

Government of Montenegro

Ministry of Economy

Questionnaire

Information requested by the European Commission to the Government of Montenegro for the preparation of the Opinion on the application of Montenegro for membership of the European Union

– ADDITIONAL QUESTIONS –

01 Free movement of goods

Minister:

Branko Vujovic

TABLE OF CONTENTS

CHAPTERS OF THE ACQUIS – ABILITY TO ASSUME THE OBLIGATIONS OF MEMBERSHIP..	5
1: Free movement of goods	6
GENERAL PRINCIPLES.....	8
A. Legislative alignment.....	8
B. Implementation capacity, including administrative capacity.....	9
HORIZONTAL MEASURES.....	14
A. Standardisation.....	14
B. Conformity assessment.....	18
C. Accreditation	20
D. Metrology	22
E. Market surveillance.....	23
OLD APPROACH PRODUCT LEGISLATION AND NEW AND GLOBAL APPROACH PRODUCT LEGISLATION.....	24
PROCEDURAL MEASURES.....	46
A. Measures having an equivalent effect to quantitative restrictions.....	46
B. Return of unlawfully removed cultural objects.....	52
Cultural goods.....	52
Annex.....	58
1. Decree On The Manner Of Exchange Of Information On Products That Pose Risk	58
2. Market Surveillance Strategy Of Montenegro.....	58
3. Law On Explosive Substances I General Provisions	59
4. Law On Cultural Property.....	59
5. Law On Museum Practice.....	60
6. Law On Archival Practice.....	60
7. Draft Law On Library Practice	61
8. Decision On Checklist Of Import, Export And Transit Of Goods.....	61
9. Decision On The Establishment And Composition Of The Programmes And Quality Committee Of The Republic Of Montenegro	62
10. The Status Of Harmonization Of Montenegrin Standards That Are Referred To Or Will Be Referred To By The Legislation.....	62
11. The Law On Control Of Manufacture And Placing On The Market Of Substances Used In The Manufacture Of Narcotic Drugs And Psychotropic Substances.....	63

CHAPTERS OF THE ACQUIS – ABILITY TO ASSUME THE OBLIGATIONS OF MEMBERSHIP

1: Free movement of goods

After Montenegro had obtained additional questions from the European Commission, we were informed, through the Ministry of Foreign Affairs of Montenegro, that the Free Trade Agreement between Montenegro and the Republic of Turkey entered into force. The Ministry of Economy of Montenegro and the Customs Administration of Montenegro have informed us that they had notified by an official letter all the relevant institutions that the mentioned Agreement entered into force on 1 March 2010.

General comment:

1. Please update the material wherever there were mentions that the deadline for a certain action was before the end of 2009.

Precursors for narcotics

The presently valid legislation in the area of precursors for narcotics is:

1. Law on the Control of Production and Trade of Substances That May be Used in the Production of Narcotic Drugs and Psychotropic Substances (precursors for drugs), adopted by the Parliament of Montenegro on 10/12/2009 and published in the Official Gazette of Montenegro No 83 of 18 December 2009.
2. Decision on the Control list for export, import and transit of goods published in the Official Gazette of Montenegro, No 12/10 of 05/03/2010.
3. Ratified United Nations Conventions relating to the area of narcotic drugs, psychotropic substances and precursors:
 - Single Convention on Narcotic Drugs, 1961, (As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961),
 - Convention on Psychotropic Substances 1971,
 - UN Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

Law on Precursors for Narcotics is harmonized with the following EU legislation and international conventions relating to the area of narcotic drugs, psychotropic substances and precursors:

- EC/111/2005
- EC/1277/2005
- EC/273/2004
- EC/1533/2000
- EC/1485/96
- EEC/3677/90
- 2003/101/EC
- 92/109/EEC

Law on Precursors for Narcotics provides for the monitoring of this area. This law regulates the monitoring and control of production and trade of substances that can be used in the production of narcotic drugs and psychotropic substances in order to prevent their misuse or use for the illicit purposes, as well as the protection of environment from harmful effects of precursors.

Control list of precursors and narcotic drugs was published in the Official Gazette of Montenegro 12/10 of 05/03/2010.

The law provides that permits to import / export / transit precursors are issued by the Ministry of Health, except in the case when such precursors fall within the group of pharmacologically active substances, and in that case the issuance of such permits fall under the authority of the Agency for Medicines and Medical Devices.

Agency for Medicines and Medical Devices of Montenegro (CALMIS) submitted annual reports for 2007 and 2008, while the quarterly report for 2009 was sent to the International Narcotics Control Board (INCB) on imported and seized quantities of precursors in Montenegro, as well as forecasts for the next year – (The Report includes data from the Police Administration of Montenegro as well).

Pharmaceutical products – please see answer to question 24.

Electromagnetic compatibility (EMC)

Radio and Telecommunications Terminal Equipment (R & TTE)

Activities on the creation of rulebooks (Rulebook on technical conditions for the import, placing into market and use of radio equipment and telecommunication terminal equipment and the Rulebook on electromagnetic compatibility) are underway, and their adoption is planned by the end of 2011, as well as the Guide for the R&TTE Directive 1995/5/EC (version 20./04/2009) for the implementation of these regulations, hence the full implementation is planned for 2012.

Lifts

Time limit for publication of the Rulebook on security of lifts, in conformity with the Directive 95/16/EC and the Amendment 2006/42/EC, has been deferred for the end of 2011. The draft regulation has been prepared, but harmonization with the new requirements of national and European legislation is underway.

Gas Appliances

Time limit for publication of the Rulebook on gas appliances, in conformity with the Directive 90/396/EC, has been postponed for the end of 2011. The draft regulation has been prepared, but harmonization with the new requirements of national and European legislation is underway.

Pressure Equipment

Time limit for publication of the Rulebook on technical requirements for pressure equipment, in conformity with the Directive 97/23/EC, has been postponed for the end of 2011. The draft regulation has been prepared, but harmonization with the new requirements of national and European legislation is underway.

Simple pressure vessels

The time limit for publication of the Rulebook on simple pressure vessels, in conformity with the Directive 87/404/EC, has been postponed for the end of 2011. The draft regulation has been prepared, but harmonization with the new requirements of national and European legislation is underway.

Cableway installations designed to carry persons

Please see combined answer to question 19.

Recreational craft

Please see combined answer to question 19.

Ecological requirements for energy-using-products (eco-design)

Law on Energy Efficiency is in the adoption procedure in the Parliament of Montenegro and its entry into force is expected by the end of April 2010, while the Rulebook on eco-design of energy-using-products will be adopted by the end of 2010.

GENERAL PRINCIPLES

A. Legislative alignment

2. (Ref. to Q. 1):

a) Please specify whether you have a general strategy on Quality Infrastructure?

Strategy on Improving Quality Infrastructure of Montenegro was adopted by the Government of Montenegro in June 2007. Strategy relates to the so-called unregulated area and objectives are to increase the number of certified organisations in Montenegro in the field of environmental protection ISO 14001 EMS, quality management system ISO 9001 QMS, implementation of HACCP guideline and standard ISO 22000 related to quality and safety of food, raising the number of accredited conformity assessment bodies in Montenegro, and similar. This is the second revised version of the Strategy and it follows changes within the generic ISO 9001 standard, thus the first version was related to the ISO 9000:1996, and the second to the ISO 9000:2000. The Strategy has contributed, in the subject area, to the increased number of certificates (of about 200), which enhanced competitiveness of Montenegrin organisation at the global and internal market. The Strategy further include the realization of greater awareness in the area of quality by giving emphasis to in-house training, conferences, round tables, and similar.

Board of the Programme of the Government of Montenegro for Quality (Board of Quality) (see answer to the question 4c) has in plan that during 2010 propose a new / innovated version of the Strategy. This revision of the Strategy should contribute to accelerated transposition of the EU technical legislation and removal of barriers if the overlap or lack of competence. The Strategy should give an answer to finding an adequate way of monitoring the overall situation in the areas of standardisation (sales, implementation by economic operators, and similar), methodology (increased number of national calibration laboratories, and similar), accreditation (increased number of applications, and similar), and conformity assessment (monitoring the needs of Montenegrin economy in order to increase the number of authorised /designated conformity assessment bodies).

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

Horizontal legislation in Montenegro is harmonized with the EU legislation related to Chapter 1 – Free movement of goods. Since the legislation was adopted mostly in the 2007 and 2008 it is necessary to review and harmonize it with the latest requirements. First of all, during 2010 will be

re-considered measures that are subject of “New package of measures for enhancing trade of products“ (Regulations 765/2008/EC, 764/2008/EC and Decision 768/2008/EC). In addition, the obligation to review this legislation has been recognised through the Decision of the Government of Montenegro for commencement of the revision of the National Program for Integration of Montenegro into the EU, for the period 2010-2014.

However, deficiencies in Chapter 1 – Free movement of goods are related to the dynamics of transposing the “vertical” legislation. Deficiencies in vertical legislation are related to horizontal legislation in regard to lack of competences in the line ministries responsible for transposing the technical regulation. The competences are missing in terms of knowledge and use of “internal notification of technical regulations” procedures, preparation of regulations related to rules of standardization, conformity assessment, accreditation, metrology, and similar. Montenegro intends to accelerate transposition and harmonize its legislation through the IPA pre-accession assistance and other forms of international assistance, as well as in the course of the ongoing internal training in the line ministries.

c) Please, specify how the self-certification principle is addressed in your legislation?

The principle of self-certification is the subject of the Law on Technical Requirements for Products and Conformity Assessment of Product with prescribe requirements, and Article 2 of the Decree on the manner and procedures of conformity assessment of product with prescribe requirements. The principle of self-certification is applied individually or in combination with other procedures of conformity assessment in accordance with the technical regulations for certain product.

B. Implementation capacity, including administrative capacity

3. (Ref. to Q. 2): Please indicate also the legal basis for market surveillance.

Inspection control of the market (general product safety and the protection of economic interests of consumers) is implemented by the competent ministries and other public administration bodies /inspection authorities/, through inspectors authorised to supervise implementation of regulations in particular areas in accordance with the competences prescribed by separate laws.

Inspection bodies control and undertake administrative measures and actions in accordance with the rules of procedure of the inspection control, authorities and duties of inspectors laid down by the Law on Inspection Control (Official Gazette of the Republic of Montenegro 39/03). The provisions of this Law are applied appropriately also by the local self-government bodies when, in line with the law and other regulations, carry out inspection control. Furthermore, inspection control is also arranged by separate laws on particular inspections (market, health-sanitary...), as well as the provisions on control that are contained in material regulations.

In addition to these regulations, the administrative measures and actions concerning the safety of products on the market, and protection of economic interests of consumers, are prescribed by material regulations related to product safety and protection of economic interests of consumers, including: the Law on Consumer Protection, Law on General Product Safety, Law on Technical Requirements for Products and Assessment of Product Conformity against Set Standards, on the basis of which the inspectors perform control in accordance with the previously issued technical regulations (provided they are not contrary to this Law), until the adoption of new technical regulations, which will transpose the EU Directive into national legislation, the Law on Standardization, Law on Accreditation, Law on Metrology, Law on Health Safety of Food Products and Articles for General Use, the provisions relating to health and other requirements for items of general use, as well as administrative measures and actions taken if these requirements have not

been fulfilled, (provisions relating to food products had ceased to be effective with the entry into force of the Law on Food Safety), Law on Medicines, Law on Medical Devices, Law on Chemicals, Law on Plant Protection Products, Law on Plant Nutrition Products, Law on Seed Material of Agricultural Plants, Law on Planting Material, Law on Restriction of the Use of Tobacco Products, Law on Tourism, Law on Electronic Communications, Law on Transport in Road Traffic, Law on Air Traffic, Law on Railroad, Law on Safety in Railway Traffic, Law on Postal Services, Energy Law, Environmental Law, Law on Genetically Modified Organisms, Law on Transport of Dangerous Goods, Law on Protection Against Ionizing Radiation, Law on Air Quality, Law on Waste Management, Law on Ratification of Amendment to the Montreal Protocol on Substances That Damage the Ozone Layer, Law on Foreign Trade, Law on Internal Trade, which regulate the conditions and forms of the conduct of internal trade, basic rules of product trading and trade services in the domestic market, protection against unfair competition, etc.

Inspection bodies responsible for control of the market are:

Ministry of Economy / Market Inspection: non-food product safety (technical, machinery, construction, furniture, textile, glass, footwear and other consumer products that are not placed under the authority of other inspections by separate regulations) in the market and protection of economic interests of consumers when purchasing products and when using services (crafts, trade and certain public services), in accordance with the laws and other regulations on consumer protection, general product safety, technical requirements for products, standardization, metrology, tobacco products, medicines, energy, trade, etc. This inspection is a section in the Sector for Internal Market and Competition of the Ministry of Economy and has 56 inspectors, which conduct control on the entire territory of Montenegro. It is organized territorially into three regional units, namely: PJ I - Central region (Podgorica, Cetinje, Danilovgrad, Kolašin, Nikšić, Plužine, Šavnik), based in Podgorica; PJ II - South area (Budva, Ulcinj, Bar, Tivat, Kotor, Herceg Novi), based in Budva; PJ III-North area (Bijelo Polje, Mojkovac, Berane, Rožaje, Plav, Andrijevica, Pljevlja, Žabljak), based in Bijelo Polje. Funds for the work of this inspection have been provided from the state budget, which after revision in 2009, due to the global economic crisis, amounted to EUR 916,183.00 of which EUR 250,533.00 were intended for material costs and equipment.

Ministry of Health / Health-Sanitary Inspection: safety and health safety of cosmetic products, toys, detergents, tobacco products, materials coming into contact with food and packaging, poisons, medicines and medical devices on the market and protection of economic interests of consumers when purchasing these products, in accordance with the laws and other regulations on health safety of items in general use, on production and trade of toxic substances, on transport of dangerous substances, on medicines, on medical devices. This inspection is a section in the Ministry of Health and has 37 inspectors of which 33 sanitary and 4 health inspectors. Sanitary inspectors conduct supervision on the entire territory of Montenegro, arranged in 8 regional units, while 3 health inspectors are organizationally located in the head office of the Section-Podgorica. Funds for the work of this inspection are provided from the state budget within the funds allocated to the Ministry of Health.

Ministry of Physical Planning and Environmental Protection - Agency for Environmental Protection / Environmental Inspection: in the area of health protection of people and condition of the environment as one of the basic rights of consumers, control of radioactivity for certain goods, control of permits for import, export and transit of ionizing radiation sources, substances that damage the ozone layer, products containing these substances, non-hazardous waste, as well as licenses for the export and transit of hazardous waste, the impact of noise in the environment, notification and putting into market of new and existing chemicals, the risk assessment of chemicals, classification, packaging, labelling, import and export of chemicals, use of ecological label in accordance with the laws and regulations in the area of environmental protection. Environmental inspection is located in the Agency for Environmental Protection and has 9 environmental inspectors, who conduct control on the entire territory of Montenegro. Funds for the work of this inspection are provided from the state budget within the funds allocated for the work of the Agency for Environmental Protection.

Ministry of Agriculture, Forestry and Water Management - Phytosanitary Administration / Phytosanitary Inspection: safety of products for plant nourishment, products for plant protection, seeds and planting material on the market, as well as protection of economic interests of consumers when purchasing them, in accordance with the laws and others regulations relating to these types of products. This inspection is a section in the Phytosanitary Administration and has 16 inspectors who conduct control on the entire territory of Montenegro. Funds for this inspection are provided from the state budget within the funds allocated for Phytosanitary Administration.

Ministry of Economics / Institute for Metrology / Metrology Inspection: trade, installation, use, maintenance and repair of measuring devices, as well as examination of the accuracy of the quantities specified and contained in the pre-packed products, in accordance with the law and other regulations that regulate the area of metrology. Control over the use of legal measurement units and devices, as well as labels on the pre-packed foods, in addition to metrology inspectors, is carried out by other inspections within their competences. The Rulebook on Internal Organization and Job Classification of the Institute has planned 2 inspectors of metrology, while the process of selection and the appointment of Chief Inspector of Metrology is underway. Metrology inspectors will, from the head office of the Institute (Podgorica), perform control of the entire territory of Montenegro. Funds for this inspection will be provided from the state budget within the funds allocated for the Institute of Metrology.

The Inspectors are officers with special authorities and responsibilities, independent in carrying out inspection control within the rights and duties determined by law and other regulations. Minister or the Head of a state body appoints the officer into the inspector's position for a period of four years. Inspections are administered by the chief inspectors appointed by the ministers or the heads of state bodies, with the consent of the Government, for a period of four years.

Administrative measures and actions taken by inspectors in the process of control, in order to conform with the prescribed conditions, are regulated by the Law on Inspection Control (Article 16). Other stated laws prescribe specific measures and actions that are taken in order to protect safety of products on the market and protection of economic interests of consumers, including:

- Order for elimination of the established irregularities,
- Taking samples and their submission for examination and conformity assessment,
- Prohibition or restriction of the placing on the market products that are not in accordance with the prescribed requirements,
- Order of prompt recall of hazardous products from the market,
- Order for destruction of product for which in the final process was determined to be dangerous,
- Order to the trader to comply with the prescribed consumer complaint cases, etc.

In accordance with the Article 63 of the Law on Inspection Control, the inspection authorities are obligated to cooperate with each other and with other bodies and organizations in the course of control. At the request of the inspector, the state bodies, local self-government bodies and organizations are obliged to submit the required data and information necessary for the implementation of the inspection control function. It is stipulated that the procedure upon requests and applications of inspectors is urgent. The competent authority is obliged to immediately take into consideration the requests and applications of inspectors, not later than 8 days from the date of application. Cooperation between these bodies is also regulated by the Decree on Joint Inspection (Official Gazette of Montenegro, 48/03), which prescribes that the inspection control may be conducted simultaneously by more than one inspection body, according to needs.

The National Program of Consumer Protection (2008-2010), also contains an obligation of cooperation between the bodies responsible for market control, while detailed manner and forms of cooperation between the inspections and other bodies involved in the market control are subject of the Market Control Strategy adopted by the Government of Montenegro at its session of 5/11/2009 when the conclusion on the formation of coordination body for market control was also adopted. Special cooperation relating to the exchange of information on dangerous products is subject of the

Law on General Product Safety, and will be regulated closer by secondary legislation that will be adopted for the implementation of this Law.

4. (Ref. to Q. 3):

a) Please describe also the Market Surveillance function;

Please see answer to question 3

b) Please provide information on the coordination mechanisms of the Quality Infrastructure bodies and the Division for Quality Infrastructure at the Ministry of Economy;

Mechanisms of coordination between the Quality Infrastructure bodies and the Section of Quality Infrastructure of the Ministry of Economy are prescribed by:

- Law on Standardization (Decision on the Establishment of the Institute for Standardization of Montenegro, Art. 21)

Supervision of the Institute in performing tasks set by the Law is performed by the ministry responsible for the Quality Infrastructure tasks, while in regard to rational use the funds allocated for the work of the Institute, which are provided from the Budget of the Republic of Montenegro and intended for realisation of the Contract of Performance, is performed by ministries responsible for finance and Quality Infrastructure tasks.

- Law on Accreditation - Article 16 (Supervision of the Accreditation Body of Montenegro)

Article 16

Supervision of the Accreditation Body in conducting activities prescribed by the law performs the ministry responsible for Quality Infrastructure activities, while in regard to rational use the funds allocated for work of the Accreditation Body, that are provided from the Budget of Montenegro, is performed by ministries responsible for finance and Quality Infrastructure tasks.

- The Law on Metrology - Article 6 paragraph 1

(1) Ministry responsible for metrology (hereinafter: Ministry) monitors the status of implementation of activities in the area of metrology.

c) Please specify the role of the Board of Quality and distinguish the functions of the Board compared to the functions of the Division for Quality Infrastructure at the Ministry of Economy.

The Board of Quality was established by the Decision on the establishment and composition of the Board of the Programme of the Government of Montenegro for Quality (Official Gazette of the Republic of Montenegro 46/03), which was adopted by the Government of Montenegro at its session held on 12 June 2003. The Board represents the continuance of the Council of the Government of the Republic of Montenegro for Quality that was formed in 1993. The Council was formed to represent the interests of the former Republic of Montenegro in various forms of federal state with the Republic of Serbia. Following declaration of independence of Montenegro, the Council was restructured by referred Decision (Annex No.) into the Board of Quality to whom only the advisory functions remained, while all administrative responsibilities were assigned to the

Ministry of Economy through a set of laws in the area of Quality Infrastructure. The Board of Quality was given the following advisory functions:

Propose to the Government of the Republic of Montenegro creation of policy and strategy in the area of Quality Infrastructure:

- Propose to the Government of the Republic of Montenegro the Strategy for improving the quality management system and Program of Measures for Improvement of Quality Management System in the Republic of Montenegro and take care of their implementation;
- Propose to the Government of the Republic of Montenegro annual plans for implementation of the Program for Quality, as well as annual plans for funding activities related to the implementation, testing and certification of quality systems, and similar;
- Propose to the Government of the Republic of Montenegro adoption of regulations and other acts in the area of standardization, accreditation, metrology and other aspects of Quality Infrastructure in accordance with international standards and guidelines;
- Monitor implementation of the Program for introduction of the quality system in all products and service activities, administrative bodies, education and health care systems and take measures for their effective implementation;
- Encourage the organization of training and other forms of professional education in the area of quality system, standardization, metrology and integrated management systems;

On the basis of new legislation was initially formed an independent Department for Quality Infrastructure in the Ministry of Economy. Following transformation of the Ministry of Economy to the Ministry of Economic Development, the referred Department for Quality Infrastructure was reassigned to the Sector for Internal Market and Competition. The tasks of the Department are defined by internal regulations on the organization and job classification of the Ministry of Economy, as follows:

- Performs tasks related to: the development and implementation of policies and strategies for development of Quality Infrastructure, monitoring and participating in drafting regulations governing the area of technical legislation, system of standardization, metrology system, a system of accreditation and compliance system, establishment and maintenance of the register of technical regulations and register of authorized bodies for conformity assessment; notification in accordance with the WTO Agreement / TBT (contact point for the WTO / TBT), harmonization of national legislation with EU legislation in the area of Quality Infrastructure; provision of logistical support for the development of Quality Infrastructure, organization of conferences, panel discussions, lectures from the Division's scope of work; providing information to interested legal entities on matters of the Division's scope of work; performs professional and administrative tasks for the Board of Quality Programme of the Government of Montenegro; keeping records necessary for monitoring and initiating activities from the Division's scope of work; establishing cooperation with other ministries and administrative bodies.

5. (Ref. to Q. 4): Please indicate in details your resources and systems to contribute to elaboration and implementation of law.

As already stated in response to question 4, the Ministry of Economy in cooperation with the Board of Quality, together with the expert assistance from the institutions of Quality Infrastructure, already provides assistance to relevant ministries in preparing technical legislation (Rulebook on liquid petroleum products, Rulebook on safety of machinery, Rulebook on electromagnetic compatibility, etc.). The insufficiency in resources is related to the number of employees in the Department for Quality Infrastructure which is downsized to three employees.

HORIZONTAL MEASURES**A. Standardisation****6. (Ref. to Q. 6):****a) Are the Internal Standardization Rules (ISME IPS) already adopted?**

The Internal Standardization Rules of the Institute (ISME IPS) are internal documents of the Institute for Standardization of Montenegro, which regulate issues related to organization, planning, preparation, adoption, review and updating of Montenegrin standards and related documents, which are aligned with the rules and recommendations of international and European organizations for standardization and the Code of Good Practices of the World Trade Organization (WTO) related to the development, adoption and application of standards. The Internal Standardization Rules of the Institute are primarily intended for the personnel of the Institute, chairpersons, secretaries and members of technical bodies of the Institute and other interested parties who are directly or indirectly involved in the process of development of Montenegrin standards and related documents.

It is envisaged that the Internal Standardization Rules of the Institute consists of six (6) documents, namely:

ISME IPS 1, Internal Standardization Rules - Part 1: *Establishment and Working Procedure for the Technical Bodies of the Institute*

ISME IPS 2, Internal Standardization Rules - Part 2: *Types of the documents and their designation*

ISME IPS 3, Internal Standardization Rules - Part 3: *Development of Montenegrin standards and related documents*

ISME IPS 4, Internal Standardization Rules - Part 4: *Participation in the work of European standards organizations in the development of European standards and related documents and adoption of European standards and related documents at national level*

ISME IPS 5, Internal Standardization Rules - Part 5: *Participation in the work of international standards organizations in the development of international standards and related documents and adoption of international standards and related documents at national level*

ISME IPS 6, Internal Standardization Rules - Part 6: *Rules for the Structure and Drafting of Montenegrin standards and related documents*

The Management Board of the Institute, in accordance with its responsibilities, adopted two of the above documents at its meeting held on 01/02/2010, as follows:

ISME IPS 1:2010, Internal Standardization Rules - Part 1: *Establishment and Working Procedure for the Technical Bodies of the Institute*

ISME IPS 2:2010, Internal Standardization Rules - Part 2: *Types of the documents and their designation*

Following the adoption, these documents were published on the Internet portal of the Institute www.isme.me (documents are currently available only in Montenegrin language) and can be found in the sub-menu Standardization / Development of Montenegrin standards.

Document ISME IPS 6, Internal Standardization Rules - Part 6: *Rules for the Structure and Drafting of Montenegrin standards and related documents* is in the status of the final draft and will be sent, in the form of proposal, for the adoption by the Board at its next session.

The remaining documents:

ISME IPS 3, Internal Standardization Rules - Part 3: *Development of Montenegrin standards and related documents*

ISME IPS 4, Internal Standardization Rules - Section 4: *Participation in the work of European standards organizations in the development of European standards and related documents and adoption of European standards and related documents at national level*

ISME IPS 5, Internal Standardization Rules - Part 5: *Participation in the work of international standards organizations in the development of international standards and related documents and adoption of international standards and related documents at national level*

are in the status of the draft and they require additional development and finalization. It is expected that these three documents will have the status of the final draft by the end of May 2010, after which will be submitted to the Management Board of the Institute for the adoption.

All these documents will be published after the adoption on the Internet portal of the Institute and available to the public. It is also planned to translate and publish them in English.

b) Please provide an outline of the budget and a breakdown of the budget sources

Article 17 of the Decisions on the establishment of the Institute for Standardization of Montenegro (Official Gazette of the Republic of Montenegro, 21/07) and Article 9, paragraph 1 of the Law on Standardization stipulates that the Institute acquire funds for its work through:

1. selling standards, related documents and other publications;
2. collection of fees;
3. collection of services;
4. the Budget of Montenegro;
5. other sources

Currently, the most significant source of funding for the Institute for Standardization of Montenegro are funds allocated from the Budget of Montenegro (item 4) which are provided through a contractual relationship between the Institute and the Government of Montenegro (Founder). Namely, pursuant to Article 4, paragraph 1 item 19 of the Decision on the Establishment of the Institute for Standardization of Montenegro, the Institute has a contractual relationship with the Founder that involves the conclusion of the Contract of Performance for each business year, which determines the number of Montenegrin standards and related documents that the Institute have to adopt on the annual level, while the Founder for this purpose provides to the Institute necessary financial means from the Budget of Montenegro. Funds for the implementation of the Contract of Performance of the Institute are transferred through the Ministry responsible for quality infrastructure (Ministry of Economy), in accordance with Article 18 of the Decision on the establishment, and are intended to:

- implementation of tasks defined by the annual Program of Activities of the Institute and the Montenegrin standards adoption plan and related documents,
- paying membership fees on the basis of membership of the Institute in international and European organizations for standardization,
- international cooperation in the area of standardization, such as the introduction of Montenegro in the work of international (ISO, IEC, ITU) and European (CEN, CENELEC, ETSI) organization for standardization.

The Law on Budget of Montenegro for 2010 allocated funds to the Institute for Standardization of Montenegro for implementation of the Contract of Performance in the amount of EUR 491,735.30. The structure of these funds by individual items is listed in the table below:

EXPENDITURES	AMOUNT
Current expenditures	491.735,30
Gross earnings and contributions	283.376,70
Net earnings	170.509,55
Income tax	22.904,27
Contributions paid by employee	61.078,05
Contributions paid by the employer	25.449,19
Municipal additional tax	3.435,64
Other personal income	10.466,50
Compensation for meals	6.655,00
Compensation for an annual holiday	3.811,50
Expenditures for goods and services	161.892,10
Expenses for material	12.000,00
Expenses for official travel	9.000,00
Representation expenses	1.200,00
Expenditures for energy	1.800,00
Expenditures for telephone services	1.200,00
Expenses for postal services	600,00
Contracted services	136.092,10
Current maintenance	1.200,00
Current maintenance of objects	1.200,00
Rent	34.800,00
Rental of objects	34.800,00

c) Please indicate how many people are working in each of the ISME departments?

ISME Rulebook on Internal Organisation and Job Descriptions envisages 32 posts for employees dealing with standardisation activities. Currently ISME employs 18 people (15 employees with university degrees and 3 secondary school graduates), with 14 posts still vacant due to the lack of space and limited resources for further development of ISME.

ISME is managed by its **director**. The director represents and acts on behalf of ISME.

The following organisational units have been set up for the performance of tasks within ISME's field of activity:

- **Standards Department,**
- **Logistics Department,**
- **Division for Development, Education, Certification and Quality, and**
- **International Cooperation Group.**

The performance of the **Standards Department** tasks is organised in two divisions and one section:

- a) General Standardisation Division (ISO/CEN) consists of six internal units:
 - Metals and Non-Metals Group;
 - Group for Mechanical Engineering, Transport and Material Transport;
 - Civil Engineering Group;
 - Group for Agriculture, Food Industry, Chemical Industry, Wood Industry and Forestry;
 - Group for Safety, Environmental Protection, Health and Medical Equipment;
 - Group for General Standards, Services, Household Appliances, Recreational Equipment and others.
- b) Division for Electrical Engineering, Telecommunications and IT (IEC/ITU/CENELEC/ETSI) consists of two internal units:
 - Electrical Engineering Group;
 - Group for Telecommunications, IT and Software.
- c) Section for Technical Preparation of Standards.

Standards Department has the total of 9 (nine) members of staff.

The performance of the **Logistics Department** tasks is organised in three sections:

- General and Legal Affairs Section,
- Sale and Financial Affairs Section
- Information and Documentation Section.

Logistics Department has the total of 7 (seven) members of staff.

International Cooperation Group has 1 (one) member of staff.

d) Please outline the IT resources of ISME?

Out of the IT resources that the Institute for Standardization of Montenegro currently has at its disposal, and which are used to perform operational tasks of the Institute, we list the following:

- existing network infrastructure (active and passive network equipment) is of satisfactory capacity and currently can support the requirements related to the work of the Institute,
- external communications support ADSL devices that provide flow of information up to 14 Mbps,
- the following computer equipment is available to the employees of the Institute:
 - 13 working stations with accompanying equipment,
 - 11 notebook computers with supporting equipment,
 - colour and black-and-white printers, scanners, multifunction devices and one network printer,
 - licensed versions of Windows XP and Vista,
 - licensed versions of Microsoft Office 2003 and 2007,
 - other programs of general use that support the working process.
- A database was designed and implemented for storage of data on Montenegrin standards and related documents. A database is located on the server that has an operating system based on Linux and the MySQL database technologies. The specified solution provides access to the base by employees as well as its connection to the Internet portal of the Institute for the on-line browsing by external users.

Bearing in mind that one of the requirements for achieving full membership in the European standardization organizations CEN / CENELEC is the existence of an advanced information system that can ensure adequate communication with the IT systems of these organizations, one of the main goals of the Institute in the coming period will be the upgrade and expansion of the existing IT system. This primarily refers to the periodic upgrade of existing IT infrastructure, as well as design, development and implementation of an expert database and associated programs that

would contribute to automatization of the process of drafting and adoption of standards, and overall communication with external users. The same system should support an active communication with European and international organizations for standardization in order to monitor and participate in the development of European and international standards.

In addition to significant funds needed for realisation of stated objective, the expert knowledge in the area of standardization is also required, as well as designing and implementing of the software solutions. Having that in mind, the Institute will aim to achieve such a demanding task through one of the projects supported by the EU intended for strengthening the administrative capacity of institutions in Montenegro.

B. Conformity assessment

7. (Ref. to Q. 11): The reply to the question does not clearly confirm that legislation is/will be in line with Decision No 768/2008/EC. Please elaborate, clarify and assess the compliance of the current conformity assessment procedures with Decision 768/2008/EC

Montenegro has harmonized the procedures for conformity assessment with the requirements of the Regulation 768/2008/EC in part of applicable requirements that are in accordance with the Montenegrin internal market administrative legislation. The requirements of the Decision relating to the Common Market *explicite* will be subject to transposition within the revision of legislation (See answer 2b) by the end of 2010. The subject requirements will in transitional provisions of horizontal legislation be given the time limit for their entry into force on the date of accession of Montenegro into the European Union, i.e. when Montenegrin internal market becomes part of the EU common market.

8. (Ref. to Q. 12): Does the answer to the question mean that conformity certificates issued by foreign manufacturers or EU notified bodies in accordance with the *acquis* are already accepted in Montenegro? Please specify whether foreign test reports are accepted in Montenegro. Please also explain how the line ministries assess the foreign certification of another country in order to accept or not the conformity certificates?

Yes, they are accepted. Foreign test reports are accepted in Montenegro if the line ministries consider that they are acceptable for the group of products belonging to their line of work. Line ministries, primarily, perform this activity through the assessment of technical regulation equivalence relating to the subject report of the examination. The equivalence assessment is performed in accordance with the procedure prescribed by the Regulation on conditions for the application of technical regulations of other countries and evidence of foreign documents on conformity.

9. (Ref. to Q. 15): Does the fact that a Division for Quality Infrastructure was established constituting the enquiry point for technical regulation both towards the WTO and the EU mean that, apart from the Enquiry Point under the WTO TBT Agreement, an Enquiry point for the notification procedure of Directive 98/34/EC has already been created? How would this be possible without any transposition of Directive 98/34/EC? Is the Enquiry Point already operational? If yes, what is its endowment with material and human resources?

The fact is that the notification procedures to the WTO and the EU are very similar and it wouldn't be rational to have two different information points in two different places related to these two procedures. Therefore, the Department for Quality Infrastructure represents the information point along with the Directive 98/34/EC. The fact is that Directive 98/34/EC has not been fully transposed, and that will be done in the period until end of 2010.

10. (Ref. to Q. 17): Please indicate how many technical regulations have been so far included in the register?

The register of technical regulations has so far included 303 technical regulations.

11. (Ref. to Q. 18): The reply to question 18 states that many manufacturers who produce products falling under the scope of the New Approach have not yet fulfilled the requirements for the CE mark and marked their products accordingly. Please elaborate further, since the Decree on the Manner and Procedures of Assessment of Conformity of Products with Prescribed Requirements (71/08) contains a transitional provision for the use of the CE marking in its Article 24 and since the CE marking can only be attached by EU notified bodies whenever third party conformity assessment is needed.

We think that there is misunderstanding in the interpretation of the answer. The answer states that Montenegro has a small number of producers whose products fall under the groups of products from the New Approach and they all have so far met the requirements and labelled their products with CE mark. Specifically, it is a case of the manufacturer who produces horizontal devices for freezing that are marked with CE, the manufacturer of welding electrodes who have marked their product and battery manufacturer, who have also marked its product. Furthermore, Montenegro expects the continuation of significant foreign direct investments, so whether a new manufacturer in this field will appear is under close attention.

With regret we must state that in Montenegro, contrary to the impression created by reading our answer, there are not enough manufacturers in the New Approach area.

C. Accreditation

12. (Ref. to Q. 21):

a) Please specify clearly the competences of the Accreditation Body of Montenegro (ATCG)?

Establish the competence of conformity assessment bodies: testing; calibration, inspection; product certification, management system certification, certification of professionals, and in other areas in accordance with the development of accreditation systems.

Determine and declares the rules of accreditation that must be based on appropriate Montenegrin, European and other international standards and documents of European and other international accreditation organizations;

Participate in the work of European and other international organizations for accreditation and represents the interests of Montenegro in accordance with the commitments undertaken by international treaties;

Maintain a register of accredited conformity assessment bodies

Organize and conducts training of personnel in the area of accreditation;

Organize seminars, congresses, conferences and consultations, and provide information to interested users in the area of accreditation;

Carry out the promotion of the importance and the role of accreditation;

Prepare and publishes books, magazines and publications important for the area of accreditation;

Perform other tasks in the area of accreditation in accordance with the Law, the Decision on Establishment and the Statute.

b) Please specify the aspects of compliance and incompliance of the Montenegro accreditation system with Regulation 765/2008

Aspects of compliance of Montenegrin accreditation system with the Regulation 765/2008 are reflected in the implementation of the articles and provisions of Regulation 765/2008 into the national Law on Accreditation (Official Gazette of Montenegro, 54/09).

In regard to technical regulations governing the area of conformity assessment in accordance with the Regulation 765/2008, can be ascertained that the certificate of accreditation is the pre-condition for appointment or authorization of conformity assessment body.

The ATCG can, in regard to conformity assessment for which accreditation is required, refer the conformity assessment body to the national accreditation body of another state which is competent to perform the accreditation in accordance with the Regulation 765/2008.

Having in mind that the Law on Accreditation entered the parliamentary procedure shortly after the Resolution 765/2008 was adopted and considering that it involves very broad and significant scope of application, the level of approximation of the Law to the Resolution will be established by the EU experts. The experts will be engaged under the EU Action Programme IPA 2007, the realization of which has just started in Montenegro.

c) Please specify which requirements of Regulation 765/2008 are met by ATCG and which are still not?

The Accreditation body of Montenegro meets the requirements provided in Article 8 of the Regulation 765/2008, which the national accreditation body of the member states must fulfil:

1. It is organized in a manner that it is independent from the conformity assessment body which performs the assessment and ensures that there is no any conflict of interest relating conformity assessment bodies (ATCG Quality Rules of Procedure, ATCG Statute, Agreement on Engagement of Evaluators on the Evaluation Activities, ATCG Code of Ethics),
2. It is organized and functions in a way which protects the objectivity and impartiality in its activities (ATCG Quality Policy, ATCG Code of Ethics),
3. Any decision on accreditation is made by competent persons who are not the same persons who performed a particular examination (Q.2.01 Rules of Accreditation),
4. Applies arrangements for keeping the confidentiality of information attained, (Contracts on Employment, Agreement on Engagement of Evaluators on the Evaluation Activities),
5. It identified the activities of conformity assessment for which is competent in the accreditation performance, referring, where necessary, to the appropriate regulations and standards of the Community and Montenegro (ATCG Statute),
6. The procedures, necessary for the effective management and proper internal control (Q.3.04 internal audits) have been established,
7. Have on disposal a sufficient number of competent personnel to carry out its task, (The ATCG Rulebook on Quality),
8. Duties, responsibilities and authorities of personnel that could jeopardize inspections of quality and verification of competence have been documented (The ATCG Rulebook on Quality),
9. It established and implements the procedures for monitoring the performance and competence of personnel involved (Q.2.07 General Rules of Verificators, Q.2.08 Rules for the Selection and Training of Verificators),
10. Verifies its accredited conformity assessment bodies whether they conduct conformity assessment activities in an adequate way, which means that they don't unnecessarily burden themselves, and that the size of company, sector in which it operates, its structure, the degree of complexity of the technology of product and mass or serial nature of the production process is taken into consideration (Q.2.01 Rules of Accreditation),
11. Publishes reports on the audit of annual accounts that are prepared in accordance with generally accepted accounting principles.

13. (Ref. to Q. 24):

a) Please explain the reasons for such a limited number of applications for accreditation?

Number of submitted applications for accreditation is conditioned by several factors: the size of the state, power of its economy and level of development.

Accreditation activities as components of a Quality Infrastructure system were located in Belgrade, until the restoration of independence and the formation of Accreditation Body of Montenegro in 2007. Moreover, as you know, the accreditation as the most reliable evidence of competence is a

demanding process in both the organizational and financial terms for the authorities responsible for conformity assessment.

b) Please explain what is done in the country to promote accreditation?

In order to promote accreditation as the highest evidence of competence of the conformity assessment body, the ATCG in cooperation with the Chamber of Commerce of Montenegro and other institutions of quality infrastructure, the Institute for Standardization of Montenegro, Central Institute for Metrology, the Intellectual Property Office organizes promotional events in various regions of Montenegro.

In addition, the ATCG marks through appropriate media coverage the World Accreditation Day, World Day of Quality, ATCG Day, as well as the awarding of the accreditation certificates.

ATCG also, in cooperation with other accreditation bodies in the region, organizes round tables and panel discussions with participation of all interested parties.

In accordance with the document of the European cooperation for accreditation ***the Accreditation Body Communication with National Regulators Best Practice Guide*** for strengthening cooperation of accreditation body with the ministries responsible for technical regulations, the ATCG, through frequent correspondence with the ministries of the Government of Montenegro, informs their competent institutions that they should use a transparent accreditation for the conformity assessment, as provided by the Regulation 765/2008 as the most reliable tool for demonstrating technical competence and protecting the necessary level of confidence in the certificates of accreditation.

D. Metrology

14. (Ref. to Q. 25): Please outline the resources of Metrology Office and the laboratories?

Since its establishment in 2006, the Bureau of Metrology has been faced with a lack of adequate space and equipment for the formation of metrology laboratories. Given that the basis for the establishment of the Bureau was the Control of measures and precious metals, which performed a control and marking of certain types of measures, the Bureau inherited very little measuring equipment. Since at that time the national measurement standards were housed in the Bureau of Measures and Precious Metals in Belgrade, they were not available to Montenegro following independence in 2006, which meant the discontinuation of traceability.

Different activities have been realized in order to establish metrology system in Montenegro, and it is expected that the significant equipment will be provided for the Bureau of Metrology within the IPA 2007: Development of Quality Infrastructure in Montenegro - Equipment for Montenegrin Bureau of Metrology.

In the Mass Laboratory, a calibration of weights Class E2 for the measuring range from 1 mg to 50 kg can be done using the existing equipment. Calibration of the Bureau's weights Class E2 measuring range from 1 mg to 5 kg, and one individual weight of 10 kg was made in the BEV (Bundesamt für Eich 'und Vermessungswesen), so these weights are traceable to the national measurement standards of Austria. In order to enhance the capacity of the Laboratory for Mass, in late 2009 was obtained a mass comparator with measuring maximum of 200 gr, susceptometre to determine the magnetic properties of weights, as well as weights Class E1 and working weights Class F1.

The Bureau has a secondary and working measurement standards in the area of electrical quantities, pressure metrology, temperature, length metrology, and high frequencies, which were taken over from the military metrological laboratories in 2007.

During 2009, the equipment was provided in order to organize the verification and control of the basic clocks within commutation system in Montenegro: protocol analyzer and a universal counter.

In late August 2009, the European Commission has launched a tender for the procurement of metrology equipment for the Bureau of Metrology, through the IPA 2007: Development of Quality Infrastructure in Montenegro - Equipment for Montenegrin Bureau of Metrology. It is expected that during 2010, the equipment worth about EUR 900,000.00, for 7 laboratories (laboratory for mass, laboratory for length, laboratory for temperature, laboratory for pressure, laboratory for volume, laboratory for time and frequency, laboratory for electrical quantities) will be delivered to the Bureau of Metrology, the same as the equipment for testing of pre-packed products. Office space area of about 670 m², has been rented in February 2010, and the activities for preparation of premises are underway in order to provide the necessary technical and metrological requirements for the installation of the existing equipment as well as the equipment that the Institute will be provided under the IPA program.

In the process of verification of measurements, the Bureau also uses measuring equipment of persons authorized for the preparation of measuring instruments for verification.

E. Market surveillance

15. (Ref. to Q. 28):

a) Please provide a translation into English of the Decree on Exchange of Information on Products Posing a Risk and the Market Surveillance Strategy.

Please see in Annex.

b) How often testing is done? Please provide statistics for the last year.

In 2008, there were a total of 89 samples of toys taken for testing, of which eight were found to be defective (toys from China). Colour instability was determined for stuffed toy animals and rubber animals, as well as the presence of unauthorized fabric softener in dolls.

In 2009, there were 29 samples of toys taken for testing, out of which four samples were confirmed to be invalid because of health reasons due to presence of phthalates above the permissible amount (PVC toys).

In the control of liquid fuel of oil origin, in trade, at each of 26 subjects of control were taken three samples (a total of 78 samples) for analysis of compliance with prescribed standards. The results of analysis showed that 6 samples did not match the prescribed standards.

c) Please describe how coordination is ensured between the product sectors and between the market surveillance authorities and the customs authorities?

Coordination between bodies for market surveillance, including customs, is regulated by the Law on General Product Safety and the Decree on the manner of exchange of information on products

that pose risk (Official Gazette of Montenegro, 13/10), which is attached to the answer to question (a.). Cooperation between these bodies and the sector of products is subject of the Rulebook on content of notification on dangerous products, which was prepared in accordance with the Law on General Product Safety by the Ministry of Economy, and submitted in the form of proposal to the Secretariat for Legislation for harmonization. Its adoption is expected by the end of May 2010.

Coordination of bodies involved in market surveillance is subject of Market Control Strategy, which is attached as Annex.

d) In short, what would be the main amendments needed to the present legislation in order to properly implement Regulation (EC) 765/2008?

Amendments to the Law on General Product Safety have been planned in order to achieve harmonization with Regulation 765/2008. Since that Regulation repealed Regulation 339/93, the amendments will, primarily, include provisions that transpose Regulation 339/93 into the Law, that relates to cooperation of customs and market surveillance authorities (Article 15), and amendments to law, that are found to be necessary, will also be made.

Furthermore, the provisions for which the practice had shown to require correction will also be included in the amendments.

Preparation of amendments of this law is planned within the IPA Project 2010, whose implementation is expected to start in the second half of 2011.

OLD APPROACH PRODUCT LEGISLATION AND NEW AND GLOBAL APPROACH PRODUCT LEGISLATION

16. (Ref. to QQ. 29 to 32): The answers to question number 29 and the answers to question number 30, as well as 31 and 32 respectively, have been separated in a manner that was not intended. The original intention was that for each product or sector of products there would be answers to both 29 and to 30 (as well as to 31 and 32 respectively). After having answered to both questions one would move to the next product and answer to both questions 29 and 30 (31 and 32), and so on. This would have also helped avoiding unnecessary repetition per product.

Montenegro fused the answers in relation to:

the answers 29 and 30 - sectoral approach

the answers 31 and 32 - new approach

17. (Ref. to Q. 29 b) and 31 b)): please specify the missing dates under “forecast (date of adoption and implementation of the EU directives)”.

Explosives for civil use and Pyrotechnic means:

Amendments to the Law on Explosive Materials have not been planned by the Work Programme of the Government of Montenegro for 2010, and the intended dynamics of transposition of these directives is 2012, consequently the implementation of the Commission Directive 2008/43/EC (of 04 April 2008) which established, in accordance with the Council Directive 93/15/EEC concerning the introduction on the market and supervision of explosives for civilian use, as well as transposing

of the Decision of the Commission 2004/388/EC of 15 April 2004 on the document for the transfer of explosives within the Community.

For additional information about these products please see answer to question 23

- Emission of pollutants in the form of gases and particles from non-road movable engines machinery.

The Draft Law on Air Protection was adopted by the Government of Montenegro in December 2009, but not by the Parliament of Montenegro. The law is currently in parliamentary procedure, and its adoption is expected during the April's session of the Parliament which is in progress.

Article 55 of the Draft Law on Air Protection stipulates that all secondary legislation for the implementation of this Law will be adopted within three years from the date of entry into force of this Law.

Dynamics of the preparation of secondary legislation for the implementation of the Law on Air Protection planned transposition of mentioned directives on the limit values of emissions from vehicles that do not participate in road traffic is for June 2013.

Noise - Please see answer 20

Equipment and systems of protection used in potentially explosive environment ATEX - Please see answer to question 26

18. (Ref. to Q. 31): Please provide a more descriptive answer to question 31 as regards many of the New Approach sectors which only list existing or forthcoming legislation without any additional explanations about the present status. Please also include a plan for adoption of all New Approach Directives with the planned dates for transposition and implementation as well as the responsible ministry?

No.	New Approach Directives	European legislation	The competent ministry		COMMENT
1.	Simple pressure vessels	87/404/EEC	ME	IV Q 2011	NPI Revision The draft made
2.	Toy Safety	88/378/EEC 93/68/EEC	MH	IV Q 2011	
3.	Machine Safety	98/37/EC 98/79/EC 2006/42/EC	ME	II Q 2010	
4.	Personal protection equipment	89/686/EEC 93/68/EEC 93/95/EEC 96/58/EC	MLSW	2010	The competent Ministry changed in June 2010
5.	Explosives for Civil Use	93/15/EEC	MIAPA	I Q 2012	
6.	Equipment and systems of protection in a potentially	94/9/EC	ME	?	NPI Revision Will also include

	explosive environment ATEX				other relevant ministries See answer to question number 26
7.	Lifts	95/16/EC	ME	IV Q 2011	NPI Revision The draft made
8.	Non-automatic instruments for measuring	90/384/EEC	ME	IV Q 2009	Transposed through the Law on Metrology (Official Gazette of Montenegro, 79/08)
9.	Instruments for measuring	2004/22/EC	ME	IV Q 2010	Partially transposed through the Law on Metrology (Official Gazette of Montenegro, 79/08)
10.	Pressure equipment	97/23/EC	ME	IV Q 2011	NPI Revision The draft made
11.	Hot-water boilers	92/42/EEC 93/68/EEC 2004/8/EC 2005/32/EC	ME	IV Q 2011	NPI Revision The draft made
12.	Gas Appliances	90/396/EEC 93/68/EEC	ME	IV Q 2011	NPI Revision The draft made
13.	Cooling devices	96/57/EEZ	ME	2010	NPI Revision
14.	Radio telecommunications terminal equipment and	99/5/EC	MMATT	IV Q 2011	NPI Revision The draft version completed
15.	Electromagnetic compatibility	2004/108/EC	MMATT	IV Q 2011	NPI Revision The draft version completed
16.	Recreational Vessels	94/25/EC 2003/44/EC	MMATT	Transposed	Law on Yachts (Official Gazette of the Republic of Montenegro, 46/07)

17.	Cable-cars for transport of people	2000/9/EC	MMATT	IV Q 2011	
18.	Fast rail	96/48/EC 2004/50/EC	MMATT	?	
19.	Construction Products	89/106/EC 93/68/EEC	MPPE	IV Q 2013	
20.	Medical devices	93/42/EEC 98/79/EC 2000/70/EC 2001/104/EC 2007/47/EC	MH	2010	
21.	Medical devices for an active implantation	90/385/EEC 93/42/EEC 93/68/EEC 2007/47/EC	MH	2010	
22.	In vitro diagnostic medical devices	98/79/EC	MH	2010	

LEGEND:

ME	Ministry of Economy
MMATT	Ministry of Maritime Affairs, Transportation and Telecommunications
MT	Ministry of Tourism
MPPE	Ministry of Physical Planning and Environment
MLSW	Ministry of Labour and Social Welfare
MIAPA	Ministry of Internal Affairs and Public Administration
MH	Ministry of Health

19. (Ref. to Q. 30 and Q.32):

a) The name of the market surveillance authority is often missing under several product sectors, please specify it;

Please see answer under 19c

b) The replies do not always answer to all what is mentioned in the question (metrology/calibration, standards, accreditation, market surveillance). Please complete the answers

See answer under 19c

c) It would be advisable to avoid too general answers like “the law says” or “the competent authority” if from the contents of the text it is not clear to the reader which law or authority is meant. This relates also to the replies to “further evolution” under questions 30 and 32. Please answers to the questions with reference to each product, avoiding unnecessary repetitions.

Chemicals - See answer to question 21

Artificial fertilizers - See answer to question 22

Textiles and footwear - See answer to question 25

Precursors for narcotics

Supervision on the implementation of this Law is described in Article 32

Article 21 of this Law prescribes the obligation of attaching the Security List - MSDS. Secondary legislation will be passed within six months from the date of enactment of this Law.

- Legal Metrology, pre-packaging and measurement units (Directive of the Old Approach)

The Bureau of Metrology, conducts the inspection through metrology inspectors on the use of measuring units and the use of weights, and following the adoption of secondary legislation which prescribe the size and shape of the conformity quantity mark of pre-packed product, the manner of placement, the metrology requirements for bottles as measuring containers, tolerable volume variation, as well as signs and labels on bottles as measuring containers, while verification of the accuracy of the amounts specified and contained in the pre-packed products will commence, as well as supervision over the use of labels on pre-packed products. In addition to metrology inspectors, the inspection supervision over the use of labels on pre-packed products will, within their competences, also performed the market inspectors. For the purpose of more effective implementation of the metrological-inspection supervision, the proposed new Rulebook on internal organization and job classification of the Bureau of Metrology has in plan to increase the number of metrology inspectors from 2 to 5. Following the opinion of the relevant institutions on the proposed Rulebook and implementation of further procedure, the dynamics of employment and implementation of planned activities in the future period will be identified. The Institute has acquired from their own resources a part of the equipment for testing of pre-packaged products, while the other part of the equipment will be provided to the Bureau by the IPA 2007: Development of Quality Infrastructure in Montenegro - Equipment for Montenegrin Bureau of Metrology, thus it is expected that in the second half of 2010 will be started with the control of the accuracy of the quantities specified and contained in the pre-packed products.

Legal Metrology: non-automatic scales, measuring instruments (measurements)

The Bureau of Metrology, through metrology inspectors performs metrological-inspection of trade, installation, use and repair of non-automatic weighing instruments, water meters, gas meters, volume conversion devices, active electrical energy meters, heat meters, measuring installations for a continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, dimensional measuring instruments and the exhaust gas analyzer. Inspection supervision on the use of some of these measures may be carried out by the

market inspectors within their authority, as well as transportation, utilities, electric-power and thermal-power inspectors. Chief Metrological Inspector is occasionally assisted in the implementation of metrological-inspection supervision by metrologists who have been assigned with a temporary authority, since the employment of an additional inspector, which was planned by applicable Rulebook on internal organization and job classification of the Bureau of Metrology has been prevented due to the economic crisis. For the purpose of more effective implementation of the metrological-inspection supervision, the proposed new Rulebook on internal organization and job classification of the Bureau of Metrology planned to increase the number of metrology inspectors from 2 to 5. After providing the opinion of the relevant institutions on the proposal of the Rulebook on internal organization and job classification and implementation of further procedure, dynamics of employment and the implementation of planned activities in the future will be identified.

Electromagnetic compatibility (EMC)

Radio and Telecommunications Terminal Equipment (R & TTE)

By adopting the aforementioned rulebooks, together with a full cooperation between the Institute for Standardization of Montenegro, Accreditation body of Montenegro, Institute for Metrology and other governmental and scientific institutions, the procedures for products from these areas should be consolidated and completed.

Further development in this area is expected through implementation of stated regulations in accordance with human resources at the level of ministries, regulatory bodies and inspection bodies.

List of harmonized standards related to electromagnetic compatibility directive (EMC) and Radio and Telecommunications Terminal Equipment (R & TTE) data is attached as Annex

Noise emitted by equipment used outdoors - Please see answer to question 20

ATEX - Please see answer to question 26

Cable drives

The Law on Safety in Railway Traffic (Official Gazette of Montenegro, 4/08), prescribes the conditions for organizing transportation of cable cars, cableways and ski lifts, in regard to technical elements and requirements for construction, reconstruction and maintenance and other conditions for safe conduct of that kind of traffic.

The area of cable drives for transport of people is also regulated through two secondary legislations:

Rulebook on technical standards for ski-lifts (Official Gazette of the Socialist Federal Republic of Yugoslavia 2/85);

Rulebook on technical norms for personal cable drives (Official Gazette of the Socialist Federal Republic of Yugoslavia 29/86).

Based on the Rulebook on technical norms for personal cable drives, it was provided that each cable car must be equipped with the instructions for use and maintenance.

b) prediction (date of adoption and implementation of EU directives).

The adoption of secondary legislation under the Law on Safety in Railway Traffic is planned in the coming period, which will regulate the area of cable drives and will implement the Directive 2000/9/EC - Cable Drives for transport of people.

The work on the harmonization of legislation for the cable drives was planned for the mid 2010 within the Twinning Project "Legal Harmonization" that was launched in February 2009 with

Slovenian partner. Adoption of this secondary legislation is planned by the end of 2011.

a) brief description and

As it can be seen from the attached table (Annex), the Institute for Standardization of Montenegro adopted 22 of 23 harmonized Montenegrin standards (MEST) that are related to the Directive 2000/9. The Institute for Standardization has forecasted that the European standard (EN 12929-2:2004) will be adopted at the national level by June 2010.

In Montenegro, there is no body for conformity assessment dealing with cable drives.

b) further development.

In question 31 we have defined when the secondary legislation will be adopted, that will regulate the area of cable drives, in which will be applied the previously mentioned standards relating to the cable drives, i.e. Directive 2000/9/EC.

Recreational Vessels

The Law on Yachts (Official Gazette of the Republic of Montenegro 46/07) implemented the EU Directive on vessels for sport and recreation (Recreational Craft Directive 94/ 25/EC and Declaration of Conformity), as well as Resolution no. 40 on Certification for Operators of Pleasure Craft (Resolution no. 40 of Economic Commission for Europe Inland Transport Committee regarding International Certificate for Operators of Pleasure Craft, TRANS/SC.3/147). Aforementioned directives and resolutions are fully harmonized.

a) prediction (date of adoption and implementation of EU directives).

Construction of boats is prescribed by the Administration for Maritime Security - Technical rules of statutory certification of boats and yachts, Part II - Monitoring / assessment of compliance during the construction of boats or yachts which fully implemented Directive 94/25/EC with amendments of the Directive 2003/44/EC.

After the expiry of the existing standard permissions, the boat constructors will be compelled by the requirements specified in the Technical Administration of maritime safety rules for statutory certification of boats and yachts, Part II - Monitoring / assessment of compliance during the construction of boats or yachts, which are related to boats intended for sport and leisure.

MONITORING / EVALUATION OF COMPLIANCE DURING CONSTRUCTION BOAT OR YACHT

(Brief description)

GENERAL

1.1 APPLICATION

1.2 DEFINITIONS

2. BASIC TECHNICAL REQUIREMENTS

2.1 GENERAL

2.2 PROJECT CATEGORY OF VESSELS

2.3 GENERAL REQUIREMENTS

2.3.1 Definition of basic meaning of vessel

2.3.2 Identification number of vessel

2.3.3 Builders plate

2.3.4 Protection of persons on board the vessel from falling into the sea, and means for embarking people who are in the sea onto the boat

2.3.5 Visibility from the main manoeuvring position of the vessel

- 2.3.6 Manual for the use of vessels
- 2.4 BASIC REQUIREMENTS FOR VESSEL CONSTRUCTION
 - 2.4.1 Structure of trunk
 - 2.4.2 Buoyancy, stability, freeboard
 - 2.4.3 Openings on the hull, deck and superstructure
 - 2.4.4 Flooding
 - 2.4.5 The largest load allowed on the vessel
 - 2.4.6 Position of life rafts
 - 2.4.7 Leaving the boat in case of accident
 - 2.4.8 Anchoring, berth and haul
- 2.5 REQUIREMENTS FOR VESSEL MANEUVERING
- 2.6 MECHANICAL DEVICES, ELECTRICAL EQUIPMENT, FIRE PROTECTION, MEANS FOR NAVIGATION
 - 2.6.1 Engine and engine room
 - 2.6.2 Fuel System
 - 2.6.3 Electrical Equipment
 - 2.6.4 Steering system
 - 2.6.5 Gas installations
 - 2.6.6 Fire Protection
 - 2.6.7 Navigational lights
 - 2.6.8 Prevention of pollution and means for discharging to land
- 2.7 BASIC REQUIREMENTS REGARDING DISCHARGES OF EXHAUST GASES FROM THE MAIN ENGINES
 - 2.7.1 Engine Identification
 - 2.7.2 Requirements for exhaust gases
 - 2.7.3 Durability
 - 2.7.4 Manual for the use of engine
- 2.8 BASIC REQUIREMENTS FOR NOISE
 - 2.8.1 Noise
 - 2.8.2 Instructions for use
- 2.9 TECHNICAL REQUIREMENTS FOR CONSTRUCTION OF INFLATABLE VESSELS
 - 2.9.1 Inflatable vessels that use propulsion engines of maximum power 4.5 kW and smaller
 - 2.9.2 Inflatable boats that use propulsion engines of over 4.5 kW but less and including 15 kW
 - 2.9.3 Inflatable boats that use propulsion engines over 15 kW
- 2.10 BASIC TECHNICAL REQUIREMENTS FOR PERSONAL USE OF THE VESSELS WITH WATER-SPOUT POWER
- 2.11 BASIC TECHNICAL REQUIREMENTS ON SOME COMPONENTS OF THE VESSEL
 - 2.11.1 General

- 2.11.2 Basic technical requirements
- 2.12 TECHNICAL DOCUMENTS WHICH MUST BE PRODUCED BY MANUFACTURER
 - 2.12.1 General
 - 2.12.2 Documentation
- 3. PROCEDURES OF CONFORMITY ASSESSMENT OF PROJECT AND CONSTRUCTION OF VESSELS
 - 3.1 GENERAL
 - 3.2 MODELS FOR EVALUATION OF CONFORMITY
 - 3.2.1 1 Internal control of production (Model "A")
 - 3.2.2 Internal control of production with the required examination (Model "AA", option 1)
 - 3.2.3 Standard approval (Model "B")
 - 3.2.4 Conformity assessment with the prototype (Model "C")
 - 3.2.5 Conformity Assessment of quality system in manufacturing (Model D)
 - 3.2.6 Conformity Assessment (Model "F")
 - 3.2.7 Individual assessment of the product (Model "G")
 - 3.2.8 Full Quality Assurance (Model "H")
 - 3.2.9 Product Quality Assurance (Model E)
 - 3.2.10 Certification of conformity on the production of exhaust gases and noise
 - 3.2.11 Declaration of Conformity Assessment
- 4. CERTIFICATION OF VESSELS FOR LEISURE AS DIRECTED 94/25/EC WITH THE ADDITIONS
 - 4.1 DEFINITION
 - 4.2 APPLICATION
 - 4.3 PROCEDURES OF CONFORMITY ASSESSMENT OF PROJECT AND THE CONSTRUCTION OF VESSELS AND INDIVIDUAL COMPONENTS
 - 4.3.1 Conformity Assessment of project and the construction of vessel other than vessel for personal use on water spout power
 - 4.3.2 Conformity Assessment of project and the construction of vessel for personal use on water spout power
 - 4.3.3 Conformity Assessment of project and construction of vessel components listed in paragraph 2.11 of this part of the Rules
 - 4.4 CONFORMITY ASSESSMENT ON THE EXHAUST GASES REQUIREMENTS
 - 4.5 CONFORMITY ASSESSMENT ON THE NOISE REQUIREMENTS
 - 4.5.1 Conformity Assessment for the vessels referred to in paragraph 4.2.3 a) and b) of this part of the Rules
 - 4.5.2 Conformity Assessment for the vessels referred to in paragraph 4.2.3 c) and d) of this part of the Rules
 - 4.6 RELATIONSHIP BETWEEN THE RULES AND DIRECTIVES 94/25/EC WITH ADDITIONS
 - 4.6.1 Basic technical requirements concerning the construction of vessels
 - 4.6.2 Basic technical requirements concerning exhaust gases
 - 4.6.3 Fundamental technical requirements for the volume of noise
 - 4.6.4 Conformity assessment procedures

4.6.5 Correlation between Montenegrin standardaa and EN and ISO standards

4.7 DECLARATION OF PRODUCER ON PLACING PARTLY CONSTRUCTED VESSELS AND VESSEL COMPONENTS ONTO THE MARKET

4.6.1 Fundamental technical requirements concerning the construction of vessels

Description of the basic technical requirements	The corresponding part of the Rules	The corresponding point in Appendix I, Part A, of Directive 94/25/EC with amendments
General Requirements	2.3	2
Mark of the vessel's hull	2.3.2	2.1
Builder's Plate	2.3.3	2.2
Protection of persons on board the vessel from falling into the sea, and means for embarking people who are in the sea onto the boat	2.3.4	2.3
Visibility from the main manoeuvring position of the vessel	2.3.5	2.4
Manual for the use of vessels	2.3.6	2.5
Requirements for the construction	2.4	3
Hull structure	2.4.1	3.1
Buoyancy, stability and freeboard	2.4.2	3.2 i 3.3
Openings on the hull, deck and superstructure	2.4.3	3.4
Flooding	2.4.4	3.5
The largest load allowed on the vessel	2.4.5	3.6
Position of life rafts	2.4.6	3.7
Leaving the boat in case of accident	2.4.7	3.8
Anchoring, berth and haul	2.4.8	3.9
Requirements for safe vessel manoeuvring	2.5	4
Mechanical appliances, electrical equipment, fire protection, means of navigation, steering systems, gas installations	2.6	5
Engine and engine room	2.6.1	5.1
In-built power engines	2.6.1.1	5.1.1

Ventilation of engine room	2.6.1.2	5.1.2
Exposed parts of the engine	2.6.1.3	5.1.3
Initiation of Outboard engines	2.6.1.4	5.1.4
Specific requirements for the power device of the water scooter	2.6.1.5	5.1.5
Fuel System	2.6.2	5.2
General requirements for the fuel system	2.6.2.1	5.2.1
Fuel tanks	2.6.2.2	5.2.2
Electrical Equipment	2.6.3	5.3
Steering system	2.6.4	5.4
General	2.6.4.1	5.4.1
Emergency steering	2.6.4.2	5.4.2
Gas installations on the ship	2.6.5	5.5
Fire-fighting protection	2.6.6	5.6
General	2.6.6.1	5.6.1
Fire-fighting equipment	2.6.6.2	5.6.2
Navigation lights	2.6.7	5.7
Prevention of pollution and equipment for discharging to land	2.6.8	5.8

4.6.2 Basic technical requirements concerning exhaust gases

Description of basic technical requirements	Corresponding part of the Rules	Corresponding point in Appendix I, Part B, of Directive 94/25/EC with additions
Identification of the engine	2.7.1	1
Requirements for the exhaust gases	2.7.2	2
Durability	2.7.3	3
Manual for use	2.7.4	4

4.6.3 Basic technical requirements for the noise volume

Description of the basic technical requirements	Corresponding part of the Rules	The corresponding point in Appendix I, Part C, of Directive 94/25/EC with additions
Noise level	2.8.1	1
Manual for use	2.8.2	2

4.6.4 Conformity Assessment procedures

Description of the basic technical requirements	Corresponding part of the Rules	Corresponding addition in the Directive 94/25/EC with additions
Internal control of production (Model "A")	3.2.1	Appendix V
Internal production control with mandatory testing (Model "AA", Option 1)	3.2.2	Appendix VI
Standard Testing (Model B)	3.2.3	Appendix VII
Conformity Assessment with the prototype (Model "C")	3.2.4	Appendix VIII
Conformity Assessment of quality system in production (Model D)	3.2.5	Appendix IX
Conformity Assessment (Model "F")	3.2.6	Appendix X
Individual assessment of the product (Model "G")	3.2.7	Appendix XI
Full quality assurance (Model "H")	3.2.8	Appendix XII
Product Quality Assurance (Model E)	3.2.9	Appendix XVI
The certification of conformity in the production concerning exhaust gases and noise	3.2.10	Appendix XVII
Declaration of Conformity	3.2.11	Appendix XV

The list of standards related to the directive relating to recreational vessels is given in the annex.

b) further development

The Maritime Safety Administration will acknowledge all ISO standards by applying these technical rules, while the control of products will pass on the so-called "Reported body", "Notification body" which is engaged by the manufacturer, with the approval of relevant authorities of Montenegro, or with the approval of recognizable Organization (IMO Res. A. 739 (18)), in order of performing conformity assessment of product with the requirements of the guidelines and standards of the EN ISO and within that implements the "EC Standard Testing" of product (eg. TUV NORD Group and

Mar-ED Group). In this way has also being respected the Directive 96/98/EC - Marine Equipment Legislation which is aimed at setting standards and use of services of the "Reported body" as a controller of EN ISO standards.

Supervision over the implementation of the Law on Yachts, pursuant to Article 40, is conducted by the ministry competent for transport, i.e. Inspector for navigation safety.

Our intention is that in the further development create the technical rules in which the standards for the production of small passenger ships and boats for economic activity will be applied.

20. (Ref. to Noise emissions by outdoors equipment at p. 63): Please note that Directive 2002/49/EC relating to the assessment and management of environmental noise does not belong under this negotiating Chapter. Directive 2000/14/EC relating to the noise emissions in the environment by equipment for use outdoors however does.

Law on Protection Against Environmental Noise (Official Gazette of the Republic of Montenegro 45/06) regulates the protection against noise in the environment and determines measures to combat the harmful effects of noise on human health.

In the meaning of this Law (Article 5, paragraph 2) a source of noise is any machine, device, equipment, installation, machinery, and assets for work and transport, technological process, electro-acoustic device for loud broadcasting of music and speech, noisy activities of humans and animals and other acts which spread the sound. Noise sources are also considered to be entities such as immovable and movable objects, indoor and outdoor spaces for sports, play, dance, shows, concerts, listening to music and similar.

Article 8 defines measures of protection against noise.

Noise protection measures are:

- 1) Normative measures:
 - regulations relating to noise limits, methods of assessment and measurement of noise and creation of noise maps and action plans;
 - **procedures for verifying and issuing certificates of conformity of noise emission with the prescribed noise sources limit values.**
- 2) Planning and urban development measures:
 - **planned location of the noise source in relation to objects and areas that need protection;**
 - plans for urban and intercity transport and planning and management of road, rail, air and maritime transport.
- 3) Technical measures:
 - **selection and use of low-noise machines, devices, means for work and transportation;**
 - execution of appropriate sound insulation in buildings in which sources of noise are located;
 - Application of acoustic protective measures in places of emergence and spread of road noise.

Article 13 of this Law defines, within the normative measure, that machines, transport vehicles, appliances and equipment which are produced in Montenegro or imported into the territory of Montenegro must, in order of being placed into circulation or use, be consistent with technical standards relating to threshold level of noise under certain conditions of use, and data on the power sound emitted under these conditions of use must be indicated on the product in accordance with special regulations and guidelines and norms of the European Union.

Technical noise protection measures in Article 16 require that noise protection measures related to the selection and use of low-noise machines, devices, assets for work and transport are conducted by applying best available techniques that are technically and economically viable, in accordance

with a separate law, while Article 18 stipulates that the sources of noise that are used for execution of work, which are temporarily used or are permanently placed in an open space at the ground level, on the walls and roofs of buildings, immovable and movable objects, or for use in water or in the air, must have information on the sound effect. **These noise sources can be used if the competent authority determines that noise from such source will not exceed the limits of noise level in the environment.**

Article 26 defines the supervision on the implementation of this Law and regulations enacted under this Law and it read as follows:

Supervision on the implementation of this Law and regulations enacted under this law is performed by:

- 1) competent state administration body, in relation to the facilities and activities for which the work permit is issued by the state administration;
- 2) competent authority of local administration, in relation to the facilities and activities for which work permit is issued by the local authority, in accordance with the law.

Rulebook on limit values of noise levels in the environment (Official Gazette of the Republic of Montenegro, 75/06) defines the limits of noise level in the environment.

Article 2 defines the limits of noise level in open residential spaces.

Article 2

Limits of the noise level in open residential spaces are:

Zone	Function of space	Boundary noise levels in open residence in the territory of $L_{Aeq,u}$ dB(A) (A)		
		Day	Evening	Night
I	Specially protected natural resources (national parks, nature parks, reserves, etc.).	35	30	30
II	Areas for relaxation and recreation, hospital and rehabilitation areas, cultural and historical sites	50	40	40
III	Tourist areas and small villages, camps and school zones	50	50	45
IV	Purely residential areas, large urban parks	55	55	45
V	Business and residential areas, tourist resorts, children's playground	60	60	50
VI	City centre, craft, trade, administrative and administrative area with housing, areas near to urban roads, motorways and highways	65	65	55

VII	Industrial, warehouse and service areas, transportation terminals with no buildings, open catering facilities outside settlements	On the border of this zone noise must not exceed limits of the noise level of the zone with which it borders
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Rulebook on limit values of noise levels in the environment (Official Gazette of the Republic of Montenegro 75/06) refers to the values of the **emission** levels of noise in the environment. The levels of noise **emission** of construction plants, equipment and the industry are not covered by this regulation.

b. prediction (date of adoption and implementation of EU directives)

The harmonization plan of Montenegrin legislation with the *acquis communautaire* envisaged the development of the new Law on Protection Against Environmental Noise that will achieve a complete harmonization with the Directive 2002/49EC on testing and management of noise in the environment. Together with the new law, a secondary legislation will define the limits of noise and transpose the relevant provisions of the directive concerning the sources of noise. This process includes harmonization with the Directive 2000/14/EC (amended by the Directive 2005/88/EC and Regulation (EC) No 219/2009) on the noise emissions from equipment used outdoors into the environment.

Adoption of the new Law on Protection Against Environmental Noise is planned by the end of 2010.

In accordance with the Directive 2000/14/EC (ANNEX III - Methods for measuring ambient noise emitted from equipment used outdoors, PART A - BASIC NOISE EMISSION STANDARDS) two basic standards for the definition of sound power levels of equipment used in the open (in accordance with Article 2, paragraph 1 of the directive) have been specified:

EN ISO 3744:2009

EN ISO 3746:2009

Both standards were adopted at the national level, according to the latest version:

MEST EN ISO 3744:2009

MEST EN ISO 3746:2009

The Directive also contains standards for certification (type-approval) of specific types of equipment - microphone position, the determination of the surface on which the tests are conducted, the manner in which the tests of the equipment under pressure are conducted, period of measuring, conditions of implementation of measuring in a closed space, and so on., which are all specifically related to the implementation of certification procedures.

21. (Ref. to Chemicals): The Montenegro Law on Chemicals appears to be a good step towards harmonisation with the REACH legislation, but the Montenegrin authorities should be aware that the distinction between new and existing chemicals does not exist in REACH. In the second paragraph (under Chemicals on page 29) it is stated that "The Law on Chemicals also includes the obligations arising from... and the Regulation 32006R1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency." It is not clear what this means. Has REACH been adopted? Some further explanation is needed.

Chapter II (Articles 7 to 21) and Chapter III (Articles 22 to 28) of the Law on Chemicals generally define the provisions relating to the registration and approval of new chemical and the manner of registration of existing chemicals. Articles 29 and 30 of Chapter IV "Evaluation of chemicals and risk assessment" of the Law on Chemicals, define evaluation and assessment of chemical risks, while Articles 54 and 55 of Chapter IX "The protection of human health and the environment" of this Law define the prohibition and restrictions on sales of dangerous chemicals. Full compliance with the REACH (1907/2006) is planned in 2011.

Law on Chemicals in Chapter IV (Article 32 to 39) is largely in agreement (terminology, class of danger) with the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD). However, the process of drafting the Rulebook on the terms and principles and classification of packaging and labelling of chemicals that will be fully in line with CLP (1272/2008) is underway.

22. (Ref. to fertilisers):

a) How does Montenegro ensure that mineral fertilisers which are marked in the following way: "EC FERTILISER" can circulate freely on its market? Is it understood that if plant nutrition products contain also dangerous substances, then regulations that regulate dangerous substances shall also be applied to the trade and application of plant nutrition products?

Article 12 of the Law on Plant Nutrition (Official Gazette of the Republic of Montenegro 48/07 and Official Gazette of Montenegro 76/08) stipulated:

- that products for plant nutrition must be declared;
- that declaration is issued by the manufacturer;
- That products for plant nutrition must conform to the characteristics stated in the declaration.

The Declaration specifically includes the following information:

- Name and address of manufacturer or importer;
- Trade name of the product for plant nutrition;
- The title "EC FERTILISER", written in large block letters, if mineral fertilizer meets the set requirements;
- Name and type of product for plant nutrition;
- Name, type and content of nutrient;
- The name and content of other substances that product for plant nutrition contains;
- Net weight or volume of product for plant nutrition;
- Guidelines on handling and storage of product for plant nutrition;

- Instructions on the conditions for the use of product for plant nutrition.

In this way is provided that the product for plant nutrition labelled "EC FERTILISER" can freely circulate in the market.

If products for the plant nutrition also contain hazardous substances, then the regulations governing hazardous materials apply for the sales and use of products for plant nutrition. This is stipulated in Article 1, paragraph 3 of the Law on the Plant Nutrition Products (Official Gazette of the Republic of Montenegro, 48/07 and Official Gazette of Montenegro, 76/08).

In the same Article in paragraph 2 is stipulated that if the products for plant nutrition contain products for crop protection, than the regulations governing crop protection also apply to the sales and use of the plant nutrition products.

b) How will Montenegro apply the 16% nitrogen limit for ammonium nitrate fertiliser as foreseen in entry 58 of Annex XVII of REACH (see Commission Regulation No 552/2009)? We have information that Montenegro currently authorizes the trade of AN containing max 28% nitrogen by mass.

As regards the application of Commission Regulation (EC) 552/2009 of 22 June 2009 amending Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII of the amended Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in accordance with the answer given to question 35 in Chapter - Chemicals - full compliance of the applicable Law on Chemicals with these regulations is planned for 2011.

Notwithstanding the abovementioned, harmonisation of the Law on Chemicals, in relation to the application of restrictions on ammonium nitrate CAS No. 6484-52-2 EC No. 229-347-8, since the adoption of the Law on Plant Nutrition Products (Official Gazette of the Republic of Montenegro, 48/07 and Official Gazette of Montenegro, 76/08), the Phytosanitary Administration intensively works on its implementation, so that the trade (import, wholesale trade and retail)* is only dealt by persons listed in the Phytosanitary Administration Register. These licensed persons sell the plant nutrition products only to persons or farmers for the use in agricultural activities.

Phytosanitary Administration will introduce the limitation on the trade of fertilizers that contain 16% or more % by weight of nitrogen in relation to the ammonium nitrate, except for direct supply in accordance with the term prescribed in paragraph 58 of Annex XVII REACH of 27 June 2010.

Specifically, Article 8 of the Law on Plant Nutrition Products (Official Gazette of the Republic of Montenegro, 48/07 and Official Gazette of Montenegro, 76/08) prescribes the possibility that if it is determined by scientific and technical facts that the plant nutrition products present a risk to health of humans, animals, plants and the environment, although it meets the conditions provided by law, the Phytosanitary authorities may:

- 1) temporarily or permanently ban the its production and trade, or
- 2) establish specific requirements for production, trade and use of plant nutrition products.

As for the information that Montenegro currently approves trade of AN containing max 28% nitrogen by weight, such fertilizers were imported under strictly controlled conditions i.e. the Phytosanitary Administration used to issue the approvals with certain conditions under which such fertilizer could be imported to Montenegro (import is granted to a licensed person for the registered end user who is engaged in agricultural activity).

*In Montenegro, there is no production of mineral fertilizers.

23. (Ref. to explosives): Please provide a translation into English of the Law on Explosive Substances (Official Gazette of Montenegro 49/08). Please specify the planned timing for the taking over of:

See answer to question 23b)

a) Commission Directive 2008/43/EC (of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses); and

See answer to question 23b)

b) Commission Decision 2004/388/EC (of 15 April 2004 on an Intra-Community transfer of explosives document).

The information missing under the "forecast, the date of the adoption and implementation of EU directives 2008/43/EC of 4 April 2008, establishing a system for identification and traceability of explosives for civil use, in accordance with the Council Directive 93/15/EEC and Commission Decision 2004/388/EC of 15 April 2004 on the document on intra-Community transfer of explosives is given in the following text:

The Law on Explosive Substances (Official Gazette of Montenegro, 49/08) regulates the conditions of production, sales, purchasing, storage and use of explosive substances in order to protect life, health and safety of people, animals and plants, environment and property, as well as the issues important for performing these activities, whereas is explicitly stated, in the meaning of this Law, what is considered an explosive substance (commercial explosives, etc.).

The authority of the Ministry of Internal Affairs and Public Administration - Department for Emergency Situations and Civil Safety is reflected in the creation and compliance of the conditions that explosive mixtures do not cause an explosion. In this regard, we are authorized to prescribe and apply regulations which will define the institute of a danger zone and security distance. Moreover, the equipment that is used and is utilized in potentially explosive environments must serve a protective function.

Technical requirements and conformity assessment procedures described in Article 11 and 15 of the Law on Explosives prescribe that the approval for placing explosives on the market or their use is issued on the request of the supplier only if its conformity have been assessed in accordance with prescribed procedural technical requirements and if explosive substances are properly marked in the manner prescribed by the Ministry.

Compliance of explosive substances with the technical regulation in the conformity assessment procedure is ensured by implementation of one of the following actions: initial testing of the product type (procedure B) by the natural or legal person authorized for conformity assessment and assessment of conformity on the manufacturer's choice with the product's type (type assessment), testing of the random samples of product (process C) by the natural or legal person authorized to assess compliance with the certified type of product (conformity with the type), providing quality of manufacturing through evaluation of the quality system, with control of the natural or legal person authorized for conformity assessment (procedure D), ensuring product's quality through quality assessment system, under the supervision of a legal or natural person authorized for conformity assessment (procedure E), inspection and testing of each product (product verification) by a legal or natural person authorized for conformity assessment (procedure F), review and testing of each product with the technical requirements (individual verification) by a legal or natural person authorized for conformity assessment (treatment G).

Professional activities of conformity assessment are carried out by physical or legal persons authorized by the Ministry. Prior to the issuance of authorizations to legal and natural persons, the

competent accreditation body must establish that they are capable to perform the conformity assessment activities in accordance with the technical requirements. When they no longer meet the requirements regarding professional qualifications or technical equipment the Ministry will remove their authority.

Technical requirements for explosive substances, procedures for conformity assessment and the conditions and manner of recognition of documents and conformity mark that are issued in another country, are prescribed by the Ministry in cooperation with the Ministry in charge of the economy. Amendments to the Law on Explosive Substances, have not being planned by the Work Programme of the Government of Montenegro 2010, while the planned dynamics of transposition of directives is 2012, so is the implementation of the Commission Directive 2008/43/EC (of April 04 2008) which establishes, in accordance with the Council Directive 93/15/EEC regarding the placing onto the market and supervision of explosives for civilian use, as well as transposing the Commission Decision 2004/388/EC of 15 April 2004, on the document for the transfer of explosives within the Community.

Documents and labels on the conformity of explosive substances, which are issued in another state are recognized in Montenegro provided that they are issued on the basis of technical regulations that are, in terms of technical requirements, identical with Montenegrin technical regulations and if the competency of the body that participated in the evaluation process of conformity is determined by the same procedure and requirements set forth for the such body in Montenegrin technical regulation. Furthermore, the Ministry may take samples of explosive substances that are in circulation in order to verify conformity, if there is suspicion that further use of explosive substances could endanger lives and health, material goods and environmental; may prior to the assessment of conformity, temporarily prohibit trade and use of explosive substances and if the sample taken does not match the required technical requirements ban the use of explosive substances, and the supplier is obliged to destroy them or return to the manufacturer. Conformity assessment is carried out by legal and natural persons, and costs of the verification of compliance is borne by the manufacturer or supplier if it is determined that the sample does not match the technical requirements, or the Ministry if the sample matches the technical requirements.

Conformity assessment procedures are prescribed in accordance with the Decision of the European Union Council 93/465/EEC and 93/15/EEC, concerning the placing on the market and surveillance of explosives for civilian use.

The Law on Explosive Substances (Official Gazette of Montenegro 49/08) is included in the Annex.

We have initiated at the Institute for Standardization of Montenegro the process of development of Montenegrin standards, and the following Montenegrin standards, in the area relating to explosives for civil use (Annex), have been adopted.

On the basis of the Law on Explosive Substances (Official Gazette of Montenegro 49/08), Law on Transport of Dangerous Goods (Official Gazette of Montenegro 5/08), Law on Protection and Rescue (Official Gazette of Montenegro 13/07) and the Law on Inspection Control (Official Gazette of The Republic of Montenegro 39/03), the competences of the Ministry of Internal Affairs and Public Administration - Sector for Emergency Situations and Civil Safety are:

- Inspection control in the area of protection from fire, explosions, accidents, technical protection of locations, personnel and facilities;
- Review of investment-technical documentation,
- Supervision of objects in which hazardous materials are stored or used in technological process in order to determine the danger zone
- Supervision of technical protection systems that directly affects to the increase of safety and reduces the risk of various accidents - fire, accidents, incidents in chemical plants;
- Control of the explosive material storage.

24. (Ref. to Pharmaceuticals): Please note that the following Directive is missing from the list of acquis to be transposed: Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products. Is there a particular reason?

There are no particular reasons why the directives 91/412/EEC is omitted. The subject Directive is at the point 5 of the answer below

Pharmaceutical products:

1. Rulebook on quality control of medicines (by the end of 2009) – Adopted: Rulebook on the content and manner of implementation of pharmaceutical testing of the medicine in order to control the quality (Official Gazette of Montenegro 4/10 of 24/01/2010),
2. Amendments to the Law on Pharmaceuticals (November-December 2009), Harmonization with the directives and regulations: 2001/83/EC, 2004/27/EC, EC/726/2004, 2004/28/EC, 2001/82 EC - postponed for second half of 2010,
3. Rulebook on clinical testing of medicines for use in human medicine including good clinical practice guidelines (GCP), (end of 2009). Harmonization with the directives 2005/28/EC, 2001/20/EC - delayed until end of 2010,
4. Rulebook on Pharmacovigilance (until the end of 2009). Harmonization with the regulations and directives 2001/83/EC and EC/726/2004 - delayed until end of 2010,
5. Rulebook on conditions to be met by legal entities that produce medicines 3. Guidelines of good manufacturing practice (first half of 2010) Harmonization with the directives: 2003/94/EC, 91/412/EEC - delayed until end of 2010,
6. Rulebook on the pharmacological-toxicological testing of medicines and the required documentation for permitting their circulation (first half of 2010th year). Harmonization with the directives 2001/83/EC, 2003/63/EC - delayed until end of 2010,
7. Rulebook on traditional herbal medicines (the other half of 2010). Harmonization with the directives 2001/83/EC, 2004/24/EC - postponed for the first half of 2011,
8. Rulebook on the marking of medicines (first half of 2010) Harmonization with the directives 2001/83/EC - delayed until end of 2010,
9. Rulebook on the notification and advertising of medicines (the second half of 2010). Harmonization with the directives 2001/83/EC - postponed for the first half of 2011,
10. Rulebook on the conditions to be met by legal persons involved with wholesale trade in medicines (first half of 2010) - delayed until end of 2010,
11. Rulebook on the intervention import of medicines (first half of 2010) - delayed until end of 2010,
12. Rulebook on homeopathic medicines (second half of 2010). Harmonization with the directives 2001/83/EC - postponed for the first half of the 2011.

In order to further clarify the part of the answer in the area of Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance we provide a detailed description in terms of quality control carried out on the market.

The Agency, under the Law on Pharmaceuticals (Articles 77-81a), has the right to conduct the following types of quality control of medicines:

Quality control of medicine prior to putting medicine on the market:

- Quality control of medicine in the procedure of permit issuance for putting medicine on the market (in the process of registration). This is particularly true in relation to manufacturers who have not yet applied the European standards of good manufacturing practices:

- Quality control of the first series of medicine after issuance of permit for putting medicine on the market (the first series that appears on the market after the registration of medicine);
- Quality control of the medicine in the process of revision and amendment, as well as renewal of permit for placing on the market, if necessary;
- Mandatory quality control (re-control) of each series of medicines that are in the category of hazardous medicines: the immune medications, radiopharmaceutical medicines and medications from the blood or plasma (the manufacturer, when releasing medicine on the market must, in addition to control in its own laboratory, make re-control in an independent laboratory (Agency for Medicines of Serbia or Agency for Medicines of Croatia or OCABR (Official Control Authority Batch Release) certification from the European Union);
- Re- control quality of medicine that possess a manufacturer's certificate on the completed quality control of the series, for medicines of domestic or foreign manufacturers that do not meet fully the standards of good manufacturing practices.

Quality control of medicine in the market (after the registration of medication):

- Taking random samples at least once during the validity of the permit to put medicine on the market (in 5 years). Inspectors of the Ministry of Health take samples from the market (from pharmacies, wholesale pharmacies, health institutions) and they are sent to one of the authorized laboratories for the analysis (226 samples from the market have already been analysed in the laboratory of the Agency of Serbia). Control of samples from the market can be performed more frequently than once during the validity of the permit for placing on the market if a problem with the medicine on the market is identified - suspicion in the quality of medicine, frequent reports of adverse effects, deviations from the specifications in the previous control. If during these spot checks (more often than once in every five years) is shown that the medicine is in accordance with the standards, the control costs are borne by the Agency.
- Quality control of each series of imported medicine (depending on whether the manufacturer has implemented the European GMP requirements and whether the *batch release* of the series is carried out in the territory of the EU determines whether to do laboratory control or control of manufacturer's certificate).

Quality control of main and Galenic medicines

Quality control of the medicine is performed through:

- Evaluation of the certificate on completed quality control of medicine issued by the manufacturer and / or licensed laboratories which must be in accordance with European, or other recognized pharmacopoeia or proven methods of analysis and / or
- Laboratory examination in licensed laboratories

The Agency currently does not have its own laboratory for quality control, and uses the services of the National Control Laboratory of the Agency for Medicines and Medical Devices of Serbia and the Agency for Medicines and Medical Products of the Republic of Croatia, on the basis of signed Agreement i.e. Protocol on Cooperation (referred laboratories participate in the OMCL *proficiency* studies with good result).

The agency also recognizes as valid the certificates issued by laboratories that are members of the network of European laboratories OMCL (Official Medicines Control Laboratory Network).

If it is determined that the medicine is not in compliance with standards (outlined in Article 23 of the Law), the Agency recommends to competent inspection of the Ministry of Health suspension, i.e. prohibition of trade and the withdrawal of medicine from the market.

The Agency is responsible for issuing licenses for medicines manufacturing and wholesale trade of medicines (wholesale pharmacies), and for that purpose it establishes the committees that inspect whether the conditions for carrying out these activities in terms of space, personnel and equipment are conducted in the manner envisaged by the Law on Medicines.

Permits for carrying out these activities are issued for unlimited period, after which the inspection of them is done by the Ministry in charge of health.

25. (Ref. to Textiles and footwear): The Montenegrin authorities undertake to transpose all the relevant EU legislation on the field of textiles and footwear, as by the time being, the Montenegrin legislation in force is not in compliance with the EU rules. All the EU legislation which is intended to be transposed is mentioned on pages 43 - 44 of the reply. The following changes should however be made:

See answer to question 25 c)

a) Montenegro refers to Directive 96/74/EC on textile names. This Directive has however been repealed by Directive 2008/121/EC on textiles names (recast). Therefore Montenegro should refer to the latter Directive and should transpose that one.

See answer to question 25 c)

b) There is a mistake: when Montenegro refers to Directive 2003/3/EC, it should be a reference to Directive 2006/3/EC instead.

See answer to question 25 c)

c) There is a new Directive, Directive 2009/121/EC, which is not yet on the Montenegrin list of legislation to be transposed in the field of textile legislation.

On the basis of the Law on Technical Requirements for Products and Conformity Assessment of Products with the Set Requirements, until the end of 2010, will be adopted the Rulebook (technical regulation), which will transpose the directives for technical requirements for textiles into the national legal framework (31997L0037, 32004L0034, 31996L0073, 31973L0044, 32007L0004, 32007L0003, 32006L0002, 32006L0003, 32008L0121, 32009L0121).

Since the revision of the National Programme for Integration of Montenegro into the EU is underway, the underlying directives 2008/121/EC, 2009/121/EC will be included in the revised version.

Please provide an update on the above if any.

26. (Ref. to ATEX at pp. 67 and 84): It seems that Montenegro is having in mind, in the "present status" and "forecast", just the mining sector; but the ATEX provisions apply also to other areas with electrical and/or mechanical equipment with potentially explosive atmospheres, such as in petro-chemical plants, offshore platforms, flour mills, silos etc. The answers should therefore have to cover also these aspects. Furthermore, "explosive substances (blasters)" have been mentioned in the answers, but these kinds of products or equipment are not covered by the ATEX directive, as the directive deals with "potentially explosive atmospheres" and not with "explosives".

The fact is that when it comes to the requirements of ATEX Directive Montenegro has identifiable competency only in the area of mines. In the period until end of 2010 the Government of Montenegro will nominate competent bodies that will be responsible for the transposition of other essential requirements. It is a very complex directive which requires transposition through more regulations in several different administrative bodies. Coordination of transposing this directive, due to the previously said, has step-by-step approach, and the first part (most of) of the requirements is identified through the mining sector.

PROCEDURAL MEASURES

A. Measures having an equivalent effect to quantitative restrictions

27. (Ref. to Q. 33b)): Please answer the following questions:

a) What are the rules of the Law on Foreign Trade?

In accordance with Article 19 paragraph 2 of the Law on Foreign Trade, the Government also may prescribe the licenses for the administrative or statistical purposes in order to improve the efficiency of foreign trade performance in Montenegro, taking into the account that this does not restrict foreign trade.

b) What do they regulate?

In accordance with the Agreement on procedures for issuance of import permits, the automatic issuance of permits is necessary when other appropriate procedures are not available. Automated permit system remains in force until the conditions that led to their introduction have been changed, or until the anticipated administrative objectives can not be achieved in more convenient way. Article 27 a) of the Law on Foreign Trade defines the conditions and manner of automatic permits issuing.

c) In particular, what is regulated by the Decision on control list for export, import and transit of goods?

The Decision on the Control list for export, import and transit of goods (Official Gazette of Montenegro.12/10), contains information on goods whose import and export is restricted in any way, in accordance with the provisions of the Law on Foreign Trade, as well as the information

about the different administration bodies of the state from which is required to obtain permission for different kinds of goods, that is in accordance with Article 22 of the Law on Foreign Trade.

Goods that are not listed in the Control List are in a free mode of export, import and transit.

d) Please describe the contents of the listed legislation requiring automatic or non-automatic import licences or permits for imported goods.

More detailed conditions and procedures for issuing of permits for export, import and transit of goods and for the implementation of protection measures are prescribed by the Decree for implementing the Law on Foreign Trade.

The laws listed in answer to a question 33b) define the conditions and procedures for issuing of permits for certain types of products. In order to provide greater efficiency and transparency of business people engaged in foreign trade was created a Control list for export, import and transit of goods, that is actually a set of rules listed in one place on the basis of which permits are issued as well as inventory of goods with the appropriate customs tariff for which permit is required.

List of goods for which permits are issued, pursuant to the Conventions on putting under protection certain plant and animal species, does not represent an integral part of the Control list.

28. (Ref. to Q. 33g): Please answer to the following questions:

a) What technical requirements do you mean exactly (national standards, international standards)?

In the meaning of the answer to the question 33g, the technical requirements can be generally expressed as harmonized international standards, and under any circumstances the technical regulations in force in Montenegro can not include national technical requirement which would constitute a trade barrier. Previously was regulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Prescribed Standards.

b) Please indicate what are the normal/minimal requirements for the labelling in order to put a product on the market in Montenegro;

Pursuant to Article 69 of the Law on Consumer Protection (Official Gazette of the Republic of Montenegro 26/07), the goods in trade must have a declaration in accordance with technical or other regulations and must be consistent with the allegations from the declaration. The Law on Consumer Protection (Article 69) provides:

- 1) The goods in trade must have a declaration in accordance with technical or other regulations and must be in compliance with the allegations on the declaration.
- 2) If it has not been established by technical or other regulation, the declaration must contain:
 - a) the name or trade name under which the goods are sold;
 - b) the name and address of the manufacturer;
 - c) the name and address of the importer and the name and country of origin, if the goods are imported;

d) information on the quantity, composition, quality, type and model of goods, production date and time limit of use, method of use, maintenance and storage of goods and warning of potential risks related to proper and improper use of the goods, depending on the nature of the goods.

Aforementioned represents common minimum requirements for placing products on the market in Montenegro. In regard to labelling of product from the field of product's conformity assessment with prescribed requirements, technical regulations may call for additional labelling.

c) Please specify what requirements actually apply for certain product groups.

Conditions listed in answer 28b apply to all products that are placed into the market. Also, the technical regulation stipulates that, for example, group of products such as "chemicals", pharmaceutical products and the like, have separated additional labelling and registration. So, for each group of products for which the harmonized EU legislation provided specific labelling is or will be provided additional labelling by special technical regulations.

29. (Ref. to Q. 33h): Please answer to the following questions:

a) Please explain better, when the declarations are needed, who fills them in, do they have some particular form, do they have to be approved by authorities or presented to them?

The Law on Consumer Protection (Official Gazette of the Republic of Montenegro 26/07), contains the provisions regarding declarations, as follows:

**“The definitions of basic concepts
Article 2**

The terms used herein shall have the following meanings:

- 13) **Declaration** represents the information about goods, manufacturer and importer displayed on the goods in accordance with the law;

Declaration

Article 69

- (1) The goods in trade must have a declaration in accordance with technical or other regulations and must be consistent with the proclamation from the declaration.
- (2) If the technical or other regulation has not been established, the declaration must contain:
- 1) name or trade name under which the goods are sold;
 - 2) Name and address of the manufacturer;
 - 3) name and address of the importer and name and country of origin, if the goods are imported;
 - 4) information on the amount, composition, quality, type and model of goods, production date and time period of use, method of use, maintenance and storage of goods and warning of potential risks related to the proper and improper use of the goods, depending on the nature of the goods.
- (3) removal or modification of data from the declaration is prohibited.

Manner of displaying the declaration

Article 70

- (1) Declaration is displayed on the goods, while on the goods of a small size or inappropriate for displaying the declaration on each individual item, the declaration is shown on the aggregate package, or on the place of offer.
- (2) In the sale of goods in bulk, the declaration is displayed on the package, or on the place of offer".

Thus, in order to protect consumers, this law provides that the declaration is mandatory in prescribed content, depending on the nature of the goods. It is completed by the manufacturer, and data from Article 69, paragraph 1 item 3 can be completed by the importer. Declaration must be in the language that is in official use in the Republic, which is stipulated by the provision that reads:

"Expressions of information

Article 82

Documents and markings on products (declarations, warranty cards, instructions, quality labels, warnings about the risks, as well as other information to consumers) must be written in language that is in official use in the Republic".

Declarations are not subject to approval by the state body. State bodies responsible for supervision, control whether the goods that are in the market have been declared in the manner prescribed.

b) What are the consequences if one does not have that declaration?

The Law on Consumer Protection contains provisions which lay down the measures that competent authorities undertake in case when products on the market are not declared in the prescribed manner, namely:

"Administrative measures

Article 127

- (1) In addition to administrative measures established by the law governing the inspection, the competent inspector will undertake an administrative measure that will temporarily ban the dealer or distributor from the sale of particular products if:
 - 7) goods in trade do not follow the prescribed declaration, if the goods are not in accordance with the allegations of the declaration, and if declaration is not displayed in the prescribed manner (Article 69 and 70);
 - 8) time limit for the use of goods has not been indicated in the prescribed manner (Article 71);
 - 10) products that are offered at discount are not marked in the prescribed manner (Article 75);
 - 11) warnings about the risks are not clearly exerted on goods (Article 79);
 - 12) documents and product labels are not in a language which is in official use in the Republic (Article 82);

VIII SANCTIONS

Violations

Article 128

- (1) A fine of thirty to three hundred times the minimum wage in the Republic shall be imposed on a trader or dealer, if:
 - 6) sell the goods without the declaration or if the goods are not in accordance with the allegations of the declaration or if the shelf life is not labelled on the goods (Article 69 paragraph 1 and 2 and Article 71);
 - 7) warnings about the risks are not clearly shown on the goods (Article 79).
- (2) A responsible person of the legal person shall be also fined by a fine ranging from five up to twenty times the minimum wage in the Republic for the offence referred to in paragraph 1 of this Article.
- (3) In addition, a physical person shall be fined for the violation of paragraph 1, items 1, 2, 4 and 6 of this Article by fine ranging from five up to twenty times the minimum wage in the Republic.

Article 129

- (1) A fine of twenty to two hundred times the minimum wage in the Republic shall be imposed on trader, if:
 - 2) sell products without labels or prescribed documents or documents provided by the manufacturer (Article 12 paragraph 4 and Article 18);
 - 22) the declaration is not displayed in the prescribed manner (Article 70);
 - 23) goods whose characteristics of use are limited in the meaning of this law does not differentiate or identify in the prescribed manner or does not inform consumers on the nature of restriction of the goods (Article 73);
- (2) For the offence referred to in paragraph 1 of this Article shall be fined a responsible person of the legal person with a fine ranging from two up to fourteen times the minimum wage in the Republic.
- (3) A fine ranging from two up to fourteen times the minimum wage in the Republic shall be imposed on an physical person for violation of paragraph 1, items 1, 3, 5, 6, 8, 20, 22, 23 and 25 of this Article ".

Therefore, in addition to administrative measures established by the law regulating the inspection, the competent inspector will undertake an administrative measure that would temporarily prohibit the dealer or distributor to sell certain products, if goods in trade are not accompanied by the prescribed declaration, if the goods are not in accordance with the allegations on the declaration and if the declaration is not displayed in the prescribed manner.

If the goods are sold without the prescribed declaration or if the goods are not in accordance with the allegations of the declaration, the Law on Consumer Protection prescribed the offence by Article 128 item 6 for which is prescribed a fine for the trader or dealer ranging from thirty up to three hundred times the minimum wage in Montenegro. In addition, Article 129 of the Law on Consumer Protection prescribed the offence for the trader if the declaration is not displayed in the prescribed manner, for which the prescribed fine range from twenty up to two hundred minimum wage in Montenegro.

c) Do nationally produced products have to have that declaration too when they are put on the market?

Domestic products must have prescribed declaration when placed into the market. Therefore, a declaration in the prescribed manner is equally required for all products, regardless of whether they are of domestic origin or imported.

d) Please provide the relevant legislation on declarations translated into English.

The provisions relating to declaring have been translated and provided within the answers to previous questions (a & b)

30. (Ref. to Q. 34): Please answer to the following questions:

a) Please, be more specific on this point (e.g. provide information about the products or some product groups that were withdrawn from the market and about the most common problems that you were facing)?

Order for withdrawal from the market of the goods that are not declared in the prescribed manner, generally includes goods of Chinese origin (clothing and footwear, bags, technical products, toys, ...), as well as other consumer goods of domestic origin and imported (construction material, including varnishes and paints, spare parts for motor vehicles, technical goods, various equipment for agriculture, ...

U 2009, out of the total number of cases of temporary trade prohibition, 2611 cases related to improperly declared goods or goods without accompanying documents. In 42 cases, the trade of goods was permanently banned because of the expiry of the date of use (varnishes, paints, and other types of construction materials).

b) What proper labelling and what exact documents were missing in most of the cases?

In addition to the prohibition of trade due to improper declaration (which also includes the declarations that are not translated into the Montenegrin language), which is the most common reason for taking temporary measures of prohibiting trade, there were also cases of illegal labelling of products with the CE mark.

In most cases, out of the prescribed documents that need to accompany certain products in trade, were missing (or were not translated into Montenegrin language) a technical manual and instructions for use, while there were also cases of missing certificate, warranty card ...).

31. (Ref. to Q. 35h): As regards your answers to question 35, please provide additional information about the labelling requirements.

Non-food products on the market must be identified and supplied with the prescribed supporting documents (instructions, warranty ,...) in accordance with the special technical regulations that prescribe the requirements for that product, or in accordance with the Law on Consumer Protection

(Official Gazette of the Republic of Montenegro 26/07 of 16/05/2007). Supporting documents and other information for consumers must be translated into Montenegrin language (Article 82).

The law on consumer protection (Article 69) provided:

- 1) The goods in trade must have a declaration in accordance with technical or other regulation and must be consistent with the allegations of the declaration.
- 2) If the technical or other regulation has not established, the declaration must contain:
 - a) the name or trade name under which the goods are sold;
 - b) the name and address of the manufacturer;
 - c) the name and address of the importer and name of the country of origin, if the goods are imported;
 - d) information on the quantity, composition, quality, type and model of goods, production date and time limit of use, method of use, maintenance and storage of goods and warning of potential risks related to the proper and improper use of the goods, depending on the nature of the goods.
- 3) It is forbidden to remove or change the data from the declaration.

B. Return of unlawfully removed cultural objects

Cultural goods

32. (Ref. to Qs. 36-40):

a) A contradiction emerges from the responses to question 36 and 37. Please specify the legal provisions for the return of unlawfully taken cultural objects to Montenegro?

In regard to question 36 we answered that Montenegro does not have legislation that provide for the recovery of cultural heritage items that were illegally taken from the territory of some European Union member states. In question 37 we reply that the recovery of cultural heritage in our country is provided by the provisions of the Law on Property-Rights Relations.

In regard to comment that a contradiction occurred in the answers to questions 36 and 37 we provide the following explanation:

Montenegro has no **special legislation or special legal provisions** that specifically regulate (ensure) the recovery of cultural objects that were illegally taken from the territory of some European Union member states. However, the recovery of cultural objects unlawfully removed from the territory of some of the countries of the European Union can be achieved through the general provisions of the Law on Property-Rights Relations (Official Gazette of Montenegro 19/09), which regulates the civil-legal protection of property rights of all movable and immovable property. The basis for the recovery is Article 112 of the Law on Property-Rights Relations, which stipulates that "The owner may file a suit to require from the holder the recovery of certain object." To succeed in this dispute, the owner must prove that has the right of property on the object whose recovery requires and that the required object is in the possession of the defendant.

Bearing in mind that only the movable objects can effectively be taken to another state, in answer to question 38, we stated that the provisions of the Law on Property-Rights Relations include the recovery of cultural objects unlawfully removed.

Montenegro has no legislation or legal provisions regarding the recovery of cultural objects unlawfully removed from its territory.

Aware of the situation that the recovery of cultural objects unlawfully removed in the manner prescribed by the Law on Property-Rights Relations does not provide an adequate legal protection and is not at the level of standards of the European Union, the Draft Law on Cultural Property provides a specific Subchapter - Recovery of cultural objects (Article 63-69), which regulated this issue in accordance with Directive 93/7 EEC on the recovery of cultural objects. These provisions will regulate the issues of recovery of cultural objects unlawfully removed from the territory of the Member States of the European Union (Articles 63-66), the territory of other states (Article 67) and from the territory of Montenegro (Art. 68-69).

b) Concerning Directive 93/7/EEC on the return of cultural goods, please provide the translation into English of the draft laws (or adopted Law if the case) on Cultural Goods, on Museums, on Archives and on Libraries mentioned in the reply to question 40. Please provide concordance tables, if possible.

We provide hereby an English translation of the provisions of the Proposal of the Law on Cultural Property (Articles 63-66), which relates to the recovery of cultural objects unlawfully removed.

Complete translation of the Proposal of the Law on Cultural Property, the Proposal of the Law on Museum Activities, the Draft Law on Archival Activities and the Proposal of the Law on Library Activity into English will deliver in Annex.

5. Recovery of cultural objects

Return of cultural object to the Member State of European Union

Article 63

- (1) The European Union Member state (hereinafter: Member state) may seek recovery of a cultural object illegally removed from its territory after 1st January 1993, if it is located in the territory of Montenegro, and if such cultural object:
 - 1) has been protected , before or after being illegally removed, as a national treasure of artistic, historical or archaeological value under its national legislation, or has been defined as such in their administrative procedure, in accordance with Article 36 of the Treaty on the Functioning of the European Union,
 - 2) falls under a group of objects included in the list of collections of objects that can be considered as the national treasure, or represent an integral part of a public collection registered in the inventory of collections of museums, archives or libraries, of a sacral collection, or collection which is property of the Member state, or local or regional government unit, public institution with headquarters in the Member state or an institution which is considerably financed by the Member state, or its local or regional government units.
- (2) The inventory of collections of objects that may be considered as national treasure in the context of paragraph 1 of this Article is determined by the Ministry.
- (3) Cultural property that has not been returned to the Member state after the deadline for temporary removal is also considered to be illegally removed.

Procedure for the recovery of cultural object

Article 64

- (1) The procedure for the recovery of cultural object illegally removed from the territory of a Member state shall be initiated law suit of the Member state against a holder of the cultural object, submitted before a competent court in Montenegro.
- (2) With the law suit referred to in paragraph 1 of this Article the following is submitted:
 - 1) authentic document of the status of the cultural object and its detailed description,
 - 2) statement of the competent authority of the Member state that the requested cultural object is protected under national legislation and illegally removed after 1st January 1993.
- (3) The procedure for recovery of the cultural object may be initiated within a year after the date as of which the Member state has learnt about the place where the cultural object is located and the identity of person possessing it, but no later than 30 year after the date as of which the cultural object has been removed from the territory of the Member state.
- (4) If the requested cultural object is a component of the public collection from Article 63 paragraph 2 of the present Law, or a sacral object under special protection of national legislation of the Member state, the procedure for recovery of cultural object may be initiated within 75 years since the date as of which the object has been removed from the territory of the Member state, unless another time limitation has been stipulated by an international Treaty.

Court action

Article 65

- (1) Cultural object referred to in Article 63 of the present Law shall be returned to the Member state, if the court determines that it has been illegally removed from its territory or that it has not been returned after the expiry of deadline for temporary removal.
- (2) In the event from paragraph 1, the court shall allocate, according to the case circumstances, to the conscientious holder of cultural object a fair compensation, at the expense of the Member state to which a cultural object is being returned.
- (3) Whether the holder of cultural object is conscientious is determined in accordance with the Montenegrin regulations in relation to his actions during acquisition and holding of the cultural object.
- (4) In case of acquisition of cultural object from Article 63 of this Law, the new holder cannot be in a more advantageous position than the person from which he acquired the cultural object.
- (5) Holder of the cultural object shall exercise the right to fair compensation referred to in paragraph 2 of this Article, after surrendering the requested cultural object to the Member state.
- (6) Payment of fair compensation and procedure costs shall not influence the right of the Member state to request damage compensation from a person that has illegally removed the cultural object.
- (7) With regard to ownership over cultural object which is returned to the Member state, the regulations of that Member state shall apply.

Cooperation with Member states

Article 66

- (1) The Ministry shall coordinate cooperation with competent authorities of Member states with respect to return of illegally removed cultural objects, and shall particularly have the following tasks:

- 1) upon the request of the Member state, in cooperation with other national bodies and institutions, to undertake actions and measures aimed at discovering cultural object and determining the identity of its holder,
- 2) to notify the interested Member state whether and where the requested cultural object is located in the territory of Montenegro and whether there is a justified reason to believe that it has been illegally removed from the territory of the Member state,
- 3) to enable the competent authority of the Member state to verify, within 60 days after the notification referred to in sub-paragraph 2 above, whether it is the requested cultural object,
- 4) to take necessary measures, in cooperation with competent authority from the Member state, for physical preservation of the requested cultural object,
- 5) to prevent by appropriate measures any action taken to avoid or make the recovery of the cultural object difficult,
- 6) to act as intermediary between the holder of the requested cultural object and an the interested Member state,
- 7) If the verification referred to in paragraph 1 sub-paragraph 3 of this Article, is not completed within the prescribed time, sub-paragraphs 4 and 5 of this Article shall not apply.

Return of the cultural object to Non-EU state

Article 67

Recovery of the cultural object illegally removed from the Non-EU state, shall be carried out in accordance with the provisions of the Law which regulates property-rights relations, if not regulated differently by international treaty.

Recovery of the cultural object illegally removed from the territory of Montenegro

Article 68

Recovery of the cultural object illegally removed from the territory of Montenegro shall be carried out in accordance with national legislation of the state on which territory the requested cultural object is located, if not regulated differently by international treaty.

Activities concerning the recovery of cultural objects

Article 69

The Ministry, in cooperation with the Administration, public institutions for the protection of cultural property and other public administration authorities, shall:

- 1) undertake measures and activities towards completing data, records and documentation on cultural objects illegally removed from Montenegro, which may be the subject of recovery,
- 2) prepare and submit request for the recovery of cultural object to the relevant authority of the state in which the cultural object illegally removed from Montenegro is located, in accordance with regulations of that state and international treaties,
- 3) submit the request to the competent court for the recovery of illegally appropriated cultural object in state property.

c) Please define the main improvements expected with the adoption of the new laws?

Recovery of cultural objects unlawfully removed from the territory of the Member State of the European Union, is comprehensively regulated by the new Draft Law on Cultural Property. This proposed legislation includes individual cultural objects that are protected in the Member State of the European Union as a national treasure that have an artistic, historic or archaeological value and cultural objects belonging to the public museum, library and archival collections, collections of sacral objects or collections that are property of the Member State or its local unit of government. Therefore, we point out that the mentioned issues are not subject to regulations of the proposed new laws on the museum, archives and library activities.

The provisions of the Proposal of the Law on Cultural Heritage, in regard to recovery of cultural property illegally removed, represents a major improvement in comparison to the existing status of regulations.

The notion of cultural objects is defined (Article 11, item 13) and the categories of cultural objects are determined, to which the prescribed manner of return apply in case of illegal removal (Article 63, paragraph 1 items 1 and 2).

Cultural object that is not returned to the EU Member State after the time limit for the temporary removal has expired is also considered to be illegally removed (Article 63, paragraph 3).

Private property on the cultural object that was illegally brought in Montenegro can not be acquired (Article 38 paragraph 2).

The cooperation of the competent authorities of Montenegro and the authorities of EU Member State is prescribed in regard to finding the required cultural property and determining the identity of a person in whose possession it is located, as well as in regard the protection of cultural objects sought, until the completion of proceedings for the recovery, elimination of all risks that may prevent or hinder return of cultural object and mediation between the state that claims the recovery and the person with whom the cultural object is located. The organs and institutions of Montenegro have an active role and are obliged to inform the interested Member State on issues that are important for the initiation of proceedings for the return of wanted cultural object (Article 66).

The procedure for the return of cultural object unlawfully removed is initiated by the lawsuit of the interested EU Member State against the person in which possession is cultural object located, before a competent court in Montenegro. In this way, the position of the Prosecutor is significantly strengthened and the possibility for presenting evidence that is necessary for success in the dispute is increased (Article 64 paragraph 1). Moreover, evidences that are required to submit together with the claim have been recognized, thereby increasing the efficiency of the procedure (Article 64 paragraph 2).

Subjective and objective time limits for the proceedings have been determined (Article 64 paragraph 4).

The conduct of the court have been regulated in regard to the decision on the recovery of cultural object unlawfully removed (Article 65, paragraph 1) and on determining a fair compensation to the conscientious holder of cultural object that is returned to an EU Member State (Article 65, paragraph 2) and the manner of exercising the right to payment of just compensation (Article 65 paragraph 3).

The proposed provisions set out a clear and coordinated procedure, which allows efficient operation of courts and other competent authorities in respect of return of cultural property that were illegally brought into Montenegro from EU Member State.

The provision of Article 67 of the Proposal of the Law on Cultural Property regulate issues of the return of cultural objects that were illegally removed from the territory of a state which is not a member of the EU by applying the Law on Property-Rights Relations and relevant international agreements.

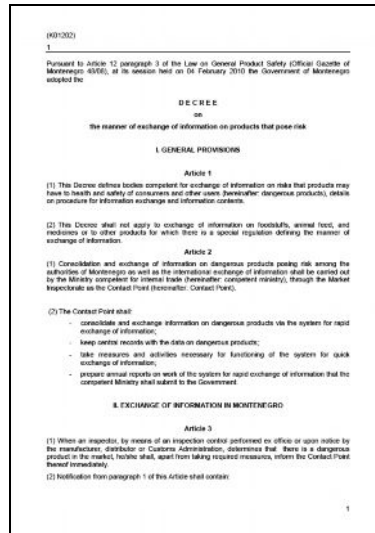
Montenegro has concluded bilateral agreements on cultural cooperation with many states, which included the issues on prevention of illegal removal and return of cultural objects.

Under the provisions of Article 68 of proposed Law, the return of cultural objects that were illegally carried from Montenegro shall be done in accordance with national legislation of the country in whose territory the cultural object is located and in accordance with international agreements. In this regard, Article 69 provides for the obligations of the competent authorities of Montenegro in terms of data collection and documentation of the cultural object illegally removed, preparation and submission of the request or claim for the recovery of cultural object.

Montenegro is committed to combating all forms of illegal removal of cultural property from its territory since it impoverishes the country of its cultural heritage, and for that reason is determined that its competent authorities take all necessary steps for the recovery of cultural property that are illegally removed from its territory, regardless of the form of ownership and to whom they belong.

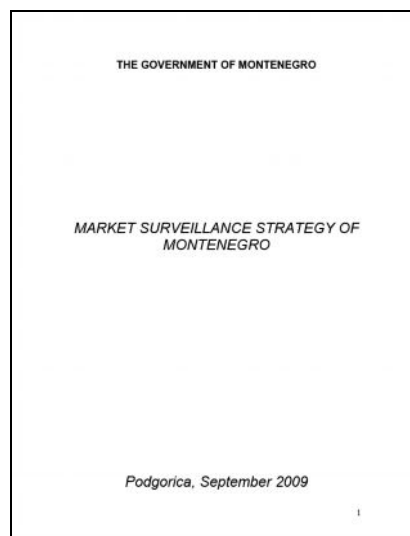
Annex

1. Decree On The Manner Of Exchange Of Information On Products That Pose Risk



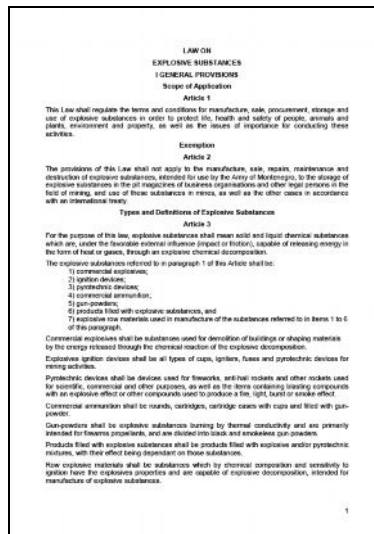
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2. Market Surveillance Strategy Of Montenegro



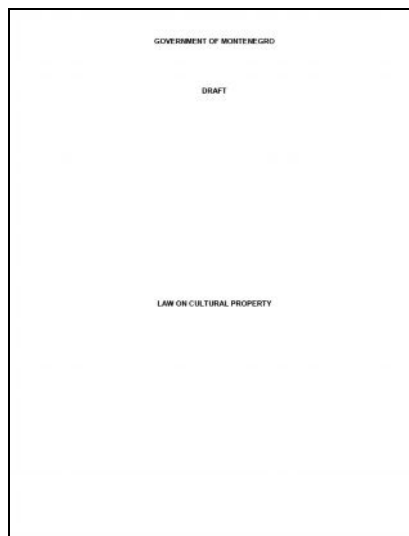
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3. Law On Explosive Substances I General Provisions



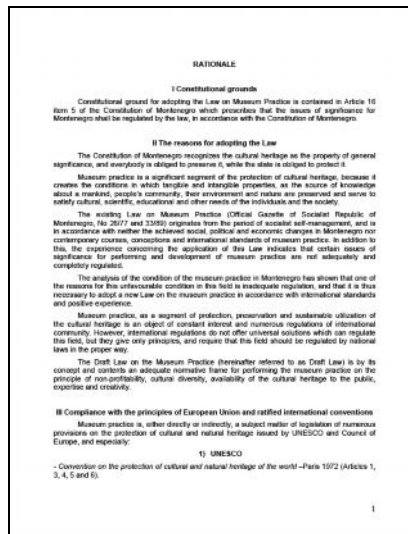
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4. Law On Cultural Property



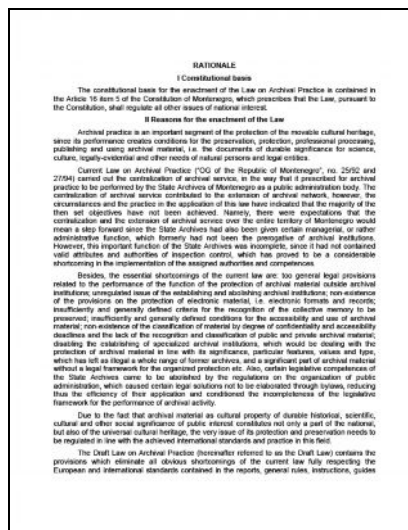
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5. Law On Museum Practice



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6. Law On Archival Practice



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7. Draft Law On Library Practice

RATIONALE

I Constitutional grounds

Constitutional ground for adopting the Law on Library Practice is contained in Article 16 Item 5 of the Constitution of Montenegro which prescribes that the issues of significance for Montenegro shall be regulated by the law, in accordance with the Constitution of Montenegro.

II The reasons for adopting the Law

Cultural heritage is of general significance, and for that reason it is prescribed in Article 70 of the Constitution of Montenegro that everyone shall be obliged to preserve it, and the state shall protect it.

Library practice is a significant part of the protection of cultural heritage, because it ensures that various library material of scientific, cultural, artistic and historical value is preserved, professionally processed and available to the public, for educational purposes, scientific research, familiarization with cultural diversities and traditions, improvement of quality of life, building and developing of peaceful and democratic society, entertainment and enjoyment.

The existing Law on Library Practice (Official Gazette of Socialist Republic of Montenegro, No 92/77 and 23/82) originates from the period of socialist self-management, and is in accordance neither with the achieved social, political and economic changes in Montenegro nor contemporary objectives, basic principles and standards of library practice. Namely, contemporary courses of development and global integration of various social and cultural communities require that library practice should switch its classical function and role with various contents which contribute to the quality of the, mutual understanding, tolerance and respect for the cultural heritage of other nations, as for its own use, viewing it as a part of the common European and world heritage.

Contemporary social settings require free, qualitative and simple availability of various pieces of information, therefore it is necessary that libraries adjust their holdings of knowledge, information, provisions and services to the needs and interests of their users, and develop the process of transparent access for the selected number of users.

The analysis of the condition of the library practice in Montenegro has clearly shown that there are big problems in this area, because neither of its part satisfies necessary parameters, conditions, standards and requirements of the classical system, especially the modern conception of the library information system.

Bad condition of the library practice is the result of the inadequate treatment of the state and local communities for over the years, very unfavourable ambient in which all cultural institutions were developing in Montenegro and surrounding countries during the last two decades, and inadequate legislation.

Although the degree of falling behind of the development of the library practice is not the same on all levels of achievement, at the moment there are no good examples of well organized libraries, i.e. libraries which meet all the proper conditions for work, international standards and other parameters through which the condition of functioning of the library information system can be perceived.

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8. Decision On Checklist Of Import, Export And Transit Of Goods

Decree to Article 4 paragraph 3 of the Law on Foreign Trade (Official Gazette of Montenegro 28/04 and 37/07) as it is amended on January 23rd 2019, for Government of Montenegro adopted the following:

DECISION
ON CHECKLIST OF IMPORT, EXPORT AND TRANSIT OF GOODS
(Official Gazette of Montenegro (OGOR) 12/18, 18th March 2019)

Article 1

Goods that are imported, exported, as well as goods in transit are classified according to types of import, i.e. import and transit into: free import, import and transit, and license-based import, export and transit.

Goods which are imported, exported and in transit based on license as referred to in paragraph 1 of the Article have been defined in the Checklist of Import, Export and Transit of Goods, which is attached to this Decision and makes its integral part.

Article 2

Goods which are imported, i.e. imported, as well as the goods in transit based on license, have been marked by designator "D" in the Checklist, while the separate license have been marked by designator "AD".

License for goods for export, import and transit of which have been marked by "D" and a special designator is issued by competent administrative authority:

- by D1 designator: goods for export, import and transit of which license is to be obtained from the Agency for Pharmaceutical and Medical Devices, or from the state administrative body competent for the license health protection;
- by D2 designator: goods for export, import and transit of which license is to be obtained from the state administrative body competent for plants and animals health protection;
- by D3 designator: goods for export, import and transit of which license is to be obtained from the state administrative body competent for environmental protection;
- by D4 designator: goods for export, import and transit of which license is to be obtained from the state administrative body competent for culture issues.

For goods export, import and transit of which is marked by "D" and "AD" with an special mark, license is issued by the state administrative body competent for foreign trade affairs.

Goods which are not listed in the Checklist are on the free import, export and transit regime.

Article 3

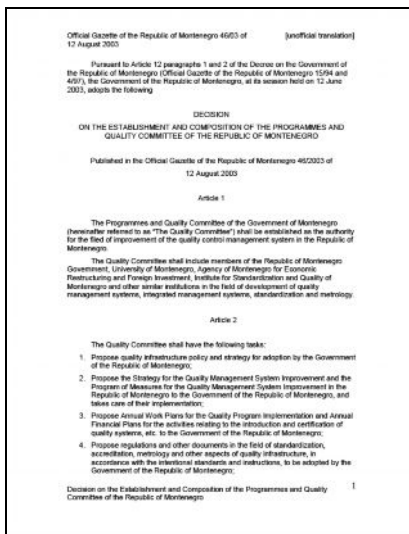
Technical requirements which are a prerequisite for putting into operation or the usage of goods are applied in accordance with the provisions of the Law on Standardization (Official Gazette of Montenegro 29/01, Law on Accreditation (Official Gazette of Montenegro 24/01), Law on Metrology (Official Gazette of Montenegro 18/02) and the Law on Technical Regulation (Regulating, Drafting, Production and Conformity Assessment) (Official Gazette of Montenegro 14/08).

Article 4

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9. Decision On The Establishment And Composition Of The Programmes And Quality Committee Of The Republic Of Montenegro



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10. The Status Of Harmonization Of Montenegrin Standards That Are Referred To Or Will Be Referred To By The Legislation

THE STATUS OF HARMONIZATION OF MONTENEGRIN STANDARDS THAT ARE REFERRED TO OR WILL BE REFERRED TO BY THE LEGISLATION

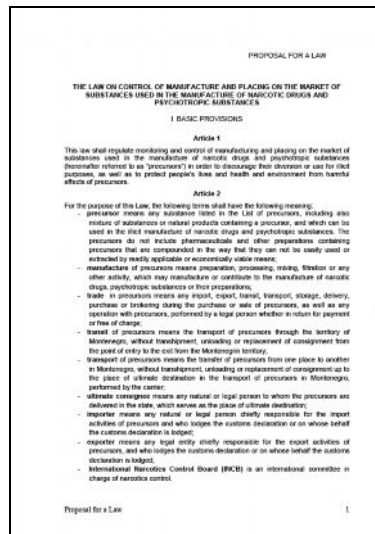
Colleges Institutions

The harmonized Montenegrin standards relating to the Directive 2000/9/EC, prepared by the Institute for Standardization of Montenegro, are given in the Table below:

Document Reference	Source Document Reference	Title English	Degree of Harmonization
MEST EN 12585-2:2003	EN 12585-2:2002	Steel wire ropes - Safety - Part 2: Standard testing and carrying testing ropes for railway installations designed to carry persons	Identical
MEST EN 12585-3:2003	EN 12585-3:2002	Steel wire ropes - Safety - Part 3: Locked coil carrying ropes for railway installations designed to carry persons	Identical
MEST EN 12587-2:2003	EN 12587-2:2004	Safety requirements for railway installations designed to carry persons - Part 2: Safety - Selection	Identical
MEST EN 12627-1:2003	EN 12627-1:2004	Safety requirements for railway installations designed to carry persons - Part 1: Selection criteria for ropes and their end fittings	Identical
MEST EN 12627-2:2003	EN 12627-2:2004	Safety requirements for railway installations designed to carry persons - Part 2: Safety - Design	Identical
MEST EN 12627-3:2003	EN 12627-3:2004	Safety requirements for railway installations designed to carry persons - Part 3: Long roping of 6 strands, hauling, carrying hauling and towing ropes	Identical
MEST EN 12627-4:2003	EN 12627-4:2004	Safety requirements for railway installations designed to carry persons - Part 4: End Connections	Identical

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11. The Law On Control Of Manufacture And Placing On The Market Of Substances Used In The Manufacture Of Narcotic Drugs And Psychotropic Substances



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