

Government of Montenegro

Ministry of Economy

**Strategy of Montenegro for the Implementation of the
Acquis Communautaire in the Field of Free Movement of
Goods 2014-2018**

CONTENTS

SUMMARY	5
I INTRODUCTION	6
II GENERAL PRINCIPLES	12
2.1 Content of general principles	12
2.2 Action Plan for compliance with Articles 34 – 36 of the Treaty on the Functioning of the EU	13
III HORIZONTAL ISSUES	14
3.1 Horizontal Legislation.....	14
3.2 Horizontal Organization.....	19
3.2.1 Ministry of Economy	19
3.2.2 Institute for Standardization of Montenegro (ISME)	22
3.2.3 Bureau of Metrology of Montenegro (BoM)	24
3.2.4 Accreditation Body of Montenegro (ATCG)	27
3.2.5 Investments concerning Quality Infrastructure institutions working premises	29
3.2.6 Market surveillance authorities	30
IV VERTICAL LEGISLATION	34
4.1 New Approach.....	34
4.1.1 Low Voltage Electrical Equipment	35
4.1.2 Lifts.....	36
4.1.3 Electromagnetic Compatibility	37
4.1.4 Simple Pressure Vessels	38
4.1.5 Pressure Equipment	39
4.1.6 Gas Appliances and Hot Water Boilers	40
4.1.7 Aerosol Dispenser	41
4.1.8 Machinery.....	42
4.1.9 ATEX – Equipment and protective systems intended for use in potentially explosive atmospheres.....	43
4.1.10 Personal Protective Equipment.....	45
4.1.11 Measuring Instruments.....	46
4.1.12 Non-Automatic Weighing Instruments	47
4.1.13 Eco Design of Energy related Products	48
4.1.14 Toys Safety.....	50
4.1.15 Medical Devices	51
4.1.16 Cableway Installations.....	52
4.1.17 Recreational Crafts	53
4.1.18 Construction Products.....	55
4.1.19 Outdoor Equipment Noise Emissions.....	57
4.1.20 Explosives for Civil Use	58
4.1.21 Pyrotechnic Articles	60
4.1.22 Radio Equipment and Telecommunications Terminal Equipment	61
4.2 Old Approach	62

4.2.1	<i>Textiles</i>	62
4.2.2	<i>Footwear</i>	63
4.2.3	<i>Crystal glass</i>	64
4.2.4	<i>Units of Measurement</i>	65
4.2.5	<i>Pre-packaged products</i>	65
4.2.6	<i>Measuring Containers (Bottles)</i>	66
4.2.7	<i>Drug Precursors</i>	67
4.2.8	<i>Cosmetics</i>	68
4.2.9	<i>Pharmaceuticals</i>	70
4.2.10.	<i>Fertilisers</i>	76
4.2.11	<i>Chemicals</i>	77
4.2.12	<i>Biocidal product</i>	80
4.2.13	<i>Motor Vehicles</i>	81
V	PROCEDURAL MEASURES	85
5.1	Notification procedures	85
5.2	External border checks	86
5.3	Control of the acquisition and possession of weapons	86
5.4	Quantitative restrictions	89
5.5.	Cultural goods	89

LIST OF ABBREVIATIONS/ACRONYMS

ATCG	Accreditation Body of Montenegro
CEFTA	Central European Free Trade Association
CEN	European Committee for Standardization
CENELEC	European Committee for Electro technical Standardization
CIPM MRA	Mutual Recognition Arrangement of the International Committee for Weights and Measures
EC	European Commission
ETSI	European Telecommunications Standards Institute
EURAMET	European Association of National Metrology Institutes
IEC	International Electro-technical Commission
ILAC MLA	International Laboratory Accreditation Cooperation – Multilateral Agreement
IMAC	Internal Market Advisory Committee
ISME	Institute for Standardization of Montenegro
ISO	International Standardization Organization
ITU	International Telecommunication Union
MoE	Ministry of Economy
MEST	Montenegrin Standards
MoIST	Ministry for Information Society and Telecommunications
MoSDT	Ministry of Sustainable Development and Tourism
MoARD	Ministry of Agriculture and Rural Development
MoTMA	Ministry of Transport and Maritime Affairs
MoI	Ministry of the Interior
MoH	Ministry of Health
NANDO	Information System (New Approach Notified and Designated Organizations)
NSO	National Standardization Organization
NTB	Non-tariff barriers to trade
OIML	International Organization of Legal Metrology
RAPEX	Rapid Alert System for Non-Food Consumer Products
REACH	EC Regulation on chemicals and their safe use
R&TTE	Radio & telecommunication terminal equipment
AIA	Administration for Inspection Affairs
WELMEC	Western European Legal Metrology Cooperation
WTO/TBT	World Trade Organization /Technical Barriers to Trade
BoM	Bureau of Metrology

SUMMARY

In order to meet one of the three benchmarks for the opening of negotiation in the Chapter 1- Free movement of goods, Montenegro has to present to the European Commission a strategy for this chapter and an action plan with milestones for the implementation of the relevant EU legislation. In other words, Montenegrin Strategy for the implementation of European Union acquis in the area of free movement of goods should ensure fulfilment of all pre-accession obligations arising from Chapter 1 – Free movement of goods. Accordingly, the Strategy has been prepared and structured based on the structure of the benchmark 1 in the Screening report for Montenegro – Chapter 1 and provides a clear list of priorities for the referred period 2014-2018 in order to achieve full alignment with the EU acquis in the area of free movement of goods.

Based on the above mentioned, key priorities of the Strategy are related to the progress in harmonisation of general principles with EU *acquis*, and drafting of the action plan where Montenegro will give priority to this area defined by the Treaty on the Functioning of the European Union, Articles 34-36. Other priorities in the Strategy are related to the improvement of coordination of all horizontal activities as well as strengthening of administrative capacities in the Ministry of Economy and participating institutions of quality infrastructure as well as in the area of market surveillance.

For the implementation of vertical measures in the areas of New Approach and sectoral – Old Approach, the Strategy provides timelines as well as the plan of strengthening administrative capacities for adopting and implementing legislation until the end of 2018, as well as an indicative allocation of financial resources. In addition, the current situation in the key priority areas where Montenegro has manufacturing capacity (e.g. construction products, medical devices) is described and next steps toward alignment of legislation in those areas with the EU acquis are clarified. In the area of procedural measures within the Strategy, Montenegro will fully implement checks on external borders, notification of technical regulations and standards, procedures for conformity assessment and services of information society. Also, legislation referring to cultural goods and weapons possession will be additionally harmonised.

In addition, in order to meet the key objective of the Strategy, an indicative Action plan with the targeted deadlines for the realization of all planned activities from the Strategy is developed for the 5 years period and it is directly linked to the Strategy. The Strategy contains a detailed plan on administrative capacities, target dates and clear responsibilities for introducing and effectively implementing legislative measures for the period 2014-2018. Furthermore, the Strategy contains an indicative allocation of the total budget for its implementation; breakdown of the budget by year, and a breakdown of indicative allocation per stakeholder/groups of products.

Based on the timeframe and activities given in the Strategy, it is expected that Montenegro will transpose and implement the whole *acquis* in the area of Free Movement of Goods by the end of 2018.¹

I INTRODUCTION

In order to target the integration in the internal market of the EU, the so-called technical legislation of the candidate country should be previously harmonized with the harmonized EU legislation. The entire *acquis communautaire* in this area is contained in the Chapter 1 - Free movement of goods. Removing unnecessary restrictions to the free movement of goods in the EU internal market has been achieved primarily through the harmonization of national technical regulations of the Member States. The European technical legislation has been adopted for the higher risk production sectors particularly for individual products or groups of related products in order to provide the equivalent level of protection of health, environment and consumers throughout the entire EU internal market. The previously mentioned means that in the EU market, in a lawful manner, a product that is not safe cannot be placed on the market. In the production sectors that are not covered by the harmonized technical legislation the principle of equivalence applies – the principle of mutual recognition, according to which products that have been lawfully produced and marketed in one EU country can move freely throughout the entire territory of the European Union.

As far as Montenegro as the EU accession country is concerned, its strategic goal is to achieve full membership in the European Union. Full membership in the European Union implies full integration of the Montenegrin market in the EU internal market, which today consists of 28 Member States markets. To be a part of the internal market means to have an open fully liberalized access to the market of over 500 million consumers, and if we also have in mind the fact that this is the most exclusive market in the world in terms of consumption then the importance of the inclusion of Montenegro is quite obvious.

A total number of acts which constitute a set of documents with which national law in the field of free movement of goods should be harmonized is 1080 (directives, regulations, decisions). The number of acts clearly shows enormity and complexity of approximation of Montenegrin technical legislation to the EU requirements and establishment of quality infrastructure system in line with the European best practices.

As free movement of goods implies the removal of all technical barriers to trade among the EU Member States, Montenegro, as a candidate country for the EU membership must remove all obstacles that can impair its full integration into the EU internal market. The previously mentioned implies not only transposition of the EU legal acts into the national legislation, but also coordination of the implementation of these requirements in the internal market of

¹ Under vertical legislation solely the numbers of initial EU legal acts are given without expressly mentioning the amending legal acts. Nevertheless, the amending legal acts are included in the work-plan.

Montenegro as well as the organization of the system of exchange of information with the EU authorities responsible for safety of products on the EU internal market.

In order to achieve above mentioned, besides other activities, it is necessary to:

- Provide permanent **Inter-ministerial coordination** towards a uniform approach from the adoption of vertical legislation to market surveillance;
- Improve **coordination between the quality infrastructure bodies** in order to systematically harmonize the area of standardization, accreditation and metrology;
- Continue with **harmonization of national legislation with the harmonized technical legislation** and constant updating in line with the changes in the EU;
- Withdraw **the national regulations (provisions)** which are contrary to the EU law and which constitute non-allowed barriers to the free movement of goods;
- Ensure effective **Implementation of national legislation** on the market through the education of suppliers (manufacturers, importers, distributors);
- Continue **with an education of consumers**;
- Establish a **network of accredited conformity assessment bodies** (laboratories, control houses, certifying bodies, etc.) as candidates for authorization/designation and notification by the competent state administration bodies;
- Strengthen **market surveillance** through proactive and reactive inspection surveillance;
- Develop an **interactive exchange of information with the European Commission representatives** as well as with other international partners (the EU and TBT/WTO competent informational checkpoints).

In order to achieve above mentioned as well as to establish a dynamic strategic program of meeting all pre-accession duties arising from the Chapter 1 - Free movement of goods, Montenegro has to adopt the Strategy for the implementation of the Acquis Communautaire in the field of free movement of goods. In other words, this Strategy shall establish a framework for further activities in the area of the Chapter 1 - Free movement of goods, in terms of measures aimed at reaching full harmonization with the *acquis communautaire*. Taking into account that the EU *acquis* and transposition of the *Acquis* are a "moving target", the Strategy contains nominal targets that do not include the developments that are going to happen in the EU *acquis*. The Strategy proposes a set of solutions addressed to all stakeholders especially state authorities and economic operators, **but it is also a statement about the accession to the EU in this field**. At the same time, preparation of the Strategy with *an action plan with milestones for the implementation of the EU legislation in the Chapter 1 - Free movement of goods* is the benchmark for the opening of negotiations in this chapter.

Pursuant to above mentioned, the Strategy is structured in a way to address all the elements that were contained in the EU document *Screening report for Montenegro in the Chapter 1 – Free Movement of Goods under Benchmark 1*:

- *Montenegro presents to the Commission a strategy and an action plan with milestones for the implementation of the EU legislation in this chapter, covering implementation plans for both the vertical (New Approach and Old Approach) and horizontal legislation and for the relevant horizontal organisations (standardisation, accreditation, metrology, and market surveillance), as well as target dates and clear responsibilities for introducing and effectively implementing legislative measures and for ensuring the necessary administrative capacity.*

The other two Benchmarks are being addressed in separate documents and for this reason they are mentioned in this Strategy only as a link to other documents in which they are addressed:

- *Montenegro amends its relevant legislation to ensure that it does not imply an obligation to apply the CE marking to goods that are put on the Montenegrin market;*
- *Montenegro provides the Commission with an action plan for compliance with Articles 34-36 TFEU, with milestones for the internal screening of domestic legislation and administrative practices, for the introduction of mutual recognition clauses, and for the necessary subsequent amendments.*

Based on this the Strategy contains the following parts related to the harmonisation of the Montenegrin legislation with the EU Acquis in area of free movements of goods:

- 1) General Principles,
- 2) Horizontal issues,
- 3) Vertical Legislation,
- 4) Procedural measures.

In each of above mentioned parts of the Strategy, descriptions of the current situation as well as target dates and clear responsibilities for introducing and effectively implementing legislative measures for the EU legislation in the chapter 1, and projections of the necessary administrative capacity and indicative financial allocation on an annual level are given.

Ministry of Economy is in charge of execution of all coordination obligations in the area of free movement of goods and for the implementation of the legislation in this area, besides the Ministry of Economy, there are seven other ministries:

- Ministry of Transport and Maritime Affairs;
- Ministry of Health;
- Ministry of the Interior;
- Ministry of Agriculture and Rural Development;
- Ministry of Sustainable Development and Tourism;
- Ministry for Information Society and Telecommunications;
- Ministry of Culture.

This Strategy includes those sectors that have been harmonized at the EU level. Timeframe to which the Strategy refers is 2014 until the end of 2018. Based on the Montenegro's EU Accession Programme for the period 2014 – 2018, the explicit aim of Montenegro is to transpose and implement the whole acquis in the area of Free movement of goods by the end of 2018.

Such a strategic decision requires an immediate start/continuation of the needed actions in all the fields covered by technical legislation as the achievements of this endeavour will reflect themselves in an improved legal environment for the Montenegrin manufacturers, importers and distributors as well as in the heightened protection of public interest (e.g. health and safety, environment, public security). The above mentioned huge workload and a relatively short five years' time limit to finalize all the needed legal and institutional transformations do not mean that there are no priorities to be taken into account. The detailed description of action plans in different sectors shows the chosen priority areas of interest for Montenegro and properly allocated resources to achieve the desired results. In addition, all target dates in the Strategy and

activities for the alignment with the EU acquis as well as its implementation are dominantly in line with the Montenegro's EU Accession Programme for the period 2014 - 2018.

Estimated budget for the implementation of the Strategy for the period 2014 - 2018 shall amount to around EUR 31.3 million or in average EUR 6.26 million on an annual level. Estimated budget per stakeholder concerning implementation of this Strategy on an annual level is provided in the Annex of the Strategy.

Overview of the procedure for the alignment of the Montenegrin legislation with the EU acquis

This part of the Strategy is providing an overview of the Montenegrin legislative procedures and explains steps which need to be taken to align the Montenegrin legislation with the acquis.

The process of the alignment of the legislation in Montenegro and duration of that process depends on whether the legislation adopted by the Parliament of Montenegro, Government of Montenegro or ministries. In other words, the Parliament is responsible for adoption of laws. The Government adopts proposals of laws and send them to the Parliament. The Government is also responsible for the adoption of the decrees and decisions as bylaws. Ministries in the Government are responsible for the adoption of the rulebooks as bylaws.

Entire procedure of the drafting of each part of legislation (laws and bylaws) in Montenegro is provided by the charts below.

Chart 1: Procedure for the adoption of laws

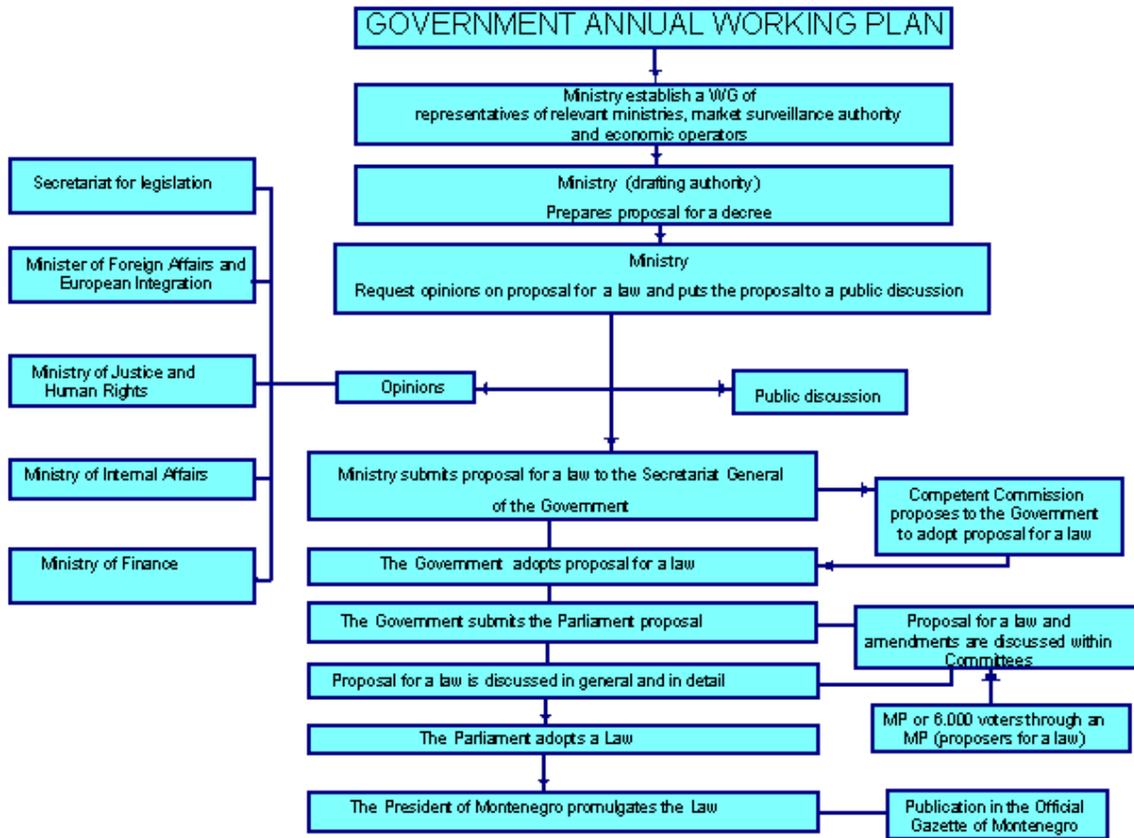


Chart 2: Procedure for adoption of by-laws – Governmental decrees

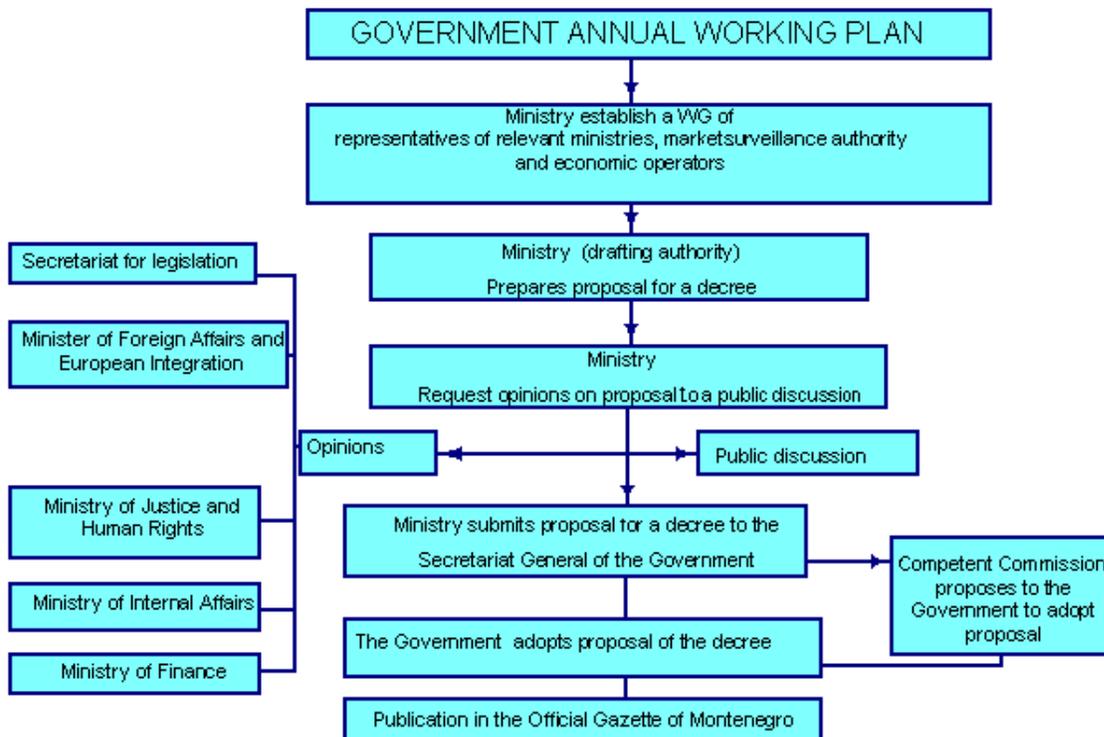
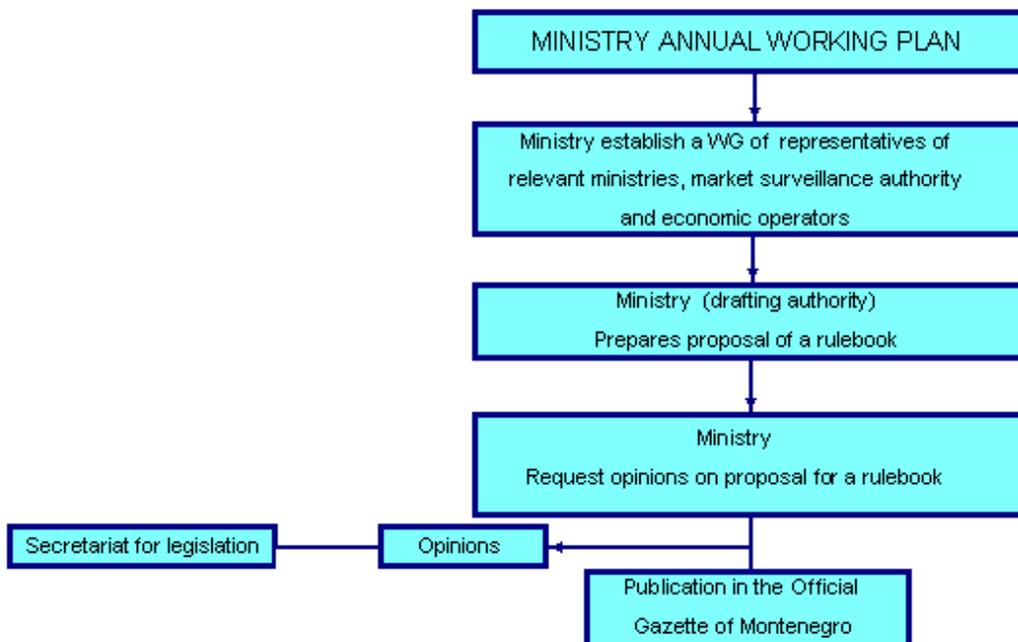


Chart 3: Procedure for adoption of bylaws – Ministerial rulebooks



Specific issues determined by the primary law may further be operationalized through by-laws necessary for law implementation. These by-laws are adopted by the Government of Montenegro (Decrees) and sector specific Ministry (Rulebooks).

Decree is further operationalizing general provisions as adopted in the law, determining the relations of importance for enforcing Constitutional and legal functions of the Government, founding of Ministries and other state authorities as well as establishing administrative bodies and organizations.

Rulebook allows for specifics on provisions provided by the Law or other by-laws.

In order to try to avoid incompatibilities (possibility leading to the need for further amending legislation) Montenegro will send proposed **primary laws** designed to align MN legislation at the draft stage (convergence tables) to the Commission, before the adoption of the "final" piece of legislation.

Regarding **by-laws** Montenegro will send tables of convergence to the European Commission for every legal act immediately after their publication in the Official Gazette of Montenegro.

II GENERAL PRINCIPLES

2.1 Content of general principles

The following part of the document is related to general principles of free movement of goods and the current situation in Montenegro in this area, as well as planned activities in the forthcoming period.

Montenegro will review the state of affairs in its legislation and procedures bearing in mind that main provisions of the Treaty governing the free movement of goods (“general principles”) are as follows:

- Article 34, which applies to the internal EU import and prohibits “quantitative restrictions and all measures having equivalent effect” between Member States;
- Article 35, which applies to exports from one Member State to another, and also prohibits “quantitative restrictions and all measures having equivalent effect”,
- Article 36, which provides for derogations from the freedom of internal market under Articles 34 and 35, which are justified on individual specific grounds.

Since, for example, the “designation of origin” and “obligation to use the national language” are listed in various documents on the topic of content of general principles as typical trade restrictions, the existing Law on Consumer Protection (Official Gazette of Montenegro 26/07) will be analysed, as it contains provisions relating to these issues. It will be assessed in the light of future negotiations with the EU whether certain provisions could constitute illegal barriers to trade.

Another example of national legislation that will be analysed is Law on Foreign Trade (Official Gazette of Montenegro 37/07), which contains provisions on the creation of the “Lists of control of exports and imports”. They contain the information on goods whose import and export are not subject to restrictions but also on goods that may be subject to restrictions when imported and exported.

National non-harmonized regulations - regulations that do not have to be harmonized with the *EU acquis*

The national non-harmonized technical regulations (allowed to exist as there is no EU harmonized legislation in the area in question) always pose a potential barrier to free trade. It is essential that all applicable regulations are registered and that there is a systematic plan for managing them. Even a very general overview of the situation when it comes to this issue shows a deficient state of affairs in Montenegro. There are areas such as e.g. medical devices, for which there are no “registered” national technical regulations, although Article 4 of the Decision on Proclamation of Independence of Montenegro (Official Gazette of Montenegro 36/06) declares that “until the adoption of appropriate regulations of the Republic of Montenegro, regulations that were valid on the day of the entry into force of the Decision, regulations of the State Union of Serbia and Montenegro (SCG) shall apply accordingly unless they are in conflict with the legal system and interests of the Republic of Montenegro”. As a rule, there are no subsequent legal acts in existence that would represent legal basis for the termination of application of a large number of technical regulations inherited from SCG. Therefore technical regulations inherited from SCG should be identified, registered and properly managed (i.e. withdrawn, replaced or fully implemented and enforced).

A system of continuous review of all applicable technical regulations needs to be established during which it would be determined whether they are in actual use and if they are subject to market surveillance enforcement. Or, is there a situation that the economic operators, due to their technical obsolescence, do not use them *de facto* any more (and the State does not enforce them), so they could/must be withdrawn (one of the important obligations under the WTO/TBT Agreement).

2.2 Action Plan for compliance with Articles 34 – 36 of the Treaty on the Functioning of the EU

The above mentioned legal issues in Montenegro (point 2.1) cannot be analysed and dealt with individually. The complexity of the topic requires a well-managed inter-sectoral cooperation. A comprehensive analysis of the subject and a subsequent action plan are needed. Firstly, all potential illegal barriers to trade have to be identified. Based on such an analysis, an action plan for elimination of illegal barriers has to be developed with precisely determined responsible persons and dynamics of the needed activities.

Implementation of the action plan requires a complex institutional infrastructure which consists of a large number of entities. As for the relevant ministries they must have a sufficient number of well-educated staff at their disposal that should be able to master the drafting and implementation of the new regulations. Continuous work of the ministries must be well coordinated in order to establish and maintain a coherent and transparent legal framework and to ensure uniform application of the prescribed rules (see the overview of the existing and planned resources in the relevant ministries and quality infrastructure institutions).

Action Plan for compliance with Art. 34-36 of TFEU will be adopted separately by the Government of Montenegro in the fourth quarter of 2014.

III HORIZONTAL ISSUES

3.1 Horizontal Legislation

Technical requirements for products

Horizontal legislation is constantly following changes and amendments to the harmonized legislation at the EU level. Horizontal legislation lays down horizontal measures that are applied in a unified manner in technical regulations where applicable.

- Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11) is in line with the Decision on a common framework for the marketing of products (768/2008/EC) and Regulation on the requirements for accreditation and market surveillance (765/2008/EC) – part on market surveillance.

Through the Law on Technical Requirements and Conformity Assessment and its by-laws a system which takes into account most of horizontal measures in prescribing essential requirements for products and conformity assessment procedures was designed. Allocation of jurisdiction of eight state administration bodies (competent ministries) is defined. The co-ordination role of state administration body responsible for quality infrastructure activities (the Ministry of Economy) is introduced. Competent Ministries are hereby given legal framework (in case of special laws a “model”) for proposing (Governmental decrees or Parliament laws) or the adoption of (Ministerial rulebooks) technical regulations which transpose the EU legislation related to products in the area of their competence. Also, a model for designation (“New Approach”) and authorization (“Old Approach”) of conformity assessment bodies relating to sectors has been developed. The difference between the state responsibility - the “Old Approach” and obligations of manufacturers – the “New Approach” has been emphasized.

Law on Technical Requirements for Products and Conformity includes also obligations for product supplier, validity of documents of conformity and conformity markings issued abroad and notification of technical regulations.

The Law created a legal basis for the adoption of secondary legislation which is being implemented taking into account also:

- ***Decree on the form, content and appearance of a mark of conformity*** (Official Gazette of Montenegro 55/12) prescribes the form, content and appearance of conformity marking of the a product with prescribed requirements as regulated in Decision 768/2008/EC and Regulation 765/2008/EC (Montenegro's assessment);

- ***Decree on manner of recognition of foreign documents of conformity and marks of conformity*** (Official Gazette of Montenegro 55/12), sets out the manner of recognition of validity

of foreign documents of conformity and foreign marks of conformity that attests the product conformity with foreign technical regulations;

- *Decree on notification of technical regulations, standards, regulations on information society services and conformity assessment procedures* (Official Gazette of Montenegro 11/13) is in MN opinion in accordance with Directive 98/34/EC and its amendment by Directive 98/48/EC;

- *Rulebook on the content and manner of keeping the register of technical regulations, conformity assessment bodies, foreign documents and conformity marking* (Official Gazette of Montenegro 18/13) regulates a systematic method of keeping and editing databases on draft technical regulations as well as published technical regulations. Also, keeping a registry involves continuous updating of decisions issued by the competent ministries on authorization of conformity assessment bodies (the old approach) and decisions on designation of bodies (the new approach);

- *Rulebook on the manner of notification of designated conformity assessment bodies* (Official Gazette of Montenegro 27/13) is in MN opinion in accordance with Decision 768/2008/EC.

CONFORMITY ASSESSMENT

Conformity assessment bodies

Conformity assessment bodies are mainly laboratories, certification bodies and inspection bodies. The Law on Technical Requirements for Products and Conformity Assessment identifies different types of CABs.

Authorized conformity assessment bodies are the bodies which on behalf of the state verify whether the products have met the prescribed technical requirements. The authorized bodies previously need to ensure conditions to prove competences by fulfilling standards that require organizational, metrology and systemic arrangement. Those bodies which meet all requirements of standards in this field and to the extent within which they apply for authorization previously should (as a rule) provide a certificate of accreditation from the national accreditation body. Competent ministry where there is a need announces a public call for authorization of conformity assessment bodies. Minister has a discretion right to determine whether one or more bodies will be selected.

Designated conformity assessment bodies for manufacturers' needs evaluate whether their product has met the essential requirements of relevant technical regulations. These bodies also (as a rule) previously have to fulfil the requirements to obtain a certificate of accreditation. Conformity assessment bodies which want to be designated apply themselves to the competent ministry. All bodies that meet the requirements in terms of competencies receive a decision on designation in the area and within the scope of the certificate of accreditation. The decision on designation does not make the state responsible for product safety, as safety of products is full responsibility of the manufacturer.

Notified conformity assessment bodies are designated bodies notified by the competent central point to the European Commission. Notified bodies obtain the decision and identification number and the European Commission publishes them in the EU Official Journal and on the NANDO web site. Only the designated body can become notified body if notification was conducted by the competent central point of the Member State. MN designated CABs for activities within the range of EU harmonized legislation will become candidates for EU Notified Bodies after the accession to EU.

In Montenegro, approximately 30 bodies (Out of 30 identified conformity assessment bodies 21 of them are already accredited) for conformity assessment in different fields have been identified. They range from testing laboratories, inspection bodies to calibration laboratories. The state of affairs in 2010 is presented on the website of the Ministry of Economy (<http://www.mek.gov.me/biblioteka/obraci>).

Depending on the speed of installing the new software for the Register of technical regulations and conformity assessment bodies the list will be updated to show the “current state”. Also, formation of association of conformity assessment bodies in Montenegro is planned for 2014 based on the model of Eurolab.

Conformity assessment procedures

The Law on Technical Requirements for Products and Conformity Assessment does not contain an explicit authorization for the adoption of the Decree of the Government which would stipulate possible procedures (modules) for conformity assessment of certain (groups of) products with the prescribed requirements. Such a decree would transpose provisions of the EU Decision 768/2008/EC which contain a description of possible modules. It will be necessary to adopt a decree at the Government level since the new EU directives do not contain provisions (annexes) on conformity assessment modules. They refer to the modules contained in the EU Decision 768/2008/EC.

Documents of conformity

The document of conformity is a declaration of conformity, test report, certificate, confirmation or report of control or another document which attests conformity of products with technical regulations. Documents of conformity in some cases can be issued by the producers (self-assessment - declaration) and in some other cases, if technical regulation demands participation of a third party additional documents of conformity are made either by the authorized or designated body. Based on the Decree on the manner of recognition of documents and conformity marking foreign conformity documents can be accepted (recognized).

Conformity marking

The most important regulation in Montenegro (due to the number of the groups of products it covers) as for putting conformity marking on industrial (non-food) products is the Law on Technical Requirements for Products and Conformity. This Law introduced in the Montenegrin legal system the possibility (but not the obligation!) to prescribe on the level of technical regulations (for the most part this means rulebooks adopted by the relevant ministers) the

obligatory CE marking. In agreement with the EC decision was made that all MN technical regulations postpone the obligation of the CE marking until the date of the accession of Montenegro to the European Union. More details on the application of CE marking rules in Montenegro are in the report sent to EC in relation to Benchmark 3.²

Adoption of the new Law on technical requirements for product and conformity assessment is planned for the fourth quarter of 2016 - pending on expected changes in EU horizontal legislation on product safety and market surveillance. The Law is planned to be fully aligned with the expected EU legislation.

STANDARDISATION

Law on Standardisation (Official Gazette of Montenegro 13/08) determines principles and objectives of standardization in Montenegro, establishment, organization and activity of the national organization for standardization, adoption, publication and application of Montenegrin standards and related documents in the field of standardization.

The existing legal framework is harmonized with the Code of Good Practice for the Preparation, Adoption and Application of Standards, which is given as the WTO/TBT Annex III. Also, the legislative framework is harmonized with basic requirements and recommendations of international and European organizations for standardization. Also, the legislative framework (Law on standardization and Decree on notification of technical regulations, standards, regulations on information society services and conformity assessment procedures) is in MN opinion aligned with the Directive 98/34/EC, which lays down procedures for information in the field of standardization.

Adoption of New Law on standardization is planned for the fourth quarter of 2015 in order to align MN legislation with the requirements of Regulation (EU) 1025/2012.

METROLOGY

Current situation

In accordance with the **Law on Metrology** (Official Gazette of Montenegro 79/08), the field of metrology in Montenegro is regulated in order to: harmonize the legal system of units of measurement with the International System of Measuring Units; establish the system of national standards and ensure their traceability to international standards; establish uniform measuring in Montenegro and establish confidence in the results of measuring conducted in order to protect consumers, life and health of humans and animals, environmental protection, general safety and protection of natural resources; support and develop appropriate metrological infrastructure which ensures traceability of the results of measuring; encourage free trade and removal of potential barriers to this trade; direct and finance metrology research activities; prepare, adopt and implement metrology regulations; conduct conformity assessment procedures with the requirements of legal metrology; and provide information in the field of metrology.

² In the first week of April 2014 EC gave positive opinion on the Montenegro's plan for corrective measures regarding CE marking.

By-laws adopted pursuant to the Law on Metrology (Official Gazette of Montenegro 79/08) in the form of decrees and rulebooks:

- Decree on legal units of measurement (Official Gazette of Montenegro 22/09), which, we believe, transposes the EU Directive on units of measurement (80/181/EEC);
- Rulebook on the pre-packaged products (Official Gazette of Montenegro 56/11), which, we believe, transposes the EU Directive on pre-packaged products (76/211/EEC and 2007/45/EEC);
- Rulebook on bottles as measuring containers (Official Gazette of Montenegro 56/11), which, we believe, transposes the EU Directive on Measuring Container Bottles (75/107/EEC);
- Rulebook on the requirements relating to devices and systems with a measuring function (Official Gazette of Montenegro 29/13), which, we believe, transposes the EU Directive on measuring instruments (MID-2004/22/EC);
- Rulebook on non-automatic weighing instruments (Official Gazette of Montenegro 29/13), which, we believe, transposes the EU Directive on non-automatic weighing instruments (NAWI-2009/23/EC).

All above mentioned acts are in MN opinion aligned with the corresponding EU legal acts.

Planned activities

In the following period, amendments of the following regulations in the field of metrology have been planned:

- Decree on Amendments to the Decree on legal units of measurement, by the fourth quarter of 2015;
- Rulebook on Amendments to the Rulebook on stricter procedure and the manner of testing and approval of the type of measuring instrument, until fourth quarter of 2015;
- Decree on legal measuring instruments for which certification that is approval of the type of measuring instrument is mandatory, by the fourth quarter of 2016;
- Rulebook on Amendments to the Rulebook on the terms of regular certification of legal measuring instruments, until fourth quarter of 2016;
- Rulebook on common provisions for both measuring instruments and methods of metrological control, by the fourth quarter of 2018.

The above mentioned legal acts planned to be fully aligned with the relevant EU legislation.

ACCREDITATION

The Law on Accreditation (Official Gazette of Montenegro 54/2009) which came into force in August 2009 in MN opinion transposes adequately the most relevant provisions of the Regulation (EC) 765/2008 relating to accreditation and is harmonized with Article 77 of the Stabilisation and Association Agreement.

Law on amendment of Law on Accreditation is planned for fourth quarter of 2014 with amendments relating on cross-border accreditation. With the planned amendments MN legislation in this area is planned to be fully aligned with the relevant EU legislation.

MARKET SURVEILLANCE

Legal framework in the area of market surveillance is:

- Law on Inspection Control (Official Gazette of Montenegro 57/11)
- Law on Market Inspectorate (Official Gazette of Montenegro 53/11) is in MN opinion partially aligned with the requirements of Regulation on the Requirements for Accreditation and Market Surveillance (765/2008/EC)
- Law on Surveillance of Products on the Market (Official Gazette of Montenegro 33/14)
- Law on General Product Safety (Official Gazette of Montenegro 48/08) in MN opinion adequately transposes requirements of Directive 2001/95/EC on general product safety and Directive 87/357/EEC 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.

Planned activities

In line with the development of legislation at the EU level, the Law on General Product Safety³ has been reviewed (with anticipated structure of the revised GPSD - without provisions on the market surveillance activities and powers - which will contain necessary reference to the Decision 2010/15/EC on guidelines for the implementation of the RAPEX system on the exchange of information on hazardous products (both consumer and non-consumer - professional equipment)).

The Law on Surveillance of Products on the Market was amended in 2014 in accordance with the structure and content of the Regulation 765/2008/EC (combined with GPSD provisions on MS) in the part referring to market surveillance. The Law repeals validity of certain provisions of the Law on Market Inspectorate (Official Gazette of Montenegro 53/11) in order to avoid duplicating the legal regime. The new Law is partially aligned with the Regulation 764/2008/EC (provision on establishing of product contact point).

3.2 Horizontal Organization

3.2.1 Ministry of Economy

According to the Decree on state administration organization and manner of work, administrative tasks in the field of quality infrastructure have been assigned to the Ministry of Economy. Since the free movement of goods is also covered by quality infrastructure activities (which cover also the area of services) proposing and/or adoption of horizontal legislation is a responsibility of the Ministry of Economy as is also the overall coordination of Chapter 1 – Free movement of goods.

³ GPSD is actually under Chapter 28 of negotiations but is mentioned also in this document as it is closely linked to legal acts under Chapter 1 – Free movement of goods

Role of the Ministry of Economy is to ensure coordination of all activities covered by Chapter 1 through cooperation with other ministries responsible for preparation and adoption of technical regulations as well as with quality infrastructure institutions (Bureau of Metrology, Institute for Standardization of Montenegro, Accreditation Body of Montenegro, Administration for Inspection Affairs and other relevant institutions)

Within the Ministry, in Directorate for internal market and competition, three officials are responsible for quality infrastructure issues.

For the adequate progress in this field and achievement of objectives defined in the above-mentioned activities; the Ministry of Economy will establish a Department for Quality Infrastructure within the Directorate for Internal Market and Competition by the end of 2014.

Future scope and structure of the activities will have to be amended to include all the needed elements to successfully co-ordinate the field of free movement of goods:

- Preparation of horizontal primary legislation in the field of technical requirements for products, standardisation, accreditation, metrology, conformity assessment, market surveillance and product safety);
- Preparation of technical regulations in the field of legal metrology;
- Implementation of obligations related to: notification of technical regulation and conformity assessment procedures according to TBT/WTO, CEFTA, preparations for 98/34/EC;
- Providing information on technical regulations and their application to economic operators and other interested parties;
- Acting as the central product contact point (in co-operation with the line ministries);
- Acting as the notifying authority for designated CABs (after the EU accession);
- Managing a register of technical regulations in preparation, register of applicable technical regulations and designated i.e. authorized conformity assessment bodies, register of foreign conformity documents and conformity markings that are valid in Montenegro;
- Cooperation with the quality infrastructure institutions and authorities responsible for the control of external borders and market surveillance authorities;
- Other activities according to the Law.

Additionally to the formal legal establishment of the Department in 2014 three new officials will be employed in order to increase the administrative capacity. By the end of 2018 it is foreseen that 9 employees are going to work in this Department.

In 2014 the Department will receive software which will enable implementation of obligations envisaged by WTO/TBT Agreement and obligations in accordance with the EU legislation. The software will consist of three elements dealing with:

1. Internal notification of technical regulations

- establishment of the internal notification is one of the most important requirements, which implies involvement of 8 ministries which are responsible for preparation and adoption of

technical regulations. Responsible ministries will have the possibility to independently and directly enter data on technical regulations which are drafted or adopted. The internal notification of technical regulations is a basic precondition for establishing an external network i.e. notification of international organisations and other stakeholders.

2. update of the existing database of technical regulations, designated/authorised conformity assessment bodies and documents and conformity markings.
- updating of databases will give an overview of technical legislation in all sectors, per groups of products, overview of designated/authorised conformity assessment bodies, as well as foreign documents and conformity markings valid in Montenegro. Such systematic data will enable to find in one place all relevant information in accordance with needs and requirements arising from the legislature of Montenegro.
3. establishing appropriate relation bases for the aim of external notification
- apart from the intranet communication i.e. internal notification, the program will enable also a connection with external bases significant for the free movement of goods.

This Department will predominantly perform the tasks of the co-ordination of free movement of goods whereby it will not take over the role of a policy maker - decision maker. The adoption of policy statements in the negotiations is the task of eight ministries dealing with various sub-areas in the field of Free movement of goods.

In order to fulfil the obligation that some decisions can be adopted in a centralized way and also for the logistics of the negotiations, by the Decision (Official Gazette of Montenegro 15/13), in January 2013 the Government of Montenegro established a Working Group for the preparation of negotiations on the accession of Montenegro to the European Union in the field of *acquis communautaire* referring to the Chapter 1- Free movement of goods (hereinafter referred to as: the Working Group). To fulfil part of the above implementation tasks which refer to cooperation of administration bodies the Working Group needs to provide support to the line ministries in transposition of vertical legislation and also for other tasks that imply inter-ministerial dialogue. The Working Group consists of representatives of market surveillance authorities, quality infrastructure institutions and representatives of relevant government bodies in charge of harmonization of national legislation with part of the EU *acquis* which refers to the Chapter 1.

Projection of administrative capacities for DQI is given in the table below:

Year	2014	2015	2016	2017	2018
DQI - The number of the newly employed in individual year	3	-	1	1	1
Total number of the newly employed in relation to 2013	3	3	4	5	6
Total number of the	6	6	7	8	9

employed					
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Projection of financial resources is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget in EUR	67.500,00	67.500,00	78.750,00	90.000,00	101.250,00
Donations and income from activities/industries in EUR	21.600,00	21.600,00	28.800,00	36.000,00	43.200,00

3.2.2 Institute for Standardization of Montenegro (ISME)

According to the Law on Standardization and the **Decision on the Establishment**, the Government of Montenegro established **ISME**, as an independent and non-profit organization, in order to achieve the objectives of national standardization and adopt Montenegrin standards and related documents. The Decision regulates the name and seat of the Institute, its activity, membership in the Institute, managing bodies, manner of financing, rights, duties and responsibilities of the Institute in legal transactions, as well as supervising the work of the Institute. The institutional framework is defined by the **Statute of the Institute for Standardization of Montenegro** (Official Gazette of Montenegro, no. 29/08). Work of ISME regarding the adoption of Montenegrin standards (MEST) and related documents is in compliance with rules and recommendations of international and European organizations for standardization and the needs of interested parties in Montenegro. Accordingly, ISME adopted Internal Rules for Standardization (ISME IPS) which would further regulate issues relating to the preparation, adoption, publication and maintenance of Montenegrin standards and related documents.

Internal Rules for Standardization consist of:

Part 1: Establishment and working procedure for Technical Bodies of the Institute,

Part 2: Types of the documents and their designation,

Part 3: Development of Montenegrin standards and related documents,

Part 4: Participation in the work of European standards organizations in the development of standardization documents and adoption of European standards and related documents at national level,

Part 5: Participation in the work of International standards organizations in the development of standardization documents and adoption of international standards and related documents at national level,

Part 6: Rules for the Structure and Drafting of Documents.

The above mentioned internal documents are in MN opinion fully aligned with the relevant EU requirements.

In the field of international cooperation, ISME has membership in the following organizations:

- ISO, as a Correspondent Member (since 1 July 2007)
- IEC, as an Associate Member (since 1 January 2009)
- CEN, as an Affiliate Member (since 1 July 2008)

- CENELEC, as an Affiliate Member (since 1 July 2009).

By 14 February 2014 ISME adopted 11.202 Montenegrin standards (MEST) and related documents. Of that number, 2.974 are harmonized MEST. All of these standards were created by taking over international and European standards. ISME regularly informs the public about the existing standards (national, European and international) and standardization activities. Users can use the web portal of the Institute (www.isme.me) where, among other things, online catalogue search of the relevant Montenegrin standards can be conducted.

Recognizing the priority areas for standardization, being of interest for Montenegro and based on the interests of stakeholders, so far ISME formed the following Technical Committees:

1. ISME/TK 001: Petroleum and petroleum products
2. ISME/TK 002: Euro-codes
3. ISME/TK 003: Food products
4. ISME/TK E 004: Energy management systems and Energy efficiency
5. ISME/TK 005: Human resource management
6. ISME/TK E 006: Electro-energetics
7. ISME/TK 007: Social responsibility
8. ISME/TK 008: Pressure equipment
9. ISME/TK 009: Construction products
10. ISME/TK 010: Environment and environmental management systems
11. ISME/TK 011: Tourism and related services
12. ISME/TK 012: Devices and equipment for storage and transport
13. ISME/TK E 013: Information technology
14. ISME/TK 014: Health protection technology
15. ISME/TK 015: Wood and wooden products.

Establishment of new Technical Committees directly depends on:

- interests of stakeholders,
- the budget transferred funds for realization of ISME plans and programs,
- ability to increase staff capacity of ISME,
- planned decisions performance regarding the development of the Institute.

Further work and development of ISME will be focused on meeting the criteria for full membership in the international (ISO, IEC) and European (CEN, CENELEC) standardization organizations, more active participation in the work of expert bodies of these organizations, more intensive promotion of standardization and benefits from applying standards.

On the basis of expressed interest and in accordance with the agreement with the Ministry of Information Society and Telecommunications, it was expected some national body entitled for telecommunications (e.g. Agency for Telecommunications) to become ETSI member, while ISME, as national standardization body (NSB), to adopt telecommunication standards. However, there is currently no responsible authority able to settle all financial obligations deriving from ETSI membership, so ISME is forced to find appropriate solution to gain ETSI membership in order to adopt telecommunication standards. In parallel, ISME plans to fulfil the criteria for CEN/CENELEC full membership. ISME plans to submit the application for CEN/CENELEC full membership within the lifespan of this Strategy.

The Institute prepared a project for Development of Information System (IS) that will be compatible with IS of the European standardization organizations. Therefore, the Institute sent the application to Delegation of the EU to Montenegro for the funds needed for this project. It is expected that realization of this project will start during 2014.

Projection of administrative capacities is given in the table below:

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	0	7	1	1	4
Total number of the newly employed in relation to 2013	0	7	8	9	13

Projection/indicative allocation of necessary financing for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget	282.456,52	600.000	650.000	700.000	800.000
Income from performed activities in EUR	25.000	40.000	50.000	50.000	80.000
Donations from other sources (IPA, TAIEX and etc.) in EUR	10.000	12.000	12.000	15.000	15.000

In order to fulfil strategic requirements (membership, development etc.) of standardization in Montenegro, a special Strategy for the Development of Standardization in Montenegro will be adopted by the end of 2014. The concerned document, being currently under development, should define comprehensive strategic framework based on international and European standardization organizations principles. By the end of 2018 MNE plans that ISME will be fully compliant with EU standards institution.

3.2.3 Bureau of Metrology of Montenegro (BoM)

Bureau of Metrology is the basic entity of the metrology system in Montenegro, which was established by the Government of Montenegro on 14 September 2006. In accordance with the Law on Metrology (Official Gazette of Montenegro 79/08), the Bureau conducts the following tasks:

- Takes care of the system of legal units of measurement in Montenegro;
- Realizes, preserves, maintains and improves state etalons;
- Provides metrological traceability;
- Organizes activity calibration;
- Conducts conformity assessment of units of measurement with defined metrology requirements: approval of the type of measuring instruments and certification of measuring instruments;
- Conducts inspection of the pre-packed products;

- Gives expert opinion for authorization of persons for conducting activities in the area of metrology;
- Represents Montenegro in international and regional metrology organizations and establishes cooperation in the field of metrology;
- Cooperates with competent inspection authorities and provides expert assistance in the field of metrology;
- Decides in administrative procedures in the field of metrology;
- Prepares expert basis for drafting regulations in the field of metrology;
- Provides metrological information and issues official gazette;
- Performs other tasks in the field of metrology.

It must be noted that so far in Montenegro there are no manufacturers of measuring instruments which are subjected to the obligatory certification that is obligatory approval of the type of measuring instrument.

In the BoM, within the Division of metrological traceability and state standards, national calibration laboratories have been established and have been developing: Mass Laboratory, Length Laboratory, Volume Laboratory, Pressure Laboratory, Temperature Laboratory, Time and Frequency Laboratory, Electric Power Laboratory and Electrical Quantities Laboratory.

At the 8th meeting of EURAMET's Technical Committee for Quality, which was held in Sarajevo from 13 March to 15 March 2013, the quality management system was initially successfully presented in accordance with the requirements of the MEST ISO/IEC 17025 standard.

Initial visit assessors from HAA (Croatian Accreditation Agency) and ABM (Accreditation Body of Montenegro) took place on 19 November 2013. In May 2014 the complete process of accreditation of three laboratories: the Laboratory for mass, Laboratory for length and Laboratory for temperature, was finished with the positive assessment.

Bureau of Metrology is planning in 2014. the preparation of three laboratories for accreditation: Laboratory for pressure, Laboratory for Time and Frequency Laboratory for electrical quantities. To achieve this goal, there is also a significant contribution from the project, Development of quality infrastructure and metrology in Montenegro (DQIM).

Verification of calibration and measurement capabilities (CMCs) in the field of mass, length and temperature of the BoM, in the database of the International Bureau of Weights and Measures is expected in 2015.

To improve capabilities of calibration laboratories in terms of providing equipment of better metrological characteristics, to improve and introduce new calibration methods, implementation and maintenance of accredited status of all laboratories and publication of calibration and measurement capabilities (CMCs) in all areas of interest, represents a commitment and a goal that Bureau of Metrology will strive for in the following period.

BoM is a full member of the **European Association of National Metrology Institutes, EURAMET** as of 7 June 2011. Representatives of the Bureau of Metrology have been appointed in the following technical EURAMET committees: TC - EM: Technical Committee for

Electricity and Magnetism (*Electricity and Magnetism*), TC - IM: Technical Committee for Interdisciplinary Metrology (*Interdisciplinary Metrology*), TC - F: Technical Committee for Flow (Flow), TC - M: Technical Committee for Mass and Related Quantities (*Mass and Related Quantities*), TC - Q: Technical Committee for Quality (Quality), TC - L Technical Committee for Length and TC - T Technical Committee for Thermometry.

BoM is a corresponding member of the **International Organization for Legal Metrology OIML** as of November 2007 and since January 2009 an associate member of the **European Cooperation in Legal Metrology WELMEC**. As of 1 August 2011 Montenegro is the associate member of the **General Conference on Weights and Measures CGPM**. Associate membership in CGPM has enabled the Bureau of Metrology to sign on 19 October 2011 the **CIPM MRA** that is **CIPM Mutual Recognition Arrangement**.

Bureau of Metrology will sign the Metre Convention by the end of 2017.

In terms of legal metrology, particularly the procedures of conformity assessment of measuring instruments with the prescribed requirements (certification and approval of the type of measuring instruments), the Bureau of Metrology has been continuously conducting capacity improvements in this regard, which includes the provision of necessary equipment, hiring new employees, as well as training of the existing personnel and vocational trainings. Following the priorities of legal metrology in Montenegro, extension or improvement of conditions for verification of the following types of criteria has been planned:

- Manometers for measuring blood pressure,
- Manometer for measuring pressure in tires,
- Measuring instruments for controlling vehicle speed,
- Evidential Breath-analysing Machine (EBM),
- Exhaust gas analysers.

The Rulebook on internal organization and systematization of the Bureau of Metrology, adopted by the Government of Montenegro in May 2013 provides job description for 32 positions, and currently 31 persons are employed in the Bureau. By the end of 2018, recruitment of the new 32 employees is planned as compared to 2013, with the dynamics of hiring new personnel as shown in the following table:

Projection of administrative capacities is given in the table below:

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	7	7	6	6	6
Total number of the newly employed in relation to 2013	7	14	20	26	32

Projection/indicative allocation of necessary financing for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget	733.907,09	988.600,00	1.130.400,00	1.270.500,00	1.397.800,00
Income from performed activities in EUR⁴	500.000,00	500.000,00	500.000,00	500.000,00	500.000,00
Donations from other sources (IPA, TAIEX and etc.) in EUR	903.000,00	654.000,00	839.000,00	815.000,00	550.000,00

By the end of the fourth quarter 2015 a Strategy for the improvement of metrology in Montenegro will be adopted. It will encompass in more details all aspects, with the dynamics of implementation, necessary for the development and improvement of metrology in Montenegro by 2018.

3.2.4 Accreditation Body of Montenegro (ATCG)

The Law on Accreditation regulates the establishment and operation of ATCG, the manner and procedure of accreditation as well as other issues of importance for accreditation. By-law of this Law, the Decision on the Establishment of the Accreditation Body of Montenegro (Official Gazette of the Republic of Montenegro 21/07) regulates in more details the activity, organizational units and manner of functioning of ATCG.

In accordance with provisions of the Regulation (EC) 765/2008, ATCG was established by the Government of Montenegro as the only national accreditation body which conducts accreditation activities following the principles of independence, impartiality and objectivity. ATCG responsibilities and tasks are clearly separated from responsibilities and tasks of other national authorities. ATCG is a non-profit organization and in order to avoid conflict of interest it does not have ownership rights or any other financial or management interests in conformity assessment bodies. General acts which regulate operations of ATCG, the Annual Work Program, Report of Operations, the Register of Accredited Bodies with scopes of accreditations, and other relevant information are made available to the public in an appropriate manner.

ATCG conducts its activity in accordance with the Law, the Decision on the Establishment, the Statute of the Accreditation Body of Montenegro, as well as in line with internal rules and procedures of ATCG (12 internal rules and 7 procedures). Its activity is based on fulfilling the requirements of the standard EN ISO/IEC 17011:2010 - Conformity Assessment - General Requirements for Accreditation Bodies which accredits conformity assessment bodies, as well as

⁴ Note: Income from activities performed by the Bureau of Metrology is directly allocated to the central state budget so that the annual budget for the Bureau depends on the Law on state budget on annual level.

the rules of the European and international organizations in the field of accreditation (EA, ILAC and IAF).

ATCG cooperates with the European Cooperation for Accreditation (EA) and it has been EA's full member since November 2011. ATCG has been the Associate Member of the International Laboratory Accreditation Cooperation (ILAC) since 2009. ATCG also has an intensive cooperation with accreditation bodies in the region with which it has signed bilateral agreements on business and technical cooperation.

Currently the system of accreditation includes a total of twenty one (21) conformity assessment bodies accredited by ATCG, of which fifteen (15) are laboratories for testing, two (2) are laboratories for calibration, three (3) control bodies and one (1) certification body for products certification. In the following period the increase in the number of accredited conformity assessment bodies is expected, particularly those operating in the regulated area and primarily because of the support that accreditation provides in the implementation of technical legislation.

According to the Rulebook on job systematization in ATCG currently there are eight full-time employees.

The Registry of Evaluators currently includes nine leading evaluators, 17 technical evaluators and 17 technical experts. Tendency in the forthcoming period is to increase the number of internal and external evaluators, which will depend on the established and new applications, that is, the newly established accreditation schemes.

The increase in the number of evaluators is in a direct correlation with organizing appropriate trainings, for which necessary funds must be provided.

In order to maintain and further strengthen the national system of accreditation in the forthcoming period it is necessary to continue to promote the role and importance of accreditation, intensify participation of stakeholders, strengthen the administrative and technical capacities of ATCG including the engagement of four newly recruited workers, ensure stable material resources needed for its continuous work, ensure recognition of accreditation in the regulated area as the most reliable known method for determining the competence of conformity assessment bodies, promote the use of accreditation in unregulated area, and strengthen bilateral, regional and international cooperation in the field of accreditation.

Apart from this, one of the main strategic objectives of ATCG is signing of Multi-lateral-agreements with EA (EA MLA) in 2016, Mutual Recognition Arrangement (ILAC MRA) with ILAC and Multi Lateral Arrangement (ILAF MLA) with IAF (International Accreditation Forum) in 2017, aimed at securing the recognition of reports/certificates issued by accredited Montenegrin conformity assessment bodies in international markets.

Projection of administrative capacities is given in the table below:

Year	2014	2015	2016	2017	2018
The number of	-	1	1	1	1

the newly employed in individual years					
Total number of the newly employed in relation to 2013	-	1	2	3	4

Projection/indicative allocation of necessary financing for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget	173.623,47	406,000	409,000	422,000	435,000
Income from performed activities in EUR	20,000	26,000	30,000	35,000	40,000
Donations from other sources (IPA, TAIEX and etc.) in EUR	-	-	140,000	160,000	140,000

In order to define more precisely the above mentioned strategic goals, to systematize them in the form of specific activities, and then within the prescribed time frames, a special Strategy for Accreditation Development in Montenegro will be adopted by the end of 2014.

3.2.5 Investments concerning Quality Infrastructure institutions working premise

As far as above mentioned horizontal organisations are concerned, based on the Master Plan for Investments in Infrastructure for sectors: Education, Health, Culture, Sport and State Administration for the period 2011-2020, a working premise for quality infrastructure institutions (accreditation, standardisation and metrology) as well as for the Directorate for internal market and competition, shall be constructed as they currently perform their activities in rented offices. Construction of the building that should be working premise of before mentioned institutions is very relevant for the succesful realisation of the Strategy of Montenegro for the Implementation of the Acquis Communautaire in the field of Freemovement of goods 2014-2018. In addition, pursuant to the Regulation EC, 765/2008, each EU Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks. In the filed of Metrology, Bureau of Metrology, as key metrology institution in Montenegro, is located at rented premises which are placed at two different location in capital of Podgorica. The total annual cost of leasing these premises is EUR 173,000. Activities which the Bureau of Metrology performs within the frame of its responsibility, demand a very high level of competence and adequate number of staff, sophisticated metrology equipment with the highest accuracy classes and dedicated constructed building for accommodation of the laboratories and also for the needs of administrative affairs. Considering these facts, as well as the plans to improve administrative and technical capacity of the Bureau specified in this Strategy, and in the Accession Program of Montenegro for 2014-2018, there is an obvious need for the construction of a suitable building for the Bureau, as well as for other QI

institutions. In addition, working premise of the Institute of Standardisation (where the printing equipment would be located) must be adequate in terms of the temperature, protection of noise and vibration, etc. And that is an additional reason why the Institute for Standardisation shall have its own working space in the new building for QI institutions.

In addition to the above reasons, related to the contribution that a suitable working area of quality infrastructure institutions has in regard to the implementation of the EU acquis in Montenegro, another very important reason for building a new facility is the reduction of state spending for leasing premises for three quality infrastructure institutions, as well as for the Directorate for Internal Market and Competition at the Ministry of Economy. Total renting cost per annum for offices renting of before mentioned 3 institutions and the Directorate of the Ministry of Economy amount around EUR 250,000. On the other hand, total estimated costs of the construction of the new building for working spaces for the three QI institutions as well as the Directorate for Internal Market and Competition in the Ministry of Economy with approximately 3.500 m², is estimated to be around EUR 3.15 million and the construction is planned for the period 2015 - 2017. Construction of the facility would bring much more benefits to the state budget compared to the construction costs (due to the current high cost of rent for QI institutions and Directorate of the Ministry of Economy premises). In addition, the construction of the building would significantly contribute to the implementation of the Strategy for Chapter 1.

3.2.6 Market surveillance authorities

Current situation in the field of market surveillance

Market surveillance system in Montenegro constantly develops in order to enable free movement of goods and establish the market in which only safe products will be placed.

Regulation on organization and functioning of public administration, which became effective on 20 January 2012, created a legal basis for establishing a single inspection body. In that way the Administration for Inspection Affairs (hereinafter referred to as „the Administration“) was formed in order to achieve greater efficiency in performing inspection control, improve economic aspects of inspection control, prevent positive and negative conflict of jurisdiction, achieve more adequate cooperation of inspection bodies, improve professionalism of inspectors, prevent possible elements of corruption, as well as to improve cooperation of inspection sectors with other bodies when performing inspection control.

The Administration started to operate on 1 June 2012. Twenty-six inspections, which used to be part of ministries and other state bodies, are now under the jurisdiction of the Administration. Twelve inspections are in charge of market surveillance: the Sector for Market Inspection, the Sector for Healthcare and Sanitary Inspection, the Sector for the Inspection of Electronic Communications and Postal Activity, the Sector for Metrological Inspection, the Sector for Phytosanitary Inspection, the Sector for Labour Inspection (protection at work), the Sector for Construction Inspection, the Sector for Electro-energetic Inspection, the Sector for Thermo-energetic Inspection, the Sector for Mining Inspection, the Sector for Environmental Inspection and the Sector for Home Inspection. In addition, it should be emphasized that all these inspection sectors are also responsible for some administrative areas. Their participation in market surveillance varies from a few percent to 40%.

Inspectorates for Traffic Control, Railways Inspectorate and Maritime Safety Inspectorate (part of Maritime Safety Authority) are organised within the Ministry of transport and Maritime Affairs. They employ 9 inspectors and cover all activities in motor vehicles, cableways, railways and recreational crafts area.

Department on Inspection Surveillance in the area of explosives for civil use and pyrotechnics is organised within the Ministry of the Interior. There are 7 inspectors employed within the Department.

Furthermore, Customs Administration is a key cooperator in the implementation of activities of market surveillance bodies and the Ministry of Economy (the Sector for Quality Infrastructure) and institutions for quality infrastructure support market surveillance.

Due to the number of bodies engaged in market surveillance, special attention was paid to coordination of bodies responsible for market surveillance through Market Surveillance Coordination Body which consists of the representatives of the abovementioned bodies and was established by the Government of Montenegro in 2010. The main task of this body is to monitor the implementation of Market Surveillance Strategy (2009), including coordinated programming of market surveillance at the national level in order to provide efficient and effective market surveillance and safe market (removal of hazardous and non-compliant products from the market).

Reconstruction of Market Surveillance Coordination Body

Starting from the new market surveillance institutional framework (the Administration for Inspection Affairs and competent inspections of the Ministry of Transport and Maritime Affairs and the Ministry of the Interior) and a new role of the Customs Administration and the Ministry of Economy as a competent body for quality infrastructure, Market Surveillance Coordination Body is planned to be reconstructed so that it includes all relevant bodies.

Two National Market Surveillance Programmes (2012 and 2013) have been adopted and implemented so far. The annual programme for 2014 is in its final phase and includes the activities of six inspection sectors: the Sector for Market Inspection, the Sector for Healthcare and Sanitary Inspection, the Sector for Metrological Inspection, the Sector for Phytosanitary Inspection and the Sector for Electronic Communications and Postal Activity).

National System for the Exchange of Information on Dangerous Products was established in 2011. The way of exchanging information on measures taken against dangerous products is compatible with RAPEX System requests and will serve as a basis for future membership of Montenegro in RAPEX System. IT system for monitoring dangerous products was established within IPA project “Consumer Protection and Market Surveillance“ and it will function in an efficient and effective way.

Further harmonization of national legislation with the EU legal acts in 2014

In accordance with the development of legislation at the EU level, the Law on General Product Safety was revised (with envisaged structure of the revised General Product Safety Directive - without Provisions on market surveillance performance) and contains necessary information from the Directive on guidelines for the implementation of RAPEX system (2010/15/EC).

In addition, the Law on Surveillance of Products on Market (which will be implemented by all competent bodies) has been adopted, with the structure and content of Regulation 765/2008/EC in the area related to market surveillance.

Revision of Market Surveillance Strategy (2016)

Taking into account numerous changes, not only at the EU level, but also in the field of market surveillance of Montenegro, it is necessary to revise Market Surveillance Strategy. This revision will be focused on identification of new elements necessary for further development of market surveillance in accordance with national needs, standards and best practice of the European Union.

Market Surveillance Strategy for the period of 2017 - 2020 will be prepared in the fourth quarter of 2016.

Strengthening cooperation between Market Surveillance Bodies and Customs from 2014 to 2018

Customs Administration is an active member of Market Surveillance Coordination Body and National System for Monitoring Dangerous Products. With the aim of further strengthening of market surveillance bodies and Customs, the Memorandum of Cooperation which is signed between the Sector for Market Inspection and Customs Administration is planned to be replaced with the Memorandum of Cooperation between the Administration for Inspection Affairs and Customs Administration (by the end of March, 2014). In that way this cooperation will include all inspection sectors of the Administration for Inspection Affairs which are responsible for market surveillance.

The Catalogue of measures for cooperation and implementation of joint activities of the abovementioned bodies will be an integral part of the new Memorandum, whereas implementation of this Catalogue and joint market surveillance and enhancement activities are planned as a next step for the second half of 2014. In addition, the Sector for Market Inspection (as a contact point in the National System for Rapid Exchange of Information on Dangerous Products) will be provided with the access to the IT system of Customs Administration in order to exchange relevant information.

Implementation of joint market surveillance activities is planned not only at the national level, but also at the regional level. The same should be achieved at the European level. Namely, joint activities of the inspection sectors from the countries in the region are planned within the regional project ORF SEE "Improvement of coordination of market surveillance institutions in order to increase efficiency and effectiveness" which will last till February, 2015. One of those joint activities will be carried out in Montenegro.

Resource Development 2014-2018

Consolidation of large number of inspection sectors responsible for market surveillance facilitates the improvement of administrative capacities in this important field. The Administration for Inspection Affairs plans to employ inspectors in the sectors which are in charge of market surveillance. In that way, the Administration will fulfill job vacancies (16) according to current

Systematization and increase number of inspectors in accordance with the new Systematization Act, which is being prepared (a total of 40 inspectors). The existing inspectors as well as the newly hired ones will strengthen the enforcement of legislation identified under IV – Vertical legislation.

Education of staff in the Administration for Inspection Affairs is planned on an annual basis in accordance with the plan established by the Programme for the Accession of Montenegro to the European Union. National budget, supporting projects, TAIEX and other sources of support are available as financial resources for education.

Responsibilities of inspection sectors have been established by the law and specified by the List of Competencies which had been proposed by the Coordination Body and adopted by the Government of Montenegro in 2011. Apart from monitoring implementation of directives in Montenegrin legislation, the inspectors will prepare workshops on directives and national and technical regulations through which directives were transposed to the inspectors who are responsible for these fields, with proposals for product checklists. In that way, knowledge will be transferred from inspector trainers to other inspectors.

Since the Administration has established information system, the members of the System for Monitoring Dangerous Products and Consumer Complaint Management System will be trained to use it. In that way, full functionality of the abovementioned systems will be provided.

Special attention in the education of inspectors will be paid to risk assessment methods. The Administration also plans to provide non-laboratory equipment for examination, so that the inspectors could perform detailed physical examination of products in addition to administrative control which they also perform.

The investment in further development of the information system of the Administration for Inspection Affairs is planned for 2014.

Inspectorates within AIA which perform market surveillance activities (12 inspectorates) are employing 136 inspectors. Market surveillance activities account for around 30% of total activities of inspectors. In other words, besides market surveillance, their activities are related to consumer protection and laws implementation in those areas. In the next five years additional 40 inspectors will be hired.

AIA projection of administrative capacities is given in the table below:

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	8	7	6	9	10
Total number of the newly employed in relation to 2013	8	15	21	30	40

AIA projection/indicative allocation of necessary financing for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget	720,000.78	798,750.00	866,250.00	967,500.00	1,080,000.00
Donations from other sources (e.g. IPA, TAIEX)			1,250 000	1,000 000	500.000,00

Necessary financing from State budget that is provided in table is related on the market surveillance activities and implementation of regulation 765/2008.

IV VERTICAL LEGISLATION

4.1 New Approach

Under the so called "New Approach" technical legislation the basic tenet is that the manufacturer (with the supporting roles of other economic operators) is fully responsible for compliance and safety of products they are placing on the market. This is the case even when in the conformity assessment procedure a role of the "third party" conformity assessment body – "notified body" is defined according to a specific legal act requirements.

Montenegro has a limited number of manufacturers in the areas covered by the "New Approach". The prescribed obligations for economic operators are therefore to be mainly implemented by importers and distributors. The ministries in charge of individual transposition legal acts will take care that relevant economic operators are duly informed about the new legal framework and their obligations regarding the products that are on the market. The needed dissemination of information will be mainly channeled through the Chamber of Economy of Montenegro and its members.

The priorities regarding the timing of the planned alignment of individual legal acts have been established taking into account several factors:

- nature of legal act (e.g. horizontality as in cases of LVD and EMC),
- existence of manufacturers,
- level of risk for consumers and other users,
- administrative capacity of responsible state administration.

Current situation as well as the planned alignment of the Montenegrin legislation with the EU acquis related to the New Approach and its implementation is given in the following text.

4.1.1 Low Voltage Electrical Equipment

Current situation in sector

In Montenegro, there is a limited number of manufacturers of equipment covered by the Directive 2006/95/EC. All of them are export oriented and as such are already placing the products on the EU internal market.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment covered by Directive 2006/95/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Rulebook on low voltage electrical equipment intended for use within certain voltage limits (Official Gazette of Montenegro 2/14).

The Rulebook entered into force on 22 January 2014 whereas its implementation will begin on 1 January 2015. Rulebook is in MN opinion fully aligned with the requirements of Directive 2006/95/EC.

On 29th March 2014 a new Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits was published. Full alignment is planned for the second quarter 2016 (20 April 2016).

Institutional framework

The competent authority for low voltage electrical equipment is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there is a limited number of manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law on Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6. as Directive 2006/95/EC is implicitly included under that point as are all legal acts contained under IV – Vertical legislation.

Administrative capacity

At this moment the Ministry of Economy does not have sufficient number of suitably trained staff for the implementation of this Rulebook. Apart from low voltage electrical equipment, Energy Directorate is also responsible for transposition and implementation of legislation dealing with lifts, pressure equipment, simple pressure vessels, gas appliances, hot water boilers, aerosol dispensers, electromagnetic compatibility. Currently, in Energy Directorate 2 employees are responsible for these directives and further education in this area is necessary.

For the work in the above mentioned areas, new recruitments in the Energy Directorate are planned for 2015 as given below:

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	/	4	/	/	/
Total number of the newly employed in relation to 2013	/	4	4	4	4

Projection of necessary financing for newly employees is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget for new employees⁵ (in EUR)		45.000	45.000	45.000	45.000
Donations and income from activities/industries in EUR		28.800	28.800	28.800	28.800

Expenses for two currently employees are EUR 22,500 per year, or EUR 112,500 for the period 2014-2018. By hiring four new employees in 2015, total costs for the implementation of above mentioned directives are **EUR 292,500 for the period 2014-2018.**

4.1.2 Lifts

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 95/16/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment covered by Directive 95/16/EC that is manufacturing, importing and placing on the market and/or putting in use are:

⁵ Note: Expenses for one employee per year cover gross salary, education, office space and office supplies

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Rulebook on safety of lifts (Official Gazette of Montenegro 2/14)

Rulebook entered into force on 22 January 2014 whereas its implementation will begin on 1 January 2015. The Rulebook is in MN opinion fully aligned with the requirements of Directive 95/16/EC⁶.

On 29 March 2014 new DIRECTIVE 2014/33/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts was published. Full alignment is planned for second quarter 2016 (20 April 2016).

Institutional framework

The competent authority for the transposition and implementation of Directive 95/16/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that represent presumption of conformity is in responsibility of Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.3 Electromagnetic Compatibility

Current situation in sector

In Montenegro, there is a limited number of manufacturers of equipment covered by the Directive 2004/108/EC. All of them are export oriented and as such are already placing the products on the EU internal market.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2004/108/EC that is manufacturing, importing and placing on the market and/or putting in use are:

⁶ Rulebook covers only new lifts. The existing lifts will be covered by separate national legal act.

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Law on Electronic Communications (Official Gazette of Montenegro 40/13);
3. Rulebook on electromagnetic compatibility (Official Gazette of Montenegro 32/12).

Rulebook entered into force on 29 June 2012 whereas its implementation began on 1 January 2013. The Rulebook is partially harmonised with Directive 2004/108/EC.

In order to achieve full alignment with requirements of Directive 2004/108/EC, adoption of the new Rulebook is planned for the fourth quarter of 2014.

On 29 March 2014 new Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility was published. Full alignment is planned for second quarter 2016 (20 April 2016).

Institutional framework

The competent authority for transposition and implementation of Directive 2004/108/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there is a limited number of manufacturers of products covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.4 Simple Pressure Vessels

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 2009/105/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2009/105/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Rulebook on simple pressure vessels (Official Gazette of Montenegro 21/14)

Rulebook entered into force on 14 May 2014 whereas its application will begin on 1 January 2015. Rulebook is in MN opinion fully aligned with the requirements of Directive 2009/105/EC

On 29th March 2014 new Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels was published. Full alignment is planned for second quarter 2016 (20th April 2016).

Institutional framework

The competent authority for transposition and implementation of Directive 2009/105/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.5 Pressure Equipment

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 97/23/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 97/23/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Rulebook on technical requirements for pressure equipment (Official Gazette of Montenegro 18/14);

Rulebook entered into force on 19th April 2014 whereas its application will begin on 1st January 2015. Rulebook is in MN opinion fully aligned with the requirements of Directive 97/23/EC

Institutional framework

The competent authority for transposition and implementation of Directive 97/23/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.6 Gas Appliances and Hot Water Boilers

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directives 2009/142/EC and 92/42/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directives 2009/142/EC and 92/42/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on gas appliances is planned for the fourth quarter of 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 2009/142/EC.

Adoption of Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels is planned for the first quarter of 2015.

Rulebook is planned to be fully aligned with the requirements of Directive 92/42/EC.

The planned timeline for adoption of the above mentioned rulebooks is based on risks related to these products as well as on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directives 2009/142/EC and 92/42/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.7 Aerosol Dispenser

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 2008/47/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2008/47/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on aerosol dispensers is planned for the fourth quarter of 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 2008/47/EC.

The planned timeline for adoption of the above mentioned rulebooks is based on risks related to these products as well as on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directive 2008/47/EC is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Directive 2008/47/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.1

4.1.8 Machinery

Current situation in sector

In Montenegro, there is a limited number of manufacturers of equipment covered by the Directive 2006/42/EC. The obligations for economic operators are going to be mainly implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2006/42/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Rulebook on safety of machinery (Official Gazette of Montenegro 22/14)

Rulebook entered into force on 24th May 2014 whereas its application will begin on 1st January 2015. Rulebook is in MN opinion fully aligned with the requirements of Directive 2006/42/EC

Further alignment with the requirements of Directive 2009/127/EC is planned for second quarter 2017.

Institutional framework

The competent authority for transposition and implementation of Directive 2006/42/EC is the Ministry of Economy, Directorate for industry and Entrepreneurship.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. In Montenegro, there are only few manufacturers of the equipment covered by the Rulebook, but currently there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, the Ministry of Economy have sufficient number of staff for the implementation of this Rulebook. Apart from machinery, Directorate for Industry and Entrepreneurship is also responsible for transposition and implementation of legislation dealing with textile, footwear and crystal glass. Currently, in Directorate for Industry and Entrepreneurship 4 employees are responsible for these directives. New recruitments in the Directorate are not planned, but further education of existing staff in this area is necessary.

Expenses for currently 4 employees are EUR 45,000 per year which means that the total costs for the implementation of above mentioned directives are **EUR 225,000 for the period 2014-2018**.

4.1.9 ATEX – Equipment and protective systems intended for use in potentially explosive atmospheres

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 2014/34/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2014/34/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on Equipment and protective systems intended for use in potentially explosive atmospheres is planned for the fourth quarter of 2018.

Rulebook is planned to be fully aligned with the requirements of Directive 2014/34/EC.

The planned timeline for adoption of the above mentioned rulebooks is based on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directive 2014/34/EC is the Ministry of Economy, Directorate for Mining and Geology Exploration.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Ministry of Economy does not have sufficient number of suitably trained staff for the implementation of ATEX Directive. Currently, in Directorate for Mining and Geology Exploration 1 employee is responsible for this directive and further education of existing staff in this area is necessary.

For the work in the above mentioned area, new recruitment in the Directorate for Mining and Geology Exploration is planned in 2018 as given in the table below:

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	/	/	/	/	1
Total number of the newly employed in relation to 2013	/	/	/	/	1

Projection of necessary financing for newly employees is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget for new employees⁷ (in EUR)	/	/	/	/	11.250
Donations and income from activities/industries in EUR	/	/	/	/	7.200

⁷ Note: Expenses for one employee cover gross salary, education, office space and office supplies

Expenses for one current employee are EUR 11,250 per year, or EUR 56,250 for the period 2014-2018. By hiring one new employee in 2018th, total costs for the implementation of the directive are **EUR 67,500 for the period 2014-2018.**

4.1.10 Personal Protective Equipment

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 89/686/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 89/686/EC that is manufacturing, importing and placing on the market and/or putting in use is:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of the Rulebook on personal protective equipment is planned for the fourth quarter of 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 89/686/EC.

The planned timeline for adoption of the above mentioned rulebooks is based on risks for consumers related to a very broad range of products covered by the directive.

Institutional framework

The competent authority for transposition and implementation of Directive 89/686/EC is the Ministry of Economy.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the products covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Economy (Directorate for Development) there is one employee responsible for transposition and implementation of this directive. New recruitments are not planned but further education of existing staff in this area is necessary.

Expenses for one current employee are EUR 11,250 per year, which means that the total costs for the implementation of above mentioned directive are **EUR 56,250 for the period 2014-2018.**

4.1.11 Measuring Instruments

Current situation in sector

In Montenegro, there are no manufacturers of the instruments covered by the directive 2004/22/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for measuring instruments that is manufacturing, importing and placing on the market and/or putting in use in are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11)
2. Law on Metrology (Official Gazette of Montenegro 79/08);
3. Rulebook on requirements referring to the devices and systems with measuring function (Official Gazette of Montenegro 29/13)

Rulebook entered into force 30th June 2013. Rulebook is in MN opinion fully aligned with directive 2004/22/EC.

On 29th March 2014 new Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments was published. Full alignment is planned for second quarter 2016 (20th April 2016).

Institutional framework

The competent authority for transposition of directive 2004/22/EC is the Ministry of Economy, Directorate for Internal Market and Competition in cooperation with Bureau of Metrology.

Bureau of metrology is responsible for implementation.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the instruments covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, Law on metrology and the Law Technical Requirements for Products and Conformity Assessment market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment Ministry of Economy does not have sufficient number of suitably trained staff for the implementation of this Rulebook. New recruitments in Directorate for Internal market and competition is planned for 2014 (See point 3.2.1). One of the newly employed will take over all the tasks in the field of metrology.

At this moment the Bureau of metrology does not have sufficient number of suitably trained staff for the implementation of this Rulebook. New recruitments in BoM are planned for 2014 (See point 3.2.3) and further education in this area is necessary.

4.1.12 Non-Automatic Weighing Instruments

Current situation in sector

In Montenegro, there are no manufacturers of the instruments covered by the Directive 2009/23/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements for non-automatic weighing instruments that is manufacturing, importing and placing on the market and/or putting in use in are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Law on Metrology (Official Gazette of Montenegro 79/08);
3. Rulebook on non-automatic weighing instruments (Official Gazette of Montenegro 29/13)

Rulebook entered into force 30th June 2013. Rulebook is in MN opinion fully aligned with requirements of Directive 2009/23/EC.

On 29th March 2014 new Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments was published. Full alignment is planned for second quarter 2016 (20th April 2016).

Institutional framework

The competent authority for transposition of Directive 2009/23/EC is the Ministry of Economy, Directorate for Internal Market and Competition in cooperation with Bureau of Metrology.

Bureau of metrology is responsible for implementation of Rulebook.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, the Law on metrology and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment Ministry of Economy does not have sufficient number of suitably trained staff for the implementation of this Rulebook. New recruitments in Directorate for Internal market and competition are planned for 2014 (See point 3.2.1). One of the newly employed will take over all the tasks in the field of metrology.

At this moment the Bureau of metrology does not have sufficient number of suitably trained staff for the implementation of this Rulebook. New recruitments in BoM are planned for 2014 (See point 3.2.3) and further education in this area is necessary.

4.1.13 Eco Design of Energy related Products

Current situation in sector

In Montenegro, there is a limited number of manufacturers of equipment covered by the Directive 2009/125/EC and related implementation legal acts. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2009/125/EC and related implementation legal acts that is manufacturing, importing and placing on the market and/or putting in use are:

- 1.Law on Energy Efficiency (Official Gazette of Montenegro 29/10);
- 2.Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of the Rulebook on eco design of energy related products is planned for the first quarter of 2015. Rulebook is planned to be fully aligned with the requirements of Directive 2009/125/EC.

In the first phase, apart from the framework directive, implementation regulations on fluorescent lamps, non-directional house hold lamps and electric motors will be included (as annexes to the Rulebook).

All the other implementing measures regarding other products will be adopted by the end 2017.

The planned two phase timeline for adoption of the above mentioned rulebooks is based on importance of different groups of products for energy consumption as well as on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directive 2009/125/EC is the Ministry of Economy, Directorate for Energy Efficiency.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there is limited number of manufacturers of equipment covered by the Directive 2009/125/EC, there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, the Law on Energy Efficiency and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Ministry of Economy does not have sufficient number of suitably trained staff for the implementation of the Rulebook. Currently, in Directorate for Energy Efficiency 2 employees are responsible for this Directive and further education of new and existing staff in this area is necessary. New recruitments in the Directorate for Energy Efficiency are planned for 2015 as given below.

Projection of needs for new employees for implementation of acquis, 2014-2018

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	/	1	/	/	/
Total number of the newly employed in relation to 2013	/	1	1	1	1

Projection of necessary financing for newly employees is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget for new employees⁸ (in EUR)	/	11250	11250	11250	11250
Donations and income from activities/industries in EUR	/	7200	7200	7200	7200

⁸ Note: Expenses for one employee cover gross salary, education, office space and office supplies

Expenses for two current employees are EUR 22,500 per year, or EUR 112,500 for the period 2014-2018. By hiring one new employee in 2015, total costs for the implementation of the directive are **EUR 157,500 for the period 2014-2018**.

4.1.14 Toys Safety

Current situation in sector

In Montenegro, there are no manufacturers of the instruments covered by the Directive 2009/48/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment covered by Directive 2009/48/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on safety of toys is planned for the fourth quarter of 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 2009/48/EC.

The planned timeline for adoption of the above mentioned rulebook is based on high level of risk for consumers.

Institutional framework

The competent authority for transposition and implementation of Directive 2009/48/EC is the Ministry of Health.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of products covered Directive 2009/48/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law on General product safety, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Health there is one employee responsible for transposition and implementation of this directive. New recruitments are not planned but further education of existing staff in this area is necessary.

Expenses for one current employee are EUR 11,250 per year, which means that the total costs for the implementation of above mentioned directive are **EUR 56,250 for the period 2014-2018**

4.1.15 Medical Devices

Current situation in sector

Montenegro currently has two domestic manufacturers of medical devices (class I) solely for domestic market. There is 48 wholesalers licensed for wholesale of medical devices.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by directives 93/42/EEC, 90/385/EEC and 98/79/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Medical Devices (Official Gazette of Montenegro 79/04 and 53/09)

The Law is partially aligned with the above mentioned directives.

Considering the ongoing revision of legislation for medical devices in EU, the possibility of harmonization with the new legislative package is being considered, depending on the time of it's adoption and transitional period for member states set. More detailed review of the adoption of primary and secondary legislation is given in the Action Plan in annex.

Institutional framework

The competent authority for transposition and implementation of Directives 93/42/EEC, 90/385/EEC and 98/79/EC is the Ministry of Health with the participation of Agency for medicines and medical devices.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there is a limited number of manufacturers of products covered by the directives there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law on Medical Devices market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.3.6.

Administrative capacity

At this moment, in the Ministry of Health there is one employee responsible for transposition and implementation of this directives. There are no plans for additional employment. Further education of existing staff in this area is necessary.

At this moment the Agency for medicines and medical devices does not have sufficient number of suitably trained staff for the implementation of the Law. Currently, in Agency for medicines and medical devices 3 employees are responsible for implementation of these directives. New recruitment in Agency for medicines and medical devices (CALIMS) is planned for 2016 as given below.

Projection of needs for new employees for implementation of acquis, 2014-2018

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year (CALIMS)	/	/	1	/	/
Total number of the newly employed in relation to 2013	/	/	1	1	1

Projection of necessary financing for newly employees is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget in EUR	/	/	/	/	/
Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries + material expenses)	/	/	17040 (9540 + 7500)	17040 (9540 + 7500)	17040 (9540 + 7500)

Expenses for currently 3 employees are EUR 51 120 per year, or EUR 255 600 for the period 2014-2018. By hiring one new employees in 2016, total costs for the implementation of above mentioned directive are **EUR 306,720 for the period 2014-2018.**

4.1.16 Cableway Installations

Current situation in sector

In Montenegro, there are no manufacturers of the instruments covered by the Directive 2000/9/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment covered by Directive 2009/9/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on safety, organization and efficiency of rail transport (Official Gazette of Montenegro 01/14);
2. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of the Rulebook on cableway installations is planned for the fourth quarter of 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 2000/9/EC.

The planned timeline for adoption of the above mentioned rulebook is based on risk related to cableways installations (there are several cableways in Montenegro) as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directives 2000/9/EC is the Ministry of Transport and Maritime Affairs, Railways Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of products covered by Directive 2000/9/EC, there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, Law on safety, organization and efficiency of rail transport and Law on Technical Requirements for Products and Conformity Assessment market surveillance is performed by Railway Inspectorate which is the part of the Ministry of Transport and Maritime Affairs.

There are two inspectors performing market surveillance of products on the market as well as inspection surveillance of products in use in the cableway installations. Additional recruitments are not planned.

Administrative capacity

At this moment the Ministry of Transport and Maritime Affairs has sufficient number of staff. Currently 4 employees are responsible for transposition and implementation of directive 2000/9/EC. New recruitments in the Directorate are not planned, but further education of existing staff in this area is necessary.

Expenses for currently 4 employees are EUR 45,000 per year which means that the total costs for the implementation of above mentioned directive are **EUR 225,000 for the period 2014-2018.**

4.1.17 Recreational Crafts

Current situation in sector

In Montenegro, there are no manufacturers of the products covered by the Directive 94/25/EC. The obligations for economic operators are going to be implemented by the importers and distributors.⁹

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment covered by Directive 94/25/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Yachts (Official Gazette of Montenegro 46/07);
2. Law on Safety of Maritime Navigation (Official Gazette of Montenegro 46/07);
3. Decree on Boats (Official Gazette of Montenegro 44/09);
4. Law on Maritime and Inland Navigation (Official Gazette of Federal Republic of Montenegro 19/78 and the following);
5. Law on Protection of Sea Pollution from Sea-Going Vessels (Official Gazette of Montenegro 20/11);
6. Rules of Statutory Certification of Yachts from 2012

Above mentioned legislation is in MN opinion partially aligned with the requirements of Directive 94/25/EC on recreational crafts.

In MN opinion, full alignment with the the Directive 94/25/EC will be achieved through the adoption of the bylaws of the Law on Safety of Maritime Navigation as well as with the amending of the Yachts Law, which is expected to be adopted by the end of 2014th. An implementation of before mentioned is expected to start by the accession of Montenegro to the EU.

Institutional framework

The competent authority for transposition and implementation of Directives 94/25/EC is the Ministry of Transport and Maritime Affairs, Maritime Directorate with the participation of Maritime Safety Authority of Montenegro.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of products covered Directive 94/25/EC, there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, the Law on Maritime and Inland Navigation, Decree on Boats market surveillance is performed by the Maritime Safety Authority of Montenegro.

⁹ After the bilateral screening MN established that there are no manufacturers (boat builders) of boats in MN which would be covered by this directive.

There are three inspectors performing market surveillance of products on the market as well as inspection surveillance of products in use in the recreational crafts. Additional recruitments are not planned.

Administrative capacity

At this moment the Ministry of Transport and Maritime Affairs have sufficient number of staff. Currently 4 employees are responsible for transposition and implementation of directive 94/25/EC. New recruitments in the Directorate are not planned, but further education of existing staff in this area is necessary.

Expenses for currently 4 employees are EUR 45,000 per year which means that the total costs for the implementation of above mentioned directive are **EUR 225,000 for the period 2014-2018.**

4.1.18 Construction Products

Current situation in sector

Construction sector of the Montenegrin market in comparison with the markets of the other European countries is quite small. However, due to the share in the Gross domestic product and the fact that investments in fixed capital still provide the biggest stimulus to the Gross domestic product growth, the importance of the construction market cannot be ignored.

		2011	2012
Gross domestic product (in thousands of EUR)	Sector	3 234 060	3 148 857
Gross value added (in thousands of EUR)	Sector	158 081	145 192
Share of construction sector in GDP (%)		4,9	4,6

Although the construction in MN in the previous period experienced significant expansion, small number of companies is dealing with production of construction products. Most materials, especially for finishing works in construction, are imported despite the fact that Montenegro has large quantities of raw materials which are the basic raw material for the production of building materials, and that there are reserves of mentioned in significant quantities and adequate quality. It is especially related to the marlstone, architectural building stone, clay and technical-building stone.

Examples of construction products which are being produced in Montenegro: fresh concrete, specific prefabricated concrete products, concrete curbs, concrete paving slabs, etc., cements, aggregates for concrete and mortar, aggregates for bituminous mixtures, asphalt, wooden external and internal doors, PVC and aluminum doors and windows, quicklime, products of natural stone, concrete iron, etc.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation 305/2011/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Spatial Development and Construction works (Official Gazette of Montenegro 51/08 as of 22 August 2008, 35/13, 34/11)

2. Law on Construction Products (Official Gazette of Montenegro 18/2014)) partially transposes the requirements of Regulation 305/2011/EC. The Law on construction product will be applied from the beginning of 2017 in order to obtain adequate infrastructure for implementation of the Law

The Laws are in MN opinion partially aligned with the Regulation (EU) 305/2011. Full alignment will be achieved by a set of rulebooks.

Vertical secondary legislation to be adopted on the basis of the Law on spatial development and construction works and the Law on construction products:

1. Rulebooks on technical regulations for various groups of construction products

Institutional framework

The competent authority for transposition and implementation of Regulation (EU) 305/2011 is the Ministry of Sustainable Development and Tourism, Construction Directorate.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

There are no immediate plans for establishing national Technical Assessment Body in Montenegro.

Conformity assessment

Currently, in Montenegro there are three accredited conformity assessment bodies that could be designated (and later notified) under Regulation (EU) 305/2011 depending on the needs of Montenegrin market.

Market surveillance

According to the Law on Inspection Control and the Law on Spatial Development and Construction works market surveillance of construction product is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Ministry of Sustainable Development and Tourism does not have sufficient number of suitably trained staff for the implementation of the legislation. Currently, in Construction Directorate, Division for Strategic Development of Construction one employee is responsible for this regulation. New recruitments in the Construction Directorate, Division for Strategic Development of Construction are planned for 2015 and 2016. Further education of new and existing staff in this area is necessary.

Projection of needs for new employees for implementation of acquis, 2014-2018:

Year	2014	2015	2016	2017	2018
Number of newly employed in a single year		1	3	/	/
Total number of newly employed compared to 2013		1	4	4	4

Projection of necessary financing (EUR) for newly employees is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget for new employees ¹⁰ (in EUR)		11.250	45.000	45.000	45.000
Donations Other	11.000	61.000	61.000	11.000	/

Expenses for one currently employee are EUR 11,250 per year, or EUR 56,250 for the period 2014-2018. By hiring one new employee in 2015 and three more in 2016 total costs for the implementation of the directive are **EUR 202,500 for the period 2014-2018.**

4.1.19 Outdoor Equipment Noise Emissions

Current situation in sector

In Montenegro, there are no manufacturers of the products covered by the Directive 2000/14/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2000/14/EC that is manufacturing, importing and placing on the market and/or putting in use is:

1. Law on the Protection against Environmental Noise (Official Gazette of Montenegro, No 28/11, 01/14)
2. Rulebook on conformity marking for sources of noise (Official Gazette of Montenegro, No 13/14)

Rulebook is in MN opinion fully aligned with the requirements of Directive 2000/14/EC.

Institutional framework

¹⁰ Note: Expenses for one employee cover gross salary, education, office space and office supplies

The competent authority for transposition and implementation of Directive 2000/14/EC is Ministry of Sustainable Development and Tourism, Directorate for Environment and Climate Change in cooperation with Agency for Environmental Protection.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of equipment covered by the Directive 2000/14/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law on the Protection against Environmental Noise, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Sustainable Development and Tourism there is one employee responsible for transposition and implementation of directive 2000/14/EC. There are no plans for additional employment but further education of new and existing staff in this area is necessary.

Expenses for one current employee are EUR 11,250 per year, which means that the total costs for the implementation of above mentioned Directive are **EUR 56,250 for the period 2014-2018.**

4.1.20 Explosives for Civil Use

Current situation in sector

Currently in Montenegro there are two manufacturers of products covered by Directive 93/15/EC on explosives for civil uses (commercial explosives).

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 93/15/EC that is manufacturing, importing and placing on the market and/or putting in use is:

1. Law on Explosive Substances (Official Gazette of Montenegro, 49/08)

This law is in MN opinion partially aligned with the requirements of Directive 93/15/EU.

Adoption of Law on amendments of Law on Explosive Substances which will further align MN legislation with the relevant EU law is planned for the third quarter 2014.

Details on adoption of secondary legislation needed for full alignment are given in an annex (see an Action plan in an annex).

On 29 March 2014 new Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making

available on the market and supervision of explosives for civil uses was published. Full alignment is planned for second quarter 2016 (20 April 2016).

The planned timeline for adoption of the above mentioned legislation is based on presence on manufacturers on MN market, on risks related to these products as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directives 93/15/EC is the Ministry of Interior, Directorate for Emergency Situations.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there is a limited number of manufacturers product covered by the Directive 93/15/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on inspection control and the Law on Explosive Substances market surveillance is performed by the Inspectorate for explosive materials which is organized within the Ministry of the Interior.

Currently, seven inspectors are responsible for this directive as well as for pyrotechnic articles and other areas.

Surveillance of the implementation of this Law is performed through inspections for explosive materials which controls mentioned two manufacturers in Montenegro in the part related to the storage, manufacturing, use and transportation.

Explosive materials are commercially available but can be sold to economic operators, only in case when they have previously been granted license from the Ministry of the Interior to carry out mining operations and transport of explosives.

Administrative capacity

At this moment, in the Ministry of the Interior, Directorate for Emergency Situations, there are five employees responsible for transposition and implementation of Directive 93/15/EC, as well as transposition and implementation of Directive 2007/23/EC. New recruitments are not planned but further education of existing staff in this area is necessary.

Expenses for five currently employees are EUR 56,250 per year which means that the total costs for the implementation of above mentioned directives are **EUR 281,250 for the period 2014-2018.**

4.1.21 Pyrotechnic Articles

Current situation in sector

In Montenegro, there are no manufacturers of the products covered by the Directive 2007/23/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 2007/23/EC that is manufacturing, importing and placing on the market and/or putting in use is:

1. Law on Explosive Substances (“Official Gazette of Montenegro”, 49/08)

This law is not aligned with the requirements of Directive 2007/23/EU.

Adoption of the Law on amendments of Law on Explosive Substances is planned for the third quarter 2014. Law will be partially aligned with the requirements of Directive 2007/23/EU.

Details on adoption of secondary legislation needed for full alignment are given in an annex (see an Action plan in an annex).

The planned timeline for adoption of the above mentioned legislation is based on risks related to these products as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directives 2007/23/EC is the Ministry of the Interior, Directorate for Emergency Situations.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the products covered by the Directive 2007/23/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on inspection control and the Law on Explosive Substances market surveillance is performed by the Inspectorate for explosive materials which is organized within the Ministry of the Interior.

Currently, seven inspectors are responsible for this directive as well as for other areas.

Surveillance of the implementation of this Law is performed through inspection for explosive materials which controls the part relating to the storage, use (in the execution of public fireworks), transportation and sale.

Administrative capacity

See point 4.1.20.

4.1.22 Radio Equipment and Telecommunications Terminal Equipment

Current situation in sector

In Montenegro, there are no manufacturers of the equipment covered by the Directive 99/5/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 99/5/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
2. Law on Electronic Communications (Official Gazette of Montenegro 40/2013);
3. Rulebook on radio equipment and telecommunications terminal equipment (Official Gazette of Montenegro 32/12).

Rulebook entered into force on 29 June 2012 whereas its application began on 1 January 2013. The Rulebook is partially harmonised with Directive 99/5/EC.

In order to achieve full alignment with requirements of Directive 99/5/EC, adoption of the new Rulebook is planned for fourth quarter of 2014.

Institutional framework

The competent authority for transposition and implementation of Directives 99/5/EC is the Ministry for Information Society and Telecommunications, Directorate for Electronic Communications, Postal Services and Radio Spectrum.

Publishing of list of standards that establish a presumption of conformity is in responsibility of the Ministry.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of the equipment covered by the Directive 99/5/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control, the Law on Technical Requirements for Products and Conformity Assessment and the Law on Electronic Communications market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry for Information Society and Telecommunications there is one employee responsible for transposition and implementation of Directive 99/5/EC. New recruitments are not planned but further education of existing staff in this area is necessary.

Expenses for one current employee are EUR 11,250 per year, which means that the total costs for the implementation of above mentioned Directive are **EUR 56,250 for the period 2014-2018.**

4.2 Old Approach

Regarding the Old Approach apart from manufacturers of relevant products also the State is liable for safety of products and therefore has to establish and empower appropriate State Authorities for performing conformity assessment tasks (e.g. registration, evaluation and approval).

The priorities regarding the timing of the planned alignment of individual legal acts have been established taking into account several factors:

- nature of legal act (e.g. horizontality as in cases of framework directives in motor vehicles area),
- level of risk for consumers and other users,
- existence of manufacturers,
- administrative capacity of responsible state administration (transposition, implementation as well as conformity assessment state activities).

4.2.1 Textiles

Current situation in sector

Regardless of the long tradition of the textile industry it is necessary to be noted that in the past ten years it was reduced to less than one tenth from what it was back in the year 2000. At this moment, in Montenegro there are few manufacturers of textile products on a micro level covered by the Regulation (EU) 1007/2011. The obligations for economic operators are going to be mainly implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EU) 1007/2011 that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on labelling and marking of textile products is planned for the first quarter 2015.

The Rulebook is planned to be fully aligned with the requirements of Regulation (EU) 1007/2011.

The planned timeline for adoption of the above mentioned rulebook is based on presence on manufacturers on MN market, importance of textile labelling and marking for consumers as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Regulation (EU) 1007/2011 is the Ministry of Economy, Directorate for Industry and Entrepreneurship.

Conformity assessment

There are currently no conformity assessment bodies which would support market surveillance activities. As in Montenegro, there are few manufacturers of textile products on a micro level covered by the Rulebook there are no plans for the establishment of MN conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.8

4.2.2 Footwear

Current situation in sector

At this moment, in Montenegro there are few manufactures of footwear and/or their components on a micro level covered by the Directive 94/11/EC. The obligations for economic operators are going to be mainly implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 94/11/EC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook on marking of footwear is planned for the fourth quarter 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 94/11/EC.

The planned timeline for adoption of the above mentioned rulebook is based on presence on manufacturers on MN market, importance of marking of footwear for consumers as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directive 94/11/EC is the Ministry of Economy, Directorate for Industry and Entrepreneurship.

Conformity assessment

There are currently no conformity assessment bodies which would support market surveillance activities. As in Montenegro, there are few manufacturers of footwear and/or their components on a micro level covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.8

4.2.3 Crystal glass

Current situation in sector

In Montenegro, there are no manufacturers of product covered by the Directive 69/493/EC. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 69/493/EEC that is manufacturing, importing and placing on the market and/or putting in use are:

1. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);

Adoption of Rulebook of products from crystal glass is planned for the fourth quarter 2014.

Rulebook is planned to be fully aligned with the requirements of Directive 69/493/EC.

The planned timeline for adoption of the above mentioned rulebook is based on importance of marking of crystal glass for consumers as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation of Directive 69/493/EC is the Ministry of Economy, Directorate for Industry and Entrepreneurship.

Conformity assessment

There are currently no conformity assessment bodies which would support market surveillance activities. As in Montenegro, there are no manufacturers of products covered by the Rulebook there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and the Law Technical Requirements for Products and Conformity Assessment, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.1.8

4.2.4 Units of Measurement

Legal framework

Legal framework for units of measurement in Montenegro are:

1. Metrology Law (Official Gazette of Montenegro 79/08);
2. Decree on legal units of measurement (Official Gazette of Montenegro 22/09).

Decree on legal units of measurement is in MN opinion fully aligned with provisions of Directive 80/181/EEC.

Institutional framework

The competent authority for transposition of Directive 80/181/EEC is the Ministry of Economy, Directorate for Internal Market and Competition in cooperation with Bureau of Metrology.

Bureau of metrology is responsible for implementation of the Rulebook.

According to the Law on metrology (Official Gazette of Montenegro 79/08), market surveillance is performed by the Administration for Inspection Affairs

Administrative capacity

At this moment the Bureau of metrology have sufficient number of staff for the implementation of this Decree. Further education in this area is necessary. For more information see point 3.2.3.

4.2.5 Pre-packaged products

Current situation in sector

In Montenegro, there are manufacturers of product covered by the Directive 76/211/EC.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 76/211/EC that is manufacturing, importing and placing on the market and/or putting in use in Montenegro are:

- 1) Metrology Law (Official Gazette of Montenegro 79/08);
- 2) Rulebook on pre-packaged products (Official Gazette of Montenegro 56/11).

Rulebook is in MN opinion fully aligned with requirements of Directive 76/211/EEC.

Institutional framework

The competent authority for transposition of Directive 76/211/EEC is the Ministry of Economy, Directorate for Internal Market and Competition in cooperation with Bureau of Metrology.

Bureau of Metrology is responsible for implementation of the Rulebook.

Metrological surveillance

Metrological surveillance for pre-packaged products is performed by Bureau of metrology.

Market surveillance

According to the Law on Inspection Control and Law on Metrology market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Bureau of metrology does not have sufficient number of suitably trained staff for the implementation of this Rulebook. Further education in this area is necessary. New recruitments in BoM are planned for 2014 (see point 3.2.3).

4.2.6 Measuring Containers (Bottles)

Current situation in sector

In Montenegro, there are no manufacturers of product covered by the Directive 75/107/EC.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 75/107/EEC that is manufacturing, importing and placing on the market and/or putting in use in Montenegro are:

- 3) Metrology Law (Official Gazette of Montenegro 79/08);
- 4) Rulebook on bottles as measuring containers (Official Gazette of Montenegro 56/11).

Rulebook is in MN opinion fully aligned with requirements of Directives 75/107/EEC on bottles as measuring containers.

Institutional framework

The competent authority for transposition of Directive 75/107/EEC is the Ministry of Economy, Directorate for Internal Market and Competition in cooperation with Bureau of Metrology.

Bureau of Metrology is responsible for implementation of the Rulebook.

Metrological surveillance

Metrological surveillance for measuring containers (bottles) is performed by Bureau of Metrology.

Market surveillance

According to the Law on Inspection Control and the Law on Metrology market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Bureau of metrology does not have sufficient number of suitably trained staff for the implementation of this Rulebook. Further education in this area is necessary. New recruitments in BoM are planned for 2014 (see point 3.2.3).

4.2.7 Drug Precursors

Current situation in sector

In Montenegro, there are no manufacturers of product covered by the Regulation (EC) 273/2004. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 273/2004 that is manufacturing, importing and placing on the market and/or putting in use in Montenegro are:

1. Law on the surveillance of production and transport of substances that can be used in the production of narcotic drugs and psychotropic substances (Official Gazette of Montenegro. 83/09)
2. Rulebook on the list of substances that can be used in the production of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro" 58/10)

The above mentioned legislation is in MN opinion partially aligned with requirements of Regulation (EC) 273/2004. Details on adoption of secondary legislation needed for complete alignment are given in annex (see Action plan in annex).

Complete alignment of primary Law in MN opinion through amendments is planned for the fourth quarter of 2018.

The planned timeline for adoption of the above mentioned rulebooks is based on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation Regulation (EC) 273/2004 are the Ministry of Health in cooperation with Agency for medicines and medical devices, Ministry of the Interior and Customs Administration.

Conformity assessment

There are currently no conformity assessment bodies. As in Montenegro, there are no manufacturers of products covered by the Regulation there are no plans for the establishment of MNE conformity assessment bodies in the area.

Market surveillance

According to the Law on Inspection Control and Law on the surveillance of production and transport of substances that can be used in the production of narcotic drugs and psychotropic substances market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Health there is one employee responsible for transposition and implementation of this directive. New recruitments are not planned. Further education of the existing staff in this area is necessary.

Expenses for one current employee are EUR 11,250 per year, which means that the total costs for the implementation of above mentioned directive are **EUR 56,250 for the period 2014-2018.**

4.2.8 Cosmetics

Current situation in sector

In Montenegro, there is a limited number of manufacturers of products covered by the Regulation (EC) 1223/2009. The obligations for economic operators are going to be mainly implemented by the importers and distributors.

Legal framework

Montenegro has not yet harmonised its legislation with the cosmetics Regulation (EC) 1223/2009. The current Montenegrin legislation is a law dating from 1991, and some provisions of the Law on General Product Safety ("Official Gazette of Montenegro", 48/08) are also applicable.

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 1223/2009 that is manufacturing, importing and placing on the market and/or putting in use in Montenegro will be:

1. Law on cosmetics product,
2. Rulebook on requirements for cosmetics products.

Adoption of the Law and by-law is planned for the fourth quarter 2016. Legislation is planned to be fully aligned with the requirements of Regulation (EC) 1223/2009.

The planned timeline for adoption of the above mentioned legislation is based on importance of cosmetics for consumers as well as on adequate administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition and implementation Regulation (EC) 1223/2009 is the Ministry of Health.

Conformity assessment

There are currently no conformity assessment bodies. There are plans for authorisation of conformity assessment bodies in accordance with the requirements of Regulations regarding safety of cosmetic products placed on the market in Montenegro.

Market surveillance

According to the Law on Inspection Control and Law on general product safety market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Health there is one employee responsible for transposition and implementation of this directive. New recruitment is planned for 2014. Further education of the new and existing staff in this area is necessary.

Projection of needs for new employees for implementation of acquis

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year	1	/	/	/	/
Total number of the newly employed in relation to 2013	1	1	1	1	1

Projection of necessary financing for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget in EUR	5.625	11.250	11.250	11.250	11.250
Donations and income from activities/industries in EUR	7.200	7.200	7.200	7.200	7.200

Expenses for one current employee are EUR 11,250 per year, or EUR 56,250 for the period 2014-2018. By hiring one new employee in the second half of 2014, total costs for the implementation of the directive are **EUR 106,875 for the period 2014-2018**.

4.2.9 Pharmaceuticals

4.2.9.1 Medicines for human use

Current situation in sector

Montenegro currently has three licensed domestic manufacturers producing medicines for human use belonging to category of SME. There is no manufacturing of innovative or biological medicines. Medicines are produced for domestic market and export. One of the manufacturers has an EU Good Manufacturing Practice (GMP) certificate and exports to some of EU countries.

Regarding the financial share of domestic manufacturers, they constitute just under 3% of total market value. Approximately 97% medicines are imported from foreign manufacturers (approx. 60% manufacturers from EEA countries and approx. 25% countries of ex -Yugoslavia).

Currently there are 27 licensed wholesalers for human medicines, Licence for wholesale of medicines containing narcotic substances must be obtained separately (9 wholesalers out of 27, currently licensed)

Legal framework

EU legal framework for the stipulation of technical requirements and conformity assessment procedures for medicinal products consists of:

1. Directive 2001/20/EC
2. Directive 2001/83/EC
3. Directive 2003/94/EC
4. Directive 2005/28/EC
5. Regulation 141/2000
6. Regulation 847/2000
7. Regulation 726/2004
8. Regulation 1901/2006
9. Regulation 1234/2008
10. Regulation 1235/2010
11. Regulation 198/2013

The above mentioned set of EU legal acts is in MN addressed by:

1. Law on Medicines (Official Gazette of Montenegro 56/11);
2. Rulebook on conditions for issuing marketing authorization (Official Gazette of Montenegro 30/2009);
3. Rulebook on detailed content of pharmaceutical testing of medicines (Official Gazette of Montenegro 38/2009);
4. Rulebook on detailed content of pharmacological-toxicological studies of medicines (Official Gazette of Montenegro No 68/2009);
5. Rulebook on quality control of medicines (Official Gazette of Montenegro 4/2010),

6. Guidelines on Good Distribution Practice (CALIMS webpage);
7. Rulebook on detailed conditions and documentation required for approval and conduct of clinical trial of medicines for human use (Official Gazette of Montenegro 2/2014);
8. Rulebook on the manner and conditions of advertisement of medicines (Official Gazette of Montenegro 2/2014).

The Law is in MN opinion partially aligned with subject EU legal acts which had become effective before the Law was passed and therefore it is necessary to amend the existing Law until the end of 2016 to further align with the relevant *acquis* and provide basis for adoption of all necessary secondary legislation.

Full harmonization will be achieved through adoption of all secondary legislation. Details on adoption of secondary legislation needed for complete alignment are given in annex (see an Action plan in the annex).

Medicinal product pricing

Legal framework by which Directive 89/105/EC is transposed into legislation of Montenegro are:

1. Law on Medicines (Official Gazette of Montenegro 56/11);
2. Law on Health Insurance (Official Gazette of Montenegro 14/12)
3. Decree on criteria for setting the maximum prices of medicines (Official Gazette 50/07 and 62/10)
4. List of medicines that are prescribed and issued at the expenses of the Fund intended to compulsory health insurance (Official Gazette of Montenegro 04/12)

The current legislation is in MN opinion partially harmonised with the requirements of Directive 89/105/EC. Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

Institutional framework

The competent authority for the transposition of all EU legal acts in the area of medicines for human use is the Ministry of Health with the participation of Agency for medicines and medical devices (CALIMS).

Implementation of the subject EU legal acts is within the competence of CALIMS.

Implementation of the Directive 89/105/EC is within the competence of the Ministry of Health, National Health Insurance Fund and CALIMS. Ministry of Health is responsible for inclusion of medicines on the positive list of medicine and setting the criteria for the procedure. According to the new Decree that is under preparation, CALIMS will be responsible for setting the maximum prices of medicines and foreseeing system of international price referencing. The current Decree does not set the timeline for decision neither the obligation of transparency nor this will be implement in the new Decree in line with the Directive. Currently prices for the medicines procured for the public health institutions are regulated by tender procedure for annual procurement of medicines, the prices of tender bids are public available.

Conformity assessment

CALIMS is issuing marketing authorisation for medicines, licensing manufacturers and wholesalers, approving clinical trials, collecting reports on adverse reaction of medicines (pharmacovigilance), and monitoring consumption of medicines.

Market surveillance

According to the Law on Inspection Control and the Law on Medicines market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in the Ministry of Health there is one employee responsible for transposition and implementation of this directives. There are no plans for additional employment. Further education of existing staff in this area is necessary.

At this moment, in CALIMS there are twenty employees responsible for implementation of existing legislation in area of medicines for human use. Additional employment is necessary in order to implement harmonised legislation.

Agency plans setting up and equipping quality control laboratory specialised for detection of substandard and falsified medicines. Currently all testing must be performed in surrounding countries. This laboratory will be specific only for this particular part of control and enable better screening of the market and since technique foreseen (x-ray diffraction) is not developed in the region it could be complementary to already existing laboratories in the region and specialised for this activity.

A twinning project with one of the EU Agencies is foreseen after 2015, when administrative capacities and regulatory framework should be sufficiently advanced for such a project in order to be able to fully implement the relevant acquis.

Further education of the new and existing staff in this area is necessary.

Projection of needs for new employees for implementation of acquis in CALIMS

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year (CALIMS)	1	2	1	1	1
Total number of the newly employed in relation to 2013	1	3	4	5	6

Projection of necessary financing for newly employed in CALIMS for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget in EUR	/	/	/	/	/
Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries + material expenses)	17040 (9540 + 7500)	51120 (28620 + 22500)	68160 (38160+ 30000)	85200 (47700+ 37500)	102240 (57240+ 45000)

Projection of needs for new employees for implementation of acquis in the Health Insurance Fund of Montenegro

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year (Health Insurance Fund of Montenegro)	1	1	2	/	/
Total number of the newly employed in relation to 2013	1	2	4	4	4

Projection of necessary financing for newly employed in the Health Insurance Fund of Montenegro, for the 5 years period is given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget in EUR	/	/	/	/	/
Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries + material expenses)	11 500	23 000	46 000	46 000	46 000

Expenses for one current employee in the Ministry of Health are EUR 11,250 per year, or EUR 56,250 for the period 2014-2018, while expenses in the Agency for Medicines and Medical Devices (twenty currently and 6 new employees) in the same period are EUR 2 027 760 and expenses in the Health Insurance Fund of Montenegro (for 4 new employees) are EUR 172,500. Therefore, total costs for the implementation of above mentioned directives, are **EUR 2 256 510 for the period 2014-2018.**

4.2.9.2 Medicines for veterinary use

Current situation in sector

There are no licensed manufacturers for veterinary medicinal products or medicinal premixes. Market is completely supplied through import. Total size of the market for the imported veterinary products in 2010 and 2011 was: 654 600 € and 461 104 € respectively. Currently there are 7 licensed wholesalers for veterinary medicines.

Legal framework

EU legal framework for the stipulation of technical requirements and conformity assessment procedures for medicinal products consists of:

1. Directive 91/412/EC
2. Directive 2001/82/EC
3. Directive 2006/130/EC
4. Regulation 1950/2006
5. Regulation 470/2009

The above mentioned set of EU legal acts is in MN addressed by:

1. Law on Medicines (Official Gazette of Montenegro 56/11);
2. Rulebook on conditions for issuing marketing authorization (Official Gazette of Montenegro 30/2009);
3. Rulebook on the manner and conditions of advertisement of medicines (Official Gazette of Montenegro 2/2014);
4. Law on Veterinary (Official Gazette of Montenegro 56/11).

The Law is in MN opinion partially aligned with subject EU legal acts which had become effective before the Law was passed and therefore it is necessary to amend the existing Law until the end of 2016 to further align with the relevant *acquis* and provide basis for adoption of all necessary secondary legislation.

Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see an Action plan in the annex)

Institutional framework

The competent authority for the transposition and implementation of all EU legal acts in the area of medicines for veterinary use is the Ministry of Health with the participation of Agency for medicines and medical devices, and the Ministry of Agriculture and Rural Development with participation of the Veterinary Administration.

Conformity assessment

Veterinary Administration which is a part of Ministry of Agriculture and Rural Development is responsible for issuing licenses for wholesale (wholesaler) and surveillance of residues in food of animal origin.

CALIMS is issuing registration (licensing the medicine), licensing manufacturers and issuing licenses for import of medicines which are not registered.

Market surveillance

According to the Law on Inspection Control and the Law on Medicines market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment, in CALIMS there are two employees responsible for implementation of existing legislation in area of medicines for veterinary use. Additional employment is necessary in order to implement harmonised legislation.

CALIMS will need to employ and train additional staff in order to implement harmonised legislation. A twining project with one of the EU Agencies is foreseen after 2015, when administrative capacities and regulatory framework should be sufficiently prepared for such a project in order to be able to fully implement the acquis.

Projection of needs for new employees for implementation of acquis

Year	2014	2015	2016	2017	2018
The number of the newly employed in individual year (CALIMS)	/	/	1	/	/
Total number of the newly employed in relation to 2013	/	/	1	/	/

Projection of necessary financing for newly employed, 2014-2018

Year	2014	2015	2016	2017	2018
State budget in EUR	/	/	/	/	/
Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries +	/	/	17040 (9540 + 7500)	/	/

material expenses					
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Expenses for two current employees in CALIMS are EUR 34 080 per year, or EUR 170,400 for the period 2014-2018. By hiring one new employee in 2016 , total costs for the implementation of the directive are **EUR 221 520 for the period 2014-2018.**

4.2.10. Fertilisers

Current situation in sector

In Montenegro, there are no manufacturers of products covered by the Regulation (EC) 2003/2003. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal Framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 2003/2003 is:

1. Law on Plant Nutrition Products (Official Gazette of Montenegro 48/07)

Law is in MN opinion partially aligned with requirements of Regulation EC 2003/2003.

Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

Apart from provisions prescribed by the Regulation, Law on Plant Nutrition Products also includes national provisions referring to other types of fertilisers such as: organic fertilisers, microbiological fertilisers, bio-stimulators, soil enrichment substances and substrates.

The planned timeline for adoption of the above mentioned legislation is based on importance of fertilities for protecting environment as well on administrative capacity of the competent institutions.

Institutional framework

The competent authority for transposition of Regulation (EU) 2003/2003 is the Ministry of Agriculture and Rural Development.

Phytosanitary Administration which is a part of the Ministry is responsible for implementation of Regulation (EU) 2003/2003.

Conformity assessment

Phytosanitary Administration is state administration body in charge of immediate execution of regulations and conduction of administrative and related professional affairs (e.g. registration of manufacturers and products).

Currently, in Montenegro one accredited laboratory is authorised for performing conformity assessment for the needs of implementing administration.

Market surveillance

According to the Law on Plant Nutrition Products market surveillance is performed by Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacities

At this moment, in the Ministry of Agriculture and Rural Development, Phytosanitary Administration, Division for Plant Health Protection, Plant Nutrition Products and Food Safety, one employee is responsible for implementation of Regulation (EU) 2003/2003. New recruitments are planned for 2015 and 2016. Further education of new and existing staff is necessary.

Projection of needs for new employees for implementation of acquis

Year	2014	2015	2016	2017	2018
Number of newly employed in a single year	1	1	/	/	/
Total number of newly employed compared to 2013	1	2	2	2	2

Projection of needs for new employees for implementation of acquis, 2014-2018

Year	2014	2015	2016	2017	2018
State budget	5.625	20.080	20.080	20.080	20.080
Donations	20.000	20.000	20.000	11.000	/
Other					

Expenses for one current employee are EUR 11,250 per year, or EUR 56,250 for the period 2014-2018. By hiring one new employee in 2014 and one more employee in 2015, total costs for the implementation of the directive are **EUR 142,195 for the period 2014-2018.**

4.2.11 Chemicals

Current situation in sector

At this moment, in Montenegro there are few manufactures of products covered by the Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 648/2004 EC. The obligations for economic operators are going to be mainly implemented by the importers and distributors.

Legal framework

Regulation (EC) 1907/2006 (REACH)

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 1907/2006 that is manufacturing, importing and placing on the market and/or putting in use in Montenegro are:

1. Law on Chemicals (Official Gazette of Montenegro 18/12)
2. Rulebook on detailed content of the Safety Data Sheet (Official Gazette of Montenegro, 13/13);
3. Rulebook on detailed contents of the files and registry chemicals (Official Gazette of Montenegro, 19/13)
4. Rulebook on the List of Substances of high concern (Official Gazette of Montenegro, 13/13);
5. Rulebook on criteria for identifying a substance such as PBT or vPvB (Official Gazette of Montenegro 13/13);
6. Rulebook on method of preparation and content of the Chemical Safety Report(Official Gazette of Montenegro 19/13);
7. Rulebook on keeping records on chemicals and issued permits for the performance of transport of hazardous chemicals (Official Gazette of Montenegro 19/13);
8. Rulebook on prohibition or permission methods of use, as well as other requirements for the production, marketing, reporting and use of a substance, mixture, or a particular product (Official Gazette of Montenegro 19/13).

Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

Regulation (EC) 1272/2008 – CLP

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 1272/2008 in Montenegro are:

1. Law on Chemicals (Official Gazette of Montenegro 18/12)
2. Rulebook on method of classification, packaging and labelling of chemicals and specific products in hazard classes („Official Gazette of Montenegro” 53/12);
3. List of classified substances (“Official Gazette of Montenegro” 58/12);
4. Rulebook on criteria for identifying a substance such as PBT or vPvB (“Official Gazette of Montenegro” 13/13);
5. Rulebook on detailed content of the Safety Data Sheet (“Official Gazette of Montenegro” 13/13);

Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

Regulation (EC) 648/2004 - Detergents

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EC) 648/2004 that is manufacturing, importing and placing on the market and/or putting in use in Montenegro are:

1. Law on Chemicals (Official Gazette of Montenegro 18/12)
2. Rulebook on the methods of testing the biodegradability surfactants, marking methods and content list on the composition of detergent (“Official Gazette of Montenegro” 50/13);

3. Rulebook on the list of surfactants that can be used in detergent (“Official Gazette of Montenegro” 36/13).

Abovementioned legislation is in MN opinion fully aligned with requirements of the Regulation (EC) 648/2004.

Institutional framework

The competent authority for transposition of Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 648/2004 is Ministry of Sustainable Development and Tourism, Directorate for Environment and Climate Change.

Environmental Protection Agency (EPA) is the implementing authority.

Conformity assessment

There are currently no conformity assessment bodies. There are plans for authorisation of conformity assessment bodies in accordance with the requirements of Regulations in Montenegro.

Regarding the Regulation (EC) 1907/2006 Environmental Protection Agency maintains register of chemicals in electronic form, performs professional assessment of the information contained in the file for a substance or mixture containing a substance causing high concern, also order amendment of the proposed measures to reduce risk, co-operating with ECHA and competent authorities of other Member State in the implementation of the regulation.

Regarding the Regulation (EC) 1272/2008 Environmental Protection Agency is competent for gathering all relevant information related to the classification, exchange of information, receiving information on the health effects of the preparations, approval for the use of alternative chemical name and for collecting SDS and Chemical Safety Report.

Regarding the Regulation (EC) 648/2004 Environmental Protection Agency is responsible for the collecting of data, issuing permits for industrial and professional use of detergents containing surfactants, as well as to verify data if the detergent used in a way that the surfactants is minimally released into the environment. The detergent with the surfactants used for industrial or professional purposes may only present minimal risk to human health and environment taking into the consideration the amount of surfactants in detergents.

Market surveillance

According to the Law on Inspection Control and the Law on general product safety, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

At this moment the Ministry of Sustainable Development and Tourism does not have sufficient number of suitably trained staff for the implementation of these regulations. Apart from these regulations, Directorate for Environment and Climate Change is responsible for Regulation on

biocidal product. Currently, 2 employees are responsible for implementation of these regulations. New recruitment is not planned.

At this moment, EPA does not have sufficient number of suitably trained staff for the implementation of these Regulations. Currently, 2 employees are responsible for implementation of these regulations. New recruitment is not planned but further education of existing staff in this area is necessary.

Expenses for currently two employees are EUR 22 500 per year which means that the total costs for the implementation of above mentioned directive are **EUR 112 500 for the period 2014-2018.**

4.2.12 Biocidal product

Current situation in sector

In Montenegro, there is currently no information on manufacturers of product covered by the Regulation (EU) 528/2012. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Montenegro has not yet harmonised its legislation with the Regulation (EU) 528/2012.

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Regulation (EU) 528/2012 that is manufacturing, importing and placing on the market and/or putting in use in Montenegro will be:

1. Law on Biocidal Products

Adoption of the Law is planned for the fourth quarter 2014. Law is planned to be aligned with the requirements of Regulation (EU) 528/2012.

Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

The planned timeline for adoption of the above mentioned legislation is based on risks related to these products as well as on administrative capacity of the competent Directorate.

Conformity assessment

There are currently no conformity assessment bodies. There are plans for authorisation of conformity assessment bodies in accordance with the requirements of Regulations in Montenegro.

Institutional framework

The competent authority for transposition of Regulation (EU) 528/2012 is Ministry of Sustainable Development and Tourism, Directorate for Environment and Climate Change.

Environmental Protection Agency (EPA) is the implementing authority.

Market surveillance

According to the Law on Inspection Control and the Law on general product safety, market surveillance is performed by the Administration for Inspection Affairs. For more information on market surveillance see point 3.2.6.

Administrative capacity

See point 4.2.12

4.2.13 Motor Vehicles

Current situation in sector

In Montenegro, there are no manufacturers of products (vehicles) covered by the Directive 2007/46 on motor vehicles, Directive 2002/24 on two or three wheeled motor vehicles, Directive 2003/37/EC on tractors, and Directive 97/68 on non-road mobile machinery. The obligations for economic operators are going to be implemented by the importers and distributors.

Legal framework

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by EU legal acts:

1. Directive 2007/46 on framework for approval motor vehicles, and relevant sectoral EU legal acts;
2. Directive 2002/24 on type approval of two or three wheeled motor vehicles, and relevant sectoral EU legal acts;
3. Directive 2003/37/EC on type approval of agricultural and forestry tractors, and relevant sectoral EU legal acts;
4. Directive 97/68 on emissions from non-road mobile machinery;

that is manufacturing, importing and placing on the market and/or putting in use in Montenegro is:

1. Law on Road Traffic Safety (Official Gazette of Montenegro 33/12);
2. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11).

The above mentioned legal framework represents administrative framework for enacting national technical regulations which will take over EU legal acts and does not contain specific technical requirements for vehicles.

Law on Road Traffic Safety is not completely aligned with the EU *acquis* in the area covered by the above mentioned directives. Complete alignment which is going to provide an adequate legal basis for the transposition and implementation of the directives will be attained by the Law on Amendments to Law on Road Traffic Safety which is planned to be adopted by the end of 2014.

Apart from the above mentioned legal acts MN is a member of two international agreements in the area of type approvals which constitute elements of national legal order:

1. Agreement Concerning the Adoption of Uniform Conditions of Approval and Reciprocal Recognition of Approval for Motor Vehicle Equipment and Parts, done at Geneva on 20 March 1958;
2. Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions, entered into force on 16 October 1995.

By notification of succession from 23 October 2006 MN informed Secretary General of UN that it takes over the obligations of implementing all the treaties previously signed by SFRJ, SRJ and SCG. By this act MN received the status of legal heir (successor) to all treaties whose depositary is UN Secretary General. Starting from 3 June 2006 MN took over the responsibilities of implementing also the two above mentioned agreements regarding the type approvals of vehicles, their components and parts in accordance with UNECE rules as well as recognizing type approvals granted by authorized laboratories of other signatories under the conditions of ECE rules.

Adoption of the Rulebook on technical requirements and conditions for vehicles, parts and equipment which are imported or placed on the market of Montenegro for the first time and on conditions which legal entity must meet for vehicle homologation is planned for the fourth quarter of 2014.

On the basis of the two Laws, apart from the above mentioned Rulebook, four additional rulebooks are going to be adopted:

1. Rulebook on approval of motor vehicles (fourth quarter of 2015),
2. Rulebook on approval of two or three wheeled motor vehicles (fourth quarter of 2017),
3. Rulebook on approval of tractors (fourth quarter of 2017),
4. Rulebook on emissions from non-road mobile machinery (fourth quarter of 2017).

The four rulebooks are planned to be fully aligned with the relevant EU legislation.

The above mentioned framework directives (Directive 2007/46, Directive 2002/24, Directive 2003/37/EC and Directive 97/68) are expressly mentioned in this document due to the fact that type approvals under UNECE rules covered by the two international agreements do not cover the whole vehicle type approvals (WVTA). This is not the case with separate directives which have almost identical content as the equivalent UNECE rules. Separate directives will be transposed into national legislation by making a simple reference in MN rulebooks to UNECE rules which are already part of MN legislation.

For more information on structure and planned timeline for adoption of rulebooks transposing relevant separate EU legal acts in the field of approval of motor vehicles, two or three wheeled motor vehicles and agricultural and forestry tractors, see Action plan in annex.

The planned timeline for adoption of the above mentioned legislation is based on importance of products as well as on administrative capacity of the competent Directorate.

Institutional framework

The competent authority for transposition of the above mentioned framework directives (as well as sectoral EU legal acts in this area – more than 100) into national legislation is the Ministry of Transport and Maritime Affairs, Directorate for Road Traffic.

Conformity assessment

Competences of “Approval authority” will be performed by the Ministry of Transport and Maritime Affairs, Directorate for Road Traffic.

Competences of “Technical services” will be performed by one or more legal entities (which will be selected on the basis of a public tender in accordance with Law on Technical Requirements for Products and Conformity Assessment) which will have a sufficient number of professional and administrative capacities.

Market surveillance

According to the Law on Inspection Control, the Law on Road Traffic Safety and the Law on Technical Requirements for Products and Conformity Assessment market surveillance is performed by Road Traffic Inspectorate which is the part of the Ministry of Transport and Maritime Affairs.

There are four inspectors performing market surveillance of vehicles on the market as well as inspection surveillance of vehicles in use. New recruitments are not planned.

Administrative capacity

At this moment Ministry of Transport and Maritime Affairs does not have sufficient number of suitably trained staff for implementation of the relevant legal acts. Currently, 2 employees are responsible for transposition and implementation of the above mentioned directives. Further education of the new and existing staff in this area is necessary.

Projection of needs for new employees for implementation of acquis

Year	2014	2015	2016	2017	2018
Number of newly employed in a single year		1	/	2	/
Total number of newly employed compared to 2013		1	1	3	3

Projection of needs for new employees for implementation of acquis, 2014-2018

Year	2014	2015	2016	2017	2018
State budget		11 250	11 250	33 750	33 750
Donations	11.000	61.000	61.000	11.000	/

Other					
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Expenses for two existing employees are EUR 22,500 per year, which means EUR 112,500 for the period 2014-2018. By hiring one new employee in 2015 and two more in 2017 total costs for the implementation of the acquis are **EUR 202,500 for the period 2014-2018.**

V PROCEDURAL MEASURES

Procedural measures include notification procedures, conformity assessment and information society services in accordance with the Directive 98/34/EC; external border checks, control of the acquisition and possession of weapons, quantitative restrictions and cultural goods.

5.1 Notification procedures

Legislative framework

Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11) has created legal framework for transposing Directive 98/34/EC into national legislation which refers to the obligation of Member States to notify each other on regulations they plan to enact, and with the aim of avoiding creation of unnecessary barriers to trade. Directive sets out so called three-month” standstill period” in order to enable Member States to give comments on submitted regulations texts. If a Member State shows concern or submits comments on the regulation within that time period, standstill period is extended. Stated standstill period prescribed by the Directive directly affects enacting of technical legislation.

Pursuant to the Article 33 of the Law, **Decree on the notification of technical regulations, standards, regulations on information society services and conformity assessment procedures** (Official Gazette of Montenegro 11/13) was adopted. The Decree also represents a basis for the notifying and informing World Trade Organisation in line with obligations from the Agreement on Technical Barriers to Trade.

In MN opinion both legal acts are fully aligned with the relevant EU acquis.

Institutional/Administrative measures

In line with the requirements of the Directive each Member State establishes contact point/information centre through which communication with European Commission will be carried out. Contact point/information centre for informing and notifying on technical regulations, regulations on services of information society, procedures of conformity assessment is Ministry in charge of quality infrastructure, and for notifying on standards Institute for Standardisation of Montenegro. Having regard to the similarity of obligations, all bodies are in charge of notifying and informing WTO/TBT.

Stated process requires appropriate organisation and computer equipment of the information centre, participation of all bodies of state administration in charge of preparation and enacting of technical regulations as well as private entities export-oriented, with respect to understanding of the procedures prescribed by the Decree, as well as their rights and obligations. In this view, it is necessary to establish strong internal communication and coordination with state administration bodies.

Pursuant to the previously mentioned, it is necessary to strengthen administrative capacities and provide education in all bodies participating in the notification process. It is necessary to ensure adequate technical assistance to all parties participating in the process with the aim of better

understanding all measures prescribed by the Decree. All the needed activities are to be done by the end of 2017.

5.2 External border checks

Law on General Products Safety (Official Gazette of Montenegro 48/08) has transposed provisions of the Directive of European Parliament and the Council 2001/95/EC regulating general product safety. Subject Law refers to all groups of products whose safety requirements have not been regulated by specific regulations.

The Law defines procedure of cooperation between authorities for market surveillance and Customs bodies controlling goods on external borders. Article 15 of the Law lays down that Customs authority in the customs procedure can postpone for three days release of a product or party/series of products and immediately inform competent inspection body if they find out:

- that certain products or parties/series of products show certain properties causing reasonable doubt of posing serious risk to health and safety of consumers;
- that certain products or parties/series of products are not accompanied by prescribed papers or that they have not been labelled in prescribed manner. If within three working days competent inspection authority does not take prescribed measures or does not inform Customs authority on taking measures within this time period, Customs authority will release product or party/series of product whose release has been deferred, if other prescribed conditions are met.

With the aim of establishing cooperation and coordination, Market Inspectorate and customs Administration have signed Memorandum/Agreement on Cooperation. In addition, expert/work group which will coordinate implementation of obligations from subject Agreement has been established.

By passing the Law on Surveillance of Products on Market, provisions referring to cooperation and products checks on external borders will be fully harmonised with the provisions of Regulation 765/2008/EC on requirements for market surveillance.

5.3 Control of the acquisition and possession of weapons

Law on Weapons ("Official Gazette of the Republic of Montenegro" 49/04 and "Official Gazette of Montenegro " 49/08 and 20/11) regulates the acquisition, possession, carrying, manufacture, trade and transport of weapons and ammunition, as well as the manner of handling weapons, seizure of weapons and ammunition, as well as bringing in and out across the state border. The provisions of the law apply to foreigners, and do not apply to weapons and ammunition for the needs of the army, police and other state administration authorities which acquire and keep weapons in accordance with special regulations or to museum artefacts. The Ministry of the Interior, which includes the Police Directorate, is in charge of the implementation of the law.

Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods ("Official Gazette of Montenegro", 80/08) stipulates that foreign trade in controlled goods (arms, military equipment and non-military lethal goods) may be conducted by all entities (legal and natural persons)

registered in the Register of persons licenced to conduct foreign trade in controlled goods. The Register is kept by the competent ministry - the Ministry of Economy. All persons registered to conduct the aforementioned activities may apply for issuance of licence for conducting foreign trade in controlled goods, in accordance with the law.

Decision on Establishing the National Control List of Weapons and Military Equipment (Official Gazette of Montenegro 43/13) is fully harmonised with the Common Military List of European union. Article 11 of the Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods (Official Gazette of Montenegro 80/08) specifies the conditions whose fulfilment is necessary to become eligible for entering in the Register of persons licensed to conduct foreign trade in controlled goods. The application for issuance of licence may be submitted only after registration.

Control List for Export and Import of Goods ("Official Gazette of Montenegro", No. 25/13) stipulates that the licence for foreign trade in antiques whose age exceeds 75 years shall be issued by the competent ministry - the Ministry of Culture of Montenegro.

Weapons are divided into categories **A, B, C and D**:

- Category A includes weapons whose acquisition, possession and carrying is prohibited (military projectiles with explosive charges, launchers and missiles; automatic; firearms disguised as other objects; ammunition with penetrating, explosive or incendiary projectiles, and the projectiles for such ammunition; pistol and revolver ammunition with expanding projectiles; military weapons; explosive weapons and parts; semi-automatic for civilian use...);
- Category B includes weapons whose acquisition, possession and carrying is prohibited without a document on the weapons(semi-automatic or repeating short firearms; single-shot short firearms with centre-fire and rim-fire percussion; hunting and shooting semi-automatic long firearms whose magazine and chamber can together hold more than three rounds; semi-automatic long firearms whose magazine and chamber cannot together hold more than three rounds; repeating and semi-automatic long firearms with smooth-bore barrels; single-shot long firearms with one or more rifled or smooth-bore barrels; antique and air weapons with power greater than or equal to 7.5J.);
- Category C includes weapons whose possession and carrying is prohibited without notification to the Ministry of the Interior (gas weapons; reproduction firearm where a single cartridge is not used, electric stun gun and mortar);
- Category D includes weapons which can be acquired, possessed and carried only by natural person soldier than 18years of age, and exceptionally, atomisers may be possessed and carried by person soldier than16 years of age (air weapons with power up to 7.5 J; archery weapons; atomiser; cold weapons).

Weapon licence shall be issued to a natural person for weapons that have been acquired on the basis of the approval (for keeping weapons-for personal safety and the owner of trophy weapons; for keeping and carrying-for practicing target shooting and hunting), and approval for keeping weapons to a company and an entrepreneur, with a validity period of five years, except for trophy weapons, which shall be issued for an unlimited period of time. Weapon licence shall not be issued for weapons for which the origin cannot be determined; which are not marked by a mark or serial number prior to being traded; which are imported or transferred from abroad, if customs

duties have not been paid; as well as in cases where the reasons for refusal are determined in the registration procedure. Authorised firearms dealer shall be obliged to notify the Ministry of the Interior about the sale of firearms within eight days from the date of sale.

Approval for collecting antique weapons shall be issued with permanent validity period to a natural person who meets the statutory requirements and who has a space for secure storing. It may also be issued to museums, which may be issued approval for collecting prohibited weapons (category A), which are not manufactured and which are not used by the army and police, regarding which the Ministry of Culture shall be notified. Legal persons engaged in filming or presenting theatrical performances may acquire, keep and carry cold weapons and weapons under categories A, B and C which are altered to fire dummy ammunition, solely for that purpose.

Weapons and ammunition seized in the final completed criminal, offence or administrative proceedings, shall become the property of the state and shall be submitted to the Ministry of the Interior for its disposal.

Repair and alternation of weapons and trade in weapons may be performed by legal persons and entrepreneurs which obtain approval for conducting such activity from the Ministry of the Interior (checks shall be performed for responsible and other persons, as well as whether the facility meets the safety and technical requirements). One manufacturer has been engaged in manufacture of weapons in Montenegro since 2012. There is a label on individual packages of weapons, which contains information on the weapons: brand, model, country of manufacture, calibre, and there are same information plus the quantity on the parcels. Labelling of weapons is carried out by the authorised person from abroad. The following information shall be imprinted on the weapons: model, brand and country of manufacture; on the pistol grip, rifle chest and on the hunting rifle head, and calibre and serial number on the barrel and the cap. Manufactured weapons shall be subject to examination-check of compliance of weapons with the technical requirements and standards and the authorised person from abroad shall affix the mark. About 200 pieces of weapon shave been sold.

In accordance with Article 6 of the Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods (“Official Gazette of Montenegro” 80/08), the Decision on Establishing the List of Non-Military Lethal Goods (“Official Gazette of Montenegro” 66/10) – weapons, ammunition, and energy material - has been adopted and in MN opinion harmonised with the EU Regulation (EU) No 258/2012. Foreign trade in the afore mentioned goods may be conducted by all persons (natural and legal) previously registered in the Register kept by the competent authority - the Ministry of Economy of Montenegro. All persons registered to conduct the afore mentioned activities may apply for issuance of licence for conducting foreign trade in afore mentioned goods, in accordance with the law.

The Ministry of the Interior has staff to implement the new regulations, who will be further educated, for which special funds are not needed.

5.4 Quantitative restrictions

In this part additional explanations to general principles (Art. 34-36 TFEU) are given. The issues will be analyzed in the frame of the Action plan for non-harmonized area.

Article 6 of the Law on Foreign Trade (Official Gazette of Montenegro 28/04, 37/07) prescribes that, by specific decision, Government shall establish, update and publish Control List for Export and Import which contains information on goods whose export or import is limited. In this view, Control List for Export and Import of Goods (Official Gazette of Montenegro 25/13) has been enacted and it sets out that foreign trade circulation is limited and realised with permission issued by competent authority, in accordance with Law.

Control List for Export, Import and Transit of Goods prescribes regime of permits (for import, export, transit) for all goods listed in 6 Annexes within the Control List. Goods listed in these Annexes do not refer to weapons, military equipment and dual purpose goods (with the exception of goods from Title 31 where fungous ammonium- nitrate for explosives is listed). Thus:

1. Pursuant to Law on Foreign Trade (Official Gazette of Montenegro 28/04, 37/07) Control List for Export and Import of Goods (Official Gazette of Montenegro 25/13) has been adopted and it contains all limitations for goods (with the exception of weapons, military equipment and dual-use goods).

2. Pursuant to the Law on Foreign Trade in Weapons, Military Equipment and Dual-Use Goods (Official Gazette of Montenegro 80/08) and Law on Control of Export of Dual-use Goods (Official Gazette of Montenegro 30/12) three control lists including weapons only have been adopted:

- a. Decision on determining national control list of weapons and military equipment (Official Gazette of Montenegro 43/13),
- b. Decision on determining national control list of dual-use goods (Official Gazette of Montenegro 37/13)
- c. Decision on determining list of non-military ordnance (Official Gazette of Montenegro 66/10).

Regarding food, Veterinary, sanitary and phytosanitary policies contained in the laws, decrees and administrative provisions, adopted at national level do not include measures which allow only traders who obtain license for production, or license for wholesale to conduct import of certain goods.

5.5. Cultural goods

Legal framework

Legal framework for the implementation of the Directive 93/7/EEC in Montenegro is:

1. Law on Cultural Property (Official Gazette of Montenegro 49/10, 2011), section IV. System of protection of cultural property - Return of a cultural property to EU Member State, articles 63-69;
2. Rulebook on the collections of objects which can be considered as national treasure of the EU Member States (Official Gazette of Montenegro, 48/13, 2013).

Law on Cultural Property, in the articles 63 to 69 regulates the questions of: Return of a cultural property to EU Member State; Procedure to return a cultural property; Court proceedings; Cooperation with Member states; Return of a cultural property illicitly taken out from the territory of the state, a non-EU member; Return of cultural property illicitly taken from the territory of Montenegro; Activities on return of cultural property.

Rulebook on the collections of objects which can be considered as national treasure of the EU Member States regulates the list of cultural objects that can be the subject of the above mentioned articles of Law.

In MN opinion above mentioned legislation is fully align with relevant EU legislation in this area.

Institutional framework

The competent authorities for the implementation of provisions regarding the return of cultural objects unlawfully removed from the territory of a Member State are Ministry of Culture and the Directorate for the Protection of Cultural Property, which is organized within the Ministry, as well as the competent courts before which Member State files a complaint.

Ministry is obligated to coordinate cooperation with competent bodies of Member States with regard to the return of cultural property illicitly taken away.

Inspection supervision of application of Cultural Property Act is carried out by the Ministry of Culture and the Directorate for the Protection of Cultural Property, through an inspector for cultural heritage and inspector for cultural property.

The Ministry is carrying out inspection supervision with regard to the implementation of provisions of the Cultural Property Act referring to the establishment of protection of cultural property and keeping a Register.

Directorate for the Protection of Cultural Property is carrying out inspection supervision with regard to the condition of cultural property, protection system and measures and rights and obligations of owners and holders of cultural property.

Administrative capacity

Some jobs that involve employees of the Ministry of Culture and the Directorate for the Protection of Cultural Property in its scope imply the implementation of the provisions of Article 63 to 69 of the Act.

Recruitment of one new employee that will be responsible for implementation of this directive is planned for 2015. Total costs for the implementation of the directive are **EUR 45,000 for the period 2014-2018.**

During the accession negotiations, Montenegro will continuously pay special attention to the implementation of measures related to the free movement of goods. For the implementation of activities presented in the Strategy and according to the defined dynamic in the Action plan, necessary capacity will be provided.

Additionally, this Strategy involves prioritization of needs of the economy of Montenegro; not only in production terms, but also in creating conditions for investment and economic growth in industrial areas. In terms of the previously mentioned and in light of the fact that Montenegro is a small market, through the free movement of goods Montenegro aims to expand the target market and to enter the EU internal market.