,110 of which (or about 50.4 %) are European electrotechnical standards published by CENELEC.

Time frame of the European standards implementation in Serbia, in the period between 1st January 2007 and 31st December 2010, is presented in the Table below:

By the end of 2011, ISS transposed over 13,896 European standards and related documents, 9,456 of which are standards published by CEN and 4,431 of which are standards published by CENELEC which makes 70% of the total number of valid European standards that Serbia was obliged to transpose by 2011.

NUMBER OF PUBLISHED AND WITHDRAWN SERBIAN STANDARDS AND RELATED DOCUMENTS IN THE PERIOD BETWEEN 1ST JANUARY 2007 AND 31ST DECEMBER 2010					
Year	Number of published Serbian standards and related documents			Number of withdrawn Serbian standards and related documents	Number of published Serbian standards and related documents transposing European standards
	In Serbian Language	In English language	In total		
Before 2007.	**300**	**-**	**300**	**-**	**300**
2007.	**65**	**393**	**458**	**128**	**277**
2008.	**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**
TOTAL	**1.413**	**9.460**	**10.873**	**1.467**	**10.214**

By the end of 2012, ISS plans to publish around 4,600 standards and related documents 3,600 of which will be standards published by CEN and 1,000 of which will be standards published by CENELEC and ETSI; by transposing the European standards in 2012, the **Republic of Serbia will fulfil its obligation** in line with international agreements – **to transpose 80% of European standards and related documents by the end of 2012.**

3.1.5. Law on Standardization

(Official Gazette of the RS, No. 36/2009)

I BASIC PROVISIONS

Article 1

This Law governs the principles and objectives of standardization in the Republic of Serbia, organization and activities of the national standardization body, and the adoption, publication and application of Serbian standards and related documents.

Article 2

This Law shall apply to standards and related documents that are adopted and published by the national standardization body in the Republic of Serbia, and to international standards and related documents of the recognized international and European organizations for standardization referred to in Article 3, points 12 and 13 of this Law which constitute the basis for the adoption of Serbian standards.

Article 3

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

1) *standardization* shall mean a set of coordinated activities aimed at adoption of standards and related documents;
2) *standard* shall mean a publicly available document defined by a consensus and adopted by a recognised body, whereas it shall determine, for general and multiple use, the rules, requirements, characteristics, instructions, recommendations or guidelines for the activities or their results with the aim of achieving the optimum level of regulation of rules in a specific area in terms of the current or potential problems;
3) *international standard* shall mean a standard adopted by the international organization for standardization;
4) *European standard* shall mean a standard adopted by the European organization for standardization;
5) *Serbian standard* shall mean a standard adopted by the national standardization body in the Republic of Serbia;
6) *related document* shall mean a document (e.g. technical specification, technical report, guideline) adopted by an international or European organization for standardization, and/or national standardization body in the Republic of Serbia and which was made publicly available, but does not meet the requirements to be adopted as a Serbian standard;
7) *interested party* shall mean a public administration authority, company, entrepreneur, consumer association or other legal entity/natural person expressing interest in standardization;

8) *consensus* shall mean an general agreement on any significant matter that is achieved by taking into account the views of all interested parties and reconciling any conflicting views; however, a consensus shall not be deemed to mean unanimity when adopting standards;

9) *adoption of a standard or related document* shall mean a set of coordinated activities that commence with the enactment of a proposal to adopt a standard or related document, and end with the adoption of a document promulgating the adoption of a standard or related document;

10) *assessment of conformity of products, processes and services* with Serbian standards shall mean an activity establishing fulfilment of the requirements contained in Serbian standards;

11) *national conformity mark* shall mean a logo which, in accordance with the rules of the national standardization body in the Republic of Serbia, confirms the conformity of products, processes or services with the Serbian standard;

12) *international organizations for standardization* shall mean the following organizations that relevant national bodies for standardization of any country can join:
- International Standardization Organization (ISO);
- International Electrotechnical Commission (IEC);
- International Telecommunication Union, Telecommunication Standardization Sector (ITU).

13) *European organizations for standardization* shall mean the following organizations that relevant national bodies for standardization of European countries can join:
- European Committee for Standardization (CEN);
- European Committee for Electrotechnical Standardization (CENELEC);
- European Telecommunication Standards Institute (ETSI).

Article 4

Standardization in the Republic of Serbia shall be based on the following principles:

1) the right of all interested parties to voluntarily take part in the adoption of Serbian standards;

2) consensus of interested parties;

3) prevention of the precedence of individual interests over the common interest of interested parties;

4) transparency of the standardization procedure and public availability of Serbian standards and related documents;

5) mutual consistency of Serbian standards and related documents;

6) taking into account development of technology and rules of international and European organizations for standardization and relevant international agreements;

7) non-discriminatory treatment of foreign products or services and same or similar domestic products or services, in accordance with ratified international agreements to which the Republic of Serbia is a signatory.

Article 5

The objectives of standardization in the Republic of Serbia shall include:

1) improved level of protection of life, health and safety of humans, animals and plants, and environmental protection;
2) upgraded level of quality of products, processes and services, their typification, compatibility and substitutability;
3) provision of a uniform technical basis;
4) development and improvement of the production and circulation of products, construction works, i.e. provision of services through the development of internationally harmonized standards with the aim of efficiently using labour, materials and energy;
5) improvement of international trade through the prevention and elimination of unnecessary technical barriers.

II NATIONAL STANDARDIZATION BODY

Article 6

For the purpose of achieving the objectives referred to in Article 5 of this Law, the Government shall issue a decision establishing the Institute for Standardization of Serbia (hereinafter referred to as: the Institute) as a national standardization body in the Republic of Serbia.

The Institute is an institution that shall be entered in the court register.

The assets used by the Institute shall be state-owned.

The provisions of the law governing public services shall apply to the issues related to establishing, organization and operation of the Institute as these are not governed by this Law.

Article 7

The Institute shall perform the following tasks:

1) adopt, publish, review and withdraw Serbian standards in accordance with the rules of the Institute;
2) provide the interpretation of Serbian standards, and interpretation of the application of Serbian standards at the request of interested parties;
3) ensure the compliance of Serbian standards with international and European standards;
4) keep the register of adopted and withdrawn Serbian standards, in accordance with the rules of the Institute;
5) participate in the preparation and review of international and European standards in the areas of interest to the Republic of Serbia;
6) cooperate with the international and European organizations for standardization

and national bodies for standardization of countries signatory to relevant agreements in the field of standardization;

7) perform standardization-related tasks in accordance with the obligations arising from ratified international agreements to which the Republic of Serbia is a signatory;
8) ensure the public availability of adopted and withdrawn Serbian standards, publications, and standards and publications of relevant international, European and national bodies for standardization, and sell the said documents;
9) at the request of the public administration authority, provides the information confirming whether a relevant Serbian standard has been adopted in the area that is being regulated by a technical regulation, or confirming whether its adoption is pending, namely whether the relevant international or European standard exists;
10) act as an Enquiry Point for standards, for providing information and notifications related to standards, in accordance with the requirements provided for in the relevant international agreements and the obligations arising from the membership in relevant international and European organizations for standardization;
11) represent and act in the interests of the Republic of Serbia in the field of standardization in the international and European organizations for standardization;
12) approve the use of national conformity mark with the Serbian standards in accordance with the rules of the Institute;
13) issue the rules used as a basis for the adoption, publication, review and withdrawal of Serbian standards;
14) delegate to the interested parties, in accordance with its rules, a task related to the preparation of proposals of Serbian standards in specific fields;
15) promote the application of Serbian standards;
16) perform other tasks in the field of standardization in accordance with the law and Act on Establishment.

The tasks performed by the Institute referred to in paragraph 1, points 1, 2, 4, 8, 13, 14 and 15 of this Article shall include the related documents.

The Institute shall not perform the tasks referred to in paragraph 1 of this Article with the aim of acquiring profit.

The manner of providing information and notifications referred to in paragraph 1, point 10 of this Article shall be governed by a regulation adopted by the Government.

Article 8

Companies, other legal entities or entrepreneurs established according to the regulations of the Republic of Serbia, and natural persons that are citizens of the Republic of Serbia can become members of the Institute.

Membership in the Institute shall be voluntary.

A member of the Institute shall be entitled to participate in the work of the Institute's bodies and in the management of the Institute in accordance with this Law, Act on Establishment and Statute of the Institute.

A member of the Institute shall be entitled to a special discount for: purchase of standards, related documents and other publications; payment of the fee for other services provided by the Institute when performing standardization-related tasks; payment of the fee for participation in seminars, conferences, conventions and other expert gatherings organized by the Institute independently or in cooperation with other legal entities and organizations, and for other benefits in accordance with the Act on Establishment and statute of the Institute.

A member of the Institute shall pay the membership fee, participate in the attainment of the objectives, programs and plans of the Institute, promote the application of Serbian standards and related documents in accordance with the Act on Establishment and Statute of the Institute.

Rights and obligations of the Institute members, the manner of acquiring and termination of the membership status with the Institute, criteria for determining the level of membership fee, and criteria for determining the special discount referred to in paragraph 4 of this Article shall be prescribed in detail in the Act on Establishment and Statute of the Institute.

Article 9

Assets for the operation of the Institute shall be provided:

1) by charging the membership fee;
2) from the sale of Serbian standards, related documents and other publications;
3) by charging for the services;
4) from the budget of the Republic of Serbia;
5) from other sources as stipulated in the law.

The assets necessary for the operation shall be determined in the annual work program of the Institute in accordance with the Act on Establishment.

The fees to be covered by the Institute for the membership in European and international organizations for standardization, which are determined in the annual work program of the Institute, shall be provided from the budget of the Republic of Serbia.

Article 10

The bodies of the Institute shall be as follows:

1) Assembly;
2) Management Board;
3) Director;
4) Supervisory Board.

The manner of establishing the bodies referred to in paragraph 1 of this Article, their scope of work, selection and appointment of the members of bodies, decision-making and other matters of importance to the operation of bodies shall be governed by the Act on Establishment.

Operation and management of the Institute, and the mode of operation of the bodies referred to in paragraph 1 of this Article shall be prescribed in detail by the Statute of the Institute.

Article 11

Technical councils and committees shall be set up as technical bodies within the Institute.

The technical councils referred to in paragraph 1 of this Article shall be set up for the purpose of directing the work of experts in specific fields of standardization in accordance with the Act on Establishment and Statute of the Institute.

The committees referred to in paragraph 1 of this Article shall be set up for the purpose of adopting standards and related documents in accordance with the rules of the Institute.

The fields of standardization for which the technical councils are set up, manner of setting up technical councils and committees, and other matters of importance to their operation shall be governed by the Act on Establishment and Statute of the Institute.

III ADOPTION AND PUBLICATION OF SERBIAN STANDARDS

Article 12

Serbian standards shall be adopted and published in accordance with this Law and the rules of the Institute which are harmonized with the rules of international and European organizations for standardization and the Code of Good Practice for the Preparation, Adoption and Application of Standards from the Agreement on Technical Barriers to Trade of the World Trade Organization.

As a rule, international standards and related documents shall be used as a basis for the adoption of Serbian standards. If there is no international standard in a particular field or if the existing international standard is unsuitable, European or national standards and related documents of other countries can be used as a basis.

The Institute shall publish in its official journal the notice on the instigation of a procedure for the adoption of a Serbian standard and, where necessary, for a related document, and the notice on instigating public discussion related to a standard or related document.

Article 13

The act promulgating the adoption of a standard or related document, and the document on the withdrawal of a Serbian standard or related document, shall be adopted in the form of a decision by the responsible body of the Institute as laid down in the Act on Establishment.

The document referred to in paragraph 1 of this Article shall be published in the "Official Gazette of the Republic of Serbia".

On the day of publication of the document promulgating the adoption of a standard or related document, such a standard or related document shall become publicly available.

Article 14

Serbian standards or related documents shall bear the identification beginning with the acronym SRPS in accordance with the rules of the Institute.

It shall not be allowed to use the acronym SRPS for marking other documents.

Article 15

Serbian standards shall be adopted and published in Serbian by using the Serbian alphabet in accordance with the law governing the official use of the language and the alphabet.

Exceptionally, where the Serbian standard or related document referred to in Article 12 paragraph 2 of this Law is used as a basis for the adoption of a Serbian standard, the Serbian standard can also be published in one of the official languages of the European organizations for standardization.

Article 16

Serbian standards and related documents shall be published as special editions of the Institute in a hardcopy or electronic format.

The Institute shall hold the copyright for Serbian standards and related documents in accordance with the law governing the copyright and related rights.

Any reproduction, in whole or in part, and distribution of Serbian standards and related documents shall be allowed only with the consent of the Institute.

IV APPLICATION OF SERBIAN STANDARDS

Article 17

Application of Serbian standards and related documents shall be voluntary.

Notwithstanding paragraph 1 of this Article, if a reference in a technical regulation to a Serbian standard implies that the fulfilment of the requirements of the standard is the only way to achieve the compliance with the requirements of the technical regulation, such a standard shall be applied as a technical regulation.

Article 18

Conformity of products, processes and services with the Serbian standard referred to in Article 17, paragraph 1 of this Law can be confirmed by means of the declaration on conformity issued by manufacturer producer or service provider.

Provider of the declaration on conformity shall confirm that it has met all the requirements of a standard.

The declaration on conformity referred to in paragraph 2 of this Article shall also include affixing of the mark of a standard to a product, its packaging or accompanying documentation.

Article 19

The Institute shall approve the use of national conformity mark in accordance with the rules of the Institute.

A conformity assessment body that carries out certification can, in accordance with its rules, approve the use of its conformity mark verifying that products, processes and services are in conformity with Serbian standards.

V SURVEILLANCE

Article 20

The surveillance of standardization activities performed by the Institute as referred to in Article 7 of this Law shall be carried out by the ministry responsible for standardization.

VI TRANSITIONAL AND FINAL PROVISIONS

Article 21

On the day of entry into force of this law, the Institute for Standardization of Serbia, established by the Act on Establishment of the Institute for Standardization of Serbia ("Official Gazette of the RS", No. 16/07), shall continue its operation.

The Act on Establishment of the Institute for Standardization of Serbia referred to in paragraph 1 of this Article shall be brought into compliance with the provisions of this Law within six months following the day of entry into force of this Law.

Article 22

The existing Serbian & Montenegrin standards and related documents the identification of which begins with the acronym SCS and which were adopted before the entry into force of this Law, shall become Serbian standards and related documents.

Identification of the existing standards and related documents, marked with the acronyms JUS and SCS, shall be replaced with the identification beginning with the acronym SRPS on the day of adoption of their amendments at the latest.

Article 23

Serbian standards with mandatory application, other than the standards referred to in Article 17, paragraph 2 of this Law, shall become voluntary on 30th June 2009.

The provisions, prescribing the mandatory application of Yugoslav standards in whole or in part, of regulations or decisions on Yugoslav standards adopted prior to the entry into force of the Law on Standardization ("Official Gazette of FRY", Nos. 30/96, 59/98, 70/01 and 8/03) shall cease to apply on 30th June 2009.

Article 24

Pending the adoption of the sub-law referred to in Article 7, paragraph 4 of this Law,

the Decree on the Manner of Providing Information and Notification of Technical Regulations, Standards and Conformity Assessment ("Official Gazette of the RS", No. 126/07) shall apply.

The Government shall adopt the sub-law referred to in Article 7, paragraph 4 of this Law within six months following the day of entry into force of this Law.

Article 25

The Law on Standardization ("Official Gazette of S&M", No. 44/05) shall be repealed with effect from the date of entry into force of this Law.

Article 26

This Law shall come into force on the eighth day following that of its publication in the "Official Gazette of the Republic of Serbia".

3.1.6. Mechanisms for the Implementation of the Law on Standardization

Sub-laws for the implementation of the new Law on Standardization are as follows:

1. **Decision on the Amendments of the Act on the Establishment of the Institute for Standardization of Serbia** (Official Gazette of RS, No. 88/09)
2. **Statute of the Institute of standardization of Serbia** (Official Gazette of the RS, No. 6/11).

Both sub-laws stipulate in detail the rights, liabilities and responsibilities of the Institute for Standardization of Serbia, especially operation and management of the Institute, work of technical bodies of the Institute, rights and obligations of the Institute members, criteria for determining the level of a membership fees, etc.

ACCREDITATION

3.1.7. What Novelties Have Been introduced into the Serbian Legal System after the Adoption of the new Law on Accreditation

Serbia has a legally established system of accreditation and the Accreditation Body of Serbia (hereinafter referred to as: ATS) as the only national accreditation body. **The accreditation system in Serbia includes, in addition to the ATS, accredited conformity assessment bodies (CABs), accreditation rules and procedures**. Given that the MERD is a policy maker and coordinator for the entire field of QI, it is also responsible for the development and implementation of accreditation development policy and strategy.

The history of development of the ATS from a public body to an independent body outside area of competence of public administration is more or less the same as that of the Institute for Standardization (see 3.1.4.). Similarly, as with the establishment of

the legal basis for the operation of the ISS, the ATS became an independent institution after the adoption of the new Law on Accreditation. The new Law was adopted in October 2010 (Official Gazette of the RS, No. 73/10) and entered into force on the eighth day following its publication in the "Official Gazette.

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, management systems and persons.* **Therefore, the key role of the ATS is assessment of CAB competence and granting of accreditation as the most reliable and efficient mode of confirming competence used most often in the event of notification and authorisation of CABs.**

Currently, there are *453 conformity assessment bodies* that have been accredited:

- *299 testing laboratories,*
- *5 medical laboratories,*
- *49 calibration laboratories,*
- *78 inspection bodies,*
- *15 certification bodies operating certification of products,*
- *7 certification bodies operating certification of management systems.*

Hence, the **new Law** on Accreditation is also **based on** the **a)** need for harmonisation with the Serbian Legal system; **b)** need for alignment with 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; **c)** need to conform to the requirements of ISO IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

a) Novelties based on the harmonisation with the legal system of the Republic of Serbia

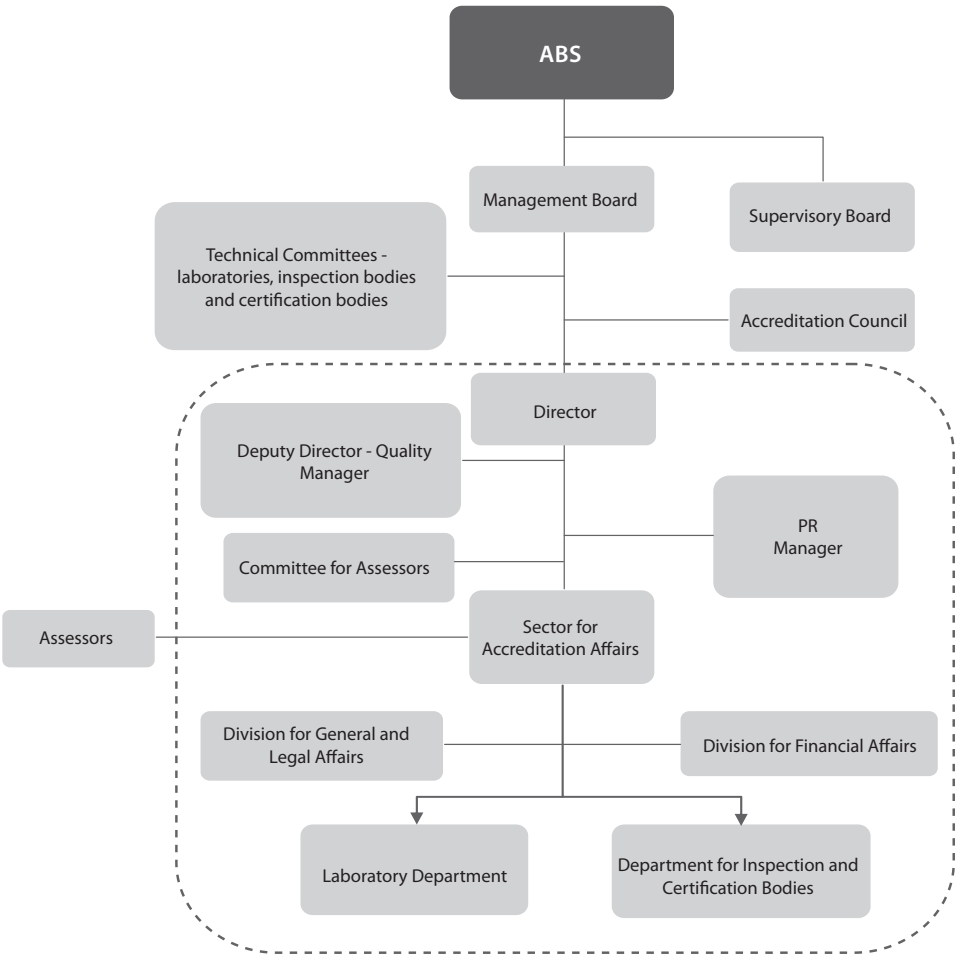
1. Adoption of the new Law on Accreditation endorsed the precise definition of the **legal status and position of the Accreditation Body of Serbia (ATS)** (the same status and position as those of the ISS, see 3.1.4.) Namely, pursuant to the provisions of the new Law, the ATS has a **public institution status operating in accordance with the regulations laying down the legal status of public services.**

2. The number of organs of the ATS has been significantly reduced; the Accreditation Council changed its legal status; **instead of being a governing body**, according to the provisions of the new Law, **the Accreditation Council is now a advisory organ** status providing professional opinions in terms of development of the accreditation system, taking the initiative for the extension of the ATS scope of activities and taking 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, including the representatives of the parties interested in accreditation (Safeguarding Committee). With this end in view**, organs of**

the Accreditation Body of Serbia are as follows: Management Board, Director and Supervisory Board.

3. Technical committees, as standing and ad hoc bodies, **have been granted an advisory, expert role for some specific fields of accreditation.** The ATS established **three standing technical committees for certain schemes of accreditation** *(laboratories, inspection bodies and certification bodies),* while ad hoc technical committees can be established when in need of the: interpretation of the requirements and documents of international organisations for certain schemes and fields of conformity assessment and accreditation, revision of the EA proposals, ILAC/IAF documents, provision of assistance to the Accreditation Body 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 ATS on the occasion of recognition of schemes of inter-laboratory comparisons and PT schemes.

The chart below clearly shows new internal organisation of the Accreditation Body of Serbia:



b) Novelties based on the alignment with 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

The operation of the Accreditation Body of Serbia is in full compliance with the requirements of Regulation (EC) 765/2008 as confirmed by the EU experts during the pre-evaluation visit performed by the assessment team of the European co-operation for Accreditation (EA) in the period between 2nd and 5th March 2010.

The provisions on general principles of the Regulation 765/2008/EC are transposed by means of the Law as follows:

1. **The ATS is the sole accreditation body in the Republic of Serbia** entrusted to perform accreditation activities, whereas this is completely in line with the EA principle requiring that each Member State "shall appoint a single national accreditation body".

2. **Accreditation Body of Serbia operates on a non-profit basis** following the Regulation principle "The national accreditation body shall operate on a not –for-profit basis".

3. The Republic of Serbia has entrusted its national accreditation body with the operation of accreditation activities as public authority activities; it is in accordance with the Regulation principle laying down that " where accreditation is not operated directly by the public authorities themselves, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity"; as previously stated, that ATS is a **public institution granted the operation of the public authority activity,** whereby the provisions of the law governing public services are to be applied to issues of establishment, organisation, status, and operation of the ATS.

4. **The Republic of Serbia shall ensure appropriate financial and personnel resources for the proper performance of tasks**; apart from that, the ATS can be funded from charging accreditation fees, and form another sources as stipulated by the Law.

5. **The ATS shall not offer or provide any activities or services that conformity assessment bodies provide, or provide consultancy services, own shares or have a financial or managerial interest in a conformity assessment body;** this is in line with the Regulation principle saying that "a national accreditation body is an body independent from assessment bodies it assesses; the Law explicitly prescribes that the ATS shall not perform the abovementioned activities since the performance of such activities could create a conflict of interest between the ATS and conformity assessment bodies.

6. **The State** performs **supervision of the operation of the accreditation body**, and the **accreditation body** performs **supervision of the operation of accredited conformity assessment bodies.** The Accreditation Body of Serbia keeps a public Register of Accredited Conformity Assessment Bodies. Should it be established that, during the accreditation validity period, a conformity assessment body made a serious breach of its obligations, the ATS shall make a decision on accreditation suspension or withdrawal.

7. **The ATS shall**, following the provisions of the new Law, **ensure balanced and effective involvement of all interested parties in the work of the ATS**; this also conforms

to the requirement of ISO/IEC 17011 saying that "national accreditation body shall set up and maintain adequate organizational structures which shall provide effective and balanced involvement of all interested parties".

8. Principle of non-competition has been transposed through the provisions of the new Law in a way that **the Accreditation Body of Serbia shall not compete with conformity assessment bodies and other national accreditations bodies;** at the same time it is a requirement of ISO/IOEC 17011: "national accreditation body must not be a competition to the conformity assessment bodies and it must be organized as a body independent from the body that is assessed"; it also must be independent from commercial pressures of any kind.

9. **Provisions laying down cross-frontier accreditation** are fully in line with Regulation (EC) 765/2008; the ATS can refer a conformity assessment body to submit an application for accreditation to an accreditation body from another country, if the ATS does not perform the accreditation activities in respect of conformity assessment activities for which the accreditation is sought, the ATS can ask an accreditation body from another country to carry out a part of accreditation procedure activities, but in such a case, the ATS shall issue the accreditation certificate.

On the other hand, the ATS can conduct the accreditation procedure on the basis of the application of a conformity assessment body from another country under the two conditions:

1) if another country did not establish a national accreditation body;
2) if an accreditation body from another country does not perform accreditation of certain conformity assessment activities for which the accreditation is sought.

Provisions of the new Law relating to the cross-frontier accreditation prescribing that the ATS can accredit conformity assessment bodies from another countries *which are not registered in the Republic of Serbia is an exception to the general rule*; namely, *according to the general rule, the ATS can accredit only a conformity assessment body registered in the Republic of Serbia (notwithstanding the origin of the founder of the body* – it can *either be a foreign natural person or legal entity).*

10. **Provisions** of Regulation 765/2008/EC **on peer evaluation** are fully transposed through the new Law on Accreditation; these provisions enabled the ATS to submit on 12th February 2009 the peer evaluation application to the European co-operation for Accreditation in order to be able to sign the bilateral agreements (BLA) and multilateral agreement (MLA). In the first half of 2011 the assessment team members of the European co-operation for Accreditation performed the peer evaluation; pursuant to the findings of the assessment team of the European co-operation for Accreditation, the Accreditation Body 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. MLA between the Republic of Serbia and EA was approved at the MAC meeting held on 18th April 2012 in Copenhagen. MLA with EA will implement an equivalent system of accreditation in Serbia to that of the EA in the following fields: *certification bodies operating certification of products, inspection bodies, testing laboratories* including medical laboratories and calibration laboratories. **MLA with EA was formally signed in Madrid at the end of May 2012**.

c) novelties based on the conformity to the requirements of ISO IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

1. **A national accreditation body must be organised and run in a way to provide and protect objectivity and impartiality**; this requirement of ISO/IEC 170111 is transposed through the provisions of the new Law related to objectivity and impartiality of the ATS organs.

2. **A national accreditation body shall put in place the procedure as regards the resolution of appeals lodged by conformity assessment bodies against ATS decisions**; this requirement of ISO/IEC 17011 is transposed through the provisions of the new Law laying down that an appeal against decisions of the ATS can be lodged with ATS within 15 days after the decision had been made. The Appeals Committee shall make decisions on the appeal within 30 days after lodging the appeal. The Appeals Committee shall be established by the ATS Management Board. The Appeals Committee consists of seven members, one of which is appointed from the Ministry in charge of accreditation, while the remaining six members are appointed from the pool of conformity assessment experts: two laboratory expert members, two inspection/inspection body expert members, and two certification body expert members.

3.1.8. Law on Accreditation

(Official Gazette of the RS, No. 73/2010)

I BASIC PROVISIONS

Article 1

This Law shall stipulate accreditation, status and operation of the national accreditation body in the Republic of Serbia and other issues of relevance to accreditation.

Article 2

The definitions used in this Law shall have the following meanings:

1) accreditation is an act of verification performed by the national accreditation body in order to confirm whether the conformity assessment bodies fulfil the requirements of relevant Serbian and/or international and European standards and, where applicable, any additional requirements defined for specific fields to carry out specific conformity assessment activities;

2) accreditation certificate is a document confirming the competence of conformity assessment body to perform, for a specific field and scope, conformity assessment activities;

3) peer evaluation is an assessment of a national accreditation body performed by national accreditation bodies from other countries or international and European

organisations for accreditation in accordance with the rules of international and European organisations for accreditation;

4) competence is demonstrated ability to perform conformity assessment activities;
5) conformity assessment is any activity demonstrating that specific requirements relating to a product, process, service, system or person have been fulfilled;
6) rules of accreditation are the rules of a national accreditation body that relate to accreditation procedure, requirements to be met by applicants for accreditation to be granted accreditation , and rights and obligations of those involved in accreditation granting and maintenance process;
7) conformity assessment body is a legal entity or part thereof that performs conformity assessment activities including testing, calibration, certification and inspection;

Definitions that are not defined in paragraph 1 of this Article, but are used in this Law, shall have the meaning regulated by the law governing technical requirements for products and conformity assessment.

Article 3

Accreditation shall be used to determine the competence of conformity assessment bodies to

carry out the following activities:

1) testing;
2) calibration;
3) inspection;
4) certification of products;
5) certification of management systems;
6) certification of persons.

In addition to the competence to perform the activities referred to in paragraph 1 of this Article, accreditation shall be used to determine competence to perform other conformity assessment activities as laid down in the specific law.

Article 4

Accreditation is voluntary.

Accreditation can be mandatory only if regulated by a specific law.

II ACCREDITATION BODY OF SERBIA

Article 5

The Accreditation Body of Serbia (hereinafter referred to as: ATSATS) is the sole accreditation body in the Republic of Serbia that is hereby entrusted to perform the accreditation activities referred to in Articles 3 and 8 of this Law.

The Founder of the ATS is the Republic of Serbia, whereas the Government of the Republic of Serbia shall, under legal powers, exercise the rights of the Founder.

During the course of its activities, the ATS shall use public funds.

The ATS shall not operate on a profit-making basis.

Article 6

The ATS is an institution that shall be registered in accordance with the law.

Provisions of the Law governing public administration shall be applied to issues of establishment, organisation, status and operation of the ATS unless otherwise stipulated by this Law.

Article 7

The ATS shall fulfil the requirements of standards determining general requirements for accreditation bodies that determine the competence of conformity assessment bodies.

The Act on Establishment, Statute and other general acts of the ATS shall regulate organisation and mode of operation of the ATS.

Article 8

In addition to the activities referred to in Article 3 of this Law, the ATS shall perform the following:

1) set forth and publish the Rules of Accreditation based on the relevant Serbian, international and European standards, and on documents of international and European organisations for accreditation;
2) keep a public Register of Accredited Conformity Assessment Bodies;
3) participate in the work of international and European organisations for accreditation;
4) perform other activities in accordance with the law, Act on Establishment and Statute.

The content and manner of keeping the Register referred to in paragraph 1, point 2) of this Article shall be determined by ATS.

Article 9

Information regarding activities performed by the ATS in accordance with Articles 3 and 8 of this Law and results of peer assessment shall be made publically available.

Article 10

The ATS shall be independent from the conformity assessment bodies it assesses.

The ATS shall not:

1) provide consultancy services to conformity assessment bodies;
2) perform activities or provide services provided by conformity assessment bodies;
3) have proprietary and/or managerial rights or any other financial interests in conformity assessment bodies.

Article 11

Organs of the ATS are as follows:

1) Management Board

2) Director

3) Supervisory Board.

Manner of the establishment of the organs referred to in paragraph 1 of this Article, their scope, selection of organ members, decision-making method and other issues of relevance to the work of the organs shall be regulated by the Act on Establishment of the ATS.

Operation and management of the ATS shall be regulated in detail by the ATS Statute.

Article 12

ATS shall set up an Accreditation Council, as an advisory organ, and standing and/or ad hoc technical committees as expert bodies for specific fields of accreditation.

The Accreditation Council operates as a consulting body in view of conferring expert opinion regarding development of the accreditation system, proposing the development of scope of operation of the ATS and takes into consideration other relevant expert issues.

The Accreditation Council is comprised of eminent experts and specialist of relevance to the performance of activities falling under the ATS competences, including the interested parties.

Technical committees are technical bodies providing expertise required for specific fields of accreditation.

Establishment and mode of operation of the Accreditation Council and technical committees, rules and criteria for the selection of members, scope, mode of operation and other issues of relevance to their work shall be regulated in detail by the Act on Establishment and general acts of the ATS in accordance with the Law.

Article 13

The ATS is funded from following sources:

1) charging accreditation fees;

2) budget of the Republic of Serbia;

3) other sources in accordance with the Law.

The sources referred to in paragraph 1, point 1) of this Article shall mean revenue made by providing services in accordance with the Charging Policy Document.

The funds from other sources shall mean other revenues made in accordance with the law.

The ATS shall not take any gifts (donations) from the service users.

The amount of financial resources necessary for the operation of the ATS shall be determined on the basis of activities defined in the Annual Work Programme in accordance with the Act on Establishment.

The fees as regards the ATS membership in international and European organisations for accreditation shall be determined in the Annual Work Programme and provided from the budget of the Republic of Serbia.

III ACCREDITATION PROCEDURE

Article 14

Accreditation procedure shall be instituted on the basis of the application submitted by a conformity assessment body.

In addition to the application for accreditation, an applicant shall submit an evidence of payment of Republic administrative fee for processing the application referred to in paragraph 1 of this Article.

The application referred to in paragraph 1 of this Article shall contain name, address, and legal status of the applicant with clearly defined requested scope of accreditation, and other data and documentation in accordance with the Rules of Accreditation.

The ATS and an applicant for accreditation shall, by means of a contract, stipulate mutual rights and obligations in accordance with the ATS general acts.

The applicant is obliged to enable members of ATS to have full access to all necessary documentation relevant for conducting accreditation procedure, to all premises relevant to activities conformity assessment accreditation is sought for and to enable contact with members of the staff involved in conformity assessment activities.

Article 15

The ATS shall make a decision on accreditation and issue the accreditation certificate if the results of conducted accreditation procedure showed that the applicant fulfils the requirements of relevant Serbian or international and European standards and, where applicable, all additional requirements including the requirements for specific fields.

The issued accreditation certificate shall be valid for a limited period of time in accordance with the rules of accreditation.

Should it be established that, during the accreditation procedure, the applicant failed to meet any of the requirements referred to in paragraph 1 of this Article, the ATS shall make a decision on the termination of accreditation procedure.

Should it be established that, after the accreditation procedure has been finalised, an applicant failed to meet the requirements referred to in paragraph 1 of this Article, the ATS shall make a decision not to grant accreditation.

Accreditation procedure shall be regulated in detail by the rules of accreditation.

Article 16

In addition to the accreditation certificate, the ATS shall award the accreditation symbol to be used by an conformity assessment body in order to prove its status of accredited conformity assessment body.

Article 17

An accredited conformity assessment body is obliged to fulfil the requirements referred to in Article 15, paragraph 1 of this Law during the accreditation validity period.

The ATS shall assess the fulfilment of the requirements referred to in Article 15, paragraph of this Law by monitoring the work of accredited conformity assessment bodies in accordance with the rules of accreditation.

During the monitoring referred to in paragraph 2 of this Article, the ATS shall make a decision on accreditation maintenance, change in accreditation scope, suspension or withdrawal.

Should it be established that, during the accreditation validity period, a conformity assessment body made a serious breach of its obligations, the ATS shall make a decision on accreditation suspension or withdrawal.

Validity period of the decision on accreditation suspension shall not exceed six months.

The ATS can make a decision confirming the change in the accreditation scope, accreditation suspension or withdrawal even on the basis of a written request made by an accredited conformity assessment body.

Article 18

At the request of an accredited conformity assessment body, accreditation can be renewed under the same procedure it was awarded.

Should it be established that, after the accreditation renewal procedure has been carried out, an applicant met the accreditation requirements referred to in Article 15, paragraph 1 of this Law, the ATS shall make a decision on accreditation renewal and shall issue the accreditation certificate.

Should it be established that, after the accreditation renewal procedure has been carried out, an applicant failed to meet the accreditation requirements referred to in Article 15, paragraph 1 of this Law, the ATS shall make a decision not to renew accreditation.

Article 19

An appeal against the decisions referred to in Articles 15, 17 and 18 of this Law can be lodged with the ATS within 15 days after the decision has been delivered.

The Appeals Committee shall make decisions on the appeal referred to in paragraph 1 of this Article within 30 days following the receipt of the appeal.

The Appeals Committee shall be established by the ATS Management Board.

The Appeals Committee consists of seven members where one member shall be appointed from the Ministry in charge of accreditation affairs, and the remaining six members shall be appointed from the pool of experts in the operation of conformity assessment bodies: two laboratory expert members, two inspection body expert members, and two certification body expert members.

The manner of establishment of the Appeals Committee and its mode of operation shall be regulated in detail by the ATS Act on Establishment and Statute.

The decision referred to paragraph 2 of this Article shall be made final, whereas an administrative dispute can be brought against it.

IV CROSS-FRONTIER ACCREDITATION

Article 20

The ATS can refer a conformity assessment body registered in the Republic of Serbia to submit an application for accreditation to an accreditation body from another country, if the ATS does not perform the accreditation activities in respect of conformity assessment activities for which accreditation is sought.

The accreditation certificate issued by an accreditation body from another country and in accordance with paragraph 1 of this Article shall be entered in the Register of Accredited Conformity Assessment Bodies kept by the ATS.

Article 21

The ATS can perform the accreditation procedure on the basis of the application of a conformity assessment body from another country in the following cases:

1) if another country did not establish a national accreditation body;

2) if an accreditation body from another country does not perform accreditation of certain conformity assessment activities for which the accreditation is sought.

Should the ATS receive an application for accreditation from the conformity assessment body of another country as referred to in paragraph 1, point 2) of this Article, the ATS shall inform the accreditation body of the country of origin.

During the accreditation procedure referred to in paragraph 2 of this Article the accreditation body from another country can participate therein as an observer.

Upon the request of an accreditation body from another country, the ATS can perform some of the conformity assessment activities that are part of the accreditation procedure in case of conformity assessment bodies from the country of origin.

Article 22

After a successful peer evaluation, the ATS can conclude agreements on mutual recognition of accreditation system equivalence with accreditation bodies of other countries, European and other international organizations for accreditation.

V SURVEILLANCE OF THE ATS

Article 23

The ministry in charge of accreditation activities shall, in accordance with the law governing the public administration activities, carry out surveillance of the ATS activities referred to in Articles 3 and 8 of this Law.

VI TRANSITIONAL AND FINAL PROVISIONS

Article 24

The Accreditation Body of Serbia established by the Act on Establishment of the Accreditation Body of Serbia ("Official Gazette of the RS", No. 96/06) shall, in accordance with this Law and Act on Establishment, continue its activities with effect from the date of entry into force of this Law.

The Act on Establishment of the Accreditation Body of Serbia shall be harmonised with the provisions of this Law within six months following the entry into force of this Law.

Article 25

Accreditation certificates issued prior to the date of entry into force of this Law shall remain valid throughout their validity period.

Accreditation activities that commenced prior to the entry into force of this Law shall be terminated in accordance with the regulations that were in force prior to the date of entry into force of this Law.

Article 26

The Law on Accreditation ("Official Journal of the S & M", No. 44/05) shall be repealed with effect from the date of entry into force of this Law.

Article 27

This Law shall enter into force on the eighth day following its publication in the „Official Gazette of the Republic of Serbia".

3.1.9. Mechanisms for the Implementation of the Law on Accreditation

Sub-laws for the implementation of the new Law on Accreditation are:

1. **Decision on the amendments of the Act of Establishment of the Accreditation Body of Serbia** (Official Gazette of the RS, No. 14/11)
2. **Statute of the Accreditation Body of Serbia** (Official Gazette of the RS, No. 97/11).

Both sub/laws elaborate details as regards rights, liabilities and responsibilities of the Accreditation Body of Serbia, especially the manner of establishment of the organs, their scope, selection of organ members, decision-making method and other issues of relevance to the work of the organs, and operation and management of the ATS. In addition to that, these sub-laws regulate the establishment and manner of operation of the Accreditation Council and technical committees, rules and criteria for the appointment of members, scope, manner of operation and other issues of relevance to their work.

METROLOGY

3.1.10. What Novelties Have Been Introduced into the Serbian Legal System after the Adoption of the New Law on Metrology

During the State union of Serbia and Montenegro, the field of metrology was within the competence of the Federal Bureaux for Metrology as a part of the Federal Ministry of Internal Economic Affairs. At that time, the area of metrology was governed by the federal Law on Metrology. After the dissolution of the State Union of Serbia and Montenegro, the MERD became competent for the field of metrology in line with the Law on Ministries, Article 9 (Official Gazette of the RS, No. 16/11). In other words **the Directorate of Measures and Precious Metals, as a part of the MERD, is in charge of metrological tasks nowadays.** With a view to get aligned with the Serbian legal system, and to follow the EU and international trends into the field of metrology, the **new Law on Metrology** (Official Gazette of the RS, No. 30/10) was adopted in 2010.

Currently, **the basic framework for organising the new metrology system in the Republic of Serbia is mirrored by the new Law on Metrology.**

When the new law was being drafted, the documents of the International Organization of Legal Metrology were taken into account: OIML D1 (elements for drafting a law on metrology), OIML D9 (laying down provisions on metrological surveillance) 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.

In addition to the abovementioned, there **are two main general reasons for the adoption of the new Law** on Metrology:

a) **enabling uniform measuring in the Republic of Serbia through:**

- provision of accurate measuring instruments harmonised with international requirements determined for specific measuring instruments;
- use of measurement units harmonized with international system of units (SI)
- provision of traceability of measurement standards in the Republic of Serbia to international measurement standards or measurement standards of other countries.

b) **establishment of an impartial and transparent performance of metrological tasks in the Republic of Serbia.**

The Directorate of Measures and Precious Metals as a part of the MERD is responsible for the performance of activities in the fields of both - legal and scientific metrology.

In the field of legal metrology where mandatory verification is prescribed: pursuant to the Law on Metrology, the Directorate is also responsible, for performance of activities from the legal metrology field, which comprises in particular assessment of conformity of measuring instruments with prescribed requirements, such as

requirements prescribed in MID and NAWI directives, and type approval, testing of pre-packed products, metrological surveillance, etc.

In the field of scientific metrology: the role of the Directorate of Measures and Precious Metals, as the National Metrology Institute of the Republic of Serbia, is to carry out research aiming at SI units' improvement, applying of SI units through the implementation of the new measuring instruments and improvement of the existing national ones, and provide their traceability to the international level, i.e. national measurement standards of other countries, 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).

Novelties in a new Law based on the harmonisation with the legal system of the Republic of Serbia and with the EU and international requirements (OIML):

1. Adoption of the new Law endorsed a **clear distinction between the competences of the institutions in the field of metrology**; in practice when the previous Law on Metrology was in force, the Bureau for Metrology within the Federal Ministry of Internal Economic Affairs, played the major role in performing metrological tasks; namely, the Bureau for Metrology performed, among other activities, verification of measuring instruments, and was, at the same time, supervising the measuring instruments that had been verified; furthermore, the Bureau for Metrology used to have a monopolistic position on the market as far as measuring instruments were concerned, since it was the only body responsible for the verification of measuring instruments;

On the other hand, by carrying out verification and, at the same time, supervision of the verification performed, the Bureau for Metrology contributed to a *typical conflict of interest* since the same institution performed activity and afterwards performed supervision of the activity it carried out.

Through the provisions of the new Law, **metrological system in the Republic of Serbia** was established in accordance with international and EU trends, and it **consists** of the following players: **the Ministry responsible for policy making in the area of metrology which is MERD; Directorate of Measures and Precious Metals (DMDM); Metrology Council; designated conformity assessment bodies, authorised bodies for measuring instruments verification, and accredited calibration laboratories**.

MERD is responsible for carrying out activities related to metrology development strategy ; DMDM is responsible for carrying out specialised activities in the field of scientific and legal metrology and acts as the National Metrology Institute (NMI); the Metrology Council represents a specialised advisory body comprising renowned experts and stakeholders' representative; authorised bodies perform verification of instruments, while designated bodies perform conformity assessment of instruments as any other products.

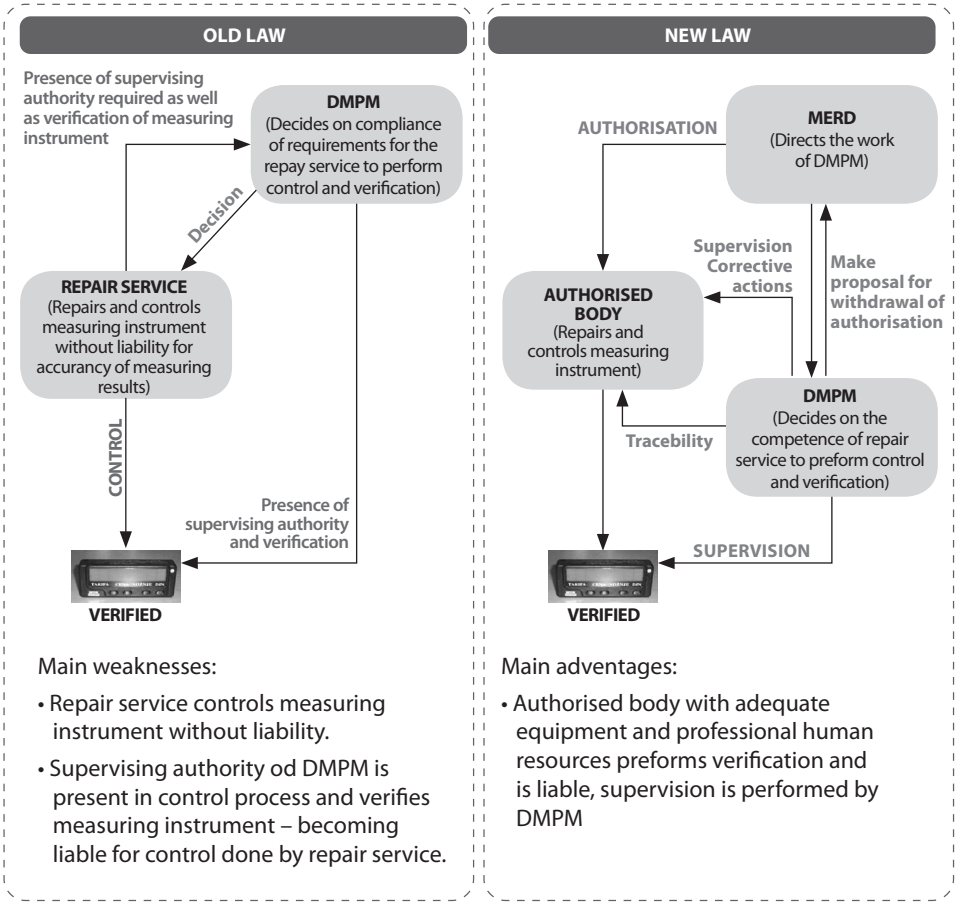
2. The new Law on Metrology introduced **a clear relation between activities of DMDM and authorised/designated bodies;** namely, verification of measuring instruments (initial, regular/ periodical or extraordinary), and assessment of conformity of measuring instruments with the prescribed requirements, shall be carried out by economic operators and other legal entities that are, in accordance with relevant procedures, au-

thorised and designated for carrying out verification/conformity assessment of measuring instruments (authorised/designated bodies). **DMDM shall be in charge of measuring instruments verification, only in case when there are no authorised/designated bodies for the verification of the instruments concerned.** Additionally, **DMDM supervises the work of the authorised/designated bodies;**

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

Thus any kind **of monopolistic position of the DMDM on the market conflict of interest within the DMDM is avoided**.

The figure below shows the activities performed by the Directorate and authorised bodies today and during the validity period of the previous Law on Metrology; verification of a taximeter is taken as an example:



Main weaknesses:

- Repair service controls measuring instrument without liability.
- Supervising authority od DMPM is present in control process and verifies measuring instrument – becoming liable for control done by repair service.

Main adventages:

- Authorised body with adequate equipment and professional human resources preforms verification and is liable, supervision is performed by DMPM

Up to now, **30 inspection bodies** for the verification of legal instruments (mostly for the verification of weighing instruments and instruments for measuring liquid fuel) have been authorised. **The more inspection bodies for the verification of measuring instruments on the market, the less chance for this kind of activity to be performed by the Directorate of Measures and Precious Metals**.

The main distinction between authorised bodies for the verification of measuring instruments as defined in the Law on Metrology and designated bodies as defined in the Law on Technical Requirements and Conformity Assessment and its sub-laws relates to their status:

- ***designated bodies*** are mostly private bodies on the market, freely selected by the producers;
- ***authorised bodies,*** mainly privately owned, although "engaged" by the state and as such they are representatives of the state given that they are granted public authorities.

As an illustration, the **following elements of the public authority could be recognised with the authorised bodies**:

1) **the state supplies authorised bodies with the marks used for the verification of measuring instruments** – the verification inspection body affixes the "state" mark to an instrument instead of issuing a certificate;
2) **price list of an authorised inspection body needs to be approved by the Serbian Government**; however, this is not the case with the bodies (testing laboratories, inspection bodies, certification bodies) designated in accordance with the Law on Technical Requirements and Conformity Assessment and its sub-laws used for the implementation thereof).

3. Pursuant to the Law on Metrology, **accreditation is a prerequisite for the authorisation of bodies to perform verification of measuring instruments.** Namely, entrepreneurs and other legal entities can carry out measuring instruments verification activities if they were previously accredited for the proper scope and type of measuring instruments to be verified.

As we can see, this solution differs from the one prescribed by the Law on Technical Requirements for Products and Conformity Assessment; namely, according to the said law, accreditation is not a prerequisite for the designation of conformity assessment bodies, but the recommended best instrument, although other documentation could also be relevant for proving the competence of conformity assessment bodies.

4. The adoption of new Law endorsed **a clear definition of the *purpose* of mandatory legal control of measuring instruments to be used thereafter:**

- trade in goods and services;
- protection of health and general safety;environmental protection;
- control and safety of traffic;
- testing of pre-packaged products and bottles as measuring containers.

Legal control of measuring instruments, as defined in the new Law on Metrology, attained **its main objective – to convince the public that the results of measuring used in commercial and official transactions are accurate.**

5. The new Law prescribes **three types of control of measuring instruments** in the Serbian legal system: verification of measuring instrument and type approval as legal control of measuring instruments and conformity assessment in line with the New Approach Directives:

a) *verification of a measuring instrument* is a procedure which includes testing and marking and/or issuing of a verification certificate confirming that **the specific measuring instrument complies with the type approval and or with all the prescribed metrological requirements.**

The following table shows 38 measuring instruments requiring mandatory legal verification, and the time lines of periodic verification:

Number	Name of measuring instrument	The time line of periodic verification (in years)
1.	dimensional measuring instruments (measuring tape, folding instruments for length, meters for textile, measuring rods for measuring liquid level or empty space in the tanks, measuring rulers, measuring tapes with plummet)*	2
2 .	machine for measuring the length of wires and cables*	2
3.	commercial containers and bottles used as measuring containers	-
4.	instruments for milk and milk cooling tanks	5
5.	tanks	5
6.	reservoir and tankers	10
7.	automatic liquid level meters*	2
8.	measuring systems for the continuous and dynamic measurement of quantities of liquids other than water*	1
9.	water meters*	5
10.	gas meters*	5
11.	weights of accuracy class F2, M1, M2 used for the trade in goods and services	2
12.	non-automatic weighing instruments	
	accuracy classes (I), (II), (III) and (IV) up to 9000 kg*	2
	accuracy classes (I), (II), (III) and (IV) over 9000 kg*	1
13.	automatic weighing instruments- discontinuous totalisers, sorting, control and labelling, continuous totaliser, measuring of moving vehicle, automatic gravimetric filling instrument*	1
14.	transducers for weighing instruments*	-

15.	electronic measuring and indicating devices for weighing*	-
16.	apparatus for determining the hectolitre mass of grain and oilseeds	1
17.	manometers for measuring blood pressure*	2
18.	manometers for measuring tire pressure*	1
19.	instruments for measuring the braking force to motor vehicles*	1
20.	instruments for density measuring of liquids used for the trade in goods and services	
	aerometer	-
	electronic instruments for measuring of density*	1
21.	alcoholometers	-
22.	ethylmeters*	1
23.	instruments for moisture measurement of grain and oilseeds*	1
24.	exhaust gas analysers*	1
25.	opacimeters*	1
26.	refractometers used for the trade in goods and services*	1
27.	medical thermometers (glass and electrical) *	-
28.	measuring transformers used for the calculation of electric power	-
29.	electric power meters	
	indirect connection*	6
	direct and semidirect connection*	12
30.	measuring instruments for testing electrical safety in low-voltage distribution networks (electrical resistance to the ground, electrical resistance of insulation, electric loop impedance, electrical resistance of earthing and equipotential, for checking the protective devices for residual electric current*	-
31.	devices for checking long and downed light on vehicle	1
32.	spectrophotometers used in healthcare*	1
33.	ionising radiation detectors used in healthcare and public safety and environmental protection	2
34.	dosimeters used in healthcare*	2
35.	sound level meters*	2
36.	Taximeters*	1
37.	measuring instruments for vehicle speed in traffic*	1
38.	heat meters – complete instruments or measuring unit*	5

The measuring instrument marked with an asterisk (*) can be verified only if a type approval certificate has been issued for the specific measuring instrument or certificate conforming conformity of the specific measuring instrument to the prescribed requirements.

b) *type approval certificate* is a certificate or document issued on basis of previous testing of a measuring type confirming that the **type of measuring instrument complies with *the relevant metrological and technical requirements* and is suitable for use in the regulated area** in such a way that is expected to provide reliable measurement results within a defined period of time; both verification of measuring instrument and type approval are mandatory since they are related to legally controlled measuring instruments; single measuring instrument must be in compliance with a certificate of type approval, or, in some cases, with the regulation governing metrological issues.

c) *conformity assessment of a measuring instrument* is a procedure of testing and evaluating measuring instruments to ascertain whether a single instrument, an instrument lot or a production series of instruments are in compliance with *all the prescribed requirements applicable to this type of instrument, and to any other product;* this type of procedure is mandatory when prescribed for the specific type of measuring instruments.

Hence the new law endorse a clear distinction between three types of metrological control; additionally, as regards conformity assessment of measuring instruments, **the conditions for placing** a measuring instrument as a product **on the market** – (not the metrological requirements only, but also the requirements prescribed for any other industrial product to be placed on the market) have been made; these provisions of the law make a legal basis for the transposition of the New Approach Directives (Measuring Instruments Directive, Non-weighing Instruments Directive and Directive on Pre-packages) into our metrological legal system;

In this way, a new concept of control has been introduced through the conformity assessment of measuring instruments as any other products on the market; *conformity assessment* of measuring instrument "as a product" *differs from its verification* as a "measuring instrument", particularly when it come to conformity assessment procedure, conformity marking and accompanying certificates of conformity and other documentation; furthermore, the Law prescribes special requirements to be met by the body designated for conformity assessment, and the manner of its designation.

6. The provisions of the new law provide a **clear and precise definition of pre-packaged products: „**pre- packaged products are the products which have been packaged without the purchaser being present and where the quantity of the product contained in the package cannot be altered without the package either being opened or undergoing a modification; pre-packaged products shall only be placed on the market when their nominal quantity is accurately, clearly and ambiguously indicated, and when their actual quantity lies within the permitted tolerance limits of indicated nominal quantity"; furthermore, the law lays down a **clear definition of the elements specific for this kind of product:**

- conformity mark (conditions for marking);
- volume standard as a measuring instrument for pre-packaged products;
- measuring bottle as a product – marketing conditions;
- extraordinary testing of conformity of pre–packaged products with metrological requirements;
- exception - free samples which are used for marketing and service provision services (airplanes, ships and trains).

7. The new Law on Metrology enabled the **upgrade of the procedure for the recognition of foreign documents and conformity marks**; namely, apart from the existing solution, when these documents are recognised in the Republic of Serbia if issued in accordance with the international agreement concluded by the Republic of Serbia, the new law envisages another possibility for the validity of foreign documents and conformity marks: The Minister has the right to recognise foreign type approval certificates, verification certificates and/or marks and other signs of conformity of foreign origin *provided that these documents and marks have been issued in accordance with conditions prescribed by the Republic of Serbia*.

8. One of the most important novelties introduced by the new Law on Metrology is a **metrological surveillance role granted to the Directorate of Measures and Precious Metals as a crucial task strictly separated form other tasks** (type approval, verification of measuring instruments for which there are no authorised bodies, etc.); pursuant to the new Law on Metrology, **surveillance covers:**

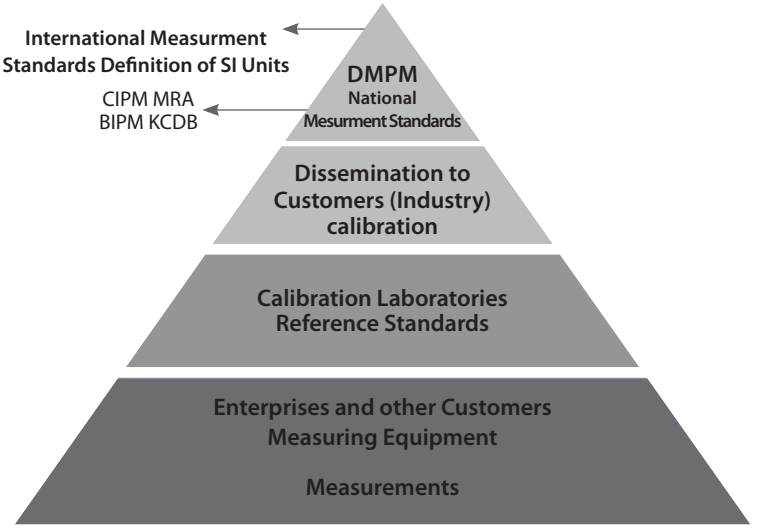
- measuring instruments on the market;
- measuring instruments in use;
- pre-packaged products;
- use of legal measurement units;
- professional work of authorised/designated bodies.

9. Adoption of the new Law on Metrology **ensured transparency of traceability to international measurement standards.**

DMDM as the National Metrology Institute (NMI) of Serbia and signatory to the CIPM MPA, for specific calibration and measurement capabilities (CMC) published in the BIPM (Bureau International des Poids et Mesures) database (BIPM KCDB) ensures traceability by calibration to international standards of SI units for all clients in the Republic of Serbia (economy, industry, calibration laboratories, conformity assessment bodies, etc.). In a continuous traceability chain, directly under the Directorate, are accredited (by the ATS) calibration laboratories that enable, by means of calibration, traceability to national standards of SI units. Clients from Serbia can, for the traceability to be ensured, address NMIs of other countries the CMCs of which are in BIPM KCDB database, or calibration laboratories accredited by accreditation bodies from other countries signatories to EA MLA and ILAC MRA.

A need for ensuring relevant traceability of measurements to SI units is particularly ex-

pressed in the field of industrial metrology. The figure below shows a manner in which the traceability chain to the national and international standards is currently implemented in Serbia.



National standards to which traceability is ensured to SI units, and the manner of ensuring traceability in the field of chemical measurements is given as an illustration.

The Directorate publishes its CMCs in the 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
TC-P	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; quantities of dimension 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.

3.1.11. Law on Metrology

(Official Gazette of the RS, No. 30/2010)

I BASIC PROVISIONS

Scope

Article 1

This Law regulates organisation of metrology activities, legal units of measurement and standards of the Republic of Serbia, placing on the market and use of measuring instruments, assessment of conformity of measuring instruments with prescribed requirements, pre-packaged products, the validity of documents and foreign conformity marks, supervision, and other metrology-related matters.

Purpose

Article 2

The purpose of this Law is to ensure unified measurements and the use of accurate measuring instruments in the Republic of Serbia, and compatibility of the national units of measurement with the International System of Units, traceability of standards of the Republic of Serbia to the international standards or national standards of other countries.

Application

Article 3

Provisions of this Law governing legal control of measuring instruments are applied to instruments used for measurement in the field of protection of health and general safety, environmental protection, control and safety of traffic, and trade in goods and services.

Provisions of this Law laying down conditions for placing measuring instruments on the market and use thereof are applied equally to all measuring instruments regardless of their origin.

Transparency of measurement results

Article 4

Results of measurements performed upon a request or for needs of national authorities in public interest, particularly in the field of protection of health and general safety, environmental protection, are available to legal entities and natural persons in accordance with the regulations governing availability of information of public importance.

Meaning of terms

Article 5

Some of the terms used in this Law shall have the following meaning:

1) *legal units (of measurement)* are units of measurement the use of which is required in the Republic of Serbia;
2) (*measurement) standard* is material measure, measuring instrument, reference material or measuring system which presents a realization of the definition of a given quantity with stated quantity value and associated measurement uncertainty, and is used as a reference.
3) *measurement standard of the Republic of Serbia* is a measurement standard which is by a decision of a public administration body competent for metrological activities recognised to serve as the basis for assigning values to other measurement standards of a specific quantity;
4) *international measurement standard* is a measurement standard recognised by signatories to an international agreement;
5) *reference material* is a material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties;
6) *certified reference material* is a reference material, accompanied by documentation certificate providing one or more specified property values with associated uncertainties and traceability;
7) *traceability* is a property of the result of a measurement or the value of a standard, whereby the result and standard can be related to stated references (usually national or international standards) through an unbroken chain of comparisons all having stated uncertainties;
8) *calibration* is a set of operations that establish, under specified conditions, the relationship between values of quantities with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties for obtaining a measurement result;
9) *measuring instrument* is a device intended to be used to make measurements, alone or in conjunction with one or more supplementary devices;
10) *legal metrological control* includes legal control of measuring instruments, metrological supervision and metrological expertise;
11) *legal control of measuring instrument* includes all legal operations to which measuring instruments may be subjected, such as type approval, verification, etc.;
12) *metrological supervision* is control exercised in respect of the manufacture, import, installation, use, maintenance and repair of measuring instruments performed in order to check that they are used correctly as regards the observance of this Law and other regulations and it includes checking the correctness of quantities indicated on and contained in pre-packages;
13) *metrological expertise* includes all the operations for the purpose of examining and demonstrating, e.g. to testify in a court of law, the condition of a measuring instru-

ment and to determine its metrological properties, among others by reference to the relevant statutory requirements;

14) *conformity assessment of a measuring instrument* is testing and evaluating measuring instruments to ascertain whether a single instrument, an instrument lot or a production series of instruments are complied with all prescribed requirements applicable to this instrument type;

15) *type approval certificate* is a certificate or document issued on a basis of previous examination of a measuring instrument type, confirming that the type of a measuring instrument complies with the relevant metrological and technical requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time;

16) *verification of a measuring instrument* is a procedure which includes the examination and marking and/or issuing of a verification certificate that ascertains and confirms that the measuring instrument complies with the prescribed metrological requirements;

17) *pre-packaged products* are the products which have been packaged without the purchaser being present and where the quantity of the product contained in the package cannot be altered without the package either being opened or undergoing a modification.

II ORGANIZATION OF METROLOGY ACTIVITIES

Performance of metrology activities

Article 6

Ministry in charge of metrology performs activities related to metrology development strategy monitors and coordinates performance of activities in the field of metrology (hereinafter referred to as: the Ministry).

Technical and their related executive activities in the field of metrology shall be performed by the Directorate of Measures and Precious Metals, an public administration authority responsible for metrology activities (hereinafter: the Directorate).

Activities of verifying measuring instruments are performed by economic operators and/or other legal entities that are in accordance with this Law authorised to perform such activities (hereinafter: authorised bodies).

Activities of assessment of conformity of measuring instruments to prescribed requirements are performed by economic operators and/or other legal entities that are, in accordance with this Law, designated to perform such activities (hereinafter referred to as: designated bodies).

The Directorate

Article 7

Directorate shall:

1) be responsible of the system of legal units of measurement in the Republic of Serbia;

2) develop, realize, proclaim, keep, maintain and continuously improve measurement standards of the Republic of Serbia;

3) provide metrological traceability;

4) conduct activities of metrological expertise;

5) conduct testing of pre-packaged products in order to check the fulfilment of metrological requirements;

6) represent the Republic of Serbia in the international metrological organizations and establish collaboration in the field of metrology;

7) perform metrological supervision;

8) perform conformity assessment of measuring instruments;

9) make decisions in administrative proceedings in the field of metrology;

10) take part in the preparation of regulations in the field of metrology;

11) keep registers of measuring instruments subject to legal control;

12) provide metrological information and publish the Official Gazette;

13) perform activities of distribution of time;

14) conduct other activities in the field of metrology in accordance with the law.

Apart from activities referred to in paragraph 1, points 1 to 13 of this Article the Directorate shall perform the activities of verification of measuring instruments for the verification of which there are no authorised bodies, whereas the said verification shall ensure independence and impartiality .

Authorised bodies

Article 8

Economic operators and other legal entities can perform verification of measuring instruments if they have an accreditation certificate acquired in the accreditation procedure and if they fulfil prescribed conditions especially regarding:

1) professional competencies of their employees and other contracted persons;

2) premises and working equipment;

3) scope of verification of measuring instruments;

4) independence and impartiality with respect to the persons related with the measuring instrument which is subjected to verification;

5) resolution of work-related appeals and decisions made;

6) confidentiality, or keeping of trade secrecy;

7) insurance against liability for damage.

The Minister in charge of metrology (hereinafter referred to as: the Minister) shall prescribe in detail the conditions referred to in paragraph 1 of this Article.

Article 9

The Minister shall issue a decision determining the fulfilment of conditions for performing the verification activities referred to in Article 8 of this Law.

The issuance of the decision referred to in paragraph 1 of this Article shall confirm that an economic operator and/or other legal entity fulfils prescribed conditions for verification of measuring instruments if the scope of activities of examining and testing of a measuring instrument is fully covered by the scope of activities referred to in the accreditation certificate which has been acquired by that legal entity in the accreditation procedure.

An Economic operator or any other legal entity shall submit to the Ministry a request for determining fulfilment of the conditions referred to in paragraph 1 of this Article.

The decision referred to in paragraph 1 of this Article shall be valid for three years.

The decision referred to in paragraph 1 of this Article shall be made final and administrative dispute can be initiated against it.

Authorised body may submit a request for reissuing the decision referred to in paragraph 1 of this Article at least three months before the expiry of the issued decision.

If the Ministry fails to make a decision within 60 days following the submittance of the request referred to in paragraph 6 of this Article and at the latest till the end of expiry period of the issued decision, an authorised body can continue to perform verification activities on the basis of existing decision.

Provisions of the Law governing general administrative procedure shall be applied to the matters that have not been separately regulated by this Law, but refer to the procedure of issuing decisions on authorisation, reissuing of authorisation and/or cancellation of authorisation.

The costs of verification of instruments performed by an authorised body are borne by an applicant as specified in the price list determined by the authorised body and approved by the Government.

An authorised body is entrusted with verification of measuring instruments.

Article 10

An authorised body is obliged to keep the records of the following data:

1) name and address, trade name and head office of the applicant submitting the request for verification of measuring instruments;
2) date of examination and verification of measuring instruments;
3) issued mark and/or verification certificate;

An authorised body is obliged to keep the records referred to in paragraph 1 of this Article for at least three years.

Upon request of the Directorate, an authorised body is obliged to deliver the records data referred to in paragraph 1 of this Article to the Directorate.

The Minister shall prescribe in detail the content and form of the records referred to in paragraph 1 of this Article and the method of keeping thereof.

Article 11

An authorised body is obliged to immediately inform the Ministry, if prescribed requirements are no longer met or in case of any changes affecting the fulfilment of the prescribed requirements.

An authorised body may cease to perform activities of verification before the expiry date of the issued decision on verification and it shall inform the Ministry thereof, whereas it shall perform activities of verification within a period which cannot be shorter than 90 days following the delivery of the notification to the Ministry.

The Ministry shall make the Register of authorised bodies for verification of measuring instruments publically available.

The Minister shall prescribe in detail the method of authorisation, keeping of the Register of authorised bodies, and other matters of relevance to the work of authorised bodies.

Metrology Council

Article 12

The Government shall set up a Metrology Council which shall operate as a consulting body providing expert opinion and participating in realisation of metrology ToR.

The Metrology Council shall:

1) advise on the development prospects of the metrology system of the Republic of Serbia;
2) propose scientific and training activities in the field of metrology;
3) propose priorities in scientific, research and development projects in the field of metrology.

The Metrology Council shall, upon a request of the Ministry, provide professional clarification or opinions regarding published metrological information of public interest.

The Metrology Council is composed of eminent experts from the field of metrology, and representatives of the parties interested in metrology-related issues.

The Metrology Council has a Chair and at least six members.

The Metrology Council shall adopt its Rules of Procedure.

Expert and administrative tasks for the needs of the Metrology Council are carried out by the Ministry.

III LEGAL MEASUREMENT UNITS

Article 13

Legal measurement units in the Republic of Serbia are as follows:

1) units of the International System of Units (Systeme International d'Units, SI);

2) measurement units that are not included in the International System of Units, but can be used in the accordance with this Law.

The legal measurement units referred to in paragraph 1, point 2 of this Article, and the manner of their use shall be regulated by the Government.

IV MEASUREMENT STANDARDS

Standards of the Republic of Serbia

Article 14

Measurement standard of the Republic of Serbia is a measurement standard recognised by a decision of the director of the Directorate to serve as the basis for assigning values to other measurement standards of specific quantities (hereinafter referred to as: national standard).

The Directorate shall develop, proclaim, keep, maintain, and continuously improve national standards and ensure their traceability to the international level.

The decision referred to in paragraph 1 of this Article is issued if a standard presents a realisation of the definition of a given quantity with stated quantity value and associated measurement uncertainty used as a reference and if it is traceable to international standards or national standards of other countries with proper metrological properties.

Exceptionally, the director of the Directorate may make the decision referred to in paragraph 1 of this Article for standard that is kept, maintained and the metrological properties of which are improved by another governmental body, and/or other legal entity that fulfils prescribed requirements, especially in terms of:

1) professional competencies of their employees and other contracted persons;
2) premises and working equipment;
3) provision of traceability to international standards or national standards of other countries.

National standards must be traceable to international standards or national standards of other countries with proper metrological properties.

The Minister shall prescribe in detail the conditions for recognising the national standards for certain quantities referred to in paragraph 1 of this Article.

V ASSESSMENT OF CONFORMITY OF MEASURING INSTRUMENTS WITH PRESCRIBED REQUIREMENTS

Article 15

A measuring instrument is placed on the market only if it conforms to prescribed requirements, if its conformity has been assessed according to a prescribed procedure, if it is marked in accordance with regulations, and if it is accompanied by prescribed certificates of conformity and other prescribed documentation.

The Minister shall, for particular types of measuring instruments, prescribe in detail the requirements, procedures of conformity assessment, marking, certificates of conformity, and documentation referred to in paragraph 1 of this Article.

Should the regulation referred to in paragraph 2 of this Article require conformity assessment to be performed by a designated body, the regulation shall also lay down conditions that have to be fulfilled, especially in terms of:

1) professional competencies of their employees and other contracted persons;
2) premises and working equipment;
3) independence and impartiality with respect to the persons related with the measuring instrument which is subjected to conformity assessment;
4) confidentiality, that is keeping of trade secrecy;
5) resolution of appeals related to the work and issued decisions;
6) insurance against liability for damage.

Article 16

The Minister shall issue a decision determining the fulfilment of the conditions referred to in Article 15 of this Law.

An economic operator and other legal entity shall submit to the Ministry a request for determining the fulfilment of the conditions referred to in paragraph 1 of this Article.

The decision referred to in paragraph 1 of this Article shall be made final and administrative dispute can be initiated against it.

The decision referred to in paragraph 1 of this Article shall be valid for three years.

A designated body may submit a request for reissuing the decision referred to in paragraph 1 of this Article at least three months before the expiry of the issued decision.

If the Ministry fails to make a decision within 60 days following the submittance of the request referred to in paragraph 5 of this Article at the latest by the end of expiry period of the issued decision, a designated body is allowed to continue to perform assessment of conformity of measuring instruments on the basis of the existing decision.

Provisions of the Law governing general administrative procedure are applied to the matters that have not been separately regulated by this Law given that they refer to the procedure of issuing decisions on designation, re-designation and/or cancellation of designation.

The Ministry shall make the Register of designated bodies publically available.

The costs of conformity assessment performed by a designated body are borne by an applicant of the request for conformity assessment as specified in the price list determined by a designated body and approved by the Government.

The Minister shall prescribe in detail the method of determining the fulfilment of conditions for designation, manner of keeping the register of designated bodies for conformity assessment of measuring instruments, and the manner of notification of designated bodies for conformity assessment of measuring instruments to the relevant international organization.

VI LEGALLY CONTROLLED MEASURING INSTRUMENTS

Use

Article 17

Legally controlled measuring instruments (hereinafter: instruments) are used as follows:

1) protection of health and general safety;
2) environmental protection;
3) control and safety of traffic;
4) trade in goods and services;
5) testing of pre-packaged products and bottles as measuring containers.

The Minister shall prescribe in detail the types of instruments referred to in paragraph 1 of this Article, and the time frames of their periodic verification.

Article 18

An instrument is placed on the market or in use only if it fulfils the requirements as laid down in this Law. Results of the measurement obtained from using the instrument referred to in paragraph 1 of this Article must be traceable to the national measurement standards or national measurement standards of other countries included in the Mutual Recognition Agreement and certificates of calibration and measurement issued by national metrological institutes (CIPM MRA) or to the international measurement standards.

Measuring instruments shall be used in accordance with their purpose.

The following principles are applied for prescription of metrological requirements:

1) application of metrological requirements from relevant international and European organizations and institutions;
2) definition of time lines for mandatory periodic calibration of standards used for verification of instruments and for certain metrological requirements for those standards where necessary;
3) avoidance of unnecessary barriers to trade;
4) application of the same procedures on measuring instruments of a country with which compatible international agreement has been signed, and on measuring instruments of domestic origin or measuring instruments originating from any other country.

Metrological requirements and method of determining the realisation of metrological requirements for instruments, and methods of measurement are prescribed by the Minister.

Obligations of persons using measuring instruments

Article 19

Persons using measuring instruments shall:

1) set up and use instruments in a manner that ensures prescribed accuracy of measurement and accuracy of measurement results;

2) maintain instruments in technical condition that ensures accuracy of measurement;

3) submit instruments to be verified in accordance with this Law and regulations adopted on the basis of this Law;

4) keep the records of maintenance and verification of legal instruments in use in accordance with the regulations.

The persons referred to in paragraph 1 of this Article, and owners of instruments are obliged to mark instruments the validity period of which has expired with the sign reading as follows "measuring instrument no longer in use". The sign shall be applied in a visible fashion.

VII TYPE APPROVAL AND VERIFICATION OF A MEASURING INSTRUMENT

Type approval

Article 20

A type approval certificate is issued by a designated body and/or by the Directorate upon a request of a domestic producer, authorised importer and/or authorised supplier of the foreign producer of a measuring instrument.

The certificate referred to in paragraph 1 of this Article confirming that the measuring instrument complies with the prescribed technical and metrological requirements is issued after testing of measuring instrument type has been conducted.

If it is determined that, after measuring type testing has been conducted , the type of a measuring instrument is not in compliance with prescribed technical and metrological requirements, a decision to reject the type approval of the measuring instrument shall be issued.

A designated authorised body shall be entrusted to perform the activities referred to in paragraph 1 of this Article.

A designated body is obliged to notify the Directorate of issued type approval certificates, amendments regarding certificates that have already been issued, and of withdrawal of certificates.

The certificate referred to in paragraph 1 of this Article shall be published in the Official Gazette of the Directorate, including the notification on withdrawal of certificate.

An appeal against the documents referred to in paragraphs 2 and 3 of this Article can be lodged with the Ministry within 15 days.

Provisions of the Law governing general administrative procedure shall be applied to the method of examining measuring type, unless otherwise stipulated by this Law.

The Minister shall prescribe in detail the method of examining measuring instrument types for particular types of measuring instruments..

Verification of a measuring instrument

Article 21

Verification of a measuring instrument includes the examination and marking and/or issuing of a verification certificate.

Verification of a measuring instrument shall be conducted by an authorised body, and/or the Directorate after the examination of a measuring instrument confirming that the instrument is in accordance with the approved type and prescribed metrological requirements.

If an authorised body and/or the Directorate determines that certain type of a measuring instrument is not in accordance with the approved type of a measuring instrument and does not meet the prescribed metrological requirements, if shall issue a decision rejecting verification of a measuring instrument.

An appeal against the decision referred to in paragraph 3 of this Article may be lodged with the Ministry within 15 days.

Verification of a measuring instrument can be initial, regular or extraordinary.

Verification certificate and date of marking of a measuring instrument shall be issued by an authorised body, and/or the Directorate upon a request of an owner and/or user of a measuring instrument.

Provisions of the Law governing general administrative procedure shall be applied to the matters not specifically regulated by this Law, but that refer to the verification of measuring instruments, issuance of decisions on authorisation, issuance of type approval certificates.

The Minister shall prescribe in detail for particular types of measuring instruments the method and conditions for verification, and manner and deadline for keeping the necessary documentation.

Initial verification of a measuring instrument

Article 22

Initial verification includes verification of the new measuring instruments and instruments which have not been previously verified.

A domestic producer, authorised importer and/or authorised dealer, natural person or legal entity shall have their measuring instruments initially verified.

Regular verification of a measuring instrument

Article 23

Measuring instruments in use shall be subjected to regular verification.

Regular verification of a measuring instrument is carried out periodically, at specified intervals for certain type of measuring instrument.

Regular verification of a measuring instrument shall be ensured by its owner and/or its user.

Regular verification of electrical energy meters, measuring transformers, dial indicators, water meters, gas meters and measuring instruments that correct the volume of fluid and/or gas, correctors and thermal energy meters shall be a responsibility of persons authorised for distribution of water and/or persons authorised for measurement of electrical and thermal energy and natural gas in accordance with the provisions regulating the field of energy.

Extraordinary verification of a measuring instrument

Article 24

Measuring instruments which have been withdrawn from use due to malfunction or other technical deficiencies and which have been repaired, measuring instruments which have been repaired and measuring instruments for which regular verification has not been performed within the prescribed period of time shall be subjected to extraordinary verification.

The person who has repaired or re-modelled the measuring instrument referred to in paragraph 1 of this Article shall ensure its extraordinary verification.

Marks

Article 25

Marks used for verification of a measuring instrument in the Republic of Serbia are national marks.

The Minister in charge shall prescribe the type, format and method of affixing national marks used for the verification of measuring instruments, and the content and format of certificates of verification of a measuring instrument and certificates of type approval.

Expiry of the validity period of a verification mark and verification certificate

Article 26

Validity period of a measuring instrument mark or verification certificate shall no longer be valid if:

1) its validity period has expired;
2) an alteration of a measuring instrument can affect its metrological properties;
3) a measuring instrument is damaged in such a way that it can lose certain properties essential for its verification;
4) a mark has be obliterated, removed, altered or damaged in any other way;
5) the characteristics of a measuring instrument have been altered after the measuring instrument has changed its place of installation.

A measuring instrument the mark or verification certificate of which is no longer valid shall not be used.

Standards and reference materials

Article 27

Calibrated working standards and certified reference materials shall be used for the verification of measuring instruments.

Extraordinary examination of a measuring instrument in use

Article 28

Where in doubt about the accuracy of a measuring instrument, an interested party can make a request to an authorised body, and/or the Directorate to perform an extraordinary examination of a measuring instrument and to issue a report on examination.

The costs of an extraordinary examination of a measuring instrument shall be borne by the applicants if a verified measuring instrument with valid mark complies with the prescribed metrological requirements.

The costs of extraordinary examination of a measuring instrument shall be borne by a person responsible for regular verification if a measuring instrument does not comply with the prescribed metrological requirements.

The Minister in charge shall prescribe in detail the method of extraordinary examination of a measuring instrument, content and deadline for keeping the reports on examination on measuring instruments.

VIII PRE-PACKAGED PRODUCTS

Article 29

Pre-packaged products shall only be placed on the market or stored with the intention to be placed on the market when their nominal quantity is accurately, clearly and unambiguously indicated, and when their actual quantity lies within the permitted tolerance levels of indicated nominal quantity.

The provisions of this Law shall not apply to pre-packaged products being labelled as free samples which are used for marketing and service provision purposes.

The Minister shall prescribe in detail the procedure of examining pre-packaged products in order to check the fulfilment of metrological requirements, requirements for equipment used for the supervision of the quantities of pre-packaged products, metrological requirements to be met by the quantities of pre-packaged products, manner of indicating the quantities and the permitted tolerance levels of actual quantities when compared with indicated ones.

Conformity marks confirming conformity of quantities of pre-packaged products with metrological requirements

Article 30

A producer can place a conformity mark confirming conformity of the quantity of a pre-packaged product with metrological requirements only after a prescribed documentation of conformity of quantity of a pre-packaged product with prescribed metrological requirements has been conducted.

The Minister in charge shall prescribe the size and format of a mark of conformity confirming the conformity of the quantity of a pre-packaged product, method of installing, and method of documenting conformity of a pre-packaged product quantity with metrological requirements.

Extraordinary testing of conformity of pre-packaged products with metrological requirements

Article 31

Extraordinary testing of pre-packaged products to assess conformity with prescribed metrological requirements and provisions of this Law shall be conducted by the Directorate, upon a request from the competent authority, natural person or legal entity.

Volume standard and measuring bottle

Article 30

Volume standard, which in the context of this Law, is used for testing pre-packaged products, shall have such metrological properties that it can be used as volume measuring instrument which fulfils prescribed metrological requirements.

A measuring bottle must be labelled with prescribed signs and notices.

The Minister shall prescribe metrological requirements for measuring bottles, permitted volume tolerance levels, and signs and notices on bottles as measuring containers.

IX VALIDITY OF FOREIGN DOCUMENTS AND CONFORMITY MARKS

Article 33

Certificates on type approval of the measuring instruments and verification of the measuring instruments, that is, marks used for verification of measuring instruments and marks of conformity issued abroad shall be valid in the Republic of Serbia if they have been issued in accordance with the international agreement concluded by the Republic of Serbia.

The mode of determining fulfilment of the certificates, marks and conformity marks referred to in paragraph 2 of this Article shall be prescribed by the Minister.

X FUNDING AND FEES

Sources of funding

Article 34

The Directorate shall be funded from:

1) the budget of the Republic of Serbia;

2) other sources as stipulated by the Law.

Fees

Article 35

Fees are paid for: verification of instruments, calibration, metrological expertise, testing of a measuring instrument type, testing of pre-packaged products and measuring bottles in order to check the fulfilment of metrological requirements and other activities conducted by the Directorate as stipulated by the Law.

The amount of the fees referred to in paragraph 1 of this Article shall be same for both domestic and foreign persons.

The amount and mode of payment referred to in paragraph 1 of this Article shall be prescribed by the Government.

The fees referred to in paragraph 1 of this Article shall be paid into the appropriate account of the public revenue budget of the Republic of Serbia.

XI SUPERVISION

Enforcement of the Law

Article 36

Enforcement and implementation of this Law and other regulations in the field of metrology shall be performed by the Ministry.

Metrological supervision

Article 37

Metrological supervision means monitoring of the production, trade, import, installation, use, maintenance and repair of instruments performed in order to check whether those measuring instruments fulfil the prescribed requirements or to check whether they are used in accordance with this Law and other regulations in the field of metrology, including the checking of the accuracy of quantities indicated on and contained in pre-packaged products.

The supervision referred to in paragraph 1 of this Article includes supervision of instruments and pre-packaged products placed on the market, and supervision of instruments in use.

Metrological supervision and supervision of use of legal measurement units in the context of this Law shall be performed by the Directorate through persons authorised for performing the metrological supervision.

Article 38

An authorised person performing metrological supervision shall be in possession of an official identification card.

The content and format of an official identification card, and the method of keeping the register of issued official identification cards referred to in paragraph 1 of this Article shall be prescribed by the Minister.

Article 39

While performing metrological supervision, persons authorised to perform metrological supervision are entitled and obligated to evaluate:

1) whether a producer of the measuring instrument performs prescribed procedure of conformity assessment of measuring instruments;
2) whether a measuring instrument placed on the market is in compliance with the prescribed requirements;
3) whether conformity of a measuring instrument with prescribed requirements is assessed in accordance with the prescribed procedure and whether a measuring instrument is marked in accordance with the law;
4) whether a measuring instrument is accompanied by prescribed certificate of conformity and other prescribed documentation;
5) whether a measuring instrument in use fulfils the requirements prescribed by this Law or by the regulations adopted on the basis of this Law;
6) whether a person using the measuring instrument is installing and using that measuring instrument in a manner that ensures the prescribed accuracy of measurement;
7) whether a person using the measuring instrument is maintaining that instrument in the technical condition that ensures accuracy of measurement and whether the records on its maintenance and verification are kept;
8) whether initial or regular verification of measuring instrument is ensured;
9) whether a mark and/or verification certificate on the measuring instrument has expired;
10) whether the measuring instrument that had been repaired or re-modelled was submitted to extraordinary verification;
11) whether the nominal quantity of pre-packaged product placed on the market is indicated in a precise, visible and unambiguous fashion;
12) whether the actual quantity of pre-packaged products is within permitted deviation levels from the indicated nominal quantity;
13) whether pre-packaged products bear a conformity mark as prescribed;
14) whether a measuring bottle placed on the market meets the prescribed metrological requirements and bears prescribed marks and notices;

15) whether the legal units of measurement prescribed by this Law or by the regulations adopted on the basis of this Law are used;

Article 40

Supervision of the measuring instruments and pre-packaged products placed on the market shall be performed by the Directorate.

Should it be established that, while performing the supervision referred to in paragraph 1 of this Article, a measuring instrument and/or pre-packaged product does not fulfil the prescribed conditions, an person authorised to perform metrological supervision shall order the remedy of established irregularities and deficiencies within the specified deadline and temporarily ban the placement on the market of the measuring instruments and/or pre-packaged products until the established non-conformities are eliminated.

If the non-conformities referred to in paragraph 2 of this Article are not eliminated within the defined deadline, a person authorised to perform metrological supervision shall issue a decision instructing the withdrawal of the measuring and/or pre-packaged product from the market.

An appeal against the decisions referred to in paragraph 3 of this Article may be lodged with the Ministry within 15 days.

The appeal shall not restrain the execution of the decision.

Article 41

Supervision of the instruments in use shall be performed by the Directorate.

Should it be established that, while performing the supervision referred to in paragraph 1 of this Article, a measuring instrument in use does not fulfil conditions prescribed by this Law or regulations governing the field of metrology, a person authorised to perform metrological supervision shall order the remedy of established irregularities and deficiencies within the defined deadline and temporarily ban the use of measuring instruments until the established non-conformities are eliminated.

If the non-conformities referred to in paragraph 2 of this Article are not eliminated within the defined deadline, a person authorised to perform metrological supervision shall issue a decision banning the use of the measuring instrument.

An appeal against the decisions referred to in paragraph 3 of this Article may be lodged with the Ministry within 15 days.

The appeal shall not restrain the execution of the decision.

Article 42

Supervision of professional work of authorised and designated bodies shall be performed by the Directorate through persons authorised to perform metrological supervision.

Article 43

While performing supervision of the expert work of authorised and designated bodies, a person authorised to perform metrological supervision is entitled and obligated to evaluate:

1) whether a designated and/or authorised body ceased to meet the prescribed requirements;

2) whether a designated and/or authorised body has informed the Ministry about the changes that could affect the fulfilment of prescribed conditions;
3) whether an authorised body, while performing verification of measuring instruments, performs examination of measuring instruments according to the prescribed manner and procedure of examination of instruments;
4) whether an authorised body performs verification of measuring instruments in accordance with the prescribed conditions;
5) whether an body authorised for the examination of measuring instruments that are being verified uses calibrated working standards and/or certified reference materials;
6) whether an authorised body keeps documentation on prescribed manner and within the prescribed deadline;
7) whether a designated body performs conformity assessment according to the prescribed procedure;
8) whether a designated body after the conformity assessment has issued prescribed conformity certificate of conformity;
9) whether a designated body keeps documentation in the prescribed manner and within prescribed deadline.

Article 44

Should a person authorised to perform metrological supervision finds out that an authorised body and/or designated body does not perform its work in accordance with the regulations, he/she shall order the elimination of established irregularities and deficiencies within the defined deadline.

If an authorised body and/or designated body fails to eliminate established irregularities within the deadline referred to in paragraph 1 of this Article, the Directorate shall make a request to the Ministry to repeal the decision on authorisation and/or designation.

If Minister repeals the decision on authorisation and/or designation, the authorised body and/or designated body shall be removed from the register of authorised and/or designated bodies.

The decision referred to paragraph 3 of this Article shall be made final and administrative dispute can be initiated against it.

Article 45

The manner of performing metrological supervision and supervision of the use of legal units of measurement shall be regulated by the Government.

Article 46

The competent Customs authority shall collaborate with other competent authorities regarding the control of measuring instruments placed on the market of the Republic of Serbia by providing information.

XII PENAL PROVISIONS

Article 47

A fine of between 500 and 50,000 RSD shall be imposed for the following offences committed by a natural person or a fine of between 5,000 and 50,000 RSD shall be imposed for the following offences committed by an entrepreneur or a fine of between 10,000 and 1,000,000 RSD shall be imposed for the following offences committed by a legal entity if:

1) it uses legal units of measurement which are not prescribed by this Law or by the regulations adopted on the basis thereof (Article 13);

2) it places on the market a measuring instrument which does not comply with the prescribed requirements the conformity of which is not assessed according to the prescribed procedure, which is not marked in accordance with the regulations and which is not accompanied by certificates of conformity and other prescribed documentation (Article 15);

3) it places on the market or puts into use a measuring instrument: which does not fulfil the requirements of this Law, metrological or technical requirements prescribed in accordance with this Law (Article 18);

4) measuring instruments are not used in the prescribed manner ensuring accuracy of measurement and if a measuring instrument is not kept in technical condition which ensures accuracy of measurement, and if the records of its maintenance and verification are not kept (Article 19);

5) initial, regular or extraordinary verification of a measuring instrument is not ensured (Articles 22, 23 and 24);

6) it uses a measuring instrument the mark and/or verification certificate of which has expired (Article 26);

7) it places on the market or stores with the intention of placing on the market pre-packaged goods the nominal quantity of which is not indicated precisely, visibly, or unambiguously, or if it places on the market a pre-packed product which does not contain the actual quantity within permitted deviation from the indicated nominal quantity (Article 29);

8) it places on the market or stores with the intention of placing on the market pre-packaged products that do not bear a conformity mark according to the prescribed manner (Article 30);

9) it places on the market a measuring bottle which does not meet the prescribed metrological requirements and does not bear the prescribed marks and notices (Article 32).

A fine of between 500 and 50,000 RSD shall be imposed for the offences referred to in paragraph 1 of this Article committed by a responsible person of a legal entity.

XIII TRANSITIONAL AND FINAL PROVISIONS

Article 48

The sub-laws prescribed by this Law shall be adopted within two years following the entry into force of this Law.

Pending the adoption of the sub-laws prescribed by this Law, regulations issued on the basis of the Law on Metrology („Official Gazette of S&M", No. 44/05) shall remain effective if not in collision with this Law.

Article 49

Certificates of type approval, verification of a measuring instrument and marks issued before the date of entry into force of this Law shall remain in force until the expiry of the validity period they were issued for.

Decisions on fulfilment of requirements for examination of measuring instruments that have been issued to legal entities before the entry into force of the Law on Metrology ("Official Gazette of S&M", No. 44/05) shall be valid for a maximum of two years after the entry into force of this Law under condition that those persons have submitted the application for accreditation to the Accreditation Body of Serbia and application for determining the fulfilment of requirements prescribed by this Law to the Ministry.

Article 50

The Law on Metrology (Official Gazette of S&M, No. 44/05) shall be repealed with effect from the date of entry into force of this Law.

Article 51

This Law shall enter into force on the eighth day following its publication in the "Official Journal of the Republic of Serbia".

3.1.12. Mechanisms for the Implementation of the Law on Metrology

Sub-laws for the implementation of the new Law on Metrology, including the years in which they were adopted by the Government, shall be as follows:

2010:

1. Regulation on amount and method of payment of fees for conducting verification of measuring instruments, metrological expertise, type examination of measuring instruments, examination of pre-packaged products and other activities in the field of metrology ("Official Gazette of the RS", Nos. 68/2010 and 72/2010 - corr.)

This regulation prescribes the amount of fees paid for: verification of instruments, calibration, metrological expertise, testing of a measuring instrument type, testing of pre-packaged products and measuring bottles in order to check the fulfilment of metrological requirements and other activities (hereinafter referred to as: fee)

performed by the DMDM in accordance with the Law on Metrology, and the mode of payment thereof.

The fee amount for conducting verification of individual types of measuring instruments and codes of these activities are given in the Annex attached to this Regulation.

2. Regulation on the Manner of Performing Metrological Supervision ("Official Gazette of the RS", No. 88/2010)

This Regulation prescribes the manner of performing metrological supervision and supervision of the use of legal measurement units.

3. Rulebook on the Types of Measuring Instruments Subject to Mandatory Verification and Intervals of Periodic Verification ("Official Gazette of the RS", No. 49/2010)

This Rulebook prescribes the types of measuring instruments subject to mandatory verification for the purpose of protecting health and public safety, environmental protection, control and safety of traffic of and trade in services and goods, and check of pre-packed products and bottles as measuring vessels, and intervals of periodic verification of such instruments.

4. Rulebook on the Manner of Recognition of Foreign Certificates, Marks and Conformity Marks ("Official Gazette of the RS", No. 86/2010)

This Rulebook prescribes the manner of recognition of validity of foreign certificates of type approval of measuring instruments and verification of measuring instruments in the Republic of Serbia, i.e. marks and other conformity marks issued abroad.

5. Rulebook on the Manner of Authorisation Granted to Economic Operators and Other Legal Entities to Perform Verification of Measuring Instruments and Keep the Register of Authorised Bodies ("Official Gazette of the RS", No. 89/2010)

This Rulebook prescribes the manner of authorisation granted to economic operators and other legal entities to perform verification of measuring instruments, keep the Register of authorised bodies, and other issues regarding the work of authorised bodies.

6. Rulebook on the conditions for Performing Verification of Measuring Instruments ("Official Gazette of the RS", No. 89/2010)

This Rulebook prescribes the conditions for economic operators and other legal entities to perform the verification of measuring instruments.

2011:

7. Regulation on Specific Legal Units of Measurement and Their Use ("Official Gazette of the RS", No. 43/2011)

This Regulation prescribes legal units of measurement that are not covered by the International System of Units (Systeme International d'Units, SI) which can be used in

the Republic of Serbia in accordance with the law regulating metrology activities and manner of their use.

The provisions of this Regulation do not apply to the units of measurement used in air, water and rail transport which are different from those the application of which under this regulation is mandatory if the use of such units is provided by international conventions and agreements binding on the Republic of Serbia.

8. Rulebook on the Type, Form and Manner of Affixing National Hallmarks Used in Verification of Measuring Instruments ("Official Gazette of the RS", No. 57/2011)

This Rulebook prescribes the type, form and manner of affixing of national hallmarks used in verification of measuring standards, and a detailed form and content of the verification certificates and type approval certificates.

9. Rulebook on the Content and Form of the Records and Manner of Record Keeping by Authorised Persons ("Official Gazette of the RS ", No. 58/2011)

This Rulebook prescribes the content and form of records, and the manner of record keeping od economic operators or other legal entities authorised to perform verification of measuring instruments.

10. Rulebook on the Conditions for the Recognition of National Measurement Standards ("Official Gazette of the RS", No. 70/2011)

This Rulebook prescribes the conditions for the recognition of measurement standards of the Republic of Serbia serving as a basis for assigning values of a quantity to other measurement standards of the quantity concerned (hereinafter referred to as: national standard).

2012:

11. Rulebook on the Verification of Measuring Instruments ("Official Gazette of the RS", No. 1/2012)

This Rulebook prescribes the periodic verification of certain types of measuring instruments, manner and conditions of verification, and the manner and deadlines for keeping the required documentation.

12. Rulebook on the Form and Content of Official Identity Cards of Persons Authorised to Conduct Metrological Supervision ("Official Gazette of the RS ", No.16/ 2012)

This Rulebook prescribes the form and content of official identity cards of persons authorised to conduct metrological supervision, and the manner of keeping the records of officially issued identity cards.

13. Rulebook on Type Examination ("Official Gazette of the RS", No. 22/2012)

This Rulebook prescribes the manner in which type examination of measuring instruments is performed for measuring instruments which require mandatory issuance of certificates of type approval.

14. Rulebook on Extraordinary Examination of Measuring Instruments ("Official Gazette of the RS", No. 54 / 2012)

This Rulebook prescribes the manner of extraordinary examination of measuring instruments, and the content and deadlines for keeping the examination reports on measuring instruments.

The following regulations are the means to transpose the three New Approach Directives (in the area of metrology) into our legal system:

1. Rulebook on the Requirements for Non-automatic Weighing Instruments

This Rulebook prescribes the metrological and technical requirements for non-automatic weighing instruments, conformity assessment procedures, certificates of conformity and documentation accompanying non-automatic weighing instruments, conditions to be met by designated bodies performing conformity assessment, and the manner of determining the fulfilment of metrological requirements.

2. Rulebook on Measuring Instruments

This Rulebook prescribes the requirements, conformity assessment procedures, marking, and certificates of conformity for specific devices and systems with measurement function (hereinafter referred to as: measuring instruments).

This Rulebook applies to the measuring instruments defined in the Annexes attached to this Rulebook and relating to: water meters, gas meters and volume conversion devices, active electrical energy meters, thermal energy meters, measuring systems for continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, materialised measures, measuring instruments of dimension and exhaust gas analysers.

3. Rulebook on Metrological Requirements and Testing Procedures of Pre-packaged Products

This Rulebook prescribes the procedure for examining pre-packaged products in order to check the fulfilment of metrological requirements, metrological requirements related to the quantities of pre-packaged products, manner of indicating the quantities and the permitted tolerance of actual quantities from indicated ones, size and format of conformity marks of the pre-packaged product quantity, method of installing and documenting conformity of the pre-packaged product quantity with metrological requirements, metrological requirements for measuring bottles, permitted volume tolerance, and notices and marks on bottles as measuring containers.

CHAPTER 4

4.1. LAWS ENSURING THE IMPLEMENTATION OF THE HORIZONTAL QI LAWS

The Law on General Product Safety (Official Gazette No. 41/09) by which the General Product safety Directive is transposed into our legal system, and the Law on Market Surveillance (Official Gazette No. 92/11) are the two laws underpinning the goal of full implementation of the above-mentioned laws and sub-laws. These laws are not the "focal point" of the Quality Infrastructure, but without them the future of re-defined, competitive and efficient QI cannot be secured!

4.1.1. Law on General Product Safety (Official Gazette of the RS No. 41/09)

The Law on General Product Safety is fully harmonised with the principles and basic requirements of the Directive on General Product Safety (2001/95/EC) (see chapter 2.1.3. explaining a mechanism of full transposition of 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. In other words, adoption of the Law on General Product Safety **endorsed full harmonisation with the EU horizontal technical legislation comprising a new framework for marketing of products, adopted in the EU in 2008.**

One of the most important novelties, introduced into our legal system by adopting this law**,** is **setting up the RAPEX system**; namely this system was introduced through the sub-law of the Law on General Product Safety - **the Regulation on the Establishment and Operation of the System for Fast Exchange of Information on Dangerous Products.** *The operation of this system aims at creation of an integrated system approach of all competent market surveillance authorities when gathering and disseminating information on dangerous products and at further development of 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 the System for Fast Exchange of Information on Dangerous Products are as follows:

1) **Contact Point -** Ministry of Agriculture, Trade, Forestry and Water Management – **Market inspectorate** was established with the purpose of collecting, integrating and disseminating the information on dangerous products. It is in charge of keeping the Central Register on Dangerous Products and Undertaken Measures/Actions. It alerts the public to dangerous products posing a serious risk and informs the Government about the operation of the system for fast exchange of information on dangerous products in which all market surveillance authorities are involved, including Customs Administration performing customs inspections.
2) **Market surveillance authorities and Customs Administration** are obliged to inform the Contact Point when they detect a dangerous product on the market and act in accordance with their powers.
3) The Contact Point forwards the information to all relevant market surveillance authorities to check for presence of a dangerous product in the entire territory and points of entry (to prevent further marketing thereof).
4) Market surveillance authorities inform the Contact Point of their findings and proceedings.
5) The Contact Point follows the available international databases on dangerous products on the market. **When a product from this database is suspected to have entered the Serbian market, all competent market surveillance authorities are informed in order to perform an intensive check for presence of a dangerous product throughout the territory and at points of entry to prevent marketing,** i.e. to withdraw it from the market and recall from the consumers and other users.
6) Market surveillance authorities inform the contact point of their findings and proceedings.

Establishment of a system for fast exchange of information on dangerous products in the Republic of Serbia is a systematic preparation for further successful integration into the EU RAPEX system established by means of the Directive on General Product Safety and improved by Regulation EC 765/2008.

4.1.2. Law on Market Surveillance
(Official Gazette of the RS No. 92/11)

The Law on Market Surveillance was adopted on 7th December 2011, and entered into force on 15th December in the same year. This Law provides in one place, for the first time in the legal system of the Republic of Serbia, codified provisions on market surveillance. Namely, for the first time and in one place it systemically regulates: general rules of market surveillance, market surveillance authorities and their scope of work, exchange of information and communication between the market surveillance authorities, cooperation between the market surveillance authorities and customs authorities, and coordination between the market surveillance authorities and monitoring of the market surveillance activities.

At the same time, this Law defines, for the first time in the legal system of the Republic of Serbia, the concept of market surveillance as a set of activities and measures undertaken by market surveillance authorities intended to ensure product compliance with safety, technical, and other requirements set out in relevant regulations, primarily technical regulations, and to ensure that the products placed on the market in the Republic of Serbia do not pose a risk of injury to human health and safety or other aspects of the protection of public interests.

Moreover, this Law provides for the first time, notwithstanding the application of other, more specific measures set out by the law governing general product safety or regulations governing relevant inspection surveillance, uniform and direct legal grounds for the performance of inspection surveillance over the implementation of technical regulations adopted on the basis of the law governing technical requirements for products and compliance assessment, harmonised with the EU legislation; and all other regulations in the non-harmonised area governing technical and other product requirements, the handling and use of products in accordance with their intended purpose, and the manner of maintenance.

Adoption of the Law on Market Surveillance endorsed the harmonisation of market surveillance with relevant EU legislation, in the first place with Regulation (EC) 765/2008 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.

The Law on Market Surveillance is the most general law relating to market surveillance (*lex generali*), subsidiary in character considering that it applies to the cases when specific market surveillance activities and measures are not regulated by other, specific laws (*lex specialis*).

This Law promotes so-called proactive approach to carrying out market surveillance since it provides for the obligation for market surveillance authorities to adopt annual market surveillance programmes, to plan in advance the type and number of controls, define the areas, products or groups of products to be subjected to control.

On the other hand, the Law imposes the obligation on market surveillance authorities to notify one another and exchange information when carrying out market surveillance activities, and to mutually synchronise controls, etc.

At the same time, the Government adopts a general market surveillance programme for a period of two years in accordance with strategic goals set to be achieved in the field of market surveillance.

The Law introduces, as a *novelty*, a specific form of coordination between market surveillance authorities through the Product Safety Council. This Council gathers together the representatives of all market surveillance authorities, Serbian Chamber of Commerce, Institute for Standardization of Serbia, Accreditation Body of Serbia, and relevant consumer protection organisations.

The Product Safety Council is constituted by the Government and its task is to: monitor and analyse the implementation of activities, the way in which market surveillance

measures are undertaken and the effect of those activities and measures; provide opinions and recommendations related to the implementation of the regulations the application of which is overseen by market surveillance authorities; monitor the functioning of the mechanism for communication and cooperation between the market surveillance authorities and between customs authorities and market surveillance authorities and other interested parties; provide recommendations to efficiently improve the application of those mechanisms, to consider and provide opinions about the reports on the resolution of complaints related to the risks arising from the products under the remit of this Law and other regulations dealing with technical and other requirements for products; and about accidents and health impairments suspected to be caused by those products, undertaking of corrective actions, and other issues related to the obligations of market surveillance authorities to coordinate the market surveillance activities and measures.

The Law on Market Surveillance particularly sets focus on the institutionalised cooperation and obligations of market surveillance authorities and customs authorities when controlling the products entering the market of the Republic of Serbia in view of their safety and compliance with statutory requirements.

General principles for the cooperation between these authorities are introduced. It is thus provided that the customs authority shall implement, in cooperation with the market surveillance authority, the control of the products entering the market of the Republic of Serbia, within the powers vested in it in accordance with the law. It shall apply it on a scale that is adequate for a particular product that presents a high level of risk to health and safety of users and other aspects of public interest which is why there is a need to take effective measures before this product is placed on the market of the Republic of Serbia.

Following the information about product, risk assessment, level of risk, and probability of harmful effects caused by that risk and other information acquired from the market surveillance authorities, customs authority shall carry out checks of product on adequate scale before the product is released for free circulation, and, within the performance of those duties, cooperate with the market surveillance authorities and exchange information that are relevant for carrying out the surveillance.

At the same time, the customs authority is under obligation to discontinue the customs procedure and suspend the release of product for free circulation where the findings are as follows:

1) the product, when properly installed, maintained, and used, displays characteristics suspected to pose a serious risk of injury to health, safety, environment, or any other aspect of public interest;

2) the product is not accompanied by documentation in hard copy or electronic format or when this documentation is not in conformity with the provisions of this Law or if the statutory conformity marking is not affixed in accordance with those regulations;

3) the CE mark has been affixed to the product in a false or misleading manner.

When any of those findings are made, the customs authority is to immediately, and no

later than 24 hours after the product entered the customs territory of the Republic of Serbia, notify the market surveillance authority.

The product the release of which was suspended by the customs authority is released for free circulation if, within three working days after the suspension of the release, the customs authority is not notified in writing, or through RAPEX about any action taken by the market surveillance authority, and provided all other requirements and formalities with regard to the release are fulfilled.

The essential *novelty* related to the cooperation and obligations of market surveillance authorities and customs authority and defined in the provisions of the Law on Market Surveillance endorses the mode of undertaking the actions taken by the market surveillance authority. Namely, if the market surveillance authority ascertains that a product mentioned in the notification received from the customs authority does not pose a serious risk of injury to health and safety or cannot be deemed to be non-compliant with the regulations the implementation of which is being monitored, the customs authority shall release the product for free circulation, provided all other requirements and formalities within the customs procedure are fulfilled.

On the other hand, if it ascertains that the product that is subject to the surveillance within the customs procedure poses a serious risk, the market surveillance authority will take a measure to prohibit the placing on the market of a dangerous product and request that the customs authority marks in the commercial invoice accompanying the product and in any other suitable accompanying document, or in the system for electronic data processing (if the processing of such data is made electronically), a notice that reads as follows: "DANGEROUS PRODUCT – RELEASE FOR FREE CIRCULATION IS NOT AUTHORISED - Law on Market Surveillance (Official Gazette of the RS, No. 92/11)".

However, when so-called *ordinary* product non-compliance with prescribed requirements is concerned, rather than a dangerous product, and the placing of product on the market is forbidden, the market surveillance authority will request the customs authority to, in the commercial invoice accompanying the product and in any other suitable accompanying document, or in the system for electronic data processing (if the processing of such data is made electronically), make a notice that reads as follows: "PRODUCT NOT IN CONFORMITY – RELEASE FOR FREE CIRCULATION NOT AUTHORISED - Law on Market Surveillance (Official Gazette of the RS, No. 92/11)".

CHAPTER 5

5.1. HOW DOES THE NEW HORIZONTAL LEGAL FRAMEWORK AFFECT THE INDUSTRY?

The new horizontal legal framework is crucial for the industry and for the consumers. Provision of product safety is the most important advantage brought up to the consumers by adopting four horizontal laws and all sub-laws needed for their implementation.

In this chapter we will focus more on the advantages/benefits for the industry, since these can be seen through several different perspectives; these analyses will be carried out, not only from the perspective of the safety of and quality of the products based on the new technologies introduced through the new standards, but also from the perspective of the competitiveness of the Serbian economy in general, more efficient procedures, more competent bodies providing the industry with specific services .... Improvement in all these segments will have a positive influence on the free movement of goods and therefore *on the increase of the Serbian export of industrial products to all markets abroad.*

5.1.1. Benefits to the Industry Resulting From the Adoption of the new Law on Technical Requirements for Products and Conformity Assessment and Its Sub-laws

The benefits that the industry will be faced with, by adopting new regulations in the field of technical regulations and conformity assessment, are as follows:

1. A legal base for the implementation of the new concept**, as far as the *production, import and export*** are concerned, ***whereby enabling special advantages for:***

   a) producers: they have a possibility to produce in line with the new standards and whereby to *introduce the new technologies in the process of production*; on the other hand, producers *have a possibility to perform conformity assessment procedures and to issue a declaration of conformity on their own* (self-certification) under the condition that they have the necessary capacities (own laboratories).

   b) importers, *including foreign investors*: new regulations create a precondition for

introducing a new certificate of conformity into the practice, as far as conformity assessment is concerned; this document is *confirmation of conformity*, issued by a relevant designated CAB as a prerequisite of placing a product, for which the document is issued, on the market of the Republic of Serbia; (see Chapter 3.,subchapter 3.1.3.); namely, foreign products that are not subjected to conformity assessment performed by a" third party" (in EU about 90% of the products are subjected to such a regime), in Serbia, they have to pass *documentary checks only, (declaration of producer, test reports and other technical documentation*...), without performing conformity assessment procedure again; this new procedure resulting in the new certificate of conformity- *confirmation of conformity*, *with no need for duplication of assessment and certification required*, has a direct positive impact *on facilitated, faster, cheaper and more efficient procedure of import and placing a product on the Serbian market*.

On the other hand, in Serbia, certificates accompanying foreign products, as a result of a "third party" conformity assessment, will undergo a procedure of recognition of foreign documents (see Chapter 3., subchapter 3.1.3.); this procedure *is simpler, cheaper and more efficient than the procedure of conformity assessment which requires duplication of sampling, testing and certification of the product*.

c) exporters *including foreign investors*: due to the application of the transposed European and international standards to which the products must be conformed in order to meet the requirements of the Directive/regulation (presumption of conformity in the regulated area: see Chapter 3., subchapter 3.1.1.), *it will be possible to export products that are safer, with higher level of quality and thus more competitive*.

2. ***Strengthened capacity*** **and** ***enhanced competitiveness in the field of conformity assessment****: designation of the CABs* introduced by the Law as the new element of the New Approach which is of great significance for the industry (see Chapter 3., subchapters 3.1.1. and 3.1.3.) The New Approach is valid for the less sensitive products (electric and electronic appliances, machines, lifts, personal protective equipment), the conformity to the technical requirements of which is assessed and certified by a designated body; once the state *designates a number of CABs they will be subjected to the market rules with special positive impacts on the industry*:

   a) producer **can choose between a number of designated CABs** thus affecting *the strengthening of the competitiveness among CABs*;

   b) since the CABs are subjected to the market rules and are outside the states area of competences, a ***producer and a designated CAB have more flexible relations based on the contractual arrangements*** (subcontracting approved by the producer could be taken as an example of the flexibility mentioned above)

   c) **accreditation certificate** is the best instrument recommended to prove the competence of the CABs as a *firm guarantee of more competence and professional-oriented CABs providing the serves to the industry*.

3. **Transparency of all industry-related information needed: A special information centre, TEHNIS,** dealing with the Serbian technical regulations was set within the Sector for QI, MERD- (www.tehnis.merr.gov.rs); *economic operators can access the TEHNIS portal at any time, whereby they can be fully informed about:*

   a) ***data from the portal itself*** (novelties in the work of QI Sector, different legal interpretations falling with the competence of the QI Sector, information on technical legislation of the Republic of Serbia, etc.)

   b) ***data from the electronic registers posted on the TEHNIS*** portal about:

      - valid technical regulations
      - technical regulations in preparation
      - designated and authorised CABs
      - CABs authorised for the verification of measuring instruments
      - foreign certificates of conformity valid in the Republic of Serbia.

5.1.2. Benefits to the industry Resulting from the new Law on Standardization and Its Sub-laws

By adopting the new Law on Standardization, ***a lot of benefits for the industry were endorsed:***

1. The industry is in a position to have **the new quality of the product** ***due to the application of the new transposed international and European standards, whereas the new quality and new technologies in the process of production were introduced***; at the same time, the industry is faced with the ***new procedure of conformity assessment with standards as a voluntary procedure, since the application of standards is voluntary*** – non-regulated area (see Chapter 3, subchapter 3.1.4.)
2. Pursuant to the provisions of the new Law on Standardization*, industry has an opportunity to be more pro-active in the process of enacting standards*; namely, *all interested parties* are involved in the work of ISS the governing bodies (Assembly, Management Board, Surveillance Board, Technical Committees and Advisory Committees); *whereby the decision-making process, as far as standards are concerned, could be influenced by the industry.*
3. Implementation of the new Law on Standardization endorsed the **strengthening of capacities of the ISS**; *new resources of the ISS both human and material resources prepared the ISS to provide new contributions to the industry through*:

   a) ***Training sessions and seminars organised by the ISS***; namely, for the first time, ISS organised seminars and workshops for the industry, mainly on the subject of "Application of Serbian standards with a special significance for the industry"; In this respect, ISS has organised up to now eight seminars for the industry on the

following subjects :

- "SRPS ISO 9001"
- "Personal protective equipment"
- "SRPS ISO/ IEC 27001"

b) ***transparency of all information of importance to the industry***; the transparency has been achieved through the development of the ISS web page accessible to all relevant interested parties; whereby all ISS data are accessible to the industry, such as:

- **standard price list** – price list of standards and all related documents is published in the Official Gazette, No. 54/11 of 22. 07.2011;
- **possibility of purchasing standards and related documents** – standards and related documents could be bought in the ISS shop directly or through the ISS site;
- **possibility of purchasing *foreign* standards and related documents** – ISS has an exclusive right to distribute foreign standards in line with the bilateral agreements signed between ISS and other national bodies for standardization; prices of the foreign standards have been defined by the national bodies for standardization;
- **potential discounts when selling standards**- ISS offers different categories of discounts when selling standards (this could be seen on the ISS web page)
- **possibility to see the content of standards without buying them** – ISS is has a library that is open to all interested parties between the period 9 a.m. to 3 p.m. each day, etc.

5.1.3. Advantages for the industry brought up by adopting the new Law on Accreditation and its sub-laws

A lot of benefits for the industry could be derived from the new *Law on Accreditation:*

- pursuant to the new Law, the accreditation procedure is performed by an independent, national body acting as a public authority (ATS*), which saves the money and increase the trust of all the interested parties involved;*
- reliable assessments and analyses provided by the accreditation *increase the trust in decision making process based on these assessments and analyses;*
- accreditation also contributes *to increased level of in trust in the safety and quality of products and services,* given that they have been assessed by *competent bodies* meeting the internationally accepted criteria; at the same time, the risk of engaging incompetent assessors is reduced;
- accreditation has a *positive impact on reducing the costs of the products and absence*

of defective and misleading products, whereby reducing the health risks;

- quality management systems certified by *accredited* certification bodies in the companies have a *positive effect on the increased level of trust in the work of the company, its competitiveness and facilitated access to the new markets.*

In addition to all the changes in the new Law, **the ATS has already signed Multilateral Agreement with the European co-operation for Accreditation;** ***as a consequence, the industry will be faced with a number of advantages*****:**

a) *all reports and analyses and certificates issued by the Serbian accredited bodies will be accepted and recognised in the European Union*

b) *Serbian products could be placed on the European market without additional costs related to conformity assessment;*

c) *all the above-mentioned will have a valuable contribution to the increase of the competitiveness of the Serbian economy in general.*

5.1.4. Benefits to the industry Resulting from the Adoption of the new Law on Metrology and Its Sub-laws

The crucial novelties imposed by the new Law on Metrology and of *importance to the industry*, are as follows:

1. The roles of all players (MERD, Directorate of Measures and Precious Metals and authorised bodies) in the field of metrology are precisely clarified and this was underpinned by a complete reorganization of metrological system in the Republic of Serbia (fully in line with OIML recommendations); this change positively affected the industry*: the old system with a monopolistic position of the Directorate of Measures and Precious Metals was replaced with the new, modern, competitive metrological system, in which more than one player is in charge of metrological tasks with full responsibility for the tasks within its area of competence;*
2. As a consequence, **the new, modern system of authorisation of the bodies for measuring instruments** subject to legal verification (legal metrology) **was set up**; due to the new system of the CABs authorisation for the verification of measuring instruments, *a potential conflict of interest among different actors in the field of metrology is completely avoided*:
   - **DMDM** is in charge of metrological supervision *and verification of measuring instruments only in cases when there are no authorised bodies;*
   - **authorised bodies** are in charge of *verification of measuring instruments* whereby conformity of the specific measurement instrument to all metrological requirements is confirmed*;*
   - **Designated bodies and DMDM** are in charge of the *assessment of conformity of measuring instruments as any other products to all requirements (metrological and technical) prescribed in the New Approach Directives.*

This clear division of the tasks in the area of metrology has a direct positive effect on the strengthening of the competitiveness in this field.

3. The new concept of calibration of measuring instruments was established in the field of industrial metrology; In line with the signed CIPM MRA, **measurement standards and documents on calibration and measurement issued by the Directorate of Measures and Precious Metals are accepted and recognised through the whole world*; it creates a special benefit for the industry in the field of production, sale and export of measuring instruments***.

Conclusion

A long-term goal of the QI Sector, MERD is based on an idea that the newly established system in the field of QI should become an integral part of the Single European market which requires fulfilment of a number of *strategic goals that should have been met earlier*:

- ***Legal framework*** for the free movement of goods in line with the EU requirements (2008 new package for goods) – we can say that this goal is fully attained *by adoption of the four key laws governing technical regulations and conformity assessment, standardization, accreditation and metrology with the main purpose of placing safe products on the Serbian market.*
- **Transposed European technical Directives for priority sectors -** *New Approach Directives falling with the area of competence of the MERD are almost already in place; by the end of this year, the transposition of the entire package of the NEW Approach Directives falling within the scope of competence of the MERD will be completed.*
- **Transposition of 80% of European standards** - *by the end of 2011, 70% of all EN standards have already been transposed; the remaining ones will be transposed by the end of 2012.*
- The Accreditation Body of Serbia should sign **the multilateral agreement with the European co-operation for Accreditation** *which will result in the recognition of the Serbian system of accreditation* –this was realised on 23rd April 2012 *and presented a huge step towards the European integrations.*
- **The system for *conformity assessment of measuring instruments, calibration of measuring instruments, legal control of measuring instruments and metrological surveillance was* established.**
- Mutual acceptance of industrial products traded with EU Members States **heralds signing of the ACCA for some specific sectors**: signing of the ACCA - realisation of this strategic goal is planned for the end of the process, namely, after setting up of all system elements, including transposition the all the New Approach Directives into our legal system, *it will be necessary to make an assessment in order to identify an important field of industry in Serbia covered by the newly-transposed Directives that would be ready for the „free movement of goods on the European and other markets".*

As we can see from the above-mentioned, the **Serbian QI system is on the right track - "on the road to European integrations"*; to be a part of the European Single Market is a key priority that can be achieved only through integrated constructive efforts of all the players - MERD ATS, ISS and DMDM.***