

**Government of Montenegro**

**Ministry of Economy**

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

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## 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.<sup>1</sup>

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<sup>1</sup>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.

## I INTRODUCTION

Due to the fact that Strategy with Indicative five year AP was adopted for the purposes of fulfillment of obligations planned for period 2014-2018, this revised document contains all information's regarding harmonization of legislation, implementation and goals achieved during 2014 and 2015. Revised Strategy also represent the adaptation of dynamics for adoption of legislation for the period of 2016 - 2018 in order to plan the execution of obligations that are not filled in the previous period and the planned additional obligations arising changing the EU acquis.

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 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 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 Chapter1-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 Chapter1-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 stake holders 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 Chapter1-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.

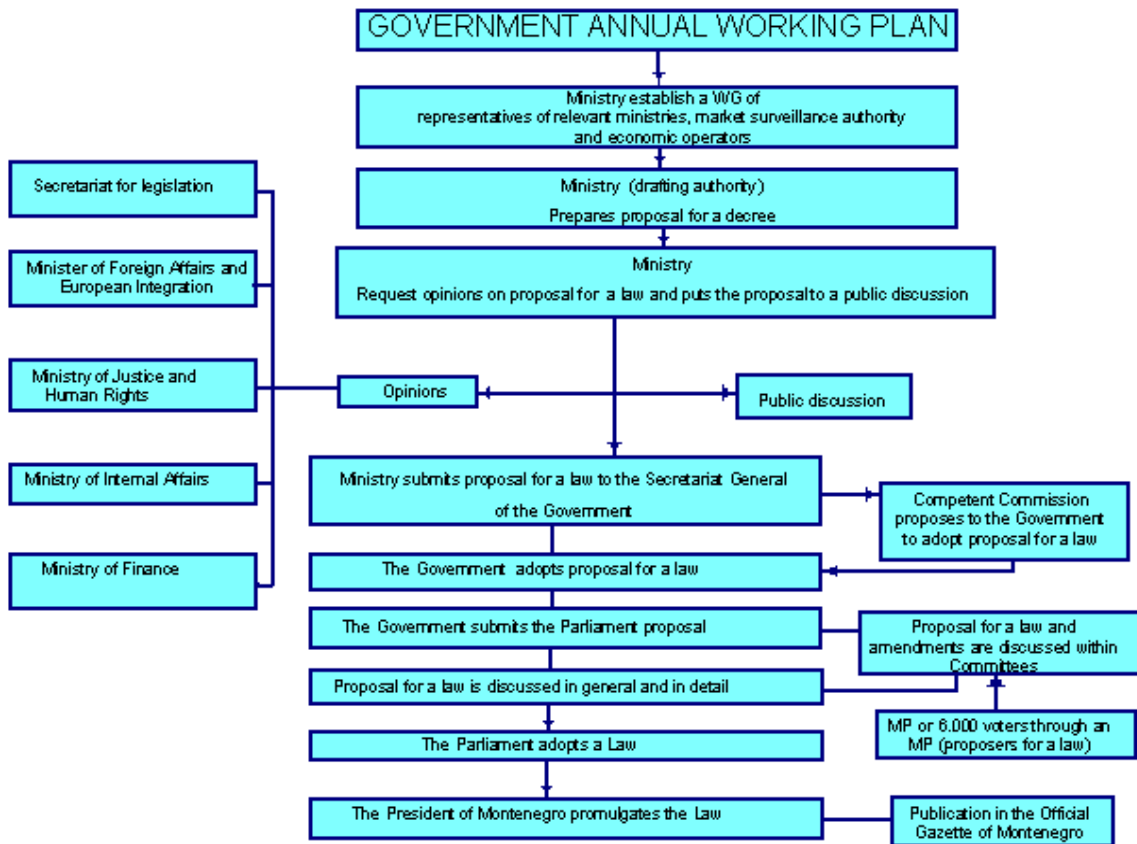
### **Overview of the procedure for the alignment of the Montenegrin legislation with the EU acquis**

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.

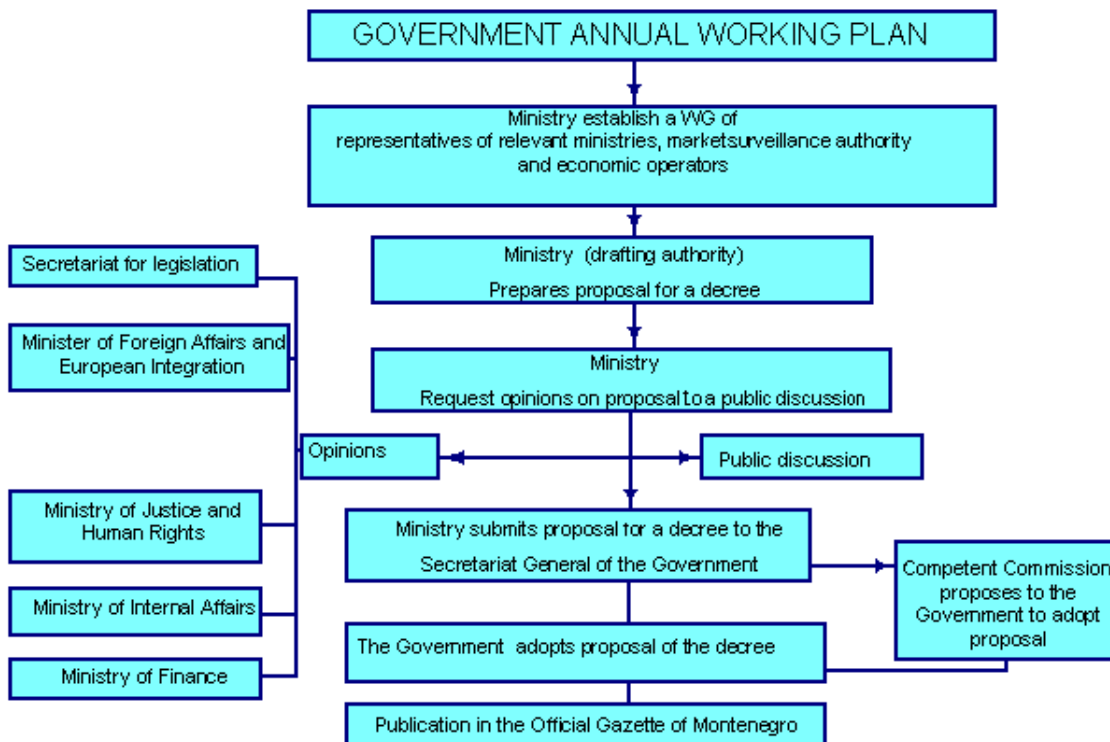
The process of the alignment of the legislation in Montenegro and duration of that process depends on whether the legislation adopted by the Parliament of Montenegro, Government of Montenegro or ministries. In other words, the Parliament is responsible for adoption of laws. The Government adopts proposals 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.

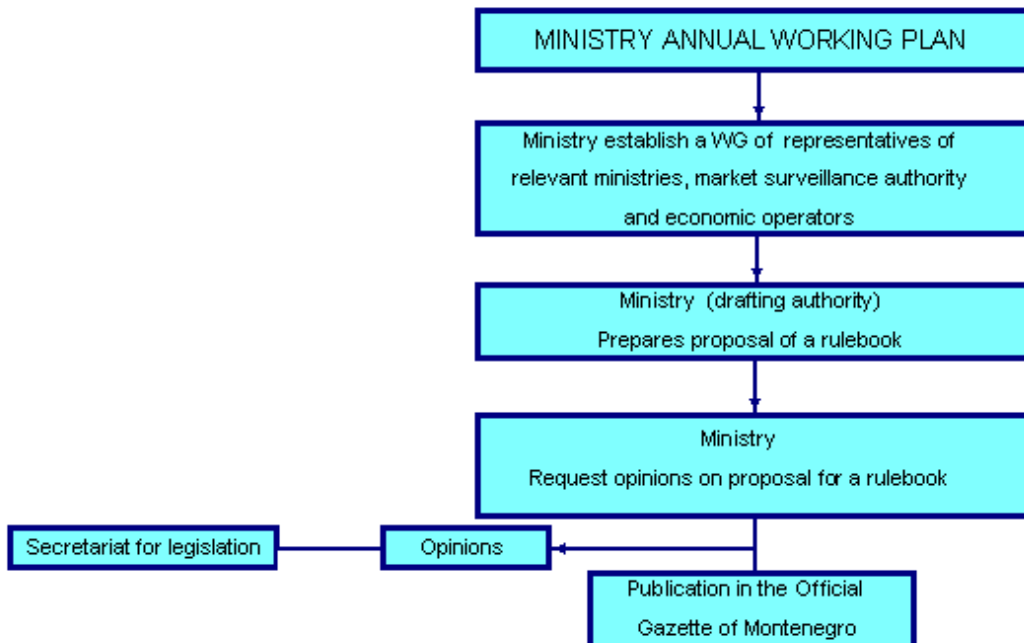
**Chart 1: Procedure for the adoption of laws**



**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 and by-laws designed to align MN legislation at the draft stage (convergence tables) to the Commission, before the adoption of the "final" piece of legislation.

## **II GENERAL PRINCIPLES**

### **2.1 Content of general principles**

#### **Action Plan for compliance with Articles 34 – 36 of the Treaty on the Functioning of the European Union**

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 has analysed 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.

On the basis of the above mentioned analysis, the Action Plan for Compliance with Articles 34 – 36 of the Treaty on the Functioning of the European Union (hereinafter referred to as: the “AP 34-36”) has been drawn up and approved by the Commission. Following the approval given by the European Commission, the Government of Montenegro adopted the AP 34-36 on 17 December 2015. The AP 34-36 contains three annexes.

Annex 1.

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

The national non-harmonized technical regulations 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. For this reason, non-harmonized technical regulations, 212 in total, are listed in the Annex 1.

Annex 2.

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 applicable Law on Consumer Protection (Official Gazette of Montenegro 26/07) has been analysed, as it contains provisions relating to these issues. It has been assessed in the light of future negotiations with the EU that certain provisions could constitute illegal barriers to trade. Another example of national legislation that has been analysed is Law on Foreign Trade (Official Gazette of Montenegro 28/04, 37/07 and 57/14), which contains provisions on the creation of the “Lists of control of exports and 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.

A system of continuous review of all applicable technical regulations will 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).

It is stipulated by the Action Plan to make annual reports on the fulfilment of activities foreseen by AP 34-36 dynamics, for the Government of Montenegro and the Commission.

## **2.2 Implementation of AP 34-36**

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.

# **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. Following the entry in force of the Law on Market Surveillance of Products, those provisions of the Law referred to market surveillance have been repealed.

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 seven 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. Authorisation is linked to the “old – sectoral” approach which implies that the state provides for general public interest by taking control in certain areas and in connection with certain groups of products. An authorization may be issued to an entity only when the state has no capacity of its own within its administrative bodies, and when not in conflict with sources of EU law transposed into the national legislation. Some specific cases are particularly related to certain products in use. For example, elevators in use in residential and business buildings, where it is essential to ensure the safety of citizens when using elevators. The source of EU law refers to new elevators and implies manufacturers’ responsibility until the first placement on the market, whereas the use itself is not harmonized. The same applies to some vessels under pressure such as “gas cylinders” –there are no manufacturers of this important production Montenegro and almost by rule they are imported second-hand from other markets; others have been in use in Montenegro for too many years and manufacturers’ declarations no longer ensure any kind of safety. Authorizations are also issued for the majority of products produced under the old approach, such as cosmetics, chemicals etc, where the source of EU law does not contain provisions whether it is the question of “self-assessment” or only declaration. For example, the EU regulation related to cosmetics stipulates the obligation of registration of cosmetic products that has to be carried out by a “competent and recognized person”. 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 depending on the level of public interest and the scope and dynamics on internal market.

Designated conformity assessment bodies for manufacturers' needs evaluate whether their product has met the essential requirements of relevant technical regulations. Designation is a manner fully harmonized with the new EU approach, as the first step in the procedure of acquisition of status of notified body. And while manufacturer and notified body are fully free to establish mutual relations, the manufacturer remains fully responsible for the security of product. Since in Montenegro there are a very small number of manufacturers producing according to the new approach, it is not sustainable to create notified bodies because they will not be competitive on the common market after the accession of Montenegro into the EU. As far as designations are concerned, the only body designated in accordance with the Law on Metrology is the Institute of Metrology, which, as the national metrology institute (NMI) according to the principle applied to all members, will automatically become the notified body for measuring instruments on the day of accession to the EU. Based on the aforesaid, the Institute of Metrology is assiduously working on accreditation of its laboratories in order to have evidence of its competences when the accession to the EU takes place. 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 publish 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, 30 bodies (Out of 30 identified conformity assessment bodies 29 of them are already accredited) for conformity assessment in different fields have been identified. They range from testing laboratories, inspection bodies to calibration laboratories.

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 2017 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 Decision768/2008/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 Decision768/2008/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.<sup>2</sup>

Adoption of the new Law on technical requirements for products and conformity assessment is planned for the second quarter of 2017. 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.

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

Adoption of New Law on standardization is planned for the fourth quarter of 2016 in order to align MN legislation with the requirements of Regulation (EU) 1025/2012. The new law will also transpose, in accordance with the regulation, provisions related to notification of standards according to the EU.

## **METROLOGY**

### **Current situation**

In accordance with the **Law on Metrology** (Official Gazette of Montenegro 79/08 and 40/11), 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.

By-laws adopted pursuant to the Law on Metrology, in which particular EU directives in the area of metrology have been transposed are:

- Decree on legal units of measurement (Official Gazette of Montenegro 22/09 and 72/15), which transposes the Directive 80/181/EEC and the Directive 2009/3/EC;
- Rulebook on the pre-packaged products (Official Gazette of Montenegro 56/11), which transposes the Directive 76/211/EEC and the Directive 2007/45/EEC;
- Rulebook on bottles as measuring containers (Official Gazette of Montenegro 56/11), which transposes the Directive 75/107/EEC;
- Rulebook on the requirements relating to devices and systems with a measuring function (Official Gazette of Montenegro 29/13), which transposes the Directive MID2004/22/EC;
- Rulebook on non-automatic weighing instruments (Official Gazette of Montenegro 29/13), which transposes the EU Directive NAWI2009/23/EC.

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

### **Planned activities**

Within the framework of the process of harmonization with the EU, in the forthcoming period (2016 – 2018), the adoption of the Rulebook relating to common provisions for both measuring instruments and methods of metrological control (Directive 2009/34/EC) has been planned, by the fourth quarter of 2018.

## **ACCREDITATION**

The Law on Accreditation (Official Gazette of Montenegro 54/09 and 43/15), in MN opinion, adequately transposes provisions of the Regulation (EC) 765/2008 that are related to accreditation and it is in line with Article 77 of the Stabilisation and Association Agreement.

## **MARKET SURVEILLANCE**

### **Current situation**

Legal framework in the area of market surveillance is:

- Law on Market Surveillance of Products (Official Gazette of Montenegro 33/14). This Law has been complemented with the following subordinate legal documents:
  - Decree on groups of products subject to market surveillance by inspection bodies (Official Gazette of Montenegro 20/15)
  - Decision on Establishment of Coordination Body for Market Surveillance (Official Gazette of Montenegro 32/15)
  
- Law on General Product Safety (Official Gazette of Montenegro 45/14) which transposes the 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. This Law has been complemented with the following subordinate legal documents:
  - Rulebook on the list of standards in the area of general safety of products (Official Gazette 32/15)
  - Rulebook on the content of notifications on dangerous products (Official Gazette 32/15)
  - Decree on the manner of exchange of information on products posing risks (Official Gazette of Montenegro 57/15). Guidelines for forms for notification on products posing risks (Official Gazette of Montenegro 60/2010) is also in use.
- Law on technical requirements for products and conformity assessment (Official Gazette of Montenegro 53/11 and 33/14)
- Law on inspection control (Official Gazette of Montenegro 57/11, 18/14 and 11/15)

### **Planned activities**

European Commission has expressed its opinion that it is necessary to make minor amendments and supplements to the Law on General Product Safety, for the purpose of its full harmonization with the Directive 2001/95/EC on general product safety and the 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. In that respect, Montenegro plans to proceed with drawing up of respective amendments and supplements in the third quarter of 2016.

It is also planned to adopt the following subordinate legal documents to the above mentioned Law:

- Guidelines for formats for notification on products posing risks IQ/2017
- Decree on amendments and supplements to the decree on the manner of exchange of information on products posing risks IQ/2017

MN plans to draw up amendments and supplements to the Law on Market Surveillance of Products in the second quarter of 2018, when a possible harmonization with revised EU legislation in this field is also expected.

## **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 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.

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, two 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 2016.

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 2016 three new officials will be employed in order to increase the administrative capacity. By the end of 2018 it is foreseen that 7 employees are going to work in this Department.

In 2015 the Department has received software dedicated to implementation of obligations envisaged by WTO/TBT Agreement and obligations in accordance with the EU legislation. The software consists 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 7 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 gives 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 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

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 seven 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 tasks which refer to cooperation of administration bodies the Working Group provides 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
<b>DQI - The number of the newly employed in individual year</b>	-	-	3	1	1
<b>realisation</b>	/	/	3	1	1
<b>Total number of the newly employed in relation to 2013</b>	-	-	3	4	5
<b>Total number of the employed</b>	3	2	5	6	7

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

Year	2014	2015	2016	2017	2018
<b>State budget in EUR</b>	67.500,00	67.500,00	78.750,00	90.000,00	101.250,00
<b>Realisation:</b>	67.500,00	33.750,00	22.500,00	67.500,00	78.750,00
<b>Donations and income from activities/industries in EUR</b>	21.600,00	21.600,00	28.800,00	36.000,00	43.200,00
<b>Realisation</b>	21.600,00	21.600,00	/	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).
- ETSI – ISME became the national body for standards in ETSI member countries (December 2014)

By 15 April 2016 ISME adopted 14.529 Montenegrin standards (MEST) and related documents. Of that number, 2.993 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](http://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
16. ISME/TK 016: Language codification.

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 international 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.

ISME plans to submit the application for full membership in CEN/CENELEC in the course of time period 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. It is expected that this project will be implemented in the forthcoming period.

Projection of administrative capacities is given in the table below:

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>The number of the newly employed in individual year</b>	0	7	1	4	5
<b>realisation</b>	/	/	1	/	/
<b>Total number of the newly employed in relation to 2013</b>	0	0	1	5	10

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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget</b>	600.000	650.000	282.456,52	600.000	650.000
<b>Realisation</b>	282,456,52	282,456,52	282,456,52	/	/
<b>Income from performed activities in EUR</b>	9.000	15.000	10.000	12.000	12.000
<b>Donations from other sources (IPA, TAIEX and etc.) in EUR</b>	/	/	7.000	10.000	12.000

In order to fulfil strategic requirements (membership, development etc.) of standardization in Montenegro, a special Strategy for the Development of Standardization in Montenegro has been adopted. The concerned document defines 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.

At the moment, in Montenegro there are no manufacturers of measuring instruments.

In the Bureau of Metrology, within the Division of metrological traceability and state standards, the following national calibration laboratories have been established and accredited by the Croatian Accreditation Agency (HAA) and the Accreditation Body of Montenegro (ATCG), according to the standard MEST ISO/IEC 17025:

- mass laboratory;
- temperature laboratory;
- length laboratory;
- pressure laboratory;
- time and frequency laboratory;
- electrical quantities laboratory;
- laboratory for small volumes (following the assessment visit, finalization of accreditation procedure is under way)
- laboratory for big volumes (following the assessment visit, finalization of accreditation procedure is under way).

Temperature laboratory and laboratory for big volumes have published CMC (*Calibration and Measurement Capabilities*) in BPIM CMC Data Base.

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.

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, or Montenegro as the state, plans to 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, and bearing in mind that the Bureau has ensured the capacities and methods of verification of particular types of meters, extension or improvement of conditions for verification of the following types of meters 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, provides a total of 52 employees, and currently 39 persons are employed in the Bureau. By the end of 2018, recruitment of the new employees is planned, with the dynamics depending on financial possibilities and circumstances, as shown in the following table: Projection of administrative capacities is given in the table below:

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>The planned number of newly employed in individual year</b>	Previously planned 7	Previously planned 7	Previously planned 6  New planned 7	Previously planned 6  New planned 12	Previously planned 6  New planned 9
<b>The number of newly employed in individual year</b>	2	4	Realized 3  To be done 4		
<b>Total number of newly employed in relation to 2013</b>	Previously planned 7  Realized 2	Previously planned 14  Realized 6	New planned 13  Realized, so far 9	New planned 25	New planned 34

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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget</b>	733.907,09	793.298,00	898.034,51	1.270.500,00	1.397.800,00
<b>Income from performed activities in EUR<sup>3</sup></b>	385.015,26	1.044.235,02 (due to a massively verification of electricity meters)	500.000,00 (depending from verification of electricity meters)	500.000,00 (depending from verification of electricity meters)	500.000,00 (depending from verification of electricity meters)
<b>Donations from other sources (IPA, TAIEX itd.) u EUR</b>	Approx. 100.000,00	Approx. 10.000,00	839.000,00	815.000,00	550.000,00

In December 2015 the Strategy for the improvement of metrology in Montenegro for the period 2016 – 2018 was adopted. It encompasses in more details in all aspects, with the objectives necessary for the development and improvement of metrology in Montenegro by 2018.

#### ***3.2.4 Accreditation Body of Montenegro (ATCG)***

**The Law on Accreditation** (“Official Gazette of Montenegro” No.54/09 and No.43/15) regulates the establishment and operation of ATCG, the rules and procedure of accreditation and other issues relevant to accreditation. By-law of the Law on Accreditation, the Decision on the Establishment of the Accreditation Body of Montenegro (“Official Gazette of the Republic of Montenegro” No.21/07) regulates in more details the activity, organization and operation of ATCG.

In accordance with provisions of the Regulation (EC) 765/2008, ATCG was established by the Government of Montenegro as the only recognized 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 independent, 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. All general acts that regulate operation of ATCG, annual Work Programmes, annual Reports on Operations, the Register of Accredited Bodies with their scope of accreditation and other relevant information are made available to the public in an appropriate manner (on website).

ATCG conducts its activity in accordance with the Law, the Decision on the Establishment, the Statute of the Accreditation Body of Montenegro and its internal rules and procedures (12 internal rules and 7 procedures) that are harmonized with the rules and procedures of the

<sup>3</sup> 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.

European and international organizations for accreditation (EA, ILAC and IAF). Furthermore, ATCG is organized and it operates in line with the requirements of the standard EN ISO/IEC 17011:2010 - Conformity Assessment - General Requirements for Accreditation Bodies which accredits conformity assessment bodies.

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 bilateral cooperation with accreditation bodies in the region with which it has signed bilateral agreements on business and technical cooperation.

Currently, the national system of accreditation involves a total of twenty-nine (29) conformity assessment bodies accredited by ATCG, of which twenty (20) are laboratories for testing, two (2) are laboratories for calibration, five (5) inspection bodies, one (1) certification body for products certification and one (1) certification body for management system 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 current Rulebook on internal organization and job systematization in ATCG there are ten job positions. At the moment, there are eight permanently employed employees.

ATCG Registry of Evaluators currently includes nine lead assessors, 17 technical assessors and 18 technical experts. Tendency in the forthcoming period is to increase the number of internal and external evaluators, which will depend on further development of already established accreditation schemes as well as on the interest of interested parties in the development of new ones. Moreover, 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 in ATCG organization and operation, strengthen the administrative and technical capacities of ATCG (including the engagement of two newly recruited workers), ensure stable financial 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 in the forthcoming period is signing of Multi-lateral-agreement between ATCG and the European Cooperation for Accreditation (EA), so-called EA MLA Agreement. According to the plan, ATCG will submit a formal application for becoming EA MLA Signatory to EA by the end of 2016. After becoming EA MLA Signatory, ATCG will apply for similar status within the international accreditation organizations ILAC/IAF, (ILAC/IAF MRA Agreements). The signature of these agreements will ensure, among other things, the recognition of the national accreditation system by other signatories of

the Agreement, and at the same time the recognition of reports/certificates issued by accredited Montenegrin conformity assessment bodies on the European and global markets.

Projection of administrative capacities is given in the table below:

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>The number of the newly employed in individual years</b>	-	1 (planned) 0 (realized)	1 (planned) 0 (realized)	1	1
<b>Total number of the newly employed in relation to 2013</b>	-	-	-	1	2

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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget</b>	173.623	406.000 (planned) 173.624 (realized)	409.000 (planned) 213,624 (realized)	422,000	435,000
<b>Income from performed activities in EUR</b>	20.000	26.000	30.000	35.000	40.000
<b>Donations from other sources (IPA, TAIEX and etc.) in EUR</b>	-	-	100,000	10,000	100,000

In order to define more precisely the above mentioned strategic goals, to systematize them in the form of specific activities to be performed within the prescribed time frames, the special Strategy for Accreditation Development in Montenegro has been adopted at the session of the Government of Montenegro of 20 November 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) 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 Free movement 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. Total renting cost per annum for offices renting of before mentioned 3 institutions 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 with approximately 3.500 m<sup>2</sup>, is estimated to be around EUR 3.15 million. The construction was planned for the period 2015-2017. Montenegro applied for the financial support for this investment in IPA 2014 planning process, but it was requested by the Delegation to the EU in Montenegro to provide cofinancing (financing of the first stage of the project) from the state budget. This was not possible to assure in the budget 2015 and 2016, as the priority of the state capital budget is construction of high-way in Montenegro, and beginning of new capital projects has dominantly been postponed. In the same time, we gave up to apply for this financing from IPA 2014.

Accordingly, we have postponed investments in this working premise to be planned in capital budget 2018 and we would apply for the support of this investment from IPA under „Competitiveness and Innovation“ sector in the next planning period.

Construction of the facility would bring much more benefits to the state budget compared to the construction costs. 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.

The Administration for Inspection Affairs (hereinafter referred to as „the Administration“) is one of the key institutions in the implementation of legal regulations in the field of market surveillance. Namely, its purpose is to achieve efficiency in performing inspection control and market organization through an integrated inspection control. The Administration counts 30 inspections, formerly parts of different ministries and other state administration bodies. Thirteen of them are in charge of market surveillance: Market Inspection, Healthcare and Sanitary Inspection, Inspection of Electronic Communications and Postal Activity, Metrology Inspection, Phytosanitary Inspection, Veterinary Inspection, Labour Inspection (occupational health and safety), Construction Inspection, Electro-energetic Inspection, Thermo-energetic Inspection,

Mining Inspection, Environmental Inspection and Housing Inspection. It should be emphasized that all these inspections, beside market surveillance duties, are also responsible for other administrative areas.

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 for Inspection Surveillance in the area of explosives for civil use and pyrotechnics is organised within the Ministry of the Interior and it employs 7 inspectors. Furthermore, Customs Administration is the key co-operator of market surveillance bodies in the implementation of their activities and the Ministry of Economy, as well as the institutions for quality infrastructure that provide support to market surveillance.

Due to the number of bodies engaged in market surveillance, special attention is paid to coordination through Market Surveillance Coordination Body, originally established by the Government of Montenegro in 2010. The main task of this body was 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**

On the basis of the Law on Market Surveillance of Products, the Government of Montenegro formed the new Market Surveillance Coordination Body (Decision on Establishment of Market Surveillance Coordination Body, Official Gazette of Montenegro 32/15), composed of the representatives of the Administration for Inspection Affairs (4), Ministry of Interior (1), Ministry of Transport and Maritime Affairs (1), Customs Administration (1) and Ministry of Economy (1). In 2015, the Market Surveillance Coordination Body held three sessions and one working meeting. A coordinated monitoring of market surveillance of products is planned on a yearly level (General Market Surveillance Program, as well as the monitoring of its implementation, and the operation of the Rapid Alert System for exchange of information on dangerous products, harmonization of national legislation with EU regulations in the area of safety of products and market surveillance, enforcement of competencies of inspections in the implementation of surveillance of products, etc. The Coordination Body submits annual reports on its work to the Government of Montenegro.

Since the adoption of the first General market surveillance program (annual) in 2012, adoption of annual programs has been done on a regular basis, and the General market surveillance program for 2016 was adopted on the basis of the Law on Market Surveillance of Products. The Coordination Body prepares annual reports on the implementation of annual programs on the basis of sectoral reports.

Through the Rapid Alert System for exchange of information on dangerous products, the contact point of which is the Market Inspection (Administration for Inspection Affairs), the exchange of

information on dangerous products is carried out at the national level, more specifically the information from RAPEX system, from the Regional network for exchange of information on dangerous products, as well as the information related to market surveillance, from customs bodies and other sources. This system represents a logical relation between the part related to the Chapter 28 “Consumer and Health Protection” and the Chapter 1 “Free movement of goods”. The Administration for Inspection Affairs submits annual reports on the work of this system to the Government of Montenegro.

Regional network for the exchange of information on dangerous products was established in mid-2013, and it is composed of the representatives of Montenegro, Bosnia and Herzegovina, Serbia, Macedonia, Kosovo and Albania. Beside information on dangerous products found on markets of the countries in the region, check lists for products are also exchanged through this network,. The contact point of the network in Montenegro is the Administration for Inspection Affairs, through the Market Inspection.

### **The New Market Surveillance Strategy**

Taking in consideration the level of development of market surveillance in Montenegro compared to the situation in this field in the period when the existing Market Surveillance Strategy was adopted (2009), as well as new challenges emerging on that path, from the aspect of the need to monitor the development of this field at the level of the European Union, it is necessary to adopt the new Strategy. The new Strategy will be drawn up with support of IPA Project and it will be focused on identification of new elements necessary for further development of market surveillance in accordance with national needs, as well as with standards and the best practices of EU, and it will be related to the period 2018 – 2020.

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

Customs Administration is an active member of Market Surveillance Coordination Body and Rapid Alert System for exchange of information on dangerous products. With the aim of further strengthening of market surveillance bodies and Customs, the earlier Memorandum of Cooperation between the Market Inspection and Customs Administration has been replaced by the new Memorandum on Cooperation between the Administration of Inspection Affairs and Customs Administration, in order to include all inspections within the Administration, responsible for market surveillance.

The Catalogue of measures for cooperation and implementation of joint activities of the abovementioned bodies is an integral part of the new Memorandum. In order to improve the exchange of information on dangerous products and to achieve a more efficient surveillance, the Administration for Inspection Affairs (Market Inspection, as a contact point in the Rapid Alert System for exchange of information on dangerous products) regularly submits to the Customs Administration abbreviated check lists for products included in the General Market surveillance program, on the basis of the signed Memorandum, this inspection uses one part of the database of Customs Administration IT system, necessary for the implementation of market surveillance of products.

### **Resource Development 2014-2018**



The Administration for Inspection Affairs, as one of the key institutions in the implementation of legal regulations in the field of market surveillance, has carried out an analysis, in cooperation with the Ministry of Foreign Affairs and European Integration and competent ministries, of needs for reinforcement of administrative capacities, based on which it has been recommended, for the purpose of furthering market surveillance, in accordance with harmonized legal regulations, to increase the number of inspectors. Namely, on the basis of the impact of market surveillance measures on implementation of vertical legislation, it has been established that the number of inspectors in competent inspections within the Administration amounts to 34 for the period 2016 – 2018.

Groups of products subject to market surveillance, pursuant to the Law on Market Surveillance of Products, are established by the above mentioned Decree on Groups of Products Subject to Market Surveillance by Inspection Bodies, which also identifies which inspections carry out market surveillance.

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, and the financing sources are provided from the national budget, supporting projects, TAIEX and other sources of support. Inspectors in charge of particular directives, beside the monitoring of implementation of directives in the Montenegrin legislation, will prepare workshops on directives, or national technical regulations in which they are transposed for inspectors in charge of respective field, including proposals for check lists for products. This is the way to ensure the transfer of knowledge from inspectors – coaches to other inspectors. Special attention in education of inspectors will be focused on risk assessment methods, whereas within IPA Project, the acquisition of non-laboratory equipment for tests is planned, in order to enable inspectors, beside the procedure of administrative check, to carry out detailed physical tests of products. It is also planned to carry out further training of members of Rapid Alert System for exchange of information on dangerous products in order to ensure its full operability, which will require the earmarking of funds for further development of the Administration for Inspection Affairs IT system.

AIA administrative capacities projections:

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>The number of the newly employed in individual years</b>	8	7	6	9	10
<b>Realisation</b>	2	11	2		
<b>Total number of the newly employed in relation to 2013</b>	2	13	15	24	34

Indicative allocation of funds (in EUR) for the Administration for Inspection Affairs

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget</b>	720.000,78	798.750,00	866.250,00	967.500,00	1.080.000,00
<b>Realisation</b>	720.000,78	798.750,00	866.250,00		
<b>Donations</b>			1,250 000	1,000 000	500.000,00

<b>from other sources (IPA, TAIEX and etc.) in EUR</b> <b>Income from performed activities in EUR</b>					
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## 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 channelled 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 are 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. Considering that the Directive 206/95/EC has been superseded by the Directive 2014/35/EU, the system will be harmonized with new requirements by the end of the second quarter of 2017.

#### **Legal framework**

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment in this field 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 and 50/14).

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

Full alignment with the new Directive 2014/35/EU is planned for the second quarter 2017.

#### **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 Market Surveillance of Products, 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.

#### **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 is given below:

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

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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget for employees (in EUR)</b>	22500	22500	33750	33750	33750
<b>Donations and income from activities/industries in EUR</b>	11250	22500	/	/	/

By hiring new employee in 2016, costs increase by 11.250,00 EUR per year.

#### *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. Considering that the Directive 95/16/EC has been superseded by the Directive 2014/33/EU, the system will be harmonized with new requirements by the end of the second quarter of 2017.

##### **Legal framework**

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products and equipment in this field with respect of 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 lifts (Official Gazette of Montenegro 2/14 and 27/14)

Rulebook entered into force on 22 January 2014 whereas its implementation began on 1 January 2015. The Rulebook is in MN opinion fully aligned with the requirements of Directive 95/16/EC<sup>4</sup>.

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 of 2017.

### **Institutional framework**

The competent authority for the security of lifts 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 Market Surveillance of Products, 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 are 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. The new Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility, was published on 29 March 2014.

### **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:

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

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<sup>4</sup> Rulebook covers only new lifts. The existing lifts will be covered by separate national legal act.

2. Law on Electronic Communications (Official Gazette of Montenegro 40/13);
3. Rulebook on electromagnetic compatibility (Official Gazette of Montenegro 32/12 and 50/14).

Rulebook entered into force on 29 June 2012 whereas its implementation began on 1 January 2013. Amendments and supplements to the Rulebook were adopted in 2014 and entered in force on 1 January 2015.

The Rulebook is partially harmonised with Directive 2004/108/EC.

Full alignment with the new Directive 2014/30/EU is planned for second quarter of 2017.

### **Institutional framework**

The competent authority for electromagnetic compatibility is the Ministry of Economy, Energy Directorate.

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

### **Conformity assessment**

There are currently no conformity assessment bodies in this field. 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 Market Surveillance of Products, 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. The new Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of simple pressure vessels was published on 29 March 2014.

### **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

Full alignment with the new Directive 2014/29/EU is planned for second quarter of 2017.

### **Institutional framework**

The competent authority for simple pressure vessels is the Ministry of Economy, Energy Directorate.

Publishing of list of standards that represent 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 Market Surveillance of Products, 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. The new Directive 2014/68/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of pressure equipment, was published on 29 March 2014.

### **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 19<sup>th</sup> April 2014 whereas its application will begin on 1<sup>st</sup> January 2015.

Rulebook is in MN opinion fully aligned with the requirements of Directive 97/23/EC.

Full alignment with the new Directive 2014/68/EU is planned for the second quarter of 2017.

### **Institutional framework**

The competent authority for the area of pressure 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 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 Market Surveillance of Products, 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 Directive 2009/142/EC. The obligations for economic operators are going to be implemented by the importers and distributors. The new Regulations EC 2013/813 and EC 2013/814 regulating the ecodesign requirements for hot air boilers was adopted in 2013 and they supersede the Directive 92/42/EC.

### **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);
2. *Rulebook on Gas-fuelled Appliances* (Official Gazette 10/15)
3. Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (Official Gazette of Montenegro, 41/15);

Rulebook on Gas-fuelled Appliances is in MN opinion aligned with the requirements of Directive 2009/142/EC. In accordance with the separation of energy efficiency and important safety requirements for gas appliances the Regulation (EU) 2016/426 will be taken through the new Ordinance on gas appliances in IVQ 2017.

The Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels entered in force on 1 January 2016.

Montenegro believes that the Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels is fully aligned with the requirements of Directive 92/42/EC. However, as the new sources of EU law (Regulative (EC) 2013/813 & Regulative (EC) 2013/814) supersede the Directive 92/42/EC, and taking in account this new situation, the Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels will be superseded by an eventual new regulation in the area of eco design (see point 4.1.13) harmonized with the new sources of EU law.

### **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 represent 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 conformity assessment bodies.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 75/324/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);
2. Rulebook on Aerosol Dispensers (Official Gazette of Montenegro 10/15)

On the basis of suggestions of EC, the Ministry of Economy will adopt in the third quarter of 2017 amendments and supplements to the Rulebook on Aerosol Dispensers, for harmonization purposes with the requirements of the Directive 75/324/EC.

##### **Institutional framework**

The competent authority for transposition and implementation of Directive 75/324/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 75/324/EC there are no plans for the establishment of MNE conformity assessment bodies in the area.

##### **Market surveillance**

According to the Law on Market Surveillance of Products, 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. The existing directive was supplemented with amendments by means

of the Directive 2009/127/EC and will be transposed in area of motor vehicles (see point 4.2.13.) because this amendments are focus on tractors and agriculture vehicles.

### **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 24<sup>th</sup> May 2014 whereas its application will begin on 1<sup>st</sup> January 2015. Rulebook is in MN opinion fully aligned with the requirements of Directive 2006/42/EC

Alignment with the requirements of Directive 2009/127/EC is planned for the second quarter of 2017 through adoption of a rulebook on amendments and supplements to the Rulebook on Safety of Machinery.

### **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 represent 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 Market Surveillance of Products, 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. This 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 Market Surveillance of Products, 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 employees (in EUR)	/	/	/	/	11.250
Donations and income from activities/industries in EUR	/	/	/	/	7.200

By hiring one new employee in 2018<sup>th</sup>, total costs for the implementation of the directive are **EUR 56,800 for the period 2016-2018.**

#### *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);
2. Rulebook on Personal Protection Equipment (Official Gazette of Montenegro 17/15)

The Rulebook was positively assessed by the Commission and is fully aligned with the Directive 89/686/EC.

##### **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 Market Surveillance of Products, 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 internal market and competition) 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. The new MID Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to making available on the market of measuring instruments, was published on 29 March 2014, and it is supplemented by the Directive 2015/13/EU of 31 October 2014.

### **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 and 40/11);
3. Rulebook on requirements referring to the devices and systems with measuring function (Official Gazette of Montenegro 29/13)

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

Full alignment with the new MID Directive 2014/32/EU and 2015/13/EU is planned by the end of the second quarter of 2017, following the adoption of the new MID Rulebook.

### **Institutional framework**

The competent authority for transposition of EU acquis in this field 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 represent a presumption of conformity is in responsibility of the Ministry.

### **Conformity assessment**

The Bureau of Metrology as the national metrology institution is the body designated in accordance with the law, and it is foreseen that it will become the EU notified body after the accession of Montenegro to the EU.

### **Market surveillance**

According to the Law on Market Surveillance of Products, Law on Inspection Control, Law on metrology, Law on Technical Requirements for Products and Conformity Assessment and the Law on Market Surveillance of Products, 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 the Bureau of Metrology are planned as continuous activity (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. The new Directive 2014/31/EU of the European Parliament and of the Council on the harmonization of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments was published on 29 March 2014.

### **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 and 40/11);

3. Rulebook on non-automatic weighing instruments (Official Gazette of Montenegro 29/13)

Rulebook entered into force 30<sup>th</sup> June 2013. Rulebook is aligned with requirements of Directive 2009/23/EC. A Rulebook which will be aligned with the new Directive is planned for adoption in the second quarter of 2017.

### **Institutional framework**

The competent authority for transposition of EU acquis in this area 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 represent a presumption of conformity is in responsibility of the Ministry.

### **Conformity assessment**

The Bureau of Metrology as the national metrology institution is the body designated in accordance with the law, and it is foreseen that it will become the EU notified body after the accession of Montenegro to the EU.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 the Bureau of Metrology are planned as continuous activity (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 are a small number of manufacturers of equipment covered by the Directive 2009/125/EC and related implementation legal acts. Obligations of manufacturers will be transferred to importers and distributors with respect to conformity certificates and product



marking. Also, an important role will be played by market surveillance competent bodies (state inspections).

### **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 57/14);
2. Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11);
3. Rulebook on ecodesign of energy related products (Official Gazette of Montenegro 9/16)

Rulebook on eco design of energy related products (Official Gazette of Montenegro 9/16) completes the transposition of requirements of the Directive 2009/125/EC into the national legislation.

In the first phase, apart from the framework directive, the adoption of three regulations transposing the requirements of implementation regulations is planned, indicatively:

1. non-directional household lamps
2. fluorescent lamps without integrated ballasts, high-intensity discharge lamps and ballasts and lamps for their operation, and
3. electric motors
4. hot-water boilers - Regulative (EC) 2013/813 and Regulative (EC) 2013/814

Regulations stipulating requirements regarding eco design of products for other groups of products included in implementation regulations will be adopted by the end of the second quarter of 2018.

**The planned two phase timeline for adoption of the above mentioned rulebooks is based on importance of different groups of energy related products 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 Market Surveillance of Products, Law on Inspection Control, the Law on Energy Efficiency and the Law Technical Requirements for Products and Conformity Assessment and 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 2017 as given below.

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

Year	2014	2015	2016	2017	2018
Planned number of the newly employed in individual year	/	1	/	1	/
Realisation	/	/	/	1	1

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

Year	2014	2015	2016	2017	2018
Planned state budget for new employees <sup>[1]</sup> (in EUR)	/	11250	11250	11250	/
Realisation	/	0	0	11250	11250
Planned donations and income from activities/industries in EUR	/	7200	7200	/	/
Realisation	/	0	0	/	/

Expenses for two current employees are EUR 22,500 per year, or EUR 67,500 for the period 2014-2018. By hiring one new employee in 2017, total costs for the implementation of the directive are **EUR 90,000 for the period 2016-2018**.

#### *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.

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<sup>[1]</sup> Note: Expenses for one employee cover gross salary, education, office space and office supplies

### **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);
2. Rulebook on Toys Safety (Official Gazette of Montenegro 4/15).

The Rulebook on Toys Safety of 28 January 2015 was published in the "Official Gazette of Montenegro" no. 4/15, entered in force on 5 February 2015, and it is implemented as of 1 July 2015. The Rulebook with compliance tables was submitted to the Commission which made its suggestions to the text and they will be incorporated into the new Rulebook. Considering that the Rulebook is partially aligned with the Directive 2009/48/EC, full alignment is planned following the adoption of the Rulebook on amendments and supplements to the Rulebook on Toys Safety, planned for the fourth quarter of 2017.

### **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 Market Surveillance of Products, 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 33,750 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, 98/79/EC, 2003/12/EC, 2003/32/EC, 2005/50/EC, 722/2012/EC and 207/2012/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 its 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 Market Surveillance of Products, 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 directive. 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	/	/	62.370,00	62.370,00	62.370,00
Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries + material expenses)	/	/	<b>17040</b> (9540 + 7500)	<b>17040</b> (9540 + 7500)	<b>17040</b> (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 employee 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 products covered by the Directive 2000/9/EC. The obligations for economic operators are going to be implemented by the importers and distributors. The Directive 2000/9/EC was superseded by the Regulation EC 2016/424 in March 2016 with the entry in force on 21 April 2018.

##### **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);
3. Rulebook on requirements for cableways for transport of people (Official Gazette of Montenegro 42/14)

Harmonization with Regulation EC 2016/424 is planned for the first quarter of 2018. By then, the current Rulebook on requirements for cableways for transport of people (Official Gazette of Montenegro 42/14) shall apply.

### **Institutional framework**

The competent authority for transposition and implementation of Regulation 2016/424 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 2016/424, there are no plans for the establishment of MNE conformity assessment bodies in the area.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 Regulation 2016/424. 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.<sup>5</sup> The Directive 2013/53/EU entered in force in 2016 superseding the Directive 94/25/EC.

### **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 and 42/15);
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);

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

Full alignment with the Directive 2013/53/EU will be achieved by the adoption of two Rulebooks based on the Yachts Law and the Law on Safety of Maritime Navigation. The deadline for adoption of these Rulebooks is the fourth quarter of 2016 for the Rulebook on Yachts Certification and the fourth quarter of 2017 for the Rulebook on Boats Certification.

### **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 Market Surveillance of Products, Law on Inspection Control, the Law on Maritime and Inland Navigation and the Decree on Boats, market surveillance is performed by the Maritime Safety Authority of Montenegro.

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<sup>5</sup> 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 aluminium 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;
3. Rulebook on detailed form and content of declaration of performance (Official Gazette of Montenegro 46/14) )- with abovementioned Rulebook the Regulation (EU) 157/2014 is aligned and Regulation EU 305/2011 and Regulation (EU) 574/2014 are partially aligned;
4. Rulebook on labelling of construction products (Official Gazette of Montenegro 46/14) – with abovementioned Rulebook, the Regulation EU 305/2011 is partially aligned.;
5. Rulebook on content of systems of assessment (Official Gazette of Montenegro 46/14)- with abovementioned Rulebook, the Regulation (EU) 568/2014 is aligned, and the Regulation EU 305/2011 is partially aligned.

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~~ four 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 Market Surveillance of Products, 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 the necessary financing (EUR) for newly employees are given in the table below (in EUR):

Year	2014	2015	2016	2017	2018
State budget for new employees <sup>6</sup> (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 employees in 2016 total costs for the implementation of the directive are **EUR 202,500 for the period 2014-2018**.

Construction department made redistribution of jobs in 2015. So, the number of employees who work on harmonization of national legislation with EU legislation in the field of construction-building products, has increased.

#### *4.1.19 Outdoor Equipment Noise Emissions*

### Current situation in sector

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<sup>6</sup> Note: Expenses for one employee cover gross salary, education, office space and office supplies

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**

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 Market Surveillance of Products, 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). Directive 2014/28/EU supersedes the Directive 93/15/EC.

### **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 Materials(Official Gazette of Montenegro, 49/08 and 31/14)
2. Rulebook on technical requirements and procedures for conformity assessment, markings and manner of labelling of explosive materials (Official Gazette of Montenegro 45/15 and 68/15).

Legislation in this field is in MN opinion partially aligned with the requirements of Directive93/15/EU. However, after having received from the EU justified suggestions on the above mentioned legal framework with regard of harmonization of national legislation, it has been established that regulations are not sufficiently aligned and that a new alignment and their replacement has to take place.

Furthermore, the new Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014on the harmonization of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses, entered in force superseding the Directive 93/15/EC. Considering that the new Directive 2014/28/EU replaced the Directive 93/15/EC, new regulations will be adopted by the end of 2018 which supersede the legislative framework for the field of explosives for civil uses and pyrotechnic articles. By then, the existing, partially aligned, legislative framework shall remain in force in order to avoid legal vacuum.

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 of this part of EU acquis is the Ministry of Interior, Directorate for Emergency Situations.

The list of standards that establish a presumption of conformity was published in the Rulebook on technical requirements and procedures for conformity assessment, markings and manner of labelling of explosive substances (Official Gazette of Montenegro 45/15.

### **Conformity assessment**

There are no conformity assessment bodies in this field in Montenegro. As in Montenegro there is a small number of manufacturers of explosive for civil uses, they use services of EU notified bodies.

### **Market surveillance**

According to the Law on Market surveillance of Products, 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 market surveillance of explosives for civil uses 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.

#### **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 EU acquis in the field of explosives for civil uses and pyrotechnic articles. 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. The Directive 2013/29/EU supersedes the Directive 2007/23/EC.

#### **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 Materials (“Official Gazette of Montenegro”, 49/08 and 31/14)
2. Rulebook on pyrotechnic articles safety requirements (Official Gazette of Montenegro 42/15 and 67/15)

Legislation in this area is in MN opinion partially aligned with the requirements of Directive 2007/23/EC. However, after having received from the EU justified suggestions on the above mentioned legal framework with regard of harmonization of national legislation, it has been established that regulations are not sufficiently aligned and that a new alignment and their replacement has to take place.

Considering that the new Directive 2013/29/EU entered in force, new regulations will be adopted by the end of 2018 superseding the legislative framework for the field of explosives for civil uses and pyrotechnic articles. By then, the existing, partially aligned, legislative framework shall remain in force in order to avoid legal vacuum.

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.

Standards establishing a presumption of conformity were published in the Rulebook on Pyrotechnic Articles Safety Requirements (Official Gazette of Montenegro 42/15).

### **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 Market Surveillance, 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 as well as for other areas.

### **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 46/14).

Rulebook on radio equipment and telecommunications terminal equipment entered into force on 8 November 2014 whereas its application began on 1 January 2015. The Rulebook is harmonised with Directive 99/5/EC.

In order to achieve alignment with requirements of Directive 2014/53/EC, adoption of the new Rulebook is planned for the second quarter of 2017.

### **Institutional framework**

The competent authority for transposition and implementation of Directive 2014/53/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 Market Surveillance of Products, 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);
2. Rulebook on marking and labelling of textile products (Official Gazette of Montenegro 48/14)

Rulebook on labelling and marking of textile products entered in force on 1 January 2015 and it was submitted to the Commission. Based on received suggestions, amendments and supplements to the Rulebook will be published, and the deadline is the fourth quarter of 2017.

The Rulebook on marking and labelling of textile products is planned to be fully aligned with the requirements of Regulation (EU) 1007/2011.

##### **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 Market Surveillance of Products, 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);
2. Rulebook on marking of footwear (Official Gazette of Montenegro 48/14).

Rulebook on marking of footwear entered in force on 1 January 2015 and it was submitted to the Commission. Based on received suggestions, amendments and supplements to the Rulebook will be published, and the deadline is the fourth quarter of 2017.

Rulebook on amendments and supplements to the Rulebook on marking of footwear 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 Market Surveillance of Products, 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);
2. Rulebook on technical requirements for crystal glass (Official Gazette of Montenegro 48/14);

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

### **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 Market Surveillance of Products, 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 and 72/15).

Decree on legal units of measurement is aligned with provisions of Directive 80/181/EEC and Directive 2009/3/EC.

##### **Institutional framework**

The competent authority for transposition of Directive 80/181/EEC and Directive 2009/3/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 the regulation, as well as the Administration for Inspection Affairs.

According to the Law on metrology (Official Gazette of Montenegro 79/08 and 40/11), market surveillance is performed by the Administration for Inspection Affairs.

##### **Administrative capacity**

At this moment the Bureau of metrology has 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 packers of products covered by the Directive 76/211/EC and Directive 2007/45/EC.

##### **Legal framework**

Legal framework for the stipulation of technical requirements and conformity assessment procedures for products covered by Directive 76/211/EC and Directive 2007/45/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 and 40/11);
- 2) Rulebook on pre-packaged products (Official Gazette of Montenegro 56/11).

Rulebook is aligned with requirements of Directive 76/211/EEC and Directive 2007/45/EC. However, due to improved experiences and knowledge regarding the implementation of the Rulebook, it is planned to make amendments and supplements to the Rulebook by the end of the second quarter of 2017.

##### **Institutional framework**

The competent authority for transposition of Directive 76/211/EEC and Directive 2007/45/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 the Rulebook, as well as the Administration for Inspection Affairs.

### **Metrological surveillance**

Metrological surveillance of pre-packaged products is performed by the Administration for Inspection Affairs.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 (see point 3.2.3).

## ***4.2.6 Measuring Containers (Bottles)***

### **Current situation in sector**

In Montenegro, there are no bottle manufacturers 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:

- 1) Metrology Law (Official Gazette of Montenegro 79/08 and 40/11);
- 2) Rulebook on bottles as measuring containers (Official Gazette of Montenegro 56/11).

Rulebook is aligned with requirements of Directive 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.

Bureau of Metrology is responsible for implementation of the Rulebook.

### **Metrological surveillance**

Metrological surveillance for measuring containers (bottles) is performed by the Administration for Inspection Affairs.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 (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 trade 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)
3. Rulebook on the content of applications for the issue of permits to use precursors and the content of permits to use precursors (Official Gazette of Montenegro 4/2015)
4. Rulebook on the content of applications for the issue of permits to import, export, transit and transport precursors and on the form of permits to import, export, transit and transport precursors (Official Gazette of Montenegro 4/2015)
5. Rulebook on the content of applications for the issue of licenses to produce precursors and the content of licenses to produce precursors (Official Gazette of Montenegro 6/2015)
6. Rulebook on the form and content of reports on true quantities of exported or imported precursors (Official Gazette of Montenegro 12/2015)
7. Rulebook on details and the content of annual reports on production and trade of precursors (Official Gazette of Montenegro 16/2015)
8. Rulebook on forms, content and manner of submission of notifications on export of precursors (Official Gazette of Montenegro 4/2015)
9. Rulebook on the form and content of statements issued by end users on intended use of precursors (Official Gazette of Montenegro 4/2015)

10. Rulebook on the content and the keeping of records of legal entities dealing with production and/or trade in precursors and of the register of legal entities involved in production, trade, export, import, transit and transport of precursors, as well as of the special register of issued permits (Official Gazette of Montenegro 32/2015).

The above mentioned legislation is in MN opinion aligned with requirements of Regulation (EC) 273/2004. To achieve full alignment with requirements of the Regulation (EC) 273/2004 for the fourth quarter of 2018, it is planned to adopt the Law on Amendments and Supplements to the Law on the surveillance of production and transport of substances that can be used in the production of narcotic drugs and psychotropic substances. Details on adopted secondary legislation are given in Annex to the Action Plan.

**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 Market Surveillance of Products, 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 regulation. 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 is planned for the second quarter of 2018, whereas the Rulebook is planned for the fourth quarter of 2018. Legislation is planned to be fully aligned with the requirements of Regulation (EC) 1223/2009.

### **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 Market Surveillance of Products, 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 2017. Further education of the new and existing staff in this area is necessary.

## ***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 and 06/13);
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 in



the first quarter of 2017 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, 06/13);
2. Law on Health Insurance (Official Gazette of Montenegro 06/16)
3. Decree on criteria for setting the maximum prices of medicines (Official Gazette 44/15 and 65/15)
4. List of medicines that are prescribed and issued at the expenses of the Fund intended to compulsory health insurance (Official Gazette of Montenegro 3/15)

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 act sin 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 Market Surveillance of Products, 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 directive. 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 twining 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

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

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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget in EUR</b>	<b>/</b>	<b>/</b>	<b>/</b>	<b>/</b>	<b>/</b>

<b>Incomes from realisation of competences (fees) and other sources (donations) in EUR (salaries + material expenses)</b>	<b>17040</b> (9540 + 7500)	<b>51120</b> (28620 + 22500)	<b>68160</b> (38160+ 30000)	<b>85200</b> (47700+ 37500)	<b>102240</b> (57240+ 45000)
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Projection of needs for new employees for implementation of acquis in the Health Insurance Fund of Montenegro

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

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):

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

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; 06/13);
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 in the first quarter of 2017 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 Market Surveillance of Products, 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 twinning 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

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

Projection of necessary financing for newly employed, 2014-2018

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

Expenses for two current employees in CALIMS are EUR 34 080 per year, or EUR 102,240 for the period 2016-2018. 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)
2. Rulebook on the types of fertilizers, the conditions for ammonium nitrate fertilizers of high nitrogen concentration, method of labeling and packaging of fertilizers (OG MNE 32/15)

Law is in MN opinion partially aligned with requirements of Regulation EC 2003/2003. Also in MN opinion fully aligned are complete with Rulebook on the types of fertilizers, the conditions for ammonium nitrate fertilizers of high nitrogen concentration, method of labeling and packaging of fertilizers (OG MNE 32/15).

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.

##### **Institutional framework**

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

Administration for food safety, veterinary, and fitosanitary afers – Fitosanitary sector, which is a part of the Ministry is responsible for implementation of Regulation (EU) 2003/2003.

##### **Conformity assessment**

Administration for food safety, veterinary, and fitosanitary afers – Fitosanitary sector, 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, Administration for food safety, veterinary, and fitosanitary afers – Fitosanitary sector, 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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Number of newly employed in a single year</b>	1	1	/	/	/
<b>Realisation</b>	1	1			
<b>Total number of the newly employed in relation to 2013</b>	1	2	2	2	2

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

<b>Year Godina</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>State budget</b>	5.625	20.080	20.080	20.080	20.080
<b>Realisation</b>	5.625	20.080	20.080		
<b>Donations Other</b>	20.000	20.000	20.000	11.000	/

Expenses for one current employee are EUR 11,250 per year, or EUR 33,750 for the period 2016-2018. By hiring one new employee in 2016 total costs for the implementation of the directive are **EUR 142,195 for the period 2014-2018.**

#### ***4.2.11 Chemicals***

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 of 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 of use, marketing and production of chemicals that pose unacceptable risk for human health and environment (Official Gazette of Montenegro 19/13).

For the purpose of further alignment with REACH Regulation, amendments and supplements to the Law on Chemicals have been drawn up, planned to be completed in the second quarter of 2016. 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);

For the purpose of further alignment with CLP Regulation, amendments and supplements to the Law on Chemicals have been drawn up, planned to be completed in the second quarter of 2016. Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

#### Regulation 689/2008

The Law on Chemicals and respective secondary legislation (Rulebook on procedure of prior informed consent and procedure of issue of approvals on the basis of prior informed consent for export of chemicals (Official Gazette of Montenegro 13/13 and 27/14), Rulebook on list of hazardous chemicals and products prohibited for export) within the legal system of Montenegro regulate the matter which in the EU is regulated by the Regulation (EC) no. 689/2008 concerning the export and import of dangerous chemicals.



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, Regulation (EC) 689/2008 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.

The Administration for Inspection Affairs, Environmental Inspection Sector, is competent for inspection supervision.

#### **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 the European Chemicals Agency (ECHA) and competent authorities of other Member States 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) 689/2008/EC export and import of chemicals included in the List of Chemicals subject to prior informed consent procedure (PIC procedure) are carried out on the basis of information submitted by EIA to a country, or in such way that EIA gets notified about

export by the competent body of the country exporting or importing chemicals. PIC procedure also applies to chemicals included in the Rotterdam Convention List.

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.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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**

MoSDT is the primary responsible institution for the transposition of EU regulations on chemicals and the monitoring of implementation of corresponding regulations. At this moment there is one employee in charge of chemicals management. New recruitments are planned according to the job systematization

EPA is in charge of implementation of regulations in the area of chemicals. There is a Department for Chemicals Management in EPA, established in accordance with the job systematization, with four employees in charge of chemicals management.

Administration for Inspection Affairs – Ecological Inspection Sector, is competent for inspection supervision of implementation of environmental regulations, including the sub-sector of chemicals. It employs six ecological inspectors, whose competences cover all environmental protection affairs in all sub-areas including chemicals management.

#### ***4.2.12 Biocidal product***

### **Current situation in sector**

In Montenegro, there is currently no information on manufacturers of products covered by the Regulation (EU) 528/2012. 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 (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

The Government of Montenegro, at its session of 24 September 2015 adopted the Draft Law on Biocidal Products which is partially aligned with requirements of the Regulation (EU) 528/2012. The Draft Law is in parliamentary procedure, it obtained approvals from all concerned parliamentary boards and it is expected to be adopted at the plenary session.

By the end of 2016, it is planned to adopt a set of subordinate legal acts on the basis of the Draft Law on Biocidal Products, by which the alignment with Regulation 528/2012 will be achieved. Details on adoption of secondary legislation needed in MN opinion to achieve full alignment are given in annex (see Action plan in annex)

### **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.

Inspection supervision of implementation of the Law on Biocidal Products is carried out by the authority competent for inspection affairs through sanitary, veterinary, phytosanitary and ecological inspectors.

### **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 establishing a framework for the approval of motor vehicles, and relevant sectoral EU legal acts;
2. Directive 2002/24 relating to the 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 and 58/14);
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.

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, signed in 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 the UN Secretary General that it takes over the obligations of implementing all the treaties previously signed by SFRY, SRY and SMN. Doing so, MN was granted the status of legal successor to all treaties depositary of which is the 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.

At the beginning of 2015, Montenegro adopted Rulebook on technical requirements and conditions for vehicles, parts and equipment which are imported or placed on the market of Montenegro ("Off. Gazette of Montenegro" no. 5/15), which represent legal basis for verification of the technical requirements and conditions pursuant to UNECE regulations and EU directives and regulations for new and used vehicles that are imported or first placed on the market in Montenegro.

On the basis of the two Laws, four additional rulebooks are going to be adopted:

1. Rulebook on approval of motor vehicles (fourth quarter of 2016),
2. Rulebook on approval of two or three wheeled motor vehicles (fourth quarter of 2018),
3. Rulebook on approval of tractors (fourth quarter of 2018),
4. Rulebook on emissions from non-road mobile machinery (fourth quarter of 2018).

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/EC, 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 vertical (separate) directives which have almost identical content as the equivalent UNECE rules. Vertical 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**

The Ministry of Transport and Maritime Affairs, Directorate for Road Traffic is the umbrella institution in the field of approval of motor vehicles.

### **Market surveillance**

According to the Law on Market Surveillance of Products, 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 the Ministry of Transport and Maritime Affairs – Road Traffic Directorate, that is, the Road Traffic Inspectorate.

There are four inspectors performing market surveillance of vehicles on the market as well as inspection surveillance of vehicles in use.

### **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

<b>Year</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Number of newly employed in a single year</b>	/	1	/	2	/

<b>Realisation</b>	/	1	/		
<b>Total number of the newly employed in relation to 2013</b>	/	1	1	3	3

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

<b>Godina</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Državni budžet</b>		11 250	22 500	33 750	33 750
<b>Donacije</b>	11.000	61.000	61.000	11.000	/
<b>Ostalo</b>					

Expenses for one existing employee are EUR 11.250 per year, which means EUR 33.750 for the period 2016-2018. By hiring one new employee in 2016 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.

For the purpose of harmonization with requirements of the Directive 2015/1535 for the second quarter of 2018, it is planned to adopt a new Decree on notification of technical regulations, regulations on information society services and conformity assessment procedures.

#### **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**

Following the adoption of 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.

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.

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.

## **5.3 Control of the acquisition and possession of weapons**

Law on Weapons (Official Gazette of Montenegro 10/15) regulates the acquisition, possession, carrying, collection and transport, as well as the conditions for manufacture, testing and marking of firearms, repairs and alterations, trade and transport of weapons, provision of services of sports-recreational shooting and training of citizens in correct use of firearms. Provisions of this Law do not apply to: acquisition, possession, carrying, collection, transport, manufacture, testing and marking of firearms, repair and alteration, trade and transport of weapons, shooting ranges for the purposes of Army, police or any other state body or legal person, this being regulated by a separate law; weapons transported through the territory of Montenegro for the purposes of competent authorities, organizations, business and other entities of other states, pursuant to international agreements. The Ministry of 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 ammunitions) may be conducted by any entity (legal or physical person) registered in the Register of persons licensed 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 the licence to conduct 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 to fill to qualify for registration into the Register of persons licensed to conduct foreign trade in controlled goods. The application for licence may be filed only after the 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 exceeding 75 years of age 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 acquisition, possession and carrying of which 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 and projectiles for such ammunition, not including ammunition for hunting or sports shooting; military weapons; explosive weapons and parts; any type of weapons with integrated silencers and silencers intended to use with firearms);
- Category B includes weapons acquisition, possession and carrying of which 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; single-shot short firearms with rimfire percussion whose overall length is less than 28 cm; 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, where the loading device is removable or where it is not certain that the weapon cannot be converted, with ordinary tools, into a weapon whose magazine and chamber can together hold more than three rounds; repeating and semi-automatic long firearms with smooth-bore barrels not exceeding 60 cm in length; **repeating long firearms other than those listed above**; long firearms with one or more single-shot rifled barrels; semi-automatic firearms other than those listed above; single-shot short firearms with rimfire percussion whose overall length is not less than 28 cm; single-shot long firearms with one or more smooth-bore barrels; antique weapons; long firearms with single-shot with combination of smooth-bore and rifled barrels, semi-automatic for civil uses, similar to automatic but not included in previous lists);
- Category C includes weapons possession and carrying of which is prohibited without notification to the Ministry of the Interior (gas weapons; reproduction firearm where a single cartridge is not used; small cannons, air weapons with power greater than 10,5J or projectile velocity greater than 250 m/s or with calibre greater than 4,5 mm; weapons with bows with tensile strength greater than 450 N;);
- Category D includes weapons which can be acquired, possessed and carried only by natural adults of 18years of age and older, and exceptionally, atomisers may be possessed and carried by persons older than16 years of age (air weapons with kinetic energy of less than 7.5 J or projectile velocity of less than 250 m/s and calibre less than 4,5 mm; weapons with bows with tensile strength less than 450 N; electric paralysers; atomiser; cold weapons).

For weapons acquired on the basis of a permit, the firearms pass shall be issued to a natural person (for keeping weapons – for personal safety; for keeping and carrying – for practicing target shooting and hunting), or a permit to keep weapons of a company or a businessman, with a validity period of ten years. Firearms pass 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 notify the Ministry of the Interior about the sale of firearms of the categories B and C within eight days from the date of sale.

Approval for collecting antique weapons shall be issued with permanent validity period to a physical or legal 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, if permanently disabled.

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.

Manufacture, trade and mediation in trade of weapons and ammunition, repair and alteration of weapons, and transport of weapons and ammunition may be performed by legal persons and entrepreneurs registered to conduct such activity and in possession of a licence issued by 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). Manufactured weapons, as well as weapons the main part of which has been changed by alteration, prior to its sale shall be subject to testing and marking with a seal or any other identification sign. Tests are performed to check the working order and marking the weapon with the seal certifies its good working order, pursuant to specific regulations. One manufacturer has been engaged in manufacture of weapons in Montenegro since 2012. Labelling of weapons is carried out by the authorised person from abroad.

Pursuant to the 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 establishment of List of non-military lethal goods (Official Gazette of Montenegro 66/10) – weapons, ammunitions, energy material – has been adopted, and in MN opinion, it is aligned with the Regulation 258/2012. Foreign trade in the above mentioned goods may be carried out by any person (physical or legal) previously registered in the Register kept by the competent body – Ministry of Economy of Montenegro. Any person registered for the performance of the above mentioned activities may apply for the licence for foreign trade in the above mentioned goods, pursuant to the law.

Montenegro will publish the new law and by-laws in this area until the fourth quarter of 2018 in accordance with the amendments to the acquis and suggestions EU Commission.

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**

Article 6 of the Law on Foreign Trade (Official Gazette of Montenegro 28/04, 37/07 and 57/14) 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 38/15) 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 and export) 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, Control List for Export and Import of Goods (Official Gazette of Montenegro 38/15) 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 42/14),
- b. Decision on determining national control list of dual-use goods (Official Gazette of Montenegro 50/15)
- 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 in this field includes the Law on Cultural Property (Official Gazette of Montenegro 49/10) and the Rulebook on the list of collections of objects which can be considered as national treasure of the EU Member States (Official Gazette of Montenegro, 48/13).

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 unlawfully removed from the territory of the state, a non-EU member; return of cultural property unlawfully removed the territory of Montenegro; activities of return of cultural property.

Rulebook on the list of 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. The above mentioned documents are partially aligned with the Directive 93/7/EEC of the Council of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State.

### **Institutional framework and administrative capacity**

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. The Ministry has the duty to coordinate the cooperation with competent bodies of Member states with respect of return of cultural properties that have been unlawfully removed.

Pursuant to the Article 76a of the Law on Inspection Supervision, inspection supervision in the field of education, sports, protection of cultural properties and cultural heritage and archiving activities shall be carried out, until 31 December 2015, by state administration bodies appointed by their respective laws, whereas stipulated provisions cease to be in force as of 31 December 2015. In that respect, inspector for cultural heritage, who in accordance with the Law supervises the implementation of provisions of the Law on Cultural Property Protection related to the establishment of protection of cultural properties and keeping the Register, and the inspector for cultural properties, who carries out the inspection supervision of the status of cultural properties, regime and measures of protection and rights and obligations of owners and holders of cultural properties, are moved to the Administration for Inspection Affairs, the body in charge of carrying out inspection supervision in this area.

The Law on Cultural Properties Protection (Official Gazette of Montenegro 49/10) and the Rulebook on the collections of objects which can be considered as national treasure of the EU Member States (Official Gazette of Montenegro 48/13) are aligned with the Directive 93/7/EEC of the Council of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State. Harmonization with the Directive 2014/60/EU of the European Parliament and of the Council of 15 May 2015 on the return of cultural objects unlawfully removed from the territory of a Member State and amending Regulation (EU) no 1024/2012 will be achieved by the end of 2018.

In the Directorate for Cultural Heritage of the Ministry of Culture two employees are engaged in normative activity, monitoring and enforcement of regulations and new employment in this area are not planned during 2016.

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.