

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

01 Free movement of goods

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

Chapter 1: Free movement of goods

GENERAL PRINCIPLES

A. Legislative alignment

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

The legal basis for product conformity is provided by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08) ([Annex 16](#)). Article 2 of the said Law stipulates the purpose of adoption and the contents of technical regulations, hence also the technical requirements for products by which the regulation of product conformity is put under the framework of product safety, which is the basic principle used in harmonised technical legislation in EU. Montenegro, thus, stipulates measures concerning product safety, not the product quality, which is in line with harmonised EU legislation in the area. Furthermore, Article 15 envisages all allowable conformity assessment methods applied through the Old Approach (sectoral), the New Approach and the Global Approach. The line ministries have been given the responsibility to adopt regulations for groups of products within their scope of competences.

In its Article 21, the Standardisation Law (Official Gazette of MNE, no 13/08) envisages that in Montenegro the standards whose application is mandatory cease to be mandatory with the date of Montenegro acceding to the World Trade Organisation. The set of quality infrastructure laws provided such a legislative framework that the presumption of conformity is met if the product meets the requirements of the standard the technical regulation refers to, i.e. the product is safe if harmonised with standards or special technical requirements from the given technical regulation.

In the absence of special technical regulations for a certain product, the Law on General Product Safety (Official Gazette of Montenegro 48/08) applies, which is designed in the same manner, therefore with the identical presumption of conformity.

B. Implementation capacity, including administrative capacity

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

The quality infrastructure legislation constitutes the legal grounds for the adoption and application of technical legislation consisting of the following:

- Law on Technical Requirement for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08)
- Standardization Law (Official Gazette of Montenegro 13/08)
- Metrology Law (Official Gazette of Montenegro 79/08)
- Accreditation Law (Official Gazette of Montenegro 54/2009) ([Annex 14](#))
- Law on General Product Safety (Official Gazette of Montenegro 48/08)

The Law on Technical Requirement for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08) stipulates an administrative structure for the adoption of technical regulations (line ministries adopt technical regulations within their respective sectors). This matter is further elaborated by secondary legislation:

- 1) Decree on the Notification Procedure in the Area of Technical Regulations, Standards and Procedures for Conformity Assessment (Official Gazette of Montenegro 55/08);
- 2) Decree on the Method for Preparation and Adoption of Technical Regulations and Technical Specifications and Register of Technical Regulations (Official Gazette of Montenegro 55/08);
- 3) Decree on the Method and Procedures for Assessment of Product Conformity against Set Requirements (Official Gazette of Montenegro 71/08);
- 4) Decree on the Conditions for the Application of Technical Regulations of Other States and Records of Foreign Conformity Certificates (Official Gazette of Montenegro 74/08).

The foregoing laws and secondary legislation transpose all the European principles horizontally, while the vertical legislation referring to particular groups of products will be gradually harmonised with the application of prescribed measures by the line ministries within their respective sectors.

3. How are these functions organised, implemented and co-ordinated?

The Standardization Law (Official Gazette of Montenegro 13/08) and its subsequent piece of secondary legislation entitled the Decision on the Establishment of the Institute for Standardization of Montenegro (Official Gazette of Montenegro 21/07) stipulates that the preparation of technical regulations also falls within the scope of competence of the Institute. The preparation of technical regulations implies the possibility on the part of the line ministries, when drafting a technical regulation, to request from the Institute an analysis of all international and foreign standards and related documents pertaining to the given product for which technical requirements are being set out. For the adoption of national standards and the acceptance of international ones the Government of Montenegro provided the initial conditions for the operation of the Institute and authorised the Ministry of Economy on behalf of the founder (the Government of Montenegro) to sign annual agreements with the Institute pursuant to the plan and programme for the current year and see to its application. The Institute for Standardization is an independent body and thus the said commercial agreement constitutes the grounds for cooperation between the state administration and the Institute.

The Accreditation Law (Official Gazette of Montenegro 54/2009) ([Annex 14](#)) creates the legal ground for the Decision on the Establishment of the Accreditation Body of Montenegro (Official Gazette of Montenegro 21/07). The link of the Accreditation Body of Montenegro and other institutions is a systemic linkage related to conformity assessment. When stipulating the technical regulations, the line ministries assess the justification for the appointment/authorisation of a conformity assessment body and if it is the requirement of the national economy or transposition of harmonised regulations, they notify the enquiry point accordingly. The enquiry point contacts the Accreditation Body for an assessment on the existence of accredited bodies for conformity assessment in the given area. The Accreditation Body of Montenegro may also directly, in cooperation with the responsible ministries, take part in the drafting of a technical regulation on these grounds. If it is confirmed that there is no accredited body for the given area and for the given extent, the responsible ministries assess the need for the recognition of foreign conformity certificates, and the Accreditation Body may take part in the assessment of equivalence of the technical regulation and hence also the accompanying conformity certificates issued by another state.

The Metrology Law (Official Gazette of Montenegro 79/08) stipulates the links in the metrology system relating to the compliance with the requirements of legal metrology. The most essential part of this system is the Metrology Office. The Metrology Office is required by law to draft metrology

regulations, conduct metrological supervision and inspection. The Metrology Office is a state administration authority supervised by the Ministry of Economy.

Within the Ministry of Economy (Internal Market and Trade Department), a Division for Quality Infrastructure was established constituting the enquiry point for technical regulation both towards the WTO, and the EU. The internal notification procedure envisages the responsible ministries to use the set form to notify the enquiry point of the adoption of technical regulations within the scope of their respective competences. The Quality Infrastructure Division cooperates with the quality infrastructure institutions within their respective fields of work. The Division notifies the ministries of the need to pass new or amend the existing technical regulations where it becomes aware of such a need through its communication with other international points of contact. The Division participates in the work of the CEFTA Subcommittee in the area of Non-Tariff Trade Barrier (NTB), coordinating Chapter 01. – Free Movement of Commodities within the EU integration processes and provides support in negotiations with the World Trade Organisation in relation to Technical Barriers to Trade (TBT/WTO). The Division provides logistic support to the activities of the Committee for the Quality Programme of the Government of Montenegro dealing with issues in non-regulated areas such as the Quality Management System (QMS), Environmental Management System (EMS), and support to the implementation of accreditation standards such as ISO 17025, ISO 17020 etc. In cooperation with the Committee, the Division performs these tasks on the basis of providing subsidies and through co-organising conventions, panel discussions and seminars.

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

With the establishment of quality infrastructure institutions and the adoption of the National Programme of Integration (NPI), Montenegro completed a fundamental preparatory stage. The first instances of transposition and application of the EU legislation are emerging in all activities and areas. However, a new stage involving much more intensive work and a considerable increase in the number of staff is expected exactly in 2010 and 2011. The competences represent a real issue, so that it is planned to organize a great number of trainings over the upcoming period, through various assistance programmes. Moreover, Montenegro studied the examples of other countries and similar to all the comparable examples it shows that the system needs to be flexible and changeable depending on the stage in which it is used, from transposition to the application and market surveillance. In the horizontal legislation, due to all the foregoing objective circumstances, an option for modifications in the systemic approach has been ensured. In relation to the foregoing preventive and corrective measures, a transformation of the Committee for Quality Programme of the Government of Montenegro is expected in order to be more actively engaged in fostering coordination and application of the legislation in particular when it comes to the training of the responsible ministries.

HORIZONTAL MEASURES

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

CEFTA AGREEMENT

Within the CEFTA Agreement, whose full application started on 22 November 2007, the Joint Committee Decision 5/2007 established a Subcommittee for Technical Barriers to trade and non-tariff barriers. The Subcommittee aims to identify, consider and propose measures to

remove technical barriers to trade and non-tariff barriers. Item 2.2 of the Decision 5/2007 stipulates that the Subcommittee for Technical Barriers to Trade and Non-tariff Barriers will:

- Encourage harmonisation of technical regulations, standards and mandatory conformity assessment procedures with WTO rules and procedures;
- Encourage harmonisation, where appropriate, of technical regulations, standards and procedures for assessment of conformity with those of the European Union;
- Encourage recognition of conformity assessment documents made by the accredited Conformity Assessment Bodies;
- Encourage negotiations to conclude multilateral agreements among the Parties.

STANDARDIZATION

- Agreement on Business and Technical Cooperation between the Institute for Standardization of Montenegro (ISME) and the Institute for Standardization of Serbia (ISS) – signed in Belgrade on 16 July 2007;
- Agreement on Business and Technical Cooperation between the Institute for Standardization of Montenegro (ISME) and the Institute for Standardization of Bosnia and Herzegovina (BAS) – signed in Sarajevo on 19 November 2007;
- Bilateral Agreement on Business and Technical Cooperation between the Institute for Standardization of Montenegro (ISME) and the Institute for Standardization of the Republic of Macedonia (ISRM) – signed in Ohrid on 18 June 2009;
- Bilateral Agreement on Business and Technical Cooperation between the Institute for Standardization of Montenegro (ISME) and the Institute for Standardization of the Republic of Albania (DPS) – signed in Ohrid on 18 June 2009.

In addition to the foregoing, on 12 August 2008, the Institute for Standardization of Montenegro (ISME) and the British Standardization Institute (BSI) signed an Agreement enabling the sale of British Standards (BS) in the territory of Montenegro by the Institute for Standardization of Montenegro (ISME).

ACCREDITATION

The Accreditation Body of Montenegro has a contractual relation with the EA (European Cooperation for Accreditation), which, following the prescribed procedure, was signed in Lisbon in November 2008 (Resolution 22 of the General Assembly). In April 2009, having complied with the requirements, the Accreditation Body became an associated member to ILAC (International Laboratory Accreditation Cooperation). Furthermore, the Accreditation Body of Montenegro signed cooperation agreements on accreditation with the following national accreditation bodies in the region:

- Accreditation Body of Serbia (ATS) on 16 January 2008;
- Albanian Directorate for Accreditation (DA) on 28 January 2008;
- Institute for Accreditation of the Republic of Macedonia (IARM) on 29 January 2008;
- Institute for Accreditation of Bosnia and Herzegovina (BATA) on 14 March 2008;
- Croatian Agency for Accreditation (HAA) on 24 July 2008.

The above agreements will support harmonisation of the accreditation process in the region, which is in line with the Central European Free Trade Agreement CEFTA 2006 Annex 1, Chapter IV Technical Barriers to Trade.

METROLOGY

In June 2008, the Institute for Metrology signed a Memorandum of Understanding with the General Directorate for Metrology of Albania, as the basis for cooperation in the area of metrology.

The Institute delivered a Memorandum of Understanding also to the Directorate for Measures and Precious Metals and the signature is expected after the completion of relevant procedure with the competent ministry in the Republic of Serbia by the Directorate.

The Institute intends shortly to initiate the conclusion of the cooperation memoranda with the National Metrology Institutes of the Republic of Macedonia and the Republic of Slovenia.

Since July 2007, the Institute has become an associate member of EURAMET, the European Association of National Metrology Institutes.

Since November 2007, the Institute has been a corresponding member of OIML, the International Organisation of Legal Metrology.

Since January 2009, the Institute has become a corresponding member of WELMEC-a, European Cooperation in Legal Metrology.

A. Standardisation

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

The Institute for Standardization of Montenegro (ISME), as the national Standardization body, was established in April 2007 with the main aim of establishing, maintaining and developing the national Standardization system. Legal grounds for the standardization system development in Montenegro, as well as for the establishment and operation of an autonomous and non-profit national organisation for Standardization, are stipulated by the Standardization Law (Official Gazette of Montenegro 13/08), the Decision on the Establishment of the Institute for Standardization of Montenegro (Official Gazette of Montenegro 21/07) and the Statute of the Institute for Standardization of Montenegro (Official Gazette of Montenegro 29/08).

In addition to the foregoing general legislation, and aiming towards their further elaboration, we are in the final stage of development of Internal Standardization Rules (ISME IPS), i.e. the documents which will ensure that the activities of the Institute for Standardization of Montenegro and the process of adoption of national standards are fully aligned with the requirements and recommendations of international and European organisations for Standardization. Internal Standardization rules (consisting of 6 documents), inter alia, aim to regulate the manner for the establishment and operation of expert bodies of the Institute (technical committees, subcommittees, working groups...), provide the possibility for inclusion of all interested parties into the standard adoption process (respecting the principle of consensus), define the process for the development of original national standards with the obligation of their notification (pursuant to Directive 98/34/EC), determine the manner of participation in the work of international and European organisations for Standardization, define the method for adoption of international and European standards and similar documents on the national level, determine the obligation of revoking the conflicting national standards, etc. The EU experts have been involved in the process of drafting of Internal Standardization Rules, adding to the assumption of these being comprehensive and of good quality. The Internal Standardization Rules are expected to be adopted at the latest by the end of 2009.

The very process of adoption of European and international standards by the Institute for Standardization of Montenegro started in 2008. As of 6 August 2009, the number of Montenegrin standards amounted to 1897, out of which 1867 had been created by taking over the European standards. Their structure and implementation was mostly caused by the process of harmonisation of Montenegrin technical legislation with the *acquis*, and hence the bulk of the Montenegrin standards (some 80%) consist of the transposed European harmonised standards.

In line with the requirements of associate membership of the European Standardization organisations of CEN and CENELEC, the Institute for Standardization has been continuously increasing its technical and expert competences and conducting the preparations for compliance with all the requirements for fully fledged membership of these organisations. Since the founding of the Institute substantial financial resources have been invested into the ICT, premises and training of staff. Within the Work Plan and Programme of the Institute, for each upcoming business year, an assessment of necessary finances for the implementation of planned activities is prepared, including the funds appropriated for increasing the technical and professional competences. It should be noted that the Institute has not yet been a beneficiary of a more substantial EU-funded project whereby an adequate expert and technical assistance would be provided and a part of its IT equipment upgraded.

7. Are staff numbers and financing adequate?

The Institute for Standardization of Montenegro has an organisational structure that for the time being ensures a rational, effective and efficient performance of Standardization tasks. The main organisational units within the Institute are the *Standards Department* (which follows the work of expert bodies of European and international Standardization organisations and performs the tasks of development of Montenegrin standards), *Logistics Department* (including an IT Centre and IT Support), and the *Department for Development, Education, Certification and Quality* and the *International Cooperation Department*. The current job classification envisages 32 positions. In line with the financial and spatial capabilities and other needs, the vacancies will be gradually filled in, as envisaged by the current job classification. We believe that over the upcoming period the number of staff in the Institute for Standardization of Montenegro needs to be increased due to an increased volume of work towards meeting the requirements for a fully fledged membership of CEN/CENELEC.

The basic source of funding for the Institute for Standardization of Montenegro is the *Agreement Implementing the Work Plan and Programme for the Adoption of Montenegrin Standards* which is concluded by and between the Institute for Standardization of Montenegro and the Government of Montenegro for each business year. To a smaller extent the ISME is financed from the sale of standards, membership fees, etc. Only the basic needs for the operation of ISME are covered by the mentioned funds. Substantial additional funds will be required for further upgrading of the ICT and the accompanying programme support, as well as for ongoing professional development and motivation of the staff.

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

All existing Montenegrin standards (100%) are identical to the European and international ones. By 6 August 2009 ISME adopted 1867 Montenegrin standards (MEST) which were identical to the European ones. Out of those, 1445 Montenegrin standards had been created by taking over CEN standards, 321 by taking over CENELEC standards and 101 by taking over ETSI standards. The remaining Montenegrin standards (the total of 30) were created by identical take over of international standards.

The percentage of the existing Montenegrin standards in relation to the total number of European standards of particular Standardization organisations may be shown as follows:

- CEN: 1445 of EN taken over, or 10% of all European standards adopted by CEN;
- CENELEC: 321 of EN/HD taken over, or 5% of all European standards adopted by CENELEC
- ETSI: 101 of EN taken over, or 2.5% of all European standards adopted by ETSI

9. Please indicate (work towards) membership of European and international standards organisations (CEN, CENELEC, ETSI, others). Is there a timetable for achievement of full membership of CEN and CENELEC? What is the relationship with the international (IEC and ISO) standards bodies?

On 1 July 2008, the Institute for Standardization of Montenegro (ISME), as the national Standardization body, became an affiliate member of CEN. A year later, on 1 July 2009, ISME became an affiliate member of CENELEC. The activities planned for the upcoming period include the membership of ETSI, and the ISME is expected to become a member of this organization in 2010 at the latest.

As for the membership of international Standardization organisations, on 1 July 2007 ISME became a correspondent member of ISO. ISME follows the work of 2 ISO Political Committees (COPOLCO - Committee on Consumer Policy and DEVCO - Committee on Developing Countries Matters), as well as the work of 17 ISO Technical Committees. On 1 January 2009 ICME became an associate member of IEC.

Since its establishment in mid 2007, the activities of ISME have been conducted to prepare for the compliance with each and every requirement for a fully-fledged membership of the European organisations for standardization (the nine legislative, organisational and technical requirements set by CEN and CENELEC). The pace, type and scope of activities towards becoming a full member of these organisations will be elaborated in the document entitled the Strategy for Development of Standardization in Montenegro, expected to be adopted in the first half of 2010. These processes are expected to be completed at the latest until the end of the period of negotiations to be launched following the confirmation of the status of a candidate country for EU membership, which usually takes 5 years.

B. Conformity assessment

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

The legislative framework for conformity assessment in Montenegro is provided through the following laws:

- Law on Technical Requirement for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08)
- Standardization Law (Official Gazette of Montenegro 13/08)
- Metrology Law (Official Gazette of Montenegro 79/08)
- Accreditation Law (Official Gazette of Montenegro 54/2009) ([Annex 14](#))

The secondary legislation providing for more detailed regulation of conformity assessment includes the following:

- Decree on the Notification Procedure in the Area of Technical Regulations, Standards and Procedures for Conformity Assessment (Official Gazette of Montenegro 55/08);
- Decree on the Method for Preparation and Adoption of Technical Regulations and Technical Specifications and Register of Technical Regulations (Official Gazette of Montenegro 55/08);
- Decree on the Method and Procedures for Assessment of Product Conformity against Set Requirements (Official Gazette of Montenegro 71/08);
- Decree on the Conditions for the Application of Technical Regulations of Other States and Records of Foreign Conformity Certificates (Official Gazette of Montenegro 74/08).

Interconnecting of the conformity assessment system in the Montenegrin internal market is in its

initial stage. So far, the competences of seven conformity assessment bodies have been confirmed through the accreditation system. However, there is a system of authorisation which had functioned even before Montenegro became independent. With the transposition of *acquis* Montenegro will gradually update the existing and introduce additional authorizations where so envisaged by the harmonised EU legislation and prepare the framework for appointments (notified bodies) in the area of new approach. Montenegro also intends to design the system in a rational manner suited to the size of its economy, meaning that to a certain extent it will use the conformity assessment bodies from the EU member states, as well as the ones from the CEFTA region. By following the principle of equality, all conformity assessment bodies have equal conditions for authorisation and appointment as stipulated by the foregoing legislation.

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

The object procedures have been harmonised through the Law on Technical Requirements for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08) and the Decree on the Method and Procedures for Assessment of Product Conformity against Set Requirements (Official Gazette of Montenegro 71/08);

12. Are foreign test reports recognised? If yes, in which conditions?

The legislative framework for the recognition of foreign conformity certificates is regulated by the Decree on the Conditions for the Application of Technical Regulations of Other States and Records of Foreign Conformity Certificates (Official Gazette of Montenegro 74/08). This Decree stipulates that foreign technical regulations may be recognised as equivalent to Montenegrin ones, even when they deviate from the measures stipulated by Montenegrin technical regulations. This measure is envisaged due to the lack of laboratory capacities for conformity assessment of all groups of products for which conformity assessment is envisaged by the European legislation. Hence, if a technical regulation of another state is assessed as equivalent by the line ministry, through its appointed working group, the conformity assessment procedures, as well as the conformity certificates issued in that state pursuant to that technical regulation are automatically recognised.

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

As for the old (sectoral) approach of EU, the line ministries are responsible for the appointment of conformity assessment bodies relevant for their respective competencies. The line ministries are also responsible for the notification (appointment) according to the new EU approach within their respective sectors, and with the accession to EU the enquiry point at the Ministry of Economy will be in charge of notifying the Conformity Assessment Bodies (CABs), as well as of the notification of technical regulation.

Standards are regarded as non-binding regulations by the Montenegrin legislation, but through the Law on Technical Requirement for Products and Assessment of Product Conformity against Set Standards (Official Gazette of Montenegro 14/08) and the accompanying secondary legislation it is recommended to the responsible ministries to use the accreditation system when verifying the competences of Conformity Assessment Bodies. This implies the use of standards from the ISO 17000 series, such as ISO 17025, ISO 17020, as well as EN 45011. In addition, all principles and requirements of the ISO 17011 standard are stipulated by the Accreditation Law (Official Gazette

of Montenegro 54/2009).

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

The initial stage of development of CAB Register is ongoing and a detailed overview is expected by the end of 2009. The data in this area have not been systematized yet since the process of transposition of most EU directives is still in progress.

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

The enquiry point is located within the Ministry of Economy, the Internal Market and Competition Department, Quality Infrastructure Division. The enquiry point is yet not operational, since there is no counterpart notification party.

For the operation of the enquiry point, the Government of Montenegro provided specialized software for the establishment of relational databases on technical regulations and designated/notified bodies for conformity assessment. In addition, the hardware (server and work stations) was purchased through the EU assistance. The enquiry point consists of three staff members who also perform additional daily activities related to quality infrastructure.

For the enquiry point to start functioning, it is necessary that Montenegro joins the World Trade Organisation. The enquiry point in the full sense of the Directive 98/34/EC will perform notification of technical regulation and designated/notified CABs with the accession to the EU, since it is not possible to notify technical regulation while having the current accession status.

16. Has the register for technical regulation been established?

The register for technical regulation is legally allocated to the ministry competent for quality infrastructure. The Ministry tasked the Quality Infrastructure Division to establish the register. For this purpose the Ministry rented an office space and secured three staff members.

17. How many and which technical regulations have been adopted/registered up to date?

The register of technical regulation currently contains the titles of valid technical regulations in Montenegro, including legal sources (Numbers and dates of publication in Official Gazettes) classified according to the chapters defined in the PINK BOOK and BLUE GUIDE EU. The activities to identify all technical regulations which are presently in use or will be in use are currently in progress, and which have recently been adopted or proposed. The register will contain full texts including the proposed measures once the responsible ministries, through the internal notification procedure, have submitted all technical regulations falling within their respective areas of responsibility in accordance with the Decree on the Notification Procedure in the Area of Technical Regulations, Standards and Procedures for Conformity Assessment (Official Gazette of Montenegro 55/08);

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

In Montenegro, technical regulations may envisage the need of using one of the conformity marks stipulated in the Decree on the Method and Procedures for Assessment of Product Conformity against Set Requirements (Official Gazette of Montenegro 71/08); Article 10:

„Before its marketing or use, a product harmonised with the technical requirement shall be marked with the conformity mark:

- **"CE" mark;**
- **"E" homologation mark for parts of motor vehicles;**
- **Other marks in accordance with technical regulations“**

Montenegro has no national product conformity mark. Montenegro opted for such an approach for the reasons of rationality related to its industrial structure where no major requirement for such marking exists. Not many manufacturers that produce the products falling under the scope of the New Approach **have already fulfilled the requirements for the CE mark and marked their respective products accordingly.** In marking, the modules envisaged by the directives and the CABs notified by the EU Notification Committee have been used.

In addition, Montenegro has in place a legislative framework for other marking, such as vehicle homologation, marking of medicines, other chemical products, previously packaged products, etc. It is extremely important to support the Montenegrin approach so that the marking method is fully harmonised with the EU requirements already from this stage. An approach contrary to this would create huge costs for the establishment of a particularly complicated and extensive network of CABs, create a permanent threat form trade barriers and require much time for de-installing and re-harmonisation. To that effect, Montenegrin horizontal legislation is already fully harmonised and so far we have not experienced any problems in the flow of goods related to product marking.

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

As many as two Montenegrin laws contain the safeguard clause:

- Law on Technical Requirements for Products and Conformity Assessment against the Set Requirements (Official Gazette of Montenegro 14/08)
- Law on General Product Safety (Official Gazette of Montenegro 48/08)

Its meaning may be illustrated by Article 12 of the Law on Technical Requirements for Products and Conformity Assessment against the Set Requirements:

„If it is established that products compliant with technical regulations may pose a threat to the public interest, in particular the security of life, the health of people, animals and plants, the environment and property, the responsible ministry shall undertake measures to withdraw such products from the market, or order their prohibition or limitation of their placing on the market or their use.“

Hence, if due to some new circumstances in the process of market surveillance it is assessed by the relevant inspection that a product is not safe, measures may be undertaken to withdraw the given product from the market even when the manufacturer has complied with and has proven to have complied with all set technical requirements. Thus, in addition to the regular measures stipulated by the two foregoing laws and the technical regulations referring to them as their legal source, such a legislative framework was created not to release on the internal Montenegrin market a product which is not safe.

20. Please describe how your legislation defines the manufacturer and importer responsibilities and manufacturer's general product liability remains to be further established.

Article 14 of the Law on Technical Requirements for Products and Conformity Assessment against the Set Requirements (Official Gazette of Montenegro 14/08) stipulates supplier obligations. Article 5 of the same Law defines the term *supplier*:

„supplier is a manufacturer, his agent with the seat in Montenegro, an importer, or a business organisation, other legal person, an entrepreneur or other natural person who has marketed the product or enabled its use“.

The technical regulation itself determines the cases when and how the traceability to the manufacturer is attained, and the whole system relies on the person releasing the product on the market observing the principles of equal responsibility, both when it involves a domestic and a foreign manufacturer or importer.

C. Accreditation

21. Does your country have an accreditation system and an accreditation body? Is the body independent? Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting certification bodies in line with the European system? Is the accreditation system aligned to the rules in Regulation (EC) 765/2008? Does the accreditation body fulfil the requirements of Regulation (EC) 765/2008?

Yes.

Montenegro has an accreditation system in place which includes a national accreditation body (Accreditation Body of Montenegro), accreditation rules and procedures, accredited conformity assessment bodies (7) and other interested parties.

The Accreditation Body of Montenegro (ABM) was founded by the Government of Montenegro as an institution managing the accreditation system in Montenegro by the Decision on the Establishment of the Accreditation Body of Montenegro (Official Gazette of Montenegro 21/07).

Is this body independent?

Yes. The Accreditation Body of Montenegro is independent as shown by the application of ABM documents:

- **Item 4.3 of the Quality Manual (paragraphs 4 and 6):** By observing own rules, procedures and instructions, the ABM ensures that all its staff involved in the accreditation process, perform their respective tasks **objectively** preventing any business, material or other influence which could threaten the **impartiality** of ABM. According to the laws and regulations, the scope of work of ABM includes no such activities or the provision of services such as conformity assessment and consultancy services which might influence its **impartiality**.
- **Article 28 of the ABM Statute (paragraph 2):** ABM's organisation structure clearly stipulates that professional activities are carried out **independently** and **impartially** and are related to the definition, implementation, maintenance and enhancement of the accreditation system and procedures.
- **Article 2 of the Agreement on Hiring Assessors (paragraph 3):** By signing this Agreement, Service Provider confirms his **independence** from the activity that is being assessed and that he is free **from influence and conflict of interest**. At the same time he undertakes to retain **objective** reasoning throughout the assessment procedure in order to

ensure that the assessment findings and conclusions are based solely on the assessment evidence.

- The Code of Ethics signed by all employees, external assessors and other ABM associates

By signing the Code of Ethics the staff and the external associates undertake to present the facts in a realistic manner and to conduct **impartial** assessment solely based on the data available in the accreditation procedures.

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

Yes.

The Accreditation Body holds the scope of technical and administrative competences required for the purpose of accreditation of certified bodies in line with the European accreditation system, guidelines and instructions EA (European Cooperation for Accreditation), ILAC (International Laboratory Accreditation Cooperation)

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

Yes.

The accreditation system is harmonised with the rules of the Regulation (EC) 765/2008 of the European Parliament and the Council which sets the requirements concerning accreditation and market surveillance related to placing the products on the market by the application of:

- Documented quality management system harmonised with the requirements of ISO IEC 17011 *Conformity Assessment, General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*;
- Montenegrin Accreditation Law (Official Gazette of Montenegro 54/2009) and
- Documented ABM rules Q2.09 Rules of Cross-Boundary Accreditation.

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

Yes.

The Accreditation Body does fulfil the requirements of Regulation (EC) 765/2008 through the application of new Montenegrin Accreditation Law (Official Gazette of Montenegro 54/2009) containing the requirements of Regulation (EC) 765/2008.

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

Yes.

The Accreditation Body of Montenegro has a contractual relation with EA (European Cooperation for Accreditation), which, following the set procedure, was signed in Lisbon in November 2008 (Resolution 22 of the General Assembly).

In April 2009, having complied with the requirements, the Accreditation Body of Montenegro became an associated member of ILAC (International Laboratory Accreditation Cooperation).

Furthermore, the Accreditation Body of Montenegro signed cooperation agreements on accreditation with the following national accreditation bodies in the region:

- Accreditation Body of Serbia (ATS) on 16 January 2008;
- Albanian Directorate for Accreditation (DA) on 28 January 2008;

- Institute for Accreditation of the Republic of Macedonia (IARM) on 29 January 2008;
- Institute for Accreditation of Bosnia and Herzegovina (BATA) on 14 March 2008;
- Croatian Agency for Accreditation (HAA) on 24 July 2008.

The foregoing agreements will facilitate the harmonization of the accreditation process in the region, which is in line with the Central European Free Trade Agreement CEFTA 2006 Annex 1, Chapter IV Technical Barriers to Trade.

23. Is it a member or working towards membership of any such organisations?

Yes.

Currently the Accreditation Body of Montenegro has a contractual relation with EA (European Cooperation for Accreditation) and is seriously preparing for a fully-fledged membership of this prestigious regional organisation.

Moreover, the Accreditation Body of Montenegro is currently an associated member of ILAC (International Laboratory Accreditation Cooperation) and is preparing for a fully-fledged membership of this global organisation.

It is the intention of the Accreditation Body of Montenegro to become a full member of IAF (International Accreditation Forum).

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

So far 7 (seven) conformity assessment bodies have been accredited in Montenegro.

- **AD¹ Institute for Ferrous Metallurgy, Department for Laboratory and Technical Testing, Nikšić** (Accreditation area – Determination of chemical composition of: iron and aluminium ore; iron, aluminium and copper and their alloys; metal and non-metal additional primary and secondary materials for the production of steel and aluminium; solid and liquid fuels; lime, dolomite, magnesite and their products, destructive testing methods, non-destructive testing methods, testing in the area of technical protection; A total of 105 methods)
- **AD Institute for Construction Materials, Geo-technology and Chemical Analyses, Laboratory for Construction, Geo-mechanic and Chemical Testing, Nikšić** (Accreditation area – Testing of construction materials; stone; composite stone; cement; concrete; clay products; asphalt. (43 methods), geo-mechanical testing (19 methods). A total of 62 methods).
- **DOO² Institute for Transport, Inspection Organisation, Podgorica** (Accreditation area – Checking the devices and equipment for powering liquefied petroleum gas (LPG) driven motor vehicles for accuracy of installation. Visual inspection; checking completeness; size control and control of water tightness of couplings of devices and equipment powering the LPG driven motor vehicles).
- **Public Enterprise, Centre for Eco-Toxicological Research of Montenegro, the Laboratory for Eco-Toxicological Testing and Protection against Radiation, Podgorica** (Accreditation area: Physical and chemical testing of: drinking water and ice;

¹ Translator's note: AD stands for the Joint Stock Company (JSC)DOO stands for the Limited Liability Company (LLC)

² Translator's note: DOO stands for the Limited Liability Company (LLC)

foodstuff of animal origin; water and wastewater; soil, sediments and mud. Testing of radioactivity in samples of: water; air; soil; foodstuff; construction material. Testing the level of ambient radiation. Testing of ionising radiation sources. Acoustic noise testing. Sampling of surface water and drinking water; sampling of surface water and drinking water; liquids and flammable liquids; soil; sediments and mud. A total of 108 methods)

- **University of Montenegro, Faculty of Mechanical Engineering, Laboratory for Checking Vehicles in Road Transportation, Podgorica** (Accreditation area: Calibration standards used for technical inspection of motor and trailer vehicles. Calibration standards for measuring the density of exhaust gases from compression-ignition engines. Calibration of instruments used to control vehicle lighting. Calibration standards for checking the composition of exhaust gases from the engines with exterior ignition source. Calibration of instruments for checking the vehicle braking force along the edge of the wheels. (A total of 4 methods).
- **AD Construction Supervision and Laboratory Testing, Laboratory, Podgorica** (Accreditation area: Testing of construction materials: stone; concrete; bitumen; asphalt (13 methods), Geo-mechanical testing (4 methods); a total of 17 methods)
- **DOO Vu-Ti Engineering, Laboratory for Electric Testing and Measurements, Bar** (Accreditation area: Electric testing; Testing of electric installations and lightning rods; Testing of electric installations of EX making; Earth resistance testing TS)

How many applications for accreditation have been submitted so far?

So far three applications for accreditation have been submitted to ABM for the following areas:

- Physical, chemical, microbiological testing of milk and dairy products;
- Physical and chemical testing of water, air, precipitation. Microbiological testing of water, sampling of air, precipitation and surface waters;
- Physical and chemical testing and sampling of oil and oil products

And 1 application to extend the area of accreditation

- Physical and chemical testing of construction materials

D. Metrology

25. What is the present metrology structure in your country?

The basis of the metrology system in Montenegro is provided by the Metrology Office established by the Government of Montenegro on 14 September 2006. Pursuant to the Law on Metrology (Official Gazette of Montenegro 79/08), the Office is in charge of the following tasks:

- Is responsible for the system of legal units of measurement in Montenegro;
- Realises, conserves, maintains and improves national measurement standards;
- Ensures metrological traceability;
- Organises the calibration activity;
- Carries out the assessment of conformity of a measuring instrument with prescribed metrological requirements: type approval and verification of a measuring instrument;
- Examines pre-packaged products;
- Gives expert opinion for the authorisation of persons to carry out activities in the field of metrology;
- Represents Montenegro in international and regional metrology organizations and establishes cooperation in the field of metrology;
- Performs metrological supervision;

- Collaborates with competent inspection bodies and provides technical assistance in the field of metrology;
- Decides in administrative proceedings in the field of metrology;
- Prepares technical bases for the development of draft legislation in the field of metrology;
- Provides metrological information and publishes official journal;
- Performs other activities related to metrology in accordance with the law.

National calibration laboratories for mass, length, electric values, time and frequency, volume and temperature are being developed within the Metrology Office; these will establish, develop and maintain Montenegrin national measurement standards for the given unit. Pursuant to the Law on Metrology (Official Gazette of Montenegro 79/08), it would be possible to outsource by a Government regulation³ the activities on the establishment, development and maintenance of the national measurement standards for certain units to an authorised person, which will cooperate with the Metrology Office.

Measuring instruments used for the purpose of trade in goods and services; protection of human and animal health, general security, property, environment and natural resources, safety at work, transport and protection from accidents; as well as checking the pre-packaged products and bottles as measuring containers, will be put to use only if compliant with the set metrological requirements and if those are verified and are labelled with the prescribed marking. In Montenegro the verification of the measuring instruments is carried out by the Metrology Office. Before the Metrology Office was established, the legal metrology activities were carried out by the Control of Measures and Precious Metals as a regional unit of the Office for Measures and Precious Metals from Belgrade. The metrological regulation inherited from the State Union of Serbia and Montenegro, as well as the established system for verification of measurement units, guided the work of the Metrology Office from its establishment until the adoption of the new law regulating, inter alia, conformity assessment of measuring instruments against the set standards, as well as the authorities in the area of metrology. The Law on Metrology (Official Gazette of Montenegro 79/08) stipulates that companies and other legal persons satisfying the prescribed requirements in the field of metrology may carry out the following activities:

- Verification of specified kinds of measuring instruments;
- Preparation of measuring instruments for verification.

The Ministry of Economy adopted the Rulebook on Technical and Metrological Requirements and the Procedure for Authorisation of Persons for the Preparation of Water Meters for Verification (Official Gazette of Montenegro 44/09). The Draft Rulebook stipulating the technical and metrological conditions, the required professional staff and the authorisation procedure for companies or other legal person for preparing measuring instrument (scales, taximeters, electrical energy meters, liquid fuel meters and liquefied petroleum gas meters) for verification, will be developed and adopted in the upcoming period⁴.

The reform of the metrology infrastructure inherited from the State Union of Serbia and Montenegro, as well as the legislative amendments and harmonisation with the EU *acquis*, are the most significant activities being continuously conducted in Montenegro. Over the upcoming period a suitable building needs to be provided for proper development of metrological laboratories of the Metrology Office, and the required laboratory equipment needs to be purchased in order to establish an efficient metrological system in Montenegro.

³ *The Transitional and Final Provisions of the Law on Metrology (Official Gazette of Montenegro 79/08) envisage that the implementing regulations for this Law will be adopted within two years from the date of the entry into force of this Law (31 December 2010).*

⁴ *The Transitional and Final Provisions of the Law on Metrology (Official Gazette of Montenegro 79/08) envisage that the implementing regulations for this Law will be adopted within two years from the date of the entry into force of this Law (31 December 2010).*

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

On 30 August 2007 the Government of Montenegro adopted the Metrology Development Strategy in Montenegro which envisages the following strategic goals:

- Development of the Metrology Office as an institution;
- Improvement of legal metrology;
- Improvement of industrial metrology;
- Establishment of traceability of measurements;
- Development of international cooperation;
- Metrological system and support to testing laboratories;
- Cooperation of scientific and other institutions in the area of metrology;
- Popularisation of metrology in Montenegro.

Two years following the adoption of the Strategy, based on the completed activities, noted problems, new findings and identified requirements for further enhancement of the metrological system in Montenegro, it was concluded that it was necessary to revise the Strategy for a short-term period.

27. How is traceability to international measurement standards ensured?

The system of national and reference measurement standards should enable measurement traceability to the SI. The Metrology Office is in charge of the establishment, conservation, maintenance and improvement of national measurement standards. National measurement standard of a unit of a specified quantity is a standard having the best metrological properties in Montenegro and serving as the basis for assigning values to other measurement standards for the kind of quantity concerned. National measurement standards are traceable to the international measurement standards or national measurement standards of other countries having appropriate metrological characteristics.

National measurement standards have not yet been established for some quantities. Pursuant to the Law on Metrology (Official Gazette of Montenegro 44/09), the Ministry of Economy is drafting secondary legislation to stipulate the requirements for declaring a reference measurement standard to be a national measurement standard, the method of declaring a national measurement standard, the end of the status of a national measurement standard, the obligation of maintenance and use of a national measurement standard. It is also envisaged that it is not necessary to set up a national measurement standard for each quantity.

Following the proclamation of independence in 2006, the traceability chain was interrupted since the measurement standard basis remained with the Office for Measures and Precious Metals in Belgrade. The working measurement standards taken over from the Control of Measures and Precious Metals of Podgorica, the working measurement standards owned by authorised persons for examining measuring instruments pursuant to the previous law, as well as secondary and working measurement standards taken over from the military metrological laboratories ML 30 and ML 36 constituted the basis for the implementation of metrological activities.

Currently the measurement standards for mass and length of the Metrology Office, calibrated at the National Metrological Institute of Austria, and the Republic of Croatia, as well as working measurement standards owned by persons authorised for examination of measuring instruments, calibrated at proper institutions, ensure traceability of measurements for mass, length, volume, and electrical quantities.

The necessary conditions for the establishment, conservation, maintenance and improvement of national measurement standards include proper premises to house the national calibration laboratories and proper equipment, which needs to be ensured as soon as possible for the Metrology Office.

E. Market surveillance

28. How does your country ensure that products on the market throughout the country meet standard requirements? (Alternatively, do you have a reliable and standardised system of pre-marketing authorisation?) What penalties apply to infringements? How is co-ordination ensured between sectors? How is market surveillance co-ordinated between market surveillance authorities and customs as regards product conformity and safety checks at external borders? Does your country have a national programme on market surveillance? What information exchange network exists between the various authorities?

Montenegro has an organised system of inspection control in place - relevant inspectorates within the line ministries and other administration bodies responsible for market surveillance of products to ensure the compliance with standards and other technical requirements. Competent inspectorates are in charge of market surveillance in the entire Montenegrin market, following the principle of divided competences and organization of joint controls as needed. Depending on the risk assessment, inspectors take samples of products in the market and submit them for testing to the compliance assessment bodies. In addition, they may request removal of unauthorised marking on products, ban or limit the marketing or order the withdrawal of noncompliant products from the market and conduct other measures. Product conformity assessment is done in accordance with the set standards, the Standardisation Law, the Law on General Product Safety, as well as the law regarding inspection control and other regulations.

- The penalties for violations of standards and other requirements for products are stipulated by the on Law on Technical Requirements for Products and Assessment of Product Conformity against Set Standards, the Law on General Product Safety, the Law on Consumer Protection and other relevant regulations. These are all pecuniary fines. The Criminal Code (Official Gazette of Montenegro 70/03, as amended in Official Gazette of Montenegro 40/08) stipulates an imprisonment sentence of up two years for the criminal offence of violation of product marking. In addition to the foregoing, the appropriate injunction is also pronounced.

- Coordination among the sectors is regulated under the Law on General Administrative Procedure, the Law on Inspection Control and the Decree on Joint Inspection Control as well as other regulations governing the competences of specific sectors (general product safety, technical requirements and conformity assessment, standardisation, accreditation, etc.).

- Coordination among the bodies in charge of market surveillance (non-food products) and customs regarding the control of product compliance and safety checks at the outer borders is stipulated by the Law on General Product Safety in line with the Regulation EC/339/93. While amending the law the given provisions will be harmonised with the new Regulation. Pursuant to the Law on General Product Safety the Draft Decree on Exchange of Information on Products Posing a Risk was prepared, to be adopted by the Government by the end of Quarter III, regulating in detail the method of cooperation.

- The Draft Market Surveillance Strategy was prepared by an inter-agency working group with the assistance of EU experts in the area of market surveillance within the framework of TRIM MNE Project. The working group was established at the initiative of the Ministry of Economy, composed of the representatives of inspections performing supervision of goods and services in the market (market, health and sanitary, veterinary, phytosanitary, tourism, environmental), as well as the representatives of customs and the quality infrastructure department. This document presents market surveillance in the EU and market surveillance in Montenegro including an analysis of the current state of affairs, strategic challenges and a strategy for the development of market surveillance in Montenegro. The legal basis for development, in addition to the national legislation, was provided also by the EU legislation, including the Guide to the Implementation of the Directives Based on the New Approach, EMARS Enhancing Market Surveillance through Best Practice, etc. The Strategy is primarily intended for the surveillance of non-food products market, but is also a good basis for the development of special sectoral strategies. Further harmonisation of this document by the working group, adoption of its draft version by the Ministry of Economy and subsequent adoption by the Government is planned by the end of the third quarter of 2009.

In addition, the National Consumer Protection Programme and the Action Plan for its implementation (already submitted to the EC), envisages the obligations of bodies in charge of market surveillance, which is the instrument of consumer protection against unsafe products in the market. This plan highlights the need for coordinated market surveillance and cooperation between the inspectorates and other bodies involved in market surveillance, as well as mutual exchange of information.

- The exchange of information among the national-level bodies is done through permanent communication (telephone, fax, e-mail, joint meetings as required). The legislative framework relating to the exchange of information on hazardous products is in the final stage of preparation; it will designate a body to act as the contact point, on the basis of which a network for the exchange of information will be developed, first among the national bodies, and at a later stage with the EC ones.

OLD APPROACH PRODUCT LEGISLATION

A. Harmonisation of laws including technical regulations

29. Please provide information regarding the:

- Motor vehicles

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

The legislation enacted before the independence of Montenegro still applies in the area of motor vehicles. Such inherited legislation implied administrative authority on various levels of the former federal state that included Montenegro. Following its independence, in order to overcome the barriers in this area, the Government of Montenegro allocated temporary competencies to various state administration bodies for the application of relevant legislation. In the area of motor vehicles in Montenegro the following regulations apply:

- Standardization Law (Official Gazette of Montenegro 13/08);
- Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro);
- Law on Road Transportation Safety (Official Gazette of the Republic of Montenegro 72/05), representing the legal basis for the adoption of technical regulations for machines and motor vehicle equipment;
- Law on Road Transportation (Official Gazette of the Republic of Montenegro 45/05)
- International Treaty on the Adoption of Uniform Conditions for Homologation and Mutual Recognition of Homologation of Equipment and Parts of Vehicles. The Treaty was adopted in 1958, in addition to the Regulation 49/EC that is applied in Montenegro on the basis of the Decision on Declaration of Independence of Montenegro (Official Gazette of the Republic of Montenegro 36/06);
- Rulebook on the Procedure of Inspection of Homologation and Environmental Orderliness of Used Motor Vehicles to be Imported (Official Gazette of the Republic of Montenegro 42/04)

- Rulebook on Special Conditions for Public Transportation Vehicles in Road Transport and Transport for Own Purposes (Official Gazette of the Republic of Montenegro 62/06).

Harmonized regulations constituting an integral part of the Treaty on the Acceptance of Uniform Conditions for Homologation and Mutual Recognition of Homologation of Equipment and Parts of Motor Vehicles, which were adopted by the former Federal Standardization Institute of Belgrade, include the following:

- Uniform regulations related to homologation of motor vehicle headlights emitting asymmetric low beam and/or high beam lights equipped with R2 category bulbs (according to ECE R. 1) (Official Gazette of the Socialist Federal Republic of Yugoslavia - supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/761/EEC, 89/517/EEC and 1999/17/EC);
- Uniform regulations related to homologation of electrical incandescent lamps for the headlights emitting one asymmetric low beam and one road beam, or either one or the other beam light (according to ECE R.2) (Official Gazette of the Socialist Federal Republic of Yugoslavia - supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/761/EEC, 89/517/EEC and 1999/17/EC);
- Uniform regulations related to the homologation of reflective devices for motor vehicles and their trailers (according to ECE R.3), (Official Gazette of the Socialist Federal Republic of Yugoslavia - supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/756/EEC, 97/29/EEC);
- Uniform regulations related to the homologation of devices for illumination of the back number plate of motor vehicles (other than motorcycles) and their trailers (according to ECE R.4), (Official Gazette of the Socialist Federal Republic of Yugoslavia -supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/760/EEC, 97/31/EEC);
- Uniform regulations related to the homologation of Sealed beams for motor vehicles, emitting asymmetric low European beam light or one high beam light pointing at the road, or both beams (according to ECE R.5), (Official Gazette of the Socialist Federal Republic of Yugoslavia - supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/761/EEC, 89/517/EEC and 1999/17/EC);
- Uniform regulations related to the homologation of turn signal lights for motor vehicles and their trailers (according to ECE R.6) (Official Gazette of the Socialist Federal Republic of Yugoslavia - supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/759/EEC, 89/277/EEC and 1999/15/EC);
- Uniform regulations related to the homologation of motor vehicles' front position lights, rear position lights and break lamps (other than motorcycles) and their trailers (according to ECE R.7) (Official Gazette of the Socialist Federal Republic of Yugoslavia – supplement: International Treaties and other Agreements 2/69), (harmonized with Directives: 76/758/EEC, 89/516/EEC and 97/30/EEC);
- Uniform regulations related to the homologation of motor vehicles' headlights emitting asymmetric low or high beam or both beams and which are equipped with halogen bulbs (H1,H2 or H3) (according to ECE R.8) (Official Gazette of the Socialist Federal Republic of Yugoslavia – supplement: International Treaties and other Agreements 2/69), (harmonized with Directives 76/761/EEC, 89/517/EEC and 1999/17/EC);
- Uniform regulations related to the homologation of three-wheel vehicles in relation to noise (according to ECE R.9) (Official Gazette of the Socialist Federal Republic of Yugoslavia – 16/72 – International Treaties and other Agreements), (harmonized with Directives 70/157/EEC, 73/350/EEC, 77/212/EEC, 81/334/EEC and 89/491/EEC);
- Uniform regulations related to the homologation of vehicles in relation to the prevention of radio disturbances (according to ECE R.10) (Official Gazette of the Socialist Federal Republic of Yugoslavia 16/72 – International Treaties and other Agreements), (harmonized with Directives 72/245/EEC, 89/491/EEC, 95/54/EC);
- Uniform regulations related to the homologation of vehicles equipped with Otto or Diesel engines in relation to emission of polluting gasses from engines - method for measuring power of Otto engines - method for measuring fuel consumption (according to ECE R.15)

- (Official Gazette of the Socialist Federal Republic of Yugoslavia 57/75 – International Treaties and other Agreements), (harmonized with Directives 70/220/EEC, 74/290/EEC, 77/102/EEC, 78/665/EEC);
- Uniform regulations related to the homologation of safety belts for adults located in motor vehicles (according to ECE R.16) (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/74 – International Treaties and other Agreements), (harmonized with Directives 77/541/EEC, 81/576/EEC, 82/319/EEC, 90/628/EEC, 96/36/EC, 2000/3/EC);
 - Uniform regulations related to the homologation of vehicles in relation to firmness of seats and their fixing, as well as in relation to the features of head support that can be built-into such seats (according to ECE R.17) (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/74 – International Treaties and other Agreements), (harmonized with Directives 74/408/EEC, 81/577/EEC, 96/37/EC);
 - Uniform regulations related to the homologation of motor vehicles fog-lights (according to ECE R.19) (Official Gazette of the Socialist Federal Republic of Yugoslavia 14/75 – International Treaties and other Agreements), (harmonized with Directives 76/762/EEC, 1999/18/EC);
 - Uniform regulations on the examination and conducting of mandatory vehicle homologation with regards to locks and door fixing devices (according to ECE R.11) (Official Gazette of the Socialist Federal Republic of Yugoslavia 59/90 – International Treaties and other Agreements), (harmonized with Directives 70/387/EEC, 98/90/EC, 2001/31/EC);
 - Uniform regulations on the examination and conducting mandatory homologation of motor vehicles in relation to breaking (according to ECE R.13) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 54/85, 26/89), (harmonized with Directives 71/320/EEC, 74/132/EEC, 75/524/EEC, 79/489/EEC, 85/647/EEC, 88/194/EEC, 91/422/EEC, 98/12/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles with regards to safety belts attachments in passenger vehicles (according to ECE R.14) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85), (harmonized with Directives 76/115/EEC, 81/575/EEC, 82/318/EEC, 90/629/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles in relation to the protection from unauthorized use (according to ECE R.18) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 11/85, 1/87, 23/88), (harmonized with Directives 74/61/EEC, 95/56/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles with regards to the related internal equipment (according to ECE R.21) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 70/90), (harmonized with Directives 74/60/EEC, 78/632/EEC, 2000/4/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of protective helmets for riders of bicycles with engine and of motorcycles and for passengers using such vehicles (according to ECE R.22) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 18/88);
 - Uniform regulations on the examination and conducting of mandatory homologation of the reversing lights of motor vehicles and their trailers (according to ECE R.23) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 59/90), (harmonized with Directives 77/539/EEC, 97/32/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation: I Diesel engines in relation to visible polluting gasses; II motor vehicles in relation to the fitting of homologated engines; III motor vehicles equipped with diesel engines with regards to visible pollution gasses; IV uniform regulations on the measuring of Diesel engine power (according to ECE R.24) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 11/85, 1/87), (harmonized with Directives 72/306/EEC, 89/491/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of head supports on motor vehicles seats (according to ECE R.25) (On the basis of the Order on

- Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 59/90), (harmonized with Directive 78/937/EC);
- Uniform regulations on the examination and conducting of mandatory homologation in relation to their external exhausts (according to ECE R.26) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 70/90), (harmonized with Directives 74/483/EEC, 79/488/EEC, 87/354/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of passenger vehicle tyres and their trailers (according to ECE R.30) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 43/83), (harmonized with Directive 92/23/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of vehicles in relation to distribution of night-time commands (according to ECE R.35) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 59/90);
 - Uniform regulations on the examination and conducting of mandatory homologation of incandescent bulbs for motor vehicles and their trailers (according to ECE R.37) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85), (harmonized with Directives 76/761/EEC, 89/517/EEC, 1999/17/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of rear fog-lights for motor vehicles and their trailers (according to ECE R.38) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 59/90), (harmonized with Directives 77/538/EEC, 89/517/EEC, 1999/14/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of vehicles in relation to speedometer and its fitting into a vehicle (according to ECE R.39) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 11/85, 1/87), (harmonized with Directives 75/443/EEC, 97/39/EC, 2000/7/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motorcycles with Otto engines with regard to the emission of polluting gasses from engines (according to ECE R.40) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 60/86);
 - Uniform regulations on the examination and conducting of mandatory homologation of motorcycles in relation to noise (according to ECE R.41) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 60/86), (harmonized with Directives: 78/1015/EEC, 87/56/EEC, 89/235/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motorized security glasses and materials for their fitting onto motor vehicles and their trailers (on the basis of ECE R.43) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 68/85);
 - Uniform regulations on the examination and conducting of mandatory homologation of bicycles with Otto engines in relation to the emission of polluting gasses from engine (according to ECE R.47) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 60/86);
 - Uniform regulations on the examination and conducting of mandatory homologation of vehicles with regards to fitting lighting and light-signalling devices (according to ECE R.48) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 68/85, 1/87, 46/87), (harmonized with Directives 76/756/EEC, 80/233/EEC, 82/244/EEC, 83/276/EEC, 84/8/EEC, 89/278/EEC, 91/663/EEC, 97/28/EEC);
 - Uniform technical specifications relating to the examination and conducting of homologation diesel engines and natural gas engines (NG) as well as Otto LPG engines (LPG) and vehicles equipped with diesel engines on NG and Otto engines on LPG, in relation to the emission of pollutants from engines (according to ECE R.49) (On the basis of the Order on Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 60/02, 64/02), (harmonized with Directives 88/77/EEC, 1999/96/EC);

- Uniform regulations on the examination and conducting of mandatory homologation of front position lights, rear position lights, breaking lamps, turn lights and rear number plate lights for bicycles with engine, motorcycles and vehicles considered as such (according to ECE R.50) (On the basis of the Order on Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 67/86);
- Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles with at least four wheels in relation to noise (according to ECE R.51) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 48/84, 1/87), (harmonized with Directives 70/157/EEC, 81/334/EEC, 84/424/EEC, 89/491/EEC, 92/97/EEC, 96/20/EC, 1999/101/EC);
- Uniform regulations on the examination and conducting of mandatory homologation of motorcycles in relation to the fitting of lighting and signalling devices (according to ECE R.53) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 68/85), (harmonized with Directive 93/92/EEC);
- Uniform regulations on the examination and conducting of mandatory homologation of the tyres for commercial vehicles and their trailers (according to ECE R.54) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 11/85), (harmonized with Directive 92/23/EEC);
- Uniform regulations on the examination and conducting of mandatory homologation of mechanical coupling devices for connecting trailers to tractive vehicles (according to ECE R.55) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 63/89);
- Uniform regulations on the examination and conducting of mandatory homologation of the headlights for bicycles with engine and vehicles treated as such (according to ECE R.56) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 67/86);
- Uniform regulations on the examination and conducting of mandatory homologation of the headlights for motorcycles and vehicles treated as such (according to ECE R.57) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 68/85);
- Uniform regulations on the examination and conducting of mandatory homologation of: I rear protective devices, II vehicles in relation to the fitting of rear protective devices with type homologation; III vehicles in relation to the protection of rear end (according to ECE R.58) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 85/87), (harmonized with Directives 70/221/EEC, 79/490/EEC, 97/19/EC);
- Uniform regulations on the examination and conducting of mandatory homologation of replaceable silencing systems for noise reduction (according to ECE R.59) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 43/92), (harmonized with Directives 81/334/EEC, 89/491/EEC, 96/20/EC, 1999/101/EC);
- Uniform regulations on the examination and conducting of mandatory homologation of bicycles with engine, with regard to noise (according to ECE R.63) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 73/87);
- Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles in relation to the measuring of maximum speed (according to ECE R.68) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 17/92);
- Uniform regulations on the examination and conducting of homologation of the plates for marking slow vehicles (by construction) and their trailers, which are mounted on the rear end of vehicles and their trailers (according to ECE R.69) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 24/90);
- Uniform regulations on the examination and conducting of mandatory homologation of the plates for marking heavy and other vehicles, which are mounted on the rear end of vehicles

- (according to ECE R.70) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 24/90);
- Uniform regulations on the examination and conducting of mandatory homologation of cargo vehicles, trailers and semi-trailers in relation to lateral protection (according to ECE R.73) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 43/92), (harmonized with Directives 89/297/EEC);
 - Uniform regulations on the examination and conducting of mandatory homologation of bicycles with engine and motorcycles with regard to breaking (according to ECE R.78) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 17/89), (harmonized with Directive 93/14/EEC);
 - Uniform technical specifications for the examination and conducting of homologation of vehicles in relation to the emission of pollutants from exhaust gases due to fuel combustion (according to ECE R.83) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 61/02), (harmonized with Directives 70/220/EEC, 83/351/EEC, 88/76/EEC, 88/436/EEC, 89/491/EEC, 91/441/EEC, 94/12/EC, 96/69/EEC, 98/69/EC, 98/77/EC, 1999/102/EC, 2001/1/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of motor vehicles equipped with internal combustion engines in relation to the measuring fuel consumption (according to ECE R.84) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 24/92), (harmonized with Directives 80/1268/EEC, 89/491/EEC, 93/116/EC, 1999/100/EC);
 - Uniform regulations on the examination and conducting of mandatory homologation of internal combustion engines used for driving motor vehicles of M and N category in the sense of measuring net power (according to ECE R.85) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 12/92), (harmonized with Directives 80/1269/EEC, 88/195/EEC, 89/491/EEC, 97/21/EC, 1999/99/EC);
 - Uniform technical specifications on the examination and conducting of mandatory homologation of vehicles intended for the transport of hazardous materials in relation to their specific structural features (according to ECE R.105) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 48/02), (harmonized with Directive 98/91/EC);
 - Uniform technical specifications on the examination and conducting of homologation of motor vehicle headlights emitting asymmetric high beam or low beam light or both, equipped with incandescent bulbs (according to ECE R.112) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Federal Republic of Yugoslavia 46/02);
 - Uniform regulations on the examination and conducting of mandatory homologation of acoustic warning devices, as well as motor vehicles with regard to acoustic signals (according to ECE R.28) (On the basis of the Order on Mandatory Homologation, Official Gazette of the Socialist Federal Republic of Yugoslavia 60/86) (harmonized with Directive 70/388/EEC);
 - Order on vehicles in international road transport that must have a certificate confirming that they meet the technical requirements in relation to the noise and emission of pollutants (Official Gazette of the Federal Republic of Yugoslavia 27/92).

Also, in order to achieve a higher degree of environment protection, the Decision on the requirements that must be met by the imported used vehicles was adopted (Official Gazette of the Republic of Montenegro 44/07), in addition to the Rulebook on the manner of verification of the compliance with the specific requirements, form and contents of the certificate and fees payable for imported used motor vehicles (Official Gazette of the Republic of Montenegro 16/08), whereby, inter alia, the standard EURO 3 was introduced as a minimum mandatory standard, in relation to the emission of exhaust gases by vehicles and the level of noise. By this Decision the EU Directives 70/220/EEC, 98/69/EC, 88/77/EEC, 1999/96/EC, 96/20/EEC and 70/157/EEC corresponding to UN/ECE Rulebooks were transposed to the national legislation.

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

In accordance with the response to the sub-question 29a relating to motor vehicles, the Government of Montenegro will identify an administrative authority for the subject area and task a line ministry to take care of the implementation of and amendments to the legislation. During the period until the end of 2011, the outdated regulations will be withdrawn and the missing regulations will be enacted so that the whole area is fully harmonised.

- Chemicals

- Limitations, classification, packaging and labelling (REACH, CLP) Detergents

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

The Law on Chemicals (Official Gazette of the Republic of Montenegro 11/07) entered into effect in 2007. This was the first law regulating the said area in Montenegro that established the procedure of registration and placing into circulation of new and existing chemicals, the process of evaluation and risk assessment of chemicals, classification, packaging and labelling of chemicals, import and export, and other issues of importance for the protection of human life and health and the environment. The Law was harmonized with the acquis and the standards on competition rights established by the Council Directive 31992L0032, i.e. the Directive 31967L0548 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, the Commission Directive 31993L0067 laying down the principles for assessment of risk to man and the environment of substances notified in accordance with the Directive 31967L0548 and the Regulation 31993R0793R (01) on the evaluation and control of risk of existing substances and 32003R0304 concerning the export and import of dangerous chemicals.

The Law on Chemicals also includes the obligations arising from the Directive 32004L0010 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, and the Decision of the Commission 31985D0071 concerning the list of chemical substances - EINECS list (*European Inventory of Existing Commercial Chemical Substances*), i.e. European inventory of the existing commercial chemicals and the Regulation 32006R1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency.

Chapter V of the Law on Chemicals (Official Gazette of the Republic of Montenegro 11/07) defines the restriction, classification, packaging and labelling of chemicals.

V. CLASSIFICATION, PACKAGING AND LABELLING OF CHEMICALS

Article 31

The List of classified chemicals is established and maintained by the Ministry,

The list of classified chemicals contains the following information: classification of chemicals, trade name and chemical name according to IUPAC nomenclature.

The List of classified chemicals referred to in paragraph 2 of this Article is published in the Official Gazette of Montenegro.

More detailed content and manner of keeping of the classified chemicals list is prescribed by the Ministry, following a prior opinion of the state administration body responsible for the environmental protection.

Article 32

A chemical that is determined to be dangerous to human life and health and the environment, is classified as follows:

- a) *Explosive chemicals* which include chemicals in solid and liquid form, chemicals and preparations in the form of paste or gelatine, which may exothermically react in case of absence of oxygen from the air where gases are rapidly created and emitted and may detonate under particular conditions, and may be easily inflamed or explode due to higher pressure, if limited by space;
- b) *Oxidizing chemicals* which include chemicals and preparations that cause strong exothermic reaction when in contact with other substances (primarily flammable);
- c) *Very easily flammable chemicals* which include liquid chemicals and preparations with an extremely low ignition temperature and low boiling point as well as gaseous chemicals and preparations which ignite when in contact with the air at normal temperature and pressure;
- d) *Easily flammable* chemicals include:
 - Chemicals and preparations, which in contact with the air warm-up and ignite at normal temperature and pressure, without bringing in an external energy;
 - solid chemicals and preparations which can ignite quickly and easily after a short contact with an ignition source and which continue to burn and combust after the ignition source is removed;
 - Chemicals and preparations in liquid form having a very low ignition temperature;
 - Chemicals and preparations which, in contact with water or moist air, release extremely flammable gasses in dangerous quantities;
- e) *Flammable chemicals* which include chemicals and preparations with a low ignition point;
- f) *Very toxic chemicals* which include chemicals that, when swallowed, inhaled or absorbed through the skin in very small quantities, cause death, or have an acute or chronic harmful effect on human health;
- g) *Toxic chemicals* include chemicals and preparations that in small quantities cause death or have an acute or chronic harmful effect on human health when swallowed, inhaled or absorbed through the skin;
- h) *Chemicals harmful to health* which include chemicals or preparations that may cause death or an acute or chronic harm to the health when swallowed, inhaled or absorbed through the skin;
- i) *Corrosive (caustic) chemicals* including the chemicals and preparations that can damage or destroy living tissue in the case of an immediate contact, or chemicals that can damage, destroy or degrade metal surfaces, stone or minerals through chemical or electro-chemical action processes, if they come in contact with those, which represents a direct threat to the commercial goods;
- j) *Irritant chemicals* including the chemicals and preparations that are not corrosive, but in the short term, long-term or repeated contact with the skin or mucous membranes cause their inflammation or other adverse effects;
- k) *Sensitizing chemicals* including the chemicals that lead to hypersensitivity, i.e. the chemicals and preparations which, if inhaled or penetrating through the skin, can cause hyper-sensitivity reaction, while a longer exposure to such chemicals may lead to significant adverse effects;

- l) Carcinogenic chemicals including the chemicals and preparations which if inhaled, swallowed or inserted through the skin (contact with the skin), may cause cancer or increase its proliferation;
- m) *Mutagenic chemicals* including the chemicals and preparations which, if swallowed, inhaled or inserted through the skin (contact with the skin), may cause modification of the genetic material;
- n) *Reproductive toxic chemicals* which include chemicals and preparations which, if inhaled, swallowed or inserted through the skin (contact with the skin), may cause or increase the proliferation of non inheritable adverse effects in the offspring and/or have adverse effects on the male or female reproductive functions;
- o) *Chemicals dangerous for the environment* including the chemicals and preparations which, if placed in the environment, cause a momentary or subsequent danger to one or multiple components of the environment.

Article 33

The chemicals that are imported and put into circulation shall be classified in accordance with this Law and the subsequent secondary legislation.

The Classification of chemicals referred to in Article 32 of this Law shall be conducted in accordance with the classification of chemicals of the same chemical composition from the list of classified chemicals, or on the basis of the EU Index of listed hazardous chemicals.

Article 34

The categorization of chemicals (substances) in the List of classified chemicals is performed on the basis of:

- Test results relating to the properties of chemical in accordance with this Law, or
- Findings from the existing data.

The classification of chemicals (preparations) is performed on the basis of:

- Prescribed calculation method;
- Direct experimental research of the toxicological properties that affect human life and health;
- Findings relating to the characteristic of chemicals, on the basis of the existing data.

If the toxicological property of a chemical has been confirmed through the application of methods referred to in paragraph 2 of this Article, the classification will use the results obtained on the basis of direct experimental study of characteristics that affect human life and health, and if the chemical is carcinogenic, mutagenic or reproductive toxic, it is mandatory to use the results obtained on the basis of the prescribed computational method, as well.

When there is no data available for the chemical or the data have not been obtained in the manner specified under this Law and the subsequent regulations, in order to avoid a research on vertebrates, the need for additional testing shall be assessed for each individual case.

Article 35

The chemical that is imported and put into circulation shall be packed and labelled in accordance with this Law and the subsequent secondary legislation.

The packaging must be adequate to the chemical properties, its purpose and manner of utilization.

Hazardous chemicals shall be packed in the packaging equipped with special closures that cannot be opened by the children and shall not be misleading regarding the content.

Hazardous chemicals must be labelled in a manner that allows the people with special needs to spot the danger.

Instructions for use of hazardous chemicals, that are classified into groups referred to in Article 32 paragraph f) to o) of this Law, which are intended for general use, must contain a warning for the safe handling of chemicals and first aid procedures in case of accident.

Article 36

A chemical which was classified as dangerous shall not be labelled or declared as less dangerous or not dangerous to human life and health and the environment.

The chemicals shall be labelled with a clearly visible and legible inscription in the language in official use in Montenegro.

Article 37

More detailed criteria, conditions, principles and method of classification, packaging and labelling of chemicals shall be regulated by the Ministry, following a prior opinion of the state administration authority in charge of environmental protection.

Article 38

The chemical that is put onto circulation shall be accompanied by the Safety List.

The Safety List shall especially contain the following: information about the manufacturer or importer, information on chemical hazardousness, basic information on the composition of chemical, measures to protect the human life and health, occupational safety measures, measures for environmental protection, date of going out of use, as well as the date of issuing of the Safety List.

The applicant who puts the chemical into circulation shall continuously monitor the latest findings relating to the chemical that is being put into circulation, and update the Safety List in accordance with the latest findings.

Any modification to the Safety List shall be submitted by the applicant to the Ministry and the users to whom the chemical had been delivered no less than 12 months before the Safety List was modified.

Persons who use hazardous chemicals shall adhere to the instructions on proper use, for the purpose of safety and health protection during the application, first aid measures, and instructions on dealing with the remnants of unused chemicals and empty packaging as well as the environmental protection measures provided by the Safety List.

More detailed content of the Safety List shall be provided by the Ministry, following a prior opinion of the state administration authority responsible for environmental protection.

Article 39

Any advertising of the chemicals referred to in Article 32 of this Law shall be prohibited, if their properties are not listed.

A more detailed manner of advertising of the chemicals referred to in paragraph 1 of this Article shall be provided by the Ministry, following a prior opinion of the state administration authority responsible for environmental protection.

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

The Law was drafted in a manner that provides solid legal basis for the adoption of complete secondary legislation in this area. In this respect the National Program for Integration of Montenegro into the European Union (NPI) was prepared for the period 2008-2012, including both short-term and mid-term priorities regarding the preparation of the required secondary legislation.

A slow-down in the implementation of planned activities results from the fact that until 3 July 2009 there were some overlaps between the competencies of the Ministry of Health, Labour and Social Welfare and the Ministry of Tourism and Environmental Protection in this area. The authority in the area of chemicals was established following the adoption of the Decree on the Organization and Manner of Operation of the State Administration (Official Gazette of the Republic of Montenegro 54/04, 78/04, 06/05, 61/05, 06/06, 32/06, 42/06, 56/06, 60/06, 72/06, 06/07, 25/07, 32/07, 35/07 and Official Gazette of Montenegro 06/07, 16/07, 26/08, 43/08, 68/08, 81/08, 04/09, 14/09 and 43/09) and the election of a new Council of Ministers. In accordance with Article 17b of the aforementioned Decree, the administrative tasks relating to the chemicals are performed by the Ministry for Spatial Planning and Environmental Protection, while Article 44c stipulates that all executive affairs related to chemicals are performed by the Agency for Environmental Protection.

In accordance with Article 15 of the Decree on the Organization and Manner of Operation of the State Administration, the Ministry of Health is responsible for the issuing of permits for the transport across the state border and internal transport of toxins, as well as for the production of and trade in toxins.

Until the adoption of planned secondary legislation in this area, according to the Law on Chemicals and the proposed activities of the NPI, the following regulations that are in accordance with the Law on Chemical will remain in force:

1. Law on the Production and Trade in Toxic Substances (Official Gazette of the Federal Republic of Yugoslavia 15/95, 28/96, 37/02);
2. List of Toxins whose Production, Trade and Utilization are Prohibited (Official Gazette of the Federal Republic of Yugoslavia 12/00);
3. Decision on the Establishment of List of Toxins (Official Gazette of the Federal Republic of Yugoslavia 25/94);
4. Law on Transportation of Hazardous Substances (Official Gazette of Montenegro 05/08).

- Detergents

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

Detergents

An overview of valid regulations relating to detergents:

The Law on Health Safety of Food Products and Articles for General Use (Official Gazette of the Federal Republic of Yugoslavia 37/02) and secondary legislation enacted on the basis of this Law:

- Rulebook on the conditions in relation to the sanitary safety of the objects for general use that may be put into circulation (Official Gazette of the Socialist Federal Republic of Yugoslavia 18/91);
- Rulebook on the conditions in relation to professional staff, office space and equipment that must be met by health and other organizations to perform analysis and super-analysis of foods and items of common use (Official Gazette of the Federal Republic of Yugoslavia 60/02);

- Instructions on the manner of sampling to perform analysis and super-analysis of foods and items of common use (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/1978);
- Law on Sanitary Control of Foods and Items of Common Use (Official Gazette of the Socialist Republic of Montenegro 4/88) and secondary legislation prepared on the basis of this Law;
- Rulebook on the conditions and manner of examination of foods and items of common use in the course of their production and the method of keeping records of the tests made (Official Gazette of the Socialist Republic of Montenegro 8/75);

The existing legislation in this area is not harmonized with the EU legislation.

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

Detergents

The National Program for Integration of Montenegro into the EU has provided for the preparation of a Rulebook on Detergents until the end of 2011, which will be harmonized with the European legislation (Regulation 684/2004 on detergents).

- Fertilisers

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

Artificial Fertilizers

The Law on Fertilizers (Official Gazette of the Republic of Montenegro 48/2007) is harmonized with the applicable EU regulations, namely with the Regulation (EC) 2003/2003, which refers to artificial fertilizers and partly with the Directive 91/676/EEC, which refers to the protection of waters from pollution caused by nitrates from agricultural sources.

Following the adoption of this Law the basis were created for the transposition of the EU legislative solutions for mineral fertilizers into Montenegrin legislation and their equalization.

The following secondary legislation issued on the basis of earlier national regulations is in force:

- Rulebook on methods of fertilizer testing (Official Gazette of the Federal Republic of Yugoslavia 11/99);
- Rulebook on conditions for the production line, circulation, import and sampling of pesticides and fertilizers (Official Gazette of the Federal Republic of Yugoslavia 12/99);
- Rulebook on types of packaging material for pesticides and fertilizers and on destruction of pesticides and fertilizers (Official Gazette of the Federal Republic of Yugoslavia 35/99);
- Rulebook on the circulation, import and sampling of fertilizers (Official Gazette of the Federal Republic of Yugoslavia 59/01);
- List of organizations authorized for testing plant protection products (pesticides) and resources for plant nutrition (fertilizers) (Official Gazette of the Federal Republic of Yugoslavia 4/2000);
- List of fertilizers permitted for circulation (Official Gazette of the Federal Republic of Yugoslavia 29/01).

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

Artificial Fertilizers

With the objective of gradual harmonization with the EU legislation, within the process of stabilization and association, the secondary legislation that derives from the Law on Fertilizers will be drafted during 2010. The enactment of secondary legislation based on this Law will provide the required harmonization.

The main disharmony in the area of plant nutrition products (fertilizers), following the adoption of the new Law, are the existing regulations on the quality of mineral fertilizers which are linked to the JUS norms.

The secondary legislation, the adoption of which is pending, will include additional EU rules concerning the use of ammonium nitrate in the production of fertilizers, in accordance with the public safety requirements regarding the protection of people and property, reduction of risk of misuse of ammonium nitrate fertilizers, in particular through the introduction of measures for preventing such manner of use, while the possibility of finding such fertilizers will be specially ensured, as well as consumer protection through the introduction of quality and registration standards.

The secondary legislation, which will be adopted, will harmonize the national legislation with the EU regulations governing this area.

- Drug precursors

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

Precursors for Narcotics

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

- Law on Medicines (Official Gazette of the Republic of Montenegro 80/04 and Official Gazette of Montenegro 18/08)
- Law on the Production and Circulation of Toxins (Official Gazette of the Socialist Republic of Montenegro 31/77, 17/92 and 27/94)
- Decision on the control list for export, import and transit of goods (Official Gazette of the Republic of Montenegro 19/06) of the Government of Montenegro, which includes Annex 1 - List of narcotic drugs and Annex 2 - List of precursors

Ratified UN Conventions covering the area of narcotics, 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;
- United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

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

Precursors for Narcotics

The Government of Montenegro adopted the Proposal of the Law on Precursors for Narcotics which was submitted to the Parliament. The Proposal of the Law is in accordance with the EU regulations mentioned below as well as the 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;
- 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;
- United Nations Convention against the illicit Traffic in Narcotic Drugs and Psychotropic substances, 1988.

The Proposal of the Law envisages a change of competences in this area. Licenses for the export/import/transit of precursors will be issued by the Ministry of Health, except in the case when such precursors fall within the group of pharmacologically active substances, where the issuing of such permits will remain in the jurisdiction of CALIMS. The Ministry will also continue to submit relevant reports to INCB.

The list of precursors will be published in the Official Gazette of Montenegro. Secondary legislation will be prepared following the adoption of the Law. The Law on Precursors will provide for the monitoring of this area.

- Explosives for civil uses (New Approach directive)

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

Explosives for civil use (Directive of the new approach)

The Law on Explosive Substances (Official Gazette of Montenegro 49/08) lays down the conditions for production, sales, purchasing, storage and use of explosives in order to protect human life, health and safety, animals and plants, environment and property, as well as the important issues regarding the conduct of these activities, although it is precisely specified what is, in the sense of that law, considered as an explosive substance (commercial explosive, etc.).

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

Explosives for Civil Use (Directive of the New Approach)

The authority of the Ministry of Internal Affairs and Public Administration - Sector for Emergency Situations and Civil Security is reflected in the creation and observance of the conditions so that no explosion is caused by explosive mixtures. In this sense, we are competent to prescribe and apply the regulations which identify the zones of danger and security distances. Additionally, the equipment used in potentially explosive environments must also have a protective function.

- Pyrotechnics (New Approach Directive)

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

Pyrotechnic materials (Directive of the new approach)

The Law on Explosive Substances (Official Gazette of Montenegro 49/08) stipulates the conditions for the production, sales, purchasing, storage and use of explosives in order to protect human life, health and safety, animals and plants, environment and property, as well as issues of importance for the conducting these activities, whereas it is precisely specified what is, in the sense of that law, considered as an explosive substance (commercial explosive, etc.).

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

Pyrotechnic materials (Directive of the new approach)

The authority of the Ministry of Internal Affairs and Public Administration - Sector for Emergency Situations and Civil Security is reflected in the creation and observance of the requirements so that no explosion is caused by explosive mixtures. In this sense, we are competent to prescribe and apply regulations which identify the zones of danger and security distances. Additionally, the equipment used in potentially explosive environments must also have a protective function.

- Good laboratory practice (GLP)

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

The following legislation in relation to Good Laboratory Practice (GLP) regulates the pharmacological - toxicological testing of medicines for use in human and veterinary medicine:

1) Law on Medicines (Official Gazette of the Republic of Montenegro 80/04 and Official Gazette of Montenegro 18/08).

In accordance to the Law on Medicines, good laboratory practice (GLP) is a system of quality assurance related to the organization and implementation of laboratory work in the preclinical pharmacological and toxicological tests.

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

The plan is to adopt a Rulebook on the content of and documentation on the pharmacological-toxicological testing of medicines for use in human and veterinary medicine for the purpose of permitting their circulation (registration of medicine) whereby the Directive 2003/63/EC will be implemented.

- Pharmaceuticals

- Transparency in relation to pricing and reimbursement of medicinal products

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

Pharmaceutical Products

The area of human and veterinary medicines is regulated by the following legislation:

- Law on Medicines (Official Gazette of the Republic of Montenegro 80/04 and Official Gazette of Montenegro 18/08). This Law is partly harmonized with the EU directives: 2001/83/EC, 2003/63/EC, 2004/24/EC, 2004/27/EC, 2001/20/EC, 2003/94/EC, and 2001/82/EC;
- Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and Official Gazette of Montenegro 27/07), which is partly harmonized with EU directives 2001/83/EC, 2003/63/EC;
- Rulebook on the conditions to be met by the companies and other legal and natural persons involved with the circulation of medicines, supplementary therapeutic means and medicinal resources, and (Official Gazette of the Federal Republic of Yugoslavia 16/94, 22/94, 49/95, 9/97, 2/2000, 66/2002 and Official Gazette of the Republic of Serbia 70/2003)

Transparency in the context of the formation of prices and compensation for medical products

The formation of prices for medical products is regulated by the following legislation in force:

1) The law on Medicines (Official Gazette of the Republic of Montenegro 80/04 and Official Gazette of Montenegro 18/08) establishes the authority to set the prices of medicines:

- The Government of Montenegro establishes the criteria for determining maximum possible prices of medicines, and maximum actual prices of medicines.
- The Ministry responsible for health issues proposes the criteria for determining maximum possible prices of medicines, and maximum actual prices of medicines in cooperation with the Ministry responsible for economic affairs.
- The Ministry responsible for market affairs performs inspection control of the prices of medicines in circulation.

The Government of Montenegro adopted the Decree on the Criteria for Determining Maximum Prices of Medicines (Official Gazette of the Republic of Montenegro 50/07).

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

Pharmaceutical products

The following legislation is planned to be enacted:

- 1) Amendments to the Law on Medicines (November-December 2009). Harmonization with the following directives and regulations: 2001/83/EC, 2004/27/EC, EC/726/2004, 2004/28/EC, 2001/82 EC;
- 2) 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;
- 3) Rulebook on Pharmacovigilance (until the end of 2009). Harmonization with the regulations and directives 2001/83/EC and EC/726/2004;
- 4) Rulebook on the conditions to be met by medicine manufacturers;
- 5) Good manufacturing practice guidelines (first half of 2010). Harmonization with the directives: 2003/94/EC, 91/412/EEC;
- 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;
- 7) Rulebook on traditional herbal medicines (the other half of 2010). Harmonization with the directives 2001/83/EC, 2004/24/EC;
- 8) Rulebook on quality control of medicines (by the end of 2009);
- 9) Rulebook on the marking of medicines (first half of 2010). Harmonization with the directive 2001/83/EC;
- 10) Rulebook on the notification and advertising of medicines (the second half of 2010). Harmonization with the directive 2001/83/EC;
- 11) Rulebook on the conditions to be met by legal persons involved with wholesale trade in medicines (first half of 2010);
- 12) Rulebook on the intervention import of medicines (first half of 2010);
- 13) Rulebook on homeopathic medicines (second half of 2010). Harmonization with the directive 2001/83/EC.

Transparency in the context of the formation of prices and compensation for medical products

The plan is to amend the Decree regulating the assignment of authority – the Agency for Medicines shall be responsible to approve the prices of medicines according to the criteria specified under the Decree.

The Decree is expected to be amended by the end of 2009.

- Cosmetics

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

Cosmetic Products

An overview of valid regulations relating to cosmetic products:

- Law on Food Safety and Items of General Use (Official Gazette of the Federal Republic of Yugoslavia 37/02) and secondary legislation enacted on the basis of this law;
- Rulebook on the conditions in relation to the sanitary safety of the objects for general use that may be put into circulation (Official Gazette of the Socialist Federal Republic of

- Yugoslavia 18/91);
- Rulebook on the conditions in terms of expert personnel, premises and equipment that must meet health and other organizations to perform the analysis and super-analysis of food and items of general use (Official Gazette of the Federal Republic of Yugoslavia 60/02);
- Instructions on the manner of sampling to perform analysis and super-analysis of foods and items of common use (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/1978);
- Rulebook on the methods to determine Ph values and quantities of toxic metals and non-metals in the products for personal hygiene, beauty care products for face and body, and to determine microbiological safety of these products (Official Gazette of the Socialist Federal Republic of Yugoslavia 46/1983);
- Law on Sanitary Control of Foods and Items of Common Use (Official Gazette of the Socialist Republic of Montenegro 4/88) and secondary legislation prepared on the basis of this Law;
- Rulebook on the conditions and manner of examination of foods and items of common use in the course of their production and the method of keeping records of the tests made (Official Gazette of the Socialist Republic of Montenegro 8/75);
- Rulebook on special protective clothing and footwear for the persons working in the production and circulation who come into direct contact with foods and persons working in production of and trade in goods for personal hygiene, and beauty care for face and body (Official Gazette of the Socialist Republic of Montenegro 16/80).

The existing legislation in this area is not harmonized with the EU legislation.

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

Cosmetic Products

The National Program for Integration of Montenegro into the EU provided for the preparation and adoption of a Rulebook on Cosmetic Products until the end of 2011, which will be harmonized with the European legislation (Directive 76/768/EC and 907/2006 on cosmetic products).

- Legal metrology, pre-packaging and units of measurement (Old Approach directive)

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

Legal Metrology, Pre-Packing and Measuring Units (Old Approach Directive)

The Metrology Law (Official Gazette of Montenegro 79/08) applies to the area of metrology in Montenegro and constitutes a legal framework for the adoption of secondary legislation which will allow the harmonization of Montenegrin legislation with the EU directives in the area of metrology. The transitional and final provisions of the Metrology Law (Official Gazette of Montenegro 79/08) stipulate that the regulations for the application of the Law on Metrology will be adopted within two years following the date of entry of that Law into force (31 December 2010).

The Decree on Legally Valid Measuring Units (Official Gazette of Montenegro 22/09) transposes the Council Directive 80/181/EEC on the harmonization of legislation of the Member States relating to the measuring units and repeal of Directive 71/354/EEC / including its amendments - Directives:

Council Directive 85/1/EEC, Council Directive 89/617/EEC Directive European Parliament and the Council 1999/103/EEC.

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

Legal Metrology, Pre-Packing and Measuring Units (Old Approach Directive)

The secondary legislation enabling the transposition of eight directives of the old approach on harmonization of the Member States laws has been prepared, relating to:

- Cold wastewater meters (Council Directive 75/33/EEC);
- Alcoholmeters and alcohol hydrometers (Council Directive 76/765/EEC);
- Alcohol metres and alcohol content (Council Directive 76/766/EEC);
- Parallelepiped weights from 5 kg to 50 kg of medium accuracy class and cylindrical weights from 1g to 10 kg of medium accuracy class (Council Directive 71/317/EEC);
- Weights from 1 mg to 50 kg above the medium accuracy class (Council Directive 74/148/EEC);
- Measurement of pressure in the tires of motor vehicles (Council Directive 86/217/EEC);
- Measurement of prescribed mass per unit volume of stored grains (Council Directive 71/347/EEC);
- Calibration of ship tanks (Council Directive 71/349/EEC).

Since the eight above mentioned directives of the old approach will not be applied in the EU as of 1 January 2010, this draft secondary legislation has not been considered for the purpose of adoption, but a working group was established in order to identify the regulations that will regulate this area of legal metrology.

The secondary legislation which will transpose relevant directives relating to the pre-packaged products is in preparation.

Implementation of the EU directives in relation to metrology is expected until the end of the 2012.

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

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

At present, there is no specific law or secondary legislation in Montenegro regulating discharge of pollutants in the form of gases and particles from the engines of non-road mobile machinery.

As for the machines that do not participate in road traffic, regulations of the EU focus on emissions of gasses and flying particles from internal combustion engines (Directive 97/68/EC and Directive 2002/88/EC, which contains amendments to the previous). It is important to note that the provisions of these directives apply to engines that are installed in river vessels and small motors with pre-ignition (petrol engines) for various machines, professional multi-position and manual machines and the equipment that does not exceed the weight of 20 kg including the weight of the engine. In this area, Montenegrin legislation is limited to the Decision on the prohibition of use of motor vehicles and trailers, construction and mining machines older than 8 years, which ceased to

be valid (Official Gazette of the Republic of Montenegro 15/2002). The subject matter is still regulated by outdated Yugoslav homologation standards.

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

In the EU legislation, this area is regulated under the initial Directive 97/68/EC and its amendments 2001/63/EC, 2002/88/EC, 2004/26/EC and 2006/105/EC, concerning the implementation of measures against the emissions of gasses and particles from internal combustion engines that are installed on non-road mobile mechanization. The transposition of Directive 97/68/EC on measures for the prevention of emissions of gasses and particles from engines installed in non-road machinery into the Montenegrin legislation will be conducted in phases, through adoption of secondary legislation following the Law on Air Protection, which is planned to be adopted in late September of the current year. The mentioned act will specify border values for the emission of pollutants into the air from the engines installed in non-road machinery, while the elements of the Directive related to the approval, registration and circulation of this type of engines will be regulated by technical regulations in the field of transport. An act on border values in emissions from vehicles that do not participate in road traffic will be passed within two years following the date of adoption of the Law on Air Protection, which is planned for the end of September 2009.

The National Program for Integration of Montenegro into the EU (NPI) for the period 2008-2012 (2008) envisages the adoption of secondary legislation in this area by transposing the above mentioned Directives.

- Aerosol dispensers (ADD)

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

Aerosol Dispensers (ADD)

Montenegro has currently no valid technical regulations regulating the group of products relating to aerosol dispensers. Moreover, there are no manufacturers of these products or announcements of investment in this type of production. Currently, this group of products, as well as all other products that are not governed by other special technical regulation are regulated by the Law on General Product Safety (Official Gazette of Montenegro 48/08).

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

Aerosol Dispensers (ADD)

As noted in the response to the question 29a, the competent Ministry of Economy will adopt a technical regulation whereby the EU legislation will be transposed in this area with special emphasis on the essential requirements of the Directive 75/324/EEC, ADD - Aerosol Dispensers Directive.

- Crystal glass

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

Crystal Glass

There are no valid technical regulations relating specifically to the products belonging to the group of glass products currently in Montenegro. A rational approach includes the regulation of all measures recommended by the EU legislation through other related areas (e.g. connection with other products such as products with glass frame, built-in construction products, and similar).

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

Preparation of a Rulebook on Crystal Glass Products is envisaged for the second quarter of 2010, in accordance with the National Program for Integration of Montenegro into the EU, as well as on the basis of the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08). The intention is to transpose the Directive 31969L0493, which refers to the crystal glass products into the Montenegrin legislation by means of that Rulebook.

- Textiles

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

Textiles

Textiles used to be regulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of the Republic of Montenegro 44/05). Since this law was taken over from the federal level, it contained certain limitations in terms of its adequate implementation on the level of Montenegro (such as undefined register of technical regulations, authorized bodies, etc.), as well as the requirement to harmonize the legislation with the EU. The entrance into force of national Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08 of 29 February 2008) enabled the creation of legal basis for the adoption of appropriate secondary legislation.

In addition to that, technical requirements for textiles are contained in the following applicable regulations:

- Order on textile products in circulation that must be provided with a certificate of quality (Official Gazette of the Socialist Federal Republic of Yugoslavia 14/92)
- Order on mandatory certificates of test for cotton (Official Gazette of the Socialist Federal Republic of Yugoslavia 65/84, 44/88)
- Order on mandatory certificates of test for wool (Official Gazette of the Socialist Federal Republic of Yugoslavia 65/84)

- Rulebook on mandatory certificates of test for jute and the conditions to be met by the organizations of associated labour accredited for certification of those products (Official Gazette of the Socialist Federal Republic of Yugoslavia 8/91).

Specific requirements, i.e. prohibitions regarding the use of particular substances in the production of textile products are also regulated under the Law on Chemicals (Official Gazette of Montenegro 11/07-22), i.e. under the secondary legislation adopted on the basis of this Law.

The issues of safety properties of textile products that have not been possibly covered by the foregoing technical regulations and mandatory standards are regulated under the Law on General Product Safety (Official Gazette of Montenegro 48/08), regulating general obligations of manufacturers and distributors, and the authority of competent inspection bodies while monitoring the situation in the market.

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

Textiles

On the basis of the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08), in the second quarter of 2010 a Rulebook (technical regulation) will be adopted whereby the Directives governing the technical requirements for textiles will be transposed into the national legal framework (Directives: 31996L0074; 31997L0037; 32004L0034; 31996L0073; 31973L0044; 32007L0004; 32007L0003; 32006L0002 ; 32003L0003).

- Footwear

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

Footwear

At present, there are no valid technical regulations relating specifically to the group of footwear products in Montenegro. A rational approach includes regulation of all measures recommended under the EU legislation through other related areas (e.g. textiles).

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

In accordance with the National Program for Integration of Montenegro into the EU, and on the basis of the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08), a Rulebook whereby the Directive 31994L0011 for footwear will be transposed into Montenegrin legislation is expected to be drafted in the second quarter of 2010.

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

30. Please provide information on the relevant regimes for the products:

- Motor vehicles

a) short description and

The Institute for Standardization of Montenegro is currently working on the transposition of the applicable international standards into the national system. The assessment of conformity in regard to homologation and other activities is conducted through a network of technical inspections. Legal persons performing technical inspection of vehicles are mostly equipped with adequate equipment according to the legal standards. Currently, legal persons that carry out technical inspections are not accredited according to the applicable standard. Market supervision in this area is carried out by the competent state inspection authorities, within their respective areas of responsibility.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Chemicals

- Limitations, classification, packaging and labelling (REACH, CLP) Detergents

a) short description and

Chapter IV of the existing Law on Chemicals (Official Gazette of the Republic of Montenegro 11/07) stipulates the procedure for evaluation and assessment of risk from chemicals, while the

classification, packaging and labelling of chemicals is stipulated under Chapter V of this Law. Supervision and penalty provisions are stipulated under Chapter XIII and Chapter XIV respectively.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as the confirmation of competence for the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Detergents

a) short description and

Supervision of the production, import and trade in detergents is performed by the Health and Sanitary Inspection, on the basis of authority conferred by the Law.

Laboratory testing of quality and health safety of detergents is conducted at the following two laboratories in Montenegro:

- The Institute of Public Health of Montenegro, Podgorica (microbiological, physical and chemical testing); and
- The Centre for Ecotoxicological Research of Montenegro, Podgorica (physical and chemical testing).

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as the confirmation of competence for the bodies responsible for conformity assessment.

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Fertilisers

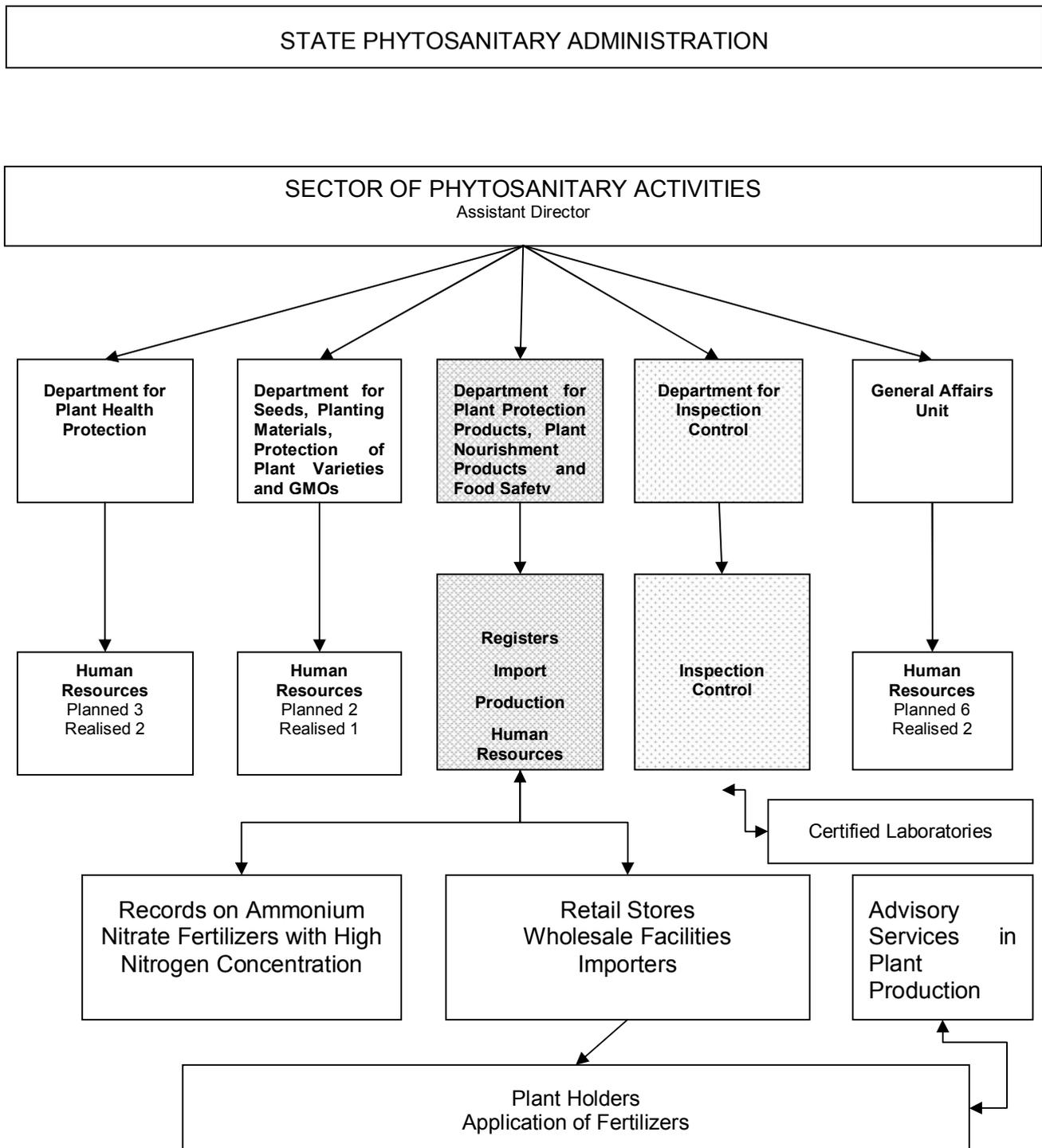
a) short description and

In accordance with the Decree Amending the Decree on Organization and Manner of Operation of the State Administration (Official Gazette of Montenegro 43/08), regulating the establishment of ministries and other administrative authorities, and the manner of operation of state administration, the State Phytosanitary Administration of Montenegro was established as a single central body under the supervision of the Government.

In addition to its primary competences in the phytosanitary sector, the competencies and authorities originating from Article 8 of the Law on Fertilizers (Official Gazette of the Republic of Montenegro 48/07) were also delegated to the State Phytosanitary Administration.

The State Phytosanitary Administration performs administrative and related technical and inspection activities and is responsible for coordination and contacts with respect to matters relating to plant nutrition products.

Following the Rulebook on Internal Organization and Job Classification of the State Phytosanitary Administration, a Department for plant health protection, plant nutrition products and food safety was established within the Sector for Phytosanitary Activities.



- There are no currently registered manufacturers of plant nutrients in the territory of Montenegro.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as the confirmation of competence for the bodies responsible for conformity assessment.

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Drug precursors

a) The current applicable legislation in the area of narcotic drugs precursors includes the following:

- 1) Law on Medicines (Official Gazette of Montenegro 80/04 and Official Gazette of Montenegro 18/08)
- 2) Law on Production and Circulation of Toxins (Official Gazette of the Republic of Montenegro 31/77, 17/92 and 27/94)
- 3) Decision on the Check List for Export, Import and Transit of Goods (Official Gazette of Montenegro 82/08) of the Government of Montenegro containing Annex 1 - List of Narcotic Drugs and Annex 2 - List of Precursors
- 4) Ratified Conventions of the United Nations relating to narcotics, 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;
 - United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

In accordance with the current Law and the Decision, the Medicines and Medical Devices Agency of Montenegro (CALIMS) is responsible for the issuing of permits for import/export/transit of precursors, allowing their import to Montenegro.

Each permit is issued for one-time import. Each permit is valid for a period of one month. Following the actual import, the importer is obliged to submit a proof of import to the Agency not later than within 15 days.

The CALIMS reports to the International Narcotics Control Board (INCB) once a year on imported and confiscated quantities of precursors in Montenegro as well as projected demand for the following year (the report also includes the data of the Police Directorate of Montenegro).

The reports for 2007 and 2008 were submitted.

b) A Draft Law on the Precursors has been prepared; it is in the process of submission to the Government of Montenegro. This draft Law is harmonized with the following EU regulations and international conventions relating to the field 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;

- 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;
- United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

The proposed Law envisaged a change of responsibilities in this area. The permits for export/import/transit of precursors will be issued by the Ministry of Health, except in the case when the precursors fall within the group of pharmacologically active substances, where the issuing of such permits will still remain within the competence of CALIMS. The Ministry will continue to report to the INCB accordingly in the future as well.

The list of precursors will be published in the Official Gazette of Montenegro.

The secondary legislation will be prepared following the adoption of the Law.

The Law on Precursors will provide for the monitoring activities in this area.

a) short description and

In accordance with the current Law and the Decision, the Medicines and Medical Devices Agency of Montenegro (CALIMS) is responsible for the issuing of permits for import/export/transit of precursors, allowing their import to Montenegro.

Each permit is issued for one-time import. Each permit is valid for a period of one month. Following the actual import, the importer is obliged to submit a proof of import to the Agency not later than within 15 days.

The CALIMS reports to the International Narcotics Control Board (INCB) once a year on imported and confiscated quantities of precursors in Montenegro as well as projected demand for the following year (the report also includes the data of the Police Directorate of Montenegro).

The reports for 2007 and 2008.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as the confirmation of competence for the bodies responsible for conformity assessment.

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Explosives for civil uses (New Approach directive)

a) short description and

There are only two manufacturers of commercial explosives in Montenegro, and both of them have their products certified by the institutions of the Republic of Serbia, while other explosive materials available at the market are imported from the Republic of Croatia, Slovenia and other European countries that are in compliance with national standards.

The procedure to develop Montenegrin standards in this field have been initiated with the Institute for Standardization.

b) further evolution.

Simultaneously with the transposition of important requirements from the related New Approach Directive, the related harmonized EN standards will also be accepted as national standards through a technical regulation. The competent ministry will assess the requirement for possible notification of the Committee for Notification by the conformity assessment body of Montenegro and forward the request to the enquiry point. Accordingly, the competent ministry will comply with all the recommendations provided under the Blue Guide and measures prescribed by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards.

- Pyrotechnics (New Approach Directive)

a) short description and

In Montenegro, there are only two manufacturers of commercial explosives which have their products certified by the institutions of the Republic of Serbia, while other explosive materials available in the market are imported from the Republic of Croatia, Slovenia and other European countries that are in compliance with national standards.

The procedure to develop Montenegrin standards in this field has been initiated with the Institute for Standardization.

b) further evolution.

Simultaneously with the transposition of important requirements from the related New Approach Directive, the related harmonized EN standards will also be accepted as national standards through a technical regulation. The competent ministry will assess the requirement for possible

notification of the Committee for Notification by the conformity assessment body of Montenegro and forward the request to the enquiry point. Accordingly, the competent ministry will comply with all the recommendations provided under the Blue Guide and measures prescribed by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards.

- Good laboratory practice (GLP)

a) short description and

The Directive 2003/63/EC neither refers to nor specifies the conditions necessary for the compliance with GLP standards; it only refers to the recognition of GLP certificates in order to ensure the quality of medicine in the procedure of and following the registration of medicine.

The Agency is not competent for the issuing of GLP certificates and standardization of a Rulebook on the conditions for good laboratory practice; it only requests to be provided with evidence on the compliance with GLP standards in relation to the organization and conducting of laboratory work in the preclinical pharmacological and toxicological tests, both before and after the registration of medicine.

b) further evolution.

The response is included under 30a.

- Pharmaceuticals

- Transparency in relation to pricing and reimbursement of medicinal products

a) short description and

Pharmaceutical Products

At present, medicines are imported to Montenegro on the basis of import permits issued by the Agency in accordance with the Law, while the condition for the issuing of such a permit is that the medicine is registered in the European Union, USA, Canada, Switzerland, Norway and the countries of the former Socialist Federative Republic of Yugoslavia. The Law stipulates that such import is permitted until March 2010. At the same time, as of the end of 2008, the process of registration of medicines in accordance with the Law and Regulation on detailed conditions for the issuing of permits for putting medicines in circulation was initiated, so that after March 2010, only medicines permitted by CALIMS and those obtained through intervention import in accordance with the Regulation for Emergency Import of Medicines will remain in circulation in Montenegro.

The Agency ensures the compliance of all medicines with the applicable quality standards by means of assessment of the documentation on medication, laboratory quality control and implementation of control procedure by the Agency, in accordance with the foregoing regulation.

Quality control of medicine is performed by:

- evaluation of the certificate on executed quality control of medicine and/or (manufacturer and/or authorized laboratories, which must be in accordance with the European or other recognized pharmacopoeia or proven methods of analysis);
- Laboratory research by certified laboratories.

Laboratory quality control of medicines is carried out by the control laboratory for pharmaceutical testing of medicines, in accordance with the rules of good laboratory control practice. The laboratory quality control of medicine is conducted in accordance with the European, national or other recognized pharmacopoeia or other validated methods of analysis.

In accordance with the Law, the Agency may establish its own control laboratory or may, by means of contract, entrust the quality control of medicines to another laboratory in Montenegro or a national laboratory for quality control of medicines of another country. The Agency currently does not have its own laboratory for quality control, but uses the services of the National Control Laboratory of the Agency for Medicines and Medical Resources of Serbia, as well as the Agency for Medicines and Medical Products of the Republic of Croatia, on the basis of signed contracts and Protocols on Cooperation. The Agency also recognizes the certificates issued by the laboratories that are members OMCL network of European laboratories (Official Medicines Control Laboratory Network).

Transparency within the Context of Establishment of Prices and Compensations for Medical Products

The European legislation envisages no stipulation of measures in the sense of this question, so that a full response relating to this area is included into the response to the question 29.

b) further evolution.

Pharmaceutical Products

The development of own control laboratory is planned as a part of permanent solution for the Agency's workspace.

The Agency plans to start introducing quality system into its operations in the period 2010-2012:

Quality management, general activity – the requirements of ISO 9001:2008

Quality management relating to quality control activities - ISO 17025

The Agency is authorised by the Law to issue certificates on application of good manufacturing practice (GMP), good clinical practice (GCP), certificates for the export of medicines in accordance with the recommendations of the World Health Organization (CPP).

The Ministry responsible for health issues performs the inspection control of manufacturers, holders of permits for wholesale trade, pharmacies, veterinary pharmacies and other entities regulated under to which the Law on Medicines applies, as well as the inspection control of advertising of medicines. The Inspection of the Ministry also prohibits the sales, i.e. orders the suspension of sales or withdrawal from circulation of medicines, which do not meet the standards of quality, safety and efficiency.

The Ministry in charge of market activities performs the inspection control of prices of medicines in circulation.

The Agency may test the samples of each medicine when assessed as required in order to ensure the appropriate quality, provided that the legal persons licensed for the production of and trade in medicines are brought in no mutually unequal position.

Transparency within the Context of Establishment of the Prices and Compensations for Medical Products

The European legislation envisages no stipulation of measures in the sense of this question, so

that a full response relating to this area is included into the response to the question 29.

- Cosmetics

a) short description and

Cosmetic Products

The Health and Sanitary Inspection supervises the production, import and circulation of cosmetic products, on the basis of authority conferred by the Law.

Laboratory testing of quality and health safety control is performed by the following two laboratories in Montenegro:

- The Institute of Public Health of Montenegro, Podgorica (microbiological, physical and chemical testing); and
- The Centre for Ecotoxicological Research of Montenegro, Podgorica (physical and chemical testing).

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Legal metrology, pre-packaging and units of measurement (Old Approach directive)

a) short description and

Legal Metrology, Pre-Packing and Measuring Units (Old Approach Directive)

In accordance with the Metrology Law (Official Gazette of Montenegro 79/08), the activity of calibration in Montenegro is organized by the Institute of Metrology. Due to absence of adequate laboratory space and equipment, the activities are restricted to calibration of weights and some industrial length standards. Other measuring devices and measuring systems must be calibrated outside of Montenegro for the time being.

In accordance with the Metrology Law (Official Gazette of Montenegro 79/08), legal measuring devices are put in use only if they meet the applicable metrology requirements, and are certified and marked with the applicable labels. Validation of a measuring device is performed following the procedure for its examination, if proven that such measuring device is in accordance with the approved type of device and that it fulfils the applicable metrology requirements. The fulfilment of the applicable technical and metrological requirements to determine the type of measuring device is established by the Institute.

b) further evolution.

Legal Metrology, pre-packing and measuring unit (Directive old approach)

The development of national calibration laboratories in the upcoming period of time will allow the calibration of certain measuring devices and measurement systems in Montenegro, while the manner of organization of calibration activities outside of Montenegro will certainly be considered.

Following the adoption of regulations that will transpose the directives relating to the pre-packaged products, the metrology inspectors will check whether, in the case of pre-packed products that are put into circulation or stored at a warehouse with the intention of being put into circulation, the nominal quantity is marked accurately, clearly and unambiguously, and if their actual quantities deviate from the indicated nominal ones, as well as whether those are marked with the conformity mark in the prescribed manner.

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

a) short description and

Calibration

The Metrology Institute of Montenegro is the main calibration body in Montenegro. The development of its capacities is in progress.

Metrology

The Metrology Institute of Montenegro is the only organization responsible for the area of metrology in the territory of Montenegro. The development of its capacities is in progress.

Standards

The Institute for Standardization of Montenegro (ISME) is the only organization responsible for the establishment of standards for all types of products and services. A significant number of European (EN) and international (ISO) standards has been transposed and published by the Institute.

Testing

Testing laboratories in the area of motor vehicles still do not exist in Montenegro, although their accreditation is ongoing, depending on the area of testing.

Certification and Conformity Assessment

Certification and conformity assessment for motor vehicles does not yet officially exist in Montenegro

Accreditation

The Accreditation Body of Montenegro is the only body responsible for accreditation of

metrological and testing laboratories in accordance with ISO 17025, as well as control organisations in accordance with ISO 17020.

Market Supervision

No market supervision in the area of emissions of gasses and particles from the engines of non-road mobile machinery has been established yet.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Aerosol dispensers (ADD)

a) short description and

Aerosol Dispensers (ADD)

Montenegro has no domestic producers in this area and there is no announcement of interest in investing into this area. There is no state body for conformity assessment authorized to perform the compliance assessment in this area. In the course of market supervision no unsafe products in this area were observed. Market supervision is performed according to the standards set under the Law on General Product Safety (Official Gazette of Montenegro 48/08), particularly with regard to assessment of unsafe products.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;

- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Crystal glass

a) short description and

Crystal Glass

Montenegro has no domestic producers in this area and there are no announcements of interest in investing into this area. There is no body for conformity assessment authorized to perform the compliance assessment in this area. In the course of market supervision no unsafe products in this area were observed. Market supervision is performed according to the standards set under the Law on General Product Safety (Official Gazette of Montenegro 48/08), particularly with regard to assessment of unsafe products.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Textiles

a) short description and

Montenegro has no laboratory which is engaged in textile product testing.

Inspection control is performed on the basis of the Law on General Safety of Products and of the Law on Inspection Control.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation.

- Footwear

a) short description and

Footwear

Montenegro has no domestic producers in this area and there are no announcements of interest in investing into this area. There is no body for conformity assessment authorized to perform the compliance assessment in this area. In the course of market supervision no unsafe products in this area were observed. Market supervision is performed according to the standards set under the Law on General Product Safety (Official Gazette of Montenegro 48/08), particularly with regard to assessment of unsafe products.

b) further evolution.

Depending on further levels of transposition of the legislation in the subject area, the competent ministry will:

- Communicate with the Institute for Standardization of Montenegro when it is required to adopt and/or implement harmonized European standards ensuring products safety in the related area;
- Announce a competition to license new or extend the existing licenses of authorized bodies for conformity assessment in the subject area;
- Apply accreditation certificates as a confirmation of competence of the bodies responsible for conformity assessment

The competent ministry will notify all the foregoing activities to the contact point in order to assess the compliance of measures stipulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and/or in relation to the content of the so-called National Allowance, so that a technical regulation may be submitted for notification to the EU and WTO in order to assess the level of its harmonisation

NEW AND GLOBAL APPROACH PRODUCT LEGISLATION

A. Harmonisation of laws including technical regulations

31. Please provide information regarding the:

- Legal metrology: non-automatic weighing instruments; measuring instruments

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

The Metrology Law (Official Gazette of Montenegro 79/08) regulates the area of metrology in Montenegro and represents a legal framework for the adoption of secondary legislation to harmonize the legislation of Montenegro with the EU Directive on measures and measuring instruments (MID – European Parliament and Council Directive 2004/22/EC) and the Directive on non-automatic weighing instruments (NAWI – Council Directive 90/384/EEC).

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

Pursuant to the transitional and final provisions of the Metrology Law (Official Gazette of Montenegro 79/08), the regulations implementing the Metrology Law shall be adopted within two years as of the date of entry into force of that Law (31 December 2010). Fulfillment of the applicable technical and metrological requirements to determine the type of measuring instrument is stipulated by the Metrology Institute.

The MID Directive (Directive 2004/22/EC of the European Parliament and of the Council) and NAWI Directive (Directive 90/384/EEC of the Council) are expected to be implemented until the end of 2012.

Regulations concerning the assessment of conformity with metrological requirements of water meters, gas meters and volume correctors, active electrical energy meters, heat meters, measuring installations for uninterrupted dynamic measurements of various fluids other than water, automatic weighing instruments, taximeters, materialized measures, dimensional meters, exhaust

gas analyzers, whereby the Directive 2004/22/EEC will be transposed, as well as the regulations concerning an assessment of conformity of non-automatic weighing instruments with metrological requirements, whereby the Directive 90/384/EEC will be transposed into the legislation of Montenegro, shall be adopted until 31 December 2011, in accordance with the Metrology Law (Official Gazette of Montenegro 79/08).

- Low-voltage equipment (LVD)

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

Existing legislation and regulations:

- Energy Law (Official Gazette of the Republic of Montenegro 39/03);
- Law on Spatial Development and Construction of Structures (Official Gazette of Montenegro 51/08);
- Law on Safety at Work (Official Gazette of the Republic of Montenegro 79/04);
- Law on Fire Protection (Official Gazette of the Socialist Republic of Montenegro 47/92);
- Regulations on Electric Power Supply (Official Gazette of the Republic of Montenegro 13/05);
- Regulations on technical standards for low-voltage electrical installations (Official Gazette of the Socialist Federal Republic of Yugoslavia 53/88, 54/88 and 28/95);
- Regulations on technical standards for the protection of low-voltage power grid and the related transformer stations (Official Gazette of the Socialist Federal Republic of Yugoslavia 13/78, including the amendments published in Official Gazette of the Federal Republic of Yugoslavia 37/95);
- Regulations on technical standards for the construction of low-voltage overhead power lines (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/92);
- Regulations on technical standards for the protection of structures against atmospheric discharge (Official Gazette of the Federal Republic of Yugoslavia 11/96);
- Rulebook on Yugoslav standards for lightning installations (Official Gazette of the Federal Republic of Yugoslavia 11/96);
- Rulebook on technical measures for operation and maintenance of power generating facilities (Official Gazette of the Socialist Federal Republic of Yugoslavia 19/68);
- Rulebook on technical standards for the protection of power generating facilities against overvoltage (Official Gazette of the Socialist Federal Republic of Yugoslavia 7/71 and 44/76);

Technical recommendation of the Power Company of Montenegro (2007) for customer connections to the low-voltage power grid TP-2.

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

Under the National Program for Integration of Montenegro into the EU, the adoption of a rulebook on low-voltage electrical equipment was envisaged for following period. To that effect, adoption of a rulebook on electrical equipment designed for utilization within specific voltage limits has been envisaged, whereby the prerequisites for the harmonization of national legislation with the EU legislation in the area of low-voltage electrical equipment (Directive 73/23/EEC) will be established.

- Electromagnetic compatibility (EMC)

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

The Sector for Electronic Communication of the line Ministry of Maritime Affairs, Transportation and Telecommunication has already taken actions to the effect of adoption of relevant secondary legislation – rulebooks regulating the stated areas (EMC and R&TTE) that emanate from the Law on Electronic Communications (Official Gazette of Montenegro 50/08).

These regulations (“Rulebook on technical requirements for import, placing into circulation and utilization of radio equipment and telecommunication terminal equipment” and “Rulebook on electromagnetic compatibility”) were drafted in direct cooperation with the Department of Quality Infrastructure of the Ministry of Economy, all in accordance with the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08) and Regulation on the procedure for drafting and adoption of technical regulations and technical specifications and register of technical regulations (Official Gazette of Montenegro 55/08).

The Rulebook on EMC is harmonized with the following EU regulations:

- Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC;
- Commission communication in the framework of the implementation of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

No approvals for import and placing into circulation and utilization are currently issued.

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

The Rulebooks referred to in the response 31A are expected to be adopted until the end of 2009, in addition to the application of Guide for R&TTE Directive 1995/5/EC (version of 20 April 2009) for the application of these Rulebooks, so that their application may start in the following year of 2010.

Following the adoption of foregoing rulebooks and through a full cooperation with the Institute for Standardization of Montenegro, Accreditation Body of Montenegro, the Metrology Institute and other state and scientific institutions, the procedure relating to the products in the concerned areas is expected to be consolidated and completed.

Further development in this area is expected with the implementation of foregoing regulations in accordance with available human resources on the level of ministries, regulatory bodies and inspectorates.

- Toys

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

An overview of the existing legislation related to toys:

- The Law on Health Safety of Food Products and Articles for General Use (Official Gazette of the Federal Republic of Yugoslavia 37/02) and secondary legislation enacted on the basis of this Law;
- Rulebook on the conditions in relation to the sanitary safety of the objects for general use that may be put into circulation (Official Gazette of the Socialist Federal Republic of Yugoslavia 18/91);
- Rulebook on the conditions in relation to professional staff, office space and equipment that must be met by health and other organizations to perform analysis and super-analysis of foods and items of common use (Official Gazette of the Federal Republic of Yugoslavia 60/02);
- Instructions on the manner of sampling to perform analysis and super-analysis of foods and items of common use (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/1978);
- Law on Sanitary Control of Foods and Items of Common Use (Official Gazette of the Socialist Republic of Montenegro 4/88) and secondary legislation prepared on the basis of this Law;
- Rulebook on the conditions and manner of examination of foods and items of common use in the course of their production and the method of keeping records of the tests made (Official Gazette of the Socialist Republic of Montenegro 8/75);

The existing legislation in this area is not harmonized with the EU legislation.

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

The National Program of Integration of Montenegro into the EU envisages the preparation and adoption of a Rulebook on Health Safety of Toys until the end of 2011, which will be harmonized with the EU regulation [Directive 88/378/EEC on safety of toys].

- Machinery

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

During the previous period, the area of safety of machinery was regulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 44/05).

Since this law was taken over from the federal level, it contained certain limitations in terms of its adequate implementation on the level of Montenegro (such as undefined register of technical regulations, authorized bodies, etc.), as well as the requirement to harmonize the legislation with the EU. The entrance into force of national Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro

14/08 of 29 February 2008) enabled the creation of legal basis for the adoption of appropriate secondary legislation.

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

Based on the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards, a Rulebook (technical regulation) will be adopted in the second quarter of 2010, whereby the directives regulating technical requirements for the safety of machinery (32006L0042; 31998L0037) will be transformed into the national legislation.

- Noise emissions by outdoors equipment (Global Approach directive based on New Approach elements)

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

The Law on the Protection against Environmental Noise (Official Gazette of the Republic of Montenegro 45/2006) regulates this area in Montenegro. By this Law the Directive 2002/49 EC relating to the assessment and management of environmental noise was transposed into the national legislation.

This Law regulates the measures for the protection against environmental noise with the objective of prevention of noise appearance, i.e. reduction of the existing noise to limit values, as well as the measures against harmful effects on human health.

- 1) Normative measures:
 - a) Regulations relating to limit values of noise level, methods for assessment and measuring of noise, mapping of noise charts and preparation of action plans;
 - b) Procedures for verification and issuing of certificates on the conformity of noise sources with standard limit values for noise emission.
- 2) Town planning measures:
 - a) Mapping of noise sources in relation to the structures and areas that need to be protected;
 - b) City and interurban traffic plans and planning and managing road, rail, air and maritime transport.
- 3) Technical measures:
 - a) Selection and utilization of low-noise machines, devices, means for work and transport;
 - b) Adequate noise insulation of structures containing noise sources;
 - c) Application of acoustic protection measures at the sources and directions of noise spreading;
- 4) Measures of prohibition and temporary restriction:
 - a) Restriction of application of noise sources in the immediate vicinity of specific structures;
 - b) Banning of the use of noise source in specific types of vessels.

Within the normative measures, Article 13 of the Law on the Protection against Environmental Noise stipulates conformity with the applicable technical standards relating to the limit level of noise under specific conditions of use, for import of machines, means of transport, as well as devices and equipment manufactured in Montenegro. Data on emitted sound levels under such conditions of use must be indicated on product according special regulations, guidelines and norms of the EU. The EU legislation regulates this issue under Directive 2000/14/EC (on the noise emission in the environment by equipment for use outdoors).

This area is regulated by the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards and four subsequent Decrees, emanating from this

Law, regulating the organization of the following activities by the Ministry of Economy:

- Adoption of technical regulations;
- The Requirement for authorization/appointment of laboratories (conformity assessment bodies);
- The manner of organization of market inspection (whether to establish a special inspectorate, assign this activity to another state inspectorate or, if assessed as of special importance, to establish within the Ministry a combined body for conformity assessment and market supervision).

Technical measures for the protection against noise stipulated by Article 18 of the Law on the Protection against Environmental Noise specify that the data on noise levels must be kept for the sources of noise that are used for business operation, temporarily used or permanently placed in open space on the ground level, walls and roofs of buildings, movable or immovable objects, or used on water and in the air.

Noise sources from paragraph 1 of this Article may be used where the competent authority determines that the limit values for environmental noise shall not be exceeded by the source noise.

Implementation of this Law and the subsequently adopted regulations shall be supervised by the competent authority of state administration, in the case of facilities and activities for which operating permits are issued by the state administration authorities and competent authorities of local self-governments respectively, in accordance with the law.

Limit values of noise were determined under the subsequent secondary legislation (Rulebook on limit values of environmental noise levels; Official Gazette of the Republic of Montenegro 75/06) for:

- Open inhabited spaces, such as specially protected natural resources (national parks, nature parks, reserves etc); areas for rest and recreation, hospital areas and sanatoriums, cultural and historical localities; tourist areas, small and rural settlements, camps and school zones; strictly residential areas, large city parks; business-residential areas, tourist areas, playgrounds; city center, crafts, trade, administrative area with apartments, zones close to the city streets, main roads and highways; industry, warehouses and service areas, transport terminals not including apartment buildings, catering facilities of open type outside the residential areas.
- Structures for temporary stay such as health care institutions, hospital rooms, doctor's offices, surgeries (not including medical devices and equipment), kindergartens, schools, faculties, reading rooms, libraries, scientific institutions, theaters, cinemas and concert halls, museums, galleries and similar, and elderly people homes.
- Reserved business areas of catering type.

Methods of noise measurement, instruments used to measure noise, reports on results of noise measurement and conditions that must be met by the organizations that conduct noise measurements, are stipulated by the Rulebook on methods and instrument of noise measurement and conditions that must be met by the organizations for noise measurement, published in the Official Gazette of the Republic of Montenegro 37/03. This Rulebook implemented the standards of JUS ISO 1996-2002 and harmonization with the standards IEC 60651 and IEC 60804.

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

The National Program for Integration of Montenegro into the EU (NPI) for the period 2008-2012 (2008) envisages adoption of the following secondary legislation:

- Rulebook on methods of assessment and measurement of noise;
- Regulation on the manner of preparation and contents of action plans and noise maps, including a strategic noise map;

- Rulebook on detailed requirements concerning space, staff and equipment for the execution of professional activities of protection against noise;
- Rulebook on the manner of supervision of legal persons performing professional activities of protection against noise.

The Ministry of Labor and Social Welfare is responsible for the adoption of this secondary legislation, while the regulation on the manner of preparation and contents of action plans and noise maps, including the strategic noise map, are adopted by Ministry following an opinion of the Ministry of Tourism and Environmental Protection (Ministry of Spatial Planning and Environmental Protection).

- Lifts

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

Currently, products included in the group of lifts in Montenegro are legally defined by following regulations:

- Standardization Law, (Official Gazette of Montenegro 13/08);
- Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08);
- Law on Protection at Work (Official Gazette of the Republic of Montenegro 79/04)
- Rulebook on technical norms for electric elevators for vertical transport of passengers and goods (Official Gazette of the Socialist Federal Republic of Yugoslavia 16/86, 28/89 and 22/92);
- Rulebook on mandatory issuing of certificate of test for electricity-powered elevators for vertical transport of persons and goods and the conditions that must be met by the organizations of associated labor authorized for the issuing of such certificates of test (Official Gazette of the Socialist Federal Republic of Yugoslavia 27/90);
- Rulebook on the procedure and schedules for periodical examinations and testing of operating equipment, means and equipment for personal protection at work and the state of working environment (Official Gazette of the Federal Republic of Yugoslavia 71/05);
- Rulebook on technical norms for the protection of structures against atmospheric discharge (Official Gazette of the Federal Republic of Yugoslavia 11/96);
- Rulebook on technical norms for low-voltage electrical installations (Official Gazette of the Federal Republic of Yugoslavia 287/95).

The Standardization Institute of Montenegro started adopting harmonized European standards in relation to elevator safety and adopted the following standards as Montenegrin standards:

- Standard –MEST EN 81-1:2008, Electric elevators;
- Standard – MEST EN 81-2:2008, Hydraulic elevators;
- Standard –MEST EN 81:28, Passenger and goods elevators;
- Standard –MEST EN 81:58, Examination and tests;
- Standard– MEST EN 81:72, Accessibility of elevators, including accessibility for persons with special needs;
- Standard– MEST EN 81:72 Elevators for firefighting purposes;
- Standard– MEST EN 81:73, Manner of elevator operation the event of fire;

- Standard– MEST EN 12385:3, Steel wire ropes;
- Standard– MEST EN 12385:5, Stranded ropes for elevators;
- Standard– MEST EN 13015, Elevators and escalators.

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

A Rulebook on the safety of elevators, in accordance with the Directive 95/16 EC of the European Parliament and of the Council and Directive 2006/42/EC amending this Directive, is currently in the process of preparation.

This Rulebook is expected to be prepared until 30 November 2009.

- Personal protective equipment (PPE)

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

National legal framework concerning personal protective equipment at work includes the Law on Protection at Work (Official Gazette of the Republic of Montenegro 79/04) and the Rulebook on means of personal protection at work and personal protective equipment (Official Gazette of the Socialist Federal Republic of Yugoslavia 35/69), as secondary legislation.

The protection at work is regulated uniformly for all categories of employees and other individuals who are engaged in a working process on no matter which grounds, and regardless of actual ownership status (private, state, communal, etc.). The Law on Protection at Work stipulates that each employer is obliged to provide and issue the means and equipment for personal protection at work that must be accompanied by the applicable documentation in the language that is in official use in Montenegro, containing all safety and technical data provided by the manufacturer or supplier relevant for an assessment of risk on the occasion of their use, and also containing a declaration confirming that all measures for the protection at work from such documentation are in accordance with the regulations on the protection at work.

Detailed measures ensuring full protection of employed personnel at work, in terms of utilization of means and equipment for personal protection at work, are stipulated under the secondary legislation.

The Ministry of Labor and Social Welfare is responsible for the adoption of legislation relating to the protection at work (including the means and equipment for personal protection at work), and to supervise its implementation.

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

The most important piece of secondary legislation transposing the Directive on Personal Protective Equipment at work is the Rulebook on minimal requirements on the protection and safety of employees while using personal protective means and equipment at work. This Rulebook is expected to be adopted in 2010.

- Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

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

The essential requirements concerning the equipment and protective systems used in potentially explosive atmospheres, covered by the New Approach Directive ATEX, are partly harmonized by means of the current Law on Mining (Official Gazette of Montenegro 65/08 of 29 October 2008).

The equipment and protective systems applied in potentially explosive atmospheres are harmonized with the Law on Mining (Official Gazette of Montenegro 65/08 of 29 October 2008) and the Rulebook on technical norms for underground exploitation of mineral raw resources of metals and non-metals (Official Gazette of the Socialist Federal Republic of Yugoslavia 24/1991), Rulebook on technical norms for underground exploitation of coal (Official Gazette of the Socialist Federal Republic of Yugoslavia 004/1989), Rulebook on technical norms for electrical facilities, equipment and installations at mines with underground exploitation (Official Gazette of the Socialist Federal Republic of Yugoslavia 21/88), Rulebook on technical norms while handling explosives and blasting activities in mining (Official Gazette of the Socialist Federal Republic of Yugoslavia 26/1988), and Rulebook on technical norms while constructing pit storages for explosives at mines with underground exploitation of mineral raw resources (Official Gazette of the Socialist Federal Republic of Yugoslavia 12/88).

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

The Work Plan for 2009 envisages full consideration of necessary secondary legislation in relation to geological research and mining to be harmonized with the EU legislation.

- Medical devices

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

Valid legislation regulating medical products:

- Law on Medical Products (Official Gazette of the Republic of Montenegro no 79/2004 and Official Gazette of Montenegro 53/2009).

The Law is (partly) harmonized with the following:

- Directive 93/42/EEC (MD);
- Directive 90/385/EEC (AIMD);
- Directive 2007/47/EC and Directives 93/42/EEC and 90/385/EEC (MD & AIMD) amending this Directive;
- Directive EU 98/79/EC (IVDMD).

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

The following secondary legislation is planned to be adopted:

Rulebooks on medical products governing the following areas:

- Method of classification of medical products;
- Assessment of conformity of medical products with general and special requirements;
- Registration of natural and legal persons involved with manufacturing, import, and whole sale or retail trade in medical products;
- Preparation of a register of medical products;
- Clinical testing;
- Vigilance and monitoring of medical products in circulation;
- Procedure for issuing medical products;
- Advertising of medical products;
- Marking of medical products;
- Import of medical products which are not recorded in the registry.

The Rulebooks shall be harmonized with Directives 90/385/EEC, 93/42/EEC, 98/79/EEC, 2007/47/EC.

The foregoing Rulebooks are expected to be adopted in 2010-2011.

The Law Amending the Law on Medical Products (Official Gazette of Montenegro no 53/2009) of August 2009 stipulates that all natural and legal persons governed by this Law must harmonize their operations accordingly not later than within one year following its entrance into force.

- Gas appliances (GAD)

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

Present status – existing legislation:

- Rulebook on technical norms for stable pressurized containers (Official Gazette of the Socialist Federative Republic of Yugoslavia 16/83);
- Rulebook on technical norms for movable gas furnaces without chimney connector (Official Gazette of the Socialist Federative Republic of Yugoslavia 43/80);
- Rulebook on technical norms for stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 9/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Order on mandatory certification of pressure regulator for liquefied propane-butane gases (Official Gazette of the Socialist Federative Republic of Yugoslavia 20/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Rulebook on technical norms for examination and testing of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federal Republic of Yugoslavia 76/90);
- Rulebook on technical norms for movable closed containers for pressurized, liquefied and pressurized dissolved gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 25/80; 9/86; 21/94; 56/95; 01/03);
- Rulebook on the construction of facilities for liquefied petroleum gas and on storing and redistribution of liquefied petroleum gas (Official Gazette of the Socialist Federative Republic of Yugoslavia 24/71 and 26/71);
- Rulebook on technical norms for designing, construction, utilization and maintenance of gas boiler rooms (Official Gazette of the Socialist Federative Republic of Yugoslavia 10/90; 52/90);

- Rulebook on technical norms for gaseous oxygen (Official Gazette of the Socialist Federative Republic of Yugoslavia 52/90);
- Rulebook on technical norms for acetylene pipelines (Official Gazette of the Socialist Federative Republic of Yugoslavia 6/92);
- Rulebook on technical norms for internal gas installations (Official Gazette of the Federative Republic of Yugoslavia 20/92; 33/92).

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

The following Rulebooks are currently under preparation:

- Rulebook on technical requirements for pressurized equipment (EU Directive 97/23/EC) – a draft version completed;
- Rulebook on simple pressurized containers (EU Directive 87/404/EC) – currently under preparation – deadline October 2009;
- Rulebook on technical requirements for the level of capacity utilization for new heat boilers powered by liquefied and gaseous fuels (EU Directive 92/42/EC) – currently under preparation – deadline November 2009;
- Rulebook for gas devices (EU Directive 90/396/EC) – currently under preparation - deadline November 2009;
- Rulebook on technical norms for devices and equipment for operation of motor vehicles powered by natural and liquefied petroleum gas (EU Directives ECE 110; ECE 150, 2005/55/EC, Directives Amending Directives 2005/78/EC; 2006/51/EC; 2008/74/EC) – a draft version of the Rulebook completed.

- Pressure equipment (PED)

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

Present status - the existing legislation:

- Rulebook on technical norms for stable pressurized containers (Official Gazette of the Socialist Federative Republic of Yugoslavia 16/83);
- Rulebook on technical norms for movable gas furnaces without chimney connector (Official Gazette of the Socialist Federative Republic of Yugoslavia 43/80);
- Rulebook on technical norms for stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 9/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Order on mandatory certification of pressure regulators for liquefied propane-butane gases (Official Gazette of the Socialist Federative Republic of Yugoslavia 20/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Rulebook on technical norms for examination and testing of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federative Republic of Yugoslavia 76/90);
- Rulebook on technical norms for movable closed containers for pressurized, liquefied and pressurized dissolved gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 25/80; 9/86; 21/94; 56/95; 01/03);
- Rulebook on construction of facilities for liquefied petroleum gas and on storing and

- redistribution of liquefied petroleum gas (Official Gazette of the Socialist Federative Republic of Yugoslavia 24/71 and 26/71);
- Rulebook on technical norms for designing, construction, utilization and maintenance of gas boiler rooms (Official Gazette of the Socialist Federative Republic of Yugoslavia 10/90; 52/90);
- Rulebook on technical norms for gaseous oxygen (Official Gazette of the Socialist Federative Republic of Yugoslavia 52/90);
- Rulebook on technical norms for acetylene pipelines (Official Gazette of the Socialist Federative Republic of Yugoslavia 6/92);
- Rulebook on technical norms for internal gas installations (Official Gazette of the Federative Republic of Yugoslavia 20/92; 33/92).

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

The following Rulebooks are currently under preparation:

- Rulebook on technical requirements for pressurized equipment (EU Directive 97/23/EC) – a draft version of the Rulebook has been completed;
- Rulebook on simple pressurized containers (EU Directive 87/404/EC) – currently under preparation – deadline October 2009;
- Rulebook on technical requirements on the level of capacity utilization for new heat boilers powered by liquefied and gaseous fuels (EU Directive 92/42/EC) – currently under preparation – deadline November 2009;
- Rulebook for gas devices (EU Directive 90/396/EC) – currently under preparation - deadline November 2009;
- Rulebook on technical norms for devices and equipment for operation of motor vehicles powered by natural and liquefied petroleum gas (EU Directives ECE 110; ECE 150, 2005/55/EC; Directives Amending Directives 2005/78/EC; 2006/51/EC; 2008/74/EC) – a draft version of the Rulebook has been completed.

- Simple pressure vessels (SPVD)

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

The following Rulebooks are currently under preparation:

- Rulebook on technical norms for stable pressurized containers (Official Gazette of the Socialist Federative Republic of Yugoslavia 16/83);
- Rulebook on technical norms for movable gas furnaces without chimney connector (Official Gazette of the Socialist Federative Republic of Yugoslavia 43/80);
- Rulebook on technical norms for stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 9/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquid atmospheric gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Order on mandatory certification of pressure regulators for liquefied propane - butane gases (Official Gazette of the Socialist Federative Republic of Yugoslavia 20/86);
- Rulebook on technical norms for installation of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federative Republic of Yugoslavia 39/88);
- Rulebook on technical norms for examination and testing of stable pressurized containers for liquefied carbon dioxide (Official Gazette of the Socialist Federative Republic of

- Yugoslavia 76/90);
- Rulebook on technical norms for movable closed containers for pressurized, liquefied and pressurized dissolved gasses (Official Gazette of the Socialist Federative Republic of Yugoslavia 25/80; 9/86; 21/94; 56/95; 01/03);
- Rulebook on the construction of facilities for liquefied petroleum gas and on storing and redistribution of liquefied petroleum gas (Official Gazette of the Socialist Federative Republic of Yugoslavia 24/71 and 26/71);
- Rulebook on technical norms for designing, construction, utilization and maintenance of gas boiler rooms (Official Gazette of the Socialist Federative Republic of Yugoslavia 10/90; 52/90);
- Rulebook on technical norms for gaseous oxygen (Official Gazette of the Socialist Federative Republic of Yugoslavia 52/90);
- Rulebook on technical norms for acetylene pipelines (Official Gazette of the Socialist Federative Republic of Yugoslavia 6/92);
- Rulebook on technical norms for internal gas installations (Official Gazette of the Federative Republic of Yugoslavia 20/92; 33/92).

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

The following regulations are currently under preparation:

- Rulebook on technical requirements for pressurized equipment (EU Directive 97/23/EC) – a draft version of the Rulebook has been completed;
- Rulebook on simple pressurized containers (EU Directive 87/404/EC) – currently under preparation– deadline October 2009;
- Rulebook on technical requirements on the level of capacity utilization for new heat boilers powered by liquefied and gaseous fuels (EU Directive 92/42/EC)- currently under preparation – deadline November 2009;
- Rulebook on gas devices (EU Directive 90/396/EC) - currently under preparation - deadline November 2009;
- Rulebook on technical norms for devices and equipment for operation of motor vehicles powered by natural and liquefied petroleum gas (EU Directive ECE 110; ECE 150, 2005/55/EC, Directives Amending Directives 2005/78/EC; 2006/51/EC; 2008/74/EC) – a draft version of the Rulebook has been prepared.

- Cableway installations

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

The Law on Safety in Railway Transport (Official Gazette of Montenegro 4/08), stipulates the requirements for organization of transport by cableway, funicular railway and ski-lifts in terms of technical components and the requirements for construction, reconstruction and maintenance in addition to other conditions for safe operation of this type of transport.

The operation of cableway installations designed to carry persons is also regulated by the following two pieces of secondary legislation:

- Rulebook on technical norms for ski-lifts (Official Gazette of the Socialist Federative Republic of Yugoslavia 2/85);
- Rulebook on technical norms for cableway installations designed to carry persons (Official Gazette of the Socialist Federative Republic of Yugoslavia 29/86).

The Rulebook on technical norms for cableway installations designed to carry persons stipulates that each cableway must be provided with the instructions for use and maintenance.

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

The adoption of secondary legislation is planned in the forthcoming period, on the basis of the Law on Safety in Railway Transport, whereby the area of cableway transport will be regulated through implementation of Directive 2000/9/EC – Cableways Designed to Carry Persons.

The Twinning Project "Legal Harmonization", which was initiated in February 2009 together with Slovenian partners, includes the activities on harmonization of the legislation on cableway installations designed to carry persons anticipated for October 2009.

- Construction products

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

The Law on Spatial Development and Construction of Structures (Official Gazette of Montenegro 51/08) regulates seven important requirements in terms of general conditions that must be met by the construction products, including environmental protection:

- Mechanical resistance and stability;
- Protection against fire and explosions;
- Hygiene and health protection;
- Environmental protection;
- Safety of structure utilization;
- Protection against noise;
- Energy conservation and energy efficiency, and other.

Under the Law on Spatial Development and Construction of Structures construction products are defined as construction materials and construction elements made of construction materials, in addition to other products or semi-fabricated products intended for permanent installation in structures.

Article 72 of this Law stipulates that "construction products, when regularly maintained and throughout an economically acceptable life cycle, must bear without significant damage all impacts of normal use and environmental impacts, so that the structure containing such elements shall continuously meet all the requirements of mechanical resistance and stability, protection against fire and explosions, hygiene and health protection, environmental protection, safety of use of the structure, protection against noise, energy conservation, energy efficiency and other, for as long as it is used."

The adopted Standardization Law (Official Gazette of Montenegro 13/08) regulates general principles and objectives of standardization in Montenegro, in addition to establishment, organization and activities of an institution for standardization in Montenegro, and also the adoption, issuing and application of Montenegrin standards and similar documents in the area of standardization, as well as inspection supervision over the implementation of this Law.

The adopted Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08) regulates the

following: the procedure of setting technical standards for products; procedure for assessment of product conformity against set standards; adoption of technical regulations; register of technical regulations; supervision of compliance with technical regulations; validity of foreign documents on conformity and conformity marks.

All secondary legislation regulating in more detail the area of construction materials, i.e. technical regulations for specific products or groups of products including relevant standards have been taken over from the former State Union.

RULEBOOKS ON CONSTRUCTION MATERIALS

1. Rulebook on technical measures and requirements for hydrocarbon insulation of roofs and terraces (Official Gazette of Socialist Federative Republic of Yugoslavia 26/69);
2. Rulebook on technical measures and requirements for reinforced concrete (Official Gazette of Socialist Federative Republic of Yugoslavia 51/71);
3. Order on mandatory certification of plywood sheets for general use in construction activities (Official Gazette of Socialist Federative Republic of Yugoslavia 61/83);
4. Order on mandatory certification of concrete (Official Gazette of Socialist Federative Republic of Yugoslavia 34/85);
5. Order on mandatory certification of prefabricated elements of aerated concrete (Official Gazette of Socialist Federative Republic of Yugoslavia 34/85);
6. Order on mandatory certification of concrete sewer pipes exceeding one meter in length (Official Gazette of Socialist Federative Republic of Yugoslavia 34/85);
7. Order on mandatory certification of profiled rubber sealing tapes for doors, lids and movable barriers of shelters and dual-purpose structures with airtight closing of wings (Official Gazette of Socialist Federative Republic of Yugoslavia 35/86);
8. Order on mandatory certification of cement (Official Gazette of Socialist Federal Republic of Yugoslavia 34/85, 67/86);
9. Order on determining insulation devices and equipment for control of insulation devices that can be placed in circulation only if accompanied by warranty certificate and technical instructions, and on the shortest possible duration of warranty period and period of guaranteed servicing of such devices and equipment (Official Gazette of Socialist Federative Republic of Yugoslavia 4/87);
10. Rulebook on technical standards for concrete and reinforced concrete (Official Gazette of Socialist Federative Republic of Yugoslavia 11/87);
11. Order on mandatory certification of stone fraction aggregate for concrete and asphalt (Official Gazette of Socialist Federative Republic of Yugoslavia 41/87);
12. Rulebook on technical standards for steel wires, bars and ropes for structure reinforcing (Official Gazette of Socialist Federative Republic of Yugoslavia 41/85, 21/88);
13. Rulebook on technical standards for designing and building structures made of prefabricated elements of concrete and reinforced aerated concrete (Official Gazette of Socialist Federative Republic of Yugoslavia 14/89);
14. Rulebook on technical standards for concrete and reinforced concrete made of natural and artificial aerated fill (Official Gazette of Socialist Federative Republic of Yugoslavia 15/90);
15. Rulebook on technical standards for constructed walls (Official Gazette of Socialist Federative Republic of Yugoslavia 87/91);
16. Rulebook on technical standards for concrete and reinforced concrete in structures exposed to the aggressive environmental impacts (Official Gazette of Federative Republic of Yugoslavia 18/92)
17. Rulebook on uniform system for marking of steel (Official Gazette of Federative Republic of Yugoslavia 01/03);
18. Rulebook on technical and other requirements for ceramic tiles (Official Gazette of Serbia and Montenegro 58/04);
19. Rulebook on technical and other requirements for ceramic sanitary equipment (Official Gazette of Serbia and Montenegro 62/04);

20. Rulebook on technical and other requirements for clay tiles for overlapping installation, concrete tiles and sintered ceramic roof plates (Official Gazette of Serbia and Montenegro 53/05);
21. Rulebook on technical and other requirements for brick products made of clay and calcium silicate bricks and blocks (Official Gazette of Serbia and Montenegro 53/05);
22. Rulebook on technical and other requirements for solid clay façade brick, hollow façade brick and clay blocks and façade calcium silicate solid and hollow bricks and blocks (Official Gazette of Serbia and Montenegro 53/05);
23. Rulebook on technical and other requirements for thermal insulation materials (Official Gazette of Serbia and Montenegro 54/2005);
24. Rulebook on technical and other requirements for ceramic tiles (Official Gazette of Serbia and Montenegro 01/2006);
25. Rulebook on technical and other requirements for hydro insulation materials (Official Gazette of Serbia and Montenegro 01/2006).

The Strategy on Development of Construction Industry in Montenegro is in the final phase of preparation, in order to determine general directions of development for the construction sector and manufacturing of construction materials in Montenegro.

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

A detailed plan of activities is provided under the National Program for Integration of Montenegro into the EU for the period 2008-2012, so that Montenegro may be internally prepared to assume its obligations originating from the EU Membership until 2012. Chapter 3.1.3.21 of the National Program for Integration, i.e. its section relating to **Free Movement of Goods – Construction Products**, envisages the following:

Construction products are, inter alia, regulated under the New Approach Directives requiring that all products bear a CE mark proving that those are safe for human, animal and environmental use (89/106/EEC; 93/68/EEC).

Directive 89/106/EEC regulates that construction products include each product manufactured for the purpose of permanent installation in the course of execution of construction works on building construction and civil engineering construction. This Directive stipulates that the only construction products that can be put into circulation and on the market are those that are harmonized with the requirements of this Directive. This means that the characteristics of construction products must be such that the works and structures where they are used, mounted or installed, provided that those are properly designed and built, are able to satisfy the essential requirements of this Directive.

Both short-term and mid-term priorities have been identified.

Mid-Term Priorities

Legislation

Preparation and adoption of a national Law on Construction Products which will be harmonized with the EU Directives for Construction Products 89/106/EEC and 93/68/EEC, in addition to the adoption of secondary legislation (rulebooks and other technical regulations), by means of which this area will be completely regulated in accordance with the New Approach Directives in this field.

Institutions

The mid-term priorities include the following:

- Establishment and equipment of institutions and staff training to carry out the procedure for evaluation of product compliance;

- Establishment and equipment of institutions and staff training to carry out inspection control of construction products in the market;
- Establishment and equipment of certified laboratories for the performance of testing in accordance with the EN regulation;
- Adoption of harmonized European standards;
- Awareness raising activities directed towards the manufacturers of construction products and all participants in the process of building construction in relation to the new approach in the area covered by Directives 89/106/EEC and 93/68/EEC.

Aiming to increase the capacities for implementation of future documents and regulations, the Ministry of Spatial Planning and Environmental Protection shall continuously work on the strengthening of administrative capacities.

The following activities have been anticipated to implement the mid-term priorities: preparation of a **National Strategy for Harmonization of Technical Regulations in the Area of Construction Building with Aquis**.

- Recreational craft

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

The construction of boats is regulated under the Technical Specifications for the Construction of Boats issued by the Maritime Safety Department in 2006, which applies to all crafts as stipulated by the Law on Maritime and Inland Navigation (Official Gazette of the Federal Republic of Yugoslavia 12/98, 44/99, 74/99 and 73/2000). These specifications establish the procedure of issuing approvals and supervision of boat construction, and relate to the boat constructors, types of boats, approvals for specific types of boats, prototype testing, supervision of construction, revocation of approval for specific types of boat, alternatively constructed boats and additional requirements related to all foregoing activities.

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

A Rulebook for Statutory Certification of Boats and Yachts is currently under preparation, whereby this area will be harmonized with Directive 94/25/EC, as amended by Directive 2003/44 EC.

This activity is expected to be completed until mid-2010.

- Eco-design requirements for energy-using products (EUP)

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

The Law on Environment (Official Gazette of Montenegro 48/08 of 11 August 2008) introduces the idea of "Eco sign". Article 64 of this Law stipulates that eco signs shall be determined for all products intended for general consumption, except for foods, beverages and pharmaceutical products which cause less pollution to the environment compared to other similar products in the process of manufacturing, placement, trade, consumption and disposal, or which are the products of waste recycling. An eco sign shall also be established for the processes and services that cause

less pollution to the environment. A legal person or entrepreneur can be granted the right to use eco sign for products, processes or services if their production, carrying out or provision shall result in a reduced: consumption of energy resources, emission of harmful and dangerous substances; production of waste; consumption of natural resources, etc. The requirements and procedure to be granted the right to use eco sign, the costs related to the approval to use eco sign, its appearance and manner of utilization shall be regulated by the line Ministry. Article 60 of this Law stipulates the manner of awarding and revocation of the right to use eco sign.

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

Draft of the Law on Energy Efficiency (a draft version has been prepared, while it is expected to be adopted until the end of 2009) is harmonized with fundamental European regulations in the field of energy efficiency, including Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005, establishing the framework for identification of eco-design requirements for energy-using products and amending Directives 92/42/EEC, 96/57/EC and 2000/55/EC. This Law shall stipulate that energy-using products can be placed on the market in accordance with the applicable requirements for eco-design.

- Radio and telecommunications terminal equipment (R&TTE)

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

The Sector for Electronic Communications of the line Ministry of Maritime Affairs, Transportation and Telecommunication has already undertaken some activities towards the adoption of relevant secondary legislation – rulebooks regulating the related areas (EMC and R&TTE) and emanating from the Law on Electronic Communications (Official Gazette of Montenegro 50/08).

Namely, Article 85 relates to the area of RTT equipment and provides for free import, placing on the market and setting into operation of RTT equipment in the territory of Montenegro. Circulation of RTT equipment in the market is regulated in more detail by the proposed secondary legislation that is currently in the process of public discussion in order to obtain the comments of relevant state authorities.

These regulations (“Rulebook on technical requirements for import, placing in circulation and utilization of radio equipment and telecommunication terminal equipment” and “Rulebook on electromagnetic compatibility”) have been prepared through direct cooperation with the Sector for Quality Infrastructure of the Ministry of Economy, according to the Law on Technical Requirements for Products and Assessment of Product Conformity against the Set Standards (Official Gazette of Montenegro 14/08) and Decree on the manner of preparation and adoption of technical standards and technical specifications and the register of technical regulations (Official Gazette of Montenegro 55/08).

The Rulebook on RTT equipment ensured a full transposition of and compliance with the following regulations of the European Union:

- Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.
- 2000/299/EC: Commission Decision of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers (notified under document number C(2000) 938)

- Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty
- Commission communication in the framework of the implementation of Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity - April 2000 (Text with EEA relevance)
- 2001/148/EC: Commission Decision of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons (Text with EEA relevance) (notified under document number C(2001) 194)
- 2005/53/EC: Commission Decision of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS) (notified under document number C(2005) 110)Text with EEA relevance
- 2005/631/EC: Commission Decision of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services (notified under document number C(2005) 3059) (Text with EEA relevance)

No approvals for import and placing into circulation and utilization are currently issued.

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

The Rulebooks referred to under the response 31A are expected to be adopted until the end of 2009, in addition to a Guide to R&TTE Directive 1995/5/EC (version of 20 April 2009) relating to the application of these Rulebooks, in order to enable their application in 2010.

Following the adoption of foregoing rulebooks and through a full cooperation with the Institute for Standardization of Montenegro, Accreditation Body of Montenegro, Metrology Institute and other state and scientific institutions, the procedure relating to the concerned products is expected to be unified and completed.

Further development in this area is expected following the implementation of the foregoing regulations in accordance with staff capacities of the ministries, regulatory bodies and inspection authorities.

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

32. Please provide information on the relevant regimes for the products:

- Legal metrology: non-automatic weighing instruments; measuring instruments

a) short description and

In accordance with the Metrology Law (Official Gazette of Montenegro 79/08), valid measuring instruments may be put to use only if the applicable metrological requirements are met and if those are verified and duly labeled. Verification of measuring instruments, as regulated under MID

Directive (Directive 2004/22/EC of the European Parliament and of the Council) and NAWI Directive (Directive 90/384/EEC of the Council), is conducted following the inspection of a measuring instrument which may be verified if proven to comply with the approved type of measuring instrument and the applicable metrological requirements. Measuring instrument is first verified by the Metrology Institute of Montenegro, and, if necessary, by the manufacturer's certified laboratories outside of Montenegro. The compliance with valid technical and metrological requirements for the identification of type of measuring instrument is established by the Metrology Institute.

Due to a lack of adequate laboratory space and equipment no calibration of measuring instruments and national measuring standards is available in the cases referred to under the MID Directive (Directive 2004/22/EC of the European Parliament and of the Council) and NAWI Directive (Directive 90/384/EEC of the Council).

b) further evolution.

Development of national calibration laboratories in forthcoming period shall enable calibration of specific measuring instruments and measuring systems in Montenegro, while the manner of organization of calibration activities outside of Montenegro shall certainly be considered as well.

- Low-voltage equipment (LVD)

a) short description and

Standards

Low-voltage equipment in Montenegro is regulated by the following standards dating from the former Yugoslavia:

- JUS N.A5.070: Degrees of protection of electrical equipment effected by means of protective cases;
- JUS N.B2.702: Electrical installations in buildings. Voltage ranges;
- JUS N.B2.730: Electrical installations in buildings. General characteristics and classification;
- JUS N.B2.741: 4.4.1. Low-voltage electrical installations. Safety requirements. Protection against electrical shock;
- JUS N.B2.743: 4.4.1. Low-voltage electrical installations. Safety requirements. Protection against excessive currents;
- JUS N.B2.743/1: 4.4.1. Low-voltage electrical installations. Safety requirements. Protection against excessive currents. Alterations;
- JUS N.B2.752: 4.4.1. Electrical installations in buildings. Electrical distribution. Maximum amount of current a cable can carry before sustaining immediate or progressive deterioration;
- JUS N.B2.754: Electrical installations in buildings. Grounding and protective conductors;
- JUS N.B2.754/1: Electrical installations in buildings. Grounding and protective conductors. Changes;
- JUSN.B2.761: Low-voltage electrical installations. Method of measuring electrical resistance of walls and floors;
- JUS N.B2.762: Low-voltage electrical installations/Measuring of earth resistance.
- JUS N.B2.763: Low-voltage electrical installations/Measuring of fault loop impedance;
- JUSN.B2.771: Electrical installations in buildings. Bathroom with bathtub and shower. Special technical requirements;

- JUS.N.E5.205, 206: Yugoslav standard – Low-voltage safety fuses.
- JUS NK5.503/88: Low-voltage switchgear assemblies. Requirements for type-tested and partially tested assemblies;
- JUS N.82.741: Low-voltage electrical installations. Safety requirements. Protection against electrical shock;
- JUS NK5.012/82: Low-voltage switches, disconnectors, disconnector switches and combination with fusible plugs. General technical requirements and testing.

Harmonization of national standards with the EU ones

The Decision on valid Montenegrin standards for low-voltage equipment (Official Gazette of Montenegro 38/08 of 20 June 2008) was adopted pursuant to the Standardization Law (Official Gazette of Montenegro 13/08). The following Montenegrin standards relating to low-voltage equipment were adopted:

- 1) Electrical accessories - sets of connecting cables and sets of extension cords MEST EN 60799:1998 (en);
- 2) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 1-1: General application - Measurement of thickness and overall dimensions - Tests for determining mechanical properties MEST EN 60811-1-1:2008 (en);
- 3) Insulation and sheathing materials for electric cables - Common test methods - Part 1-2: General application - Thermal ageing methods MEST EN 60811-1-2:2008 (en);
- 4) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 1-3: General application - Methods for density identification - Water absorption tests – Test for tightening MEST EN 60811-1-3:2008 (en);
- 5) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 1-4: General application - Tests at low temperature MEST EN 60811-1-4:2008 (en);
- 6) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 2-1: Methods specific to elastomeric compounds - Ozone resistance, hot set and mineral oil immersion tests MEST EN 60811-2-1:2008 (en);
- 7) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 3-1: Methods specific to PVC compounds - Pressure test at high temperature - Tests for resistance to cracking MEST EN 60811-3-1:2008 (en);
- 8) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 3-2: Methods specific to PVC compounds - Loss of mass test - Thermal stability test MEST EN 60811-3-2:2008 (en);
- 9) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 4-1: Methods specific to polyethylene and polypropylene compounds - Resistance to environmental stress cracking - Measurement of the melt flow index - Carbon black and/or mineral filler content measurement in polyethylene by direct combustion - Measurement of carbon black content by thermo-gravimetric analysis (TGA) - Assessment of carbon black dispersion in polyethylene using a microscope MEST EN 60811-4-1:2008 (en);
- 10) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 4-2: Methods specific to polyethylene and polypropylene compounds - Tensile strength and elongation at break after previous conditioning at elevated temperature - Wrapping test after previous conditioning at elevated temperature - Wrapping test after thermal ageing in air - Measurement of mass increase - Long-term stability test - Test method for copper-catalyzed oxidative degradation MEST EN 60811-4-2:2008 (en);
- 11) Insulation and sheathing materials for electric and optical cables - Common test methods - Part 5-1: Methods specific to filling compounds - Drop point - Separation of oil - Lower temperature brittleness - Total acid number - Absence of corrosive components - Permittivity at 23 °C - D.C. resistance at 23 °C and 100 °C MEST EN 60811-5-1:2008 (en)
- 12) Safety of laser products - Part 1: Equipment classification and requirements MEST EN 60825-1:2008 (en)
- 13) Safety of laser products - Part 2: Safety of optical fiber communication systems MEST EN 60825-2:2008 (en)
- 14) Safety of laser products - Part 4: Laser guards MEST EN 60825-4:2008 (en)

- 15) Safety of laser products - Part 12: Safety of free space optical communication systems used for transmission of information MEST EN 60825-12:2008 (en)
- 16) Shunt power condensers of self-healing type for AC systems having a rated voltage of up to and including 1 kV - Part 1: General - Performance, testing and rating - Safety requirements - Guide for installation and operation MEST EN 60831-1:2008 (en)

b) further evolution.

Simultaneously with the transposition of essential requirements of the related New Approach Directive, the corresponding EN standards shall be adopted as national standards by means of technical regulation. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Electromagnetic compatibility (EMC)

a) short description and

Following the Directive **2004/108/EC** on **Electromagnetic compatibility**, **79** harmonized European standards have been transposed into national legislation, i.e. 56.83% all harmonized standards related to the Directive.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Toys

a) short description and

The Health and Sanitary Inspectorate supervises the production, import and trade in toys, pursuant to the law.

Laboratory testing of health safety of toys in Montenegro is currently performed by the following two laboratories:

- The Institute of Public Health of Montenegro, Podgorica (microbiological and physical-chemical analyses),

- The Center for Toxicological Research, Podgorica (physical-chemical analyses),

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Machinery

a) short description and

Following the Directive **98/37/EC on Machinery safety, 55** harmonized European standards have been transposed into the national legislation, i.e. 7.39% of all harmonized standards related to this Directive.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products.

- Noise emissions by outdoors equipment (Global Approach directive based on New Approach elements)

a) short description and

Article 32 of the Law on Environment (Official Gazette of the Republic of Montenegro 48/08) stipulates that "the State shall provide for a continuous monitoring of environmental conditions". Monitoring includes systemic and regular observation, measuring and assessment of environmental parameters (water, air, soil, biodiversity, etc.) and possible changes in quality and quantity of the environment, emissions of pollutant substances and exploitation of natural resources.

The Environmental Monitoring Program of Montenegro for 2009 includes the following seven programs:

- 1) Air quality control program;

- 2) Program for checking the presence of dangerous and harmful substances in soil;
- 3) Program for checking radionuclide presence in the environment;
 - Sub-program Radon map of Montenegro;
- 4) Program for monitoring the condition of coastal ecosystems of Montenegro;
- 5) Biodiversity monitoring program
 - Bio-monitoring sub-program for the Lake Skadar;
- 6) Program for measuring of noise in the environment;
- 7) Program of systemic testing of quantity and quality of surface and ground waters.

Pursuant to valid legislation (Law on the Protection from Environmental Noise; Official Gazette of the Republic of Montenegro 45/2006; and Rulebook on limit values of environmental noise levels; Official Gazette of the Republic of Montenegro 75/06), the following three sub-programs were identified under the Environmental Noise Measuring Program:

- Identification of noise levels in urban areas and settlements that originate from motor vehicles, air traffic, railway traffic and various acoustic devices and other machines;
- Identification of noise levels in the vicinity of structures of public interest (schools, kindergartens, hospitals, sports halls, hotels, etc.);
- Identification of noise levels in national parks and other protected natural resources, where no disturbance of present fauna species is permitted, and also in the areas for relaxation and recreation.

Organizations or institutions that meet the criteria relating to the professional staff, equipment and workspace according to the Law on the Protection from Environmental Noise may be licensed for measuring of environmental noise. This is confirmed by a Decision issued by the Ministry. The following organizations or institutions have been licensed accordingly:

- Public Institution - Center for Toxicological Research of Montenegro;
- Institute for Research and Development in the Field of Protection at Work
- “D.O.O. Sigurnost” (LLC Company “Sigurnost”)
- Public Institution - Public Health Institute
- Institute for Transport INTRA

The function of monitoring of environmental noise for 2009 is carried out by the Institute for Research and Development in the Field of Protection at Work.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Lifts

a) short description and

No authority is currently authorized for compliance assessment for elevators. The Public Institution - Institute for Development and Research in the Fields of Protection at Work, Podgorica, which performs the testing of elevators, is currently in the process of accreditation.

Market supervision of elevators currently falls within the competence of Inspectorate for the Protection at Work, and relates to safety of elevators in terms of installation and utilization.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Personal protective equipment (PPE)

a) short description and

Following the Directive **89/686/EC on Personal protective equipment, 195** harmonized European standards have been transposed into the national legislation, i.e. 71.74% of all harmonized standards related to this Directive.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)

a) short description and

Montenegro has no certified and accredited laboratory for such testing activities for the time being. The activity of handling explosive substances (blasters) may be performed by an employed person who meets the applicable requirements and is duly licensed.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Medical devices

a) short description and

Until the moment of full harmonization (registration in accordance with the Law), permits for the import of medical products will be issued by the Agency in accordance with the Law.

The Agency ensures full compliance of all medical products with the applicable quality standards by assessing the accompanying documentation on medical product.

In accordance with the Law on Medical Products, only products that are registered by the Agency for medicines and medical products can put on the market in Montenegro.

The Agency enters records into the register of medical products following a document, declaration, or certificate of compliance.

During the procedure of registration of medical products, the Agency accepts all conformity certificates issued by the Notifying body (body for assessment of compliance registered by the competent authority of the European Union with the European Commission as the authorized body for evaluation of product compliance with the requirements stipulated under the EU Directives) and conformity mark for medical products issued in accordance with the EU technical regulations (EN ISO standards).

Medical product is labeled with proper conformity mark in accordance with the declaration of conformity.

Exceptionally, a medical product which is intended for clinical research or manufactured as ordered by a specific user is not required to be labeled with such conformity mark.

Exceptionally, if there is no certified legal person, the activities of conformity assessment for medical products having no declaration issued by the Notifying body is performed by the Agency, following the opinion of a Committee established by the Agency, following prior approval by the Ministry of Health.

The Ministry competent for health issues carries out inspection supervision of certified legal persons for assessment of conformity of medical products, manufacturers and legal persons and entrepreneurs that are trading in medical products in accordance with the law. Inspectors of the Ministry of Health may also ban the trade and order termination of trade or withdrawal of medical products from circulation where those fail to meet the applicable general and special requirements.

b) further evolution.

The obligation for all devices in the market to bear a mark issued by the notifying authority is planned to be introduced over the following three years.

- Gas appliances (GAD)

a) short description and

Standards

In Montenegro, the standards dating from the former Yugoslavia still apply to the pressurized equipment and gas equipment belonging to the following groups of standards: JUS. M. E2; JUS. M. E3; JUS. M. E5; JUS. M. E6; JUS. M. E7; JUS. M. Z2; JUS. M. Z3; JUS. C. T3, as well as EN standards and ISO.

Harmonization of standards with EC standards

Following the Standardization Law (Official Gazette of Montenegro 13/08), the Decision on adopted Montenegrin standards in the area of pressurized equipment was passed (Official Gazette of Montenegro 38/08 of 20 June 2008). The following Montenegrin standards were adopted in the area of pressurized equipment:

- 1) Pressurized Equipment - Part 5: Documentation on Compliance and Control of Materials MEST EN 764- 5:2008 (en);
- 2) Copper and copper alloys - Seamless, round copper pipes for water and gas in sanitary and heating applications MEST EN 1057:2008 (en);
- 3) Cryogenic vessels - Gas/material compatibility MEST EN 1797:2008 (en);
- 4) Mobile fire extinguishers MEST EN 1866:2008 (en);
- 5) Flat products made of steels for operation under pressure - Part 1: General requirements MEST EN 10028-1:2008 (en);
- 6) Metal products - Types of inspection documents MEST EN 10204:2008 (en);
- 7) Steel castings intended for operation under pressure MEST EN 10213:2008 (en);
- 8) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specific properties at indoor air temperature MEST EN 10216-1:2008 (en);
- 9) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Non-alloy and alloy steel pipes with specific properties at high temperatures MEST EN 10216-2:2008 (en);
- 10) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 3: Fine grain alloy steel pipes MEST EN 10216-3:2008 (en);
- 11) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Non-alloy and alloy steel pipes with specific properties at low temperatures MEST EN 10216-4:2008 (en);
- 12) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specified room temperature properties MEST EN 10217-

- 1:2008 (en);
- 13) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Electric welded non-alloy and alloy steel pipes with specific properties at higher temperatures MEST EN 10217-2:2008 (en);
 - 14) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 3: fine grain alloy steel pipes MEST EN 10217-3:2008 (en);
 - 15) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Electric welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-4:2008 (en);
 - 16) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 5: Submerged arc welded non-alloy and alloy steel pipes with specific properties at high temperatures MEST EN 10217-5:2008 (en);
 - 17) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 6: Submerged arc welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-6:2008 (en);
 - 18) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 7: Stainless steel pipes MEST EN 10217-7:2008 (en);
 - 19) Steel forgings intended for operation under pressure - Part 1: General requirements for open die forgings MEST EN 10222-1:2008 (en);
 - 20) Steel forgings intended for operation under pressure - Part 3: Nickel alloy coated steel with specified properties at low temperatures MEST EN 10222-3:2008 (en);
 - 21) Steel forgings intended for operation under pressure - Part 4: Weldable fine grain steels with high tightening strength MEST EN 10222-4:2008 (en);
 - 22) Stainless steel bars for operation under pressure MEST EN 10272:2008 (en);
 - 23) Hot rolled weldable steel bars for operation under pressure with specified properties at high temperature MEST 10273:2008 (en);
 - 24) Steel pipes for precision applications - Technical specifications for delivery - Part 4: Seamless cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-4:2008 (en);
 - 25) Steel pipes for precision applications - Technical specifications for delivery - Part 6: Welded cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-6:2008 (en);
 - 26) Copper and copper alloys - Seamless, round pipes for heat exchangers MEST EN 12451:2008 (en);
 - 27) Copper and copper alloys - Rolled, finned, seamless pipes for heat exchangers MEST EN 12452:2008 (en);
 - 28) Water tube boilers and auxiliary installations - Part 1: General MEST EN 12952-1:2008 (en)
 - 29) Water tube boilers and auxiliary installations - Part 7: Standards for boiler equipment MEST EN 12952-7:2008 (en);
 - 30) Water tube boilers and auxiliary installations - Part 8: Standards for liquid and gaseous fuel feeding systems for the boiler MEST EN 12952-8:2008 (en);
 - 31) Water tube boilers and auxiliary installations - Part 9: Standards for pulverized solid fuel feeding systems for the boiler MEST EN 12952-9:2008 (en);
 - 32) Water tube boilers and auxiliary installations - Part 10: Standards for safeguard against excessive pressure MEST EN 12952-10:2008 (en);
 - 33) Water tube boilers and auxiliary installations - Part 14: Standards for flue gas DENOX-systems using liquefied pressurized ammonia and ammonia water solution MEST EN 12952-14:2008 (en);
 - 34) Water tube boilers and auxiliary installations - Part 16: Standards for solid fuel combustion systems on screens and fluidized bed MEST EN 12952-16:2008 (en);
 - 35) Shell boilers - Part 1: General MEST EN 12953-1:2008 (en);
 - 36) Shell boilers - Part 2: Materials for parts of boilers under pressure and accessories MEST EN 12953-2:2008 (en);
 - 37) Shell boilers - Part 3: Design and calculation for parts under pressure MEST EN 12953-3:2008 (en);
 - 38) Shell boilers - Part 4: Manufacturing and structure of boiler parts under pressure MEST EN 12953-4:2008 (en);

- 39) Shell boilers - Part 5: Inspection during construction, documentation and marking of boiler parts under pressure MEST EN 12953-5:2008 (en);
- 40) Shell boilers - Part 7: Standards for systems feeding liquid and gaseous fuels to boilers MEST EN 12953- 7:2008 (en);
- 41) Shell boilers - Part 8: Standards for safeguard against excessive pressure MEST EN 12953- 8:2008 (en).

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Pressure equipment (PED)

a) short description and

Standards

In Montenegro, the following groups of standards dating from the period of former Yugoslavia still apply to pressurized equipment and gas equipment: JUS. M. E2; JUS. M. E3; JUS. M. E5; JUS. M. E6; JUS. M. E7; JUS. M. Z2; JUS. M. Z3; JUS. C. T3, as well as EN standards and ISO.

Harmonization of standards with EC standards

Following the Standardization Law (Official Gazette of Montenegro 13/08), the Decision on adopted Montenegrin standards in the area of pressurized equipment (Official Gazette of Montenegro 38/08 of 20 June 2008) was adopted. The following adopted Montenegrin standards regulate the area of pressurized equipment:

- 1) Pressurized Equipment - Part 5: Documentation on Compliance and Control of Materials MEST EN 764- 5:2008 (en);
- 2) Copper and copper alloys - Seamless, round copper pipes for water and gas in sanitary and heating applications MEST EN 1057:2008 (en);
- 3) Cryogenic vessels - Gas/material compatibility MEST EN 1797:2008 (en);
- 4) Mobile fire extinguishers MEST EN 1866:2008 (en);
- 5) Flat products made of steels for operation under pressure - Part 1: General requirements MEST EN 10028-1:2008 (en);
- 6) Metal products - Types of inspection documents MEST EN 10204:2008 (en);
- 7) Steel castings intended for operation under pressure MEST EN 10213:2008 (en);
- 8) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specific properties at indoor air temperature MEST EN 10216-1:2008 (en);
- 9) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Non-alloy and alloy steel pipes with specific properties at high temperatures MEST EN 10216-2:2008 (en);
- 10) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 3: Fine grain alloy steel pipes MEST EN 10216-3:2008 (en);

- 11) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Non-alloy and alloy steel pipes with specific properties at low temperatures MEST EN 10216-4:2008 (en);
- 12) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specified room temperature properties MEST EN 10217-1:2008 (en);
- 13) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Electric welded non-alloy and alloy steel pipes with specific properties at higher temperatures MEST EN 10217- 2:2008 (en);
- 14) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 3: fine grain alloy steel pipes MEST EN 10217-3:2008 (en);
- 15) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Electric welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-4:2008 (en);
- 16) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 5: Submerged arc welded non-alloy and alloy steel pipes with specific properties at high temperatures MEST EN 10217-5:2008 (en);
- 17) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 6: Submerged arc welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-6:2008 (en);
- 18) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 7: Stainless steel pipes MEST EN 10217-7:2008 (en);
- 19) Steel forgings intended for operation under pressure - Part 1: General requirements for open die forgings MEST EN 10222-1:2008 (en);
- 20) Steel forgings intended for operation under pressure - Part 3: Nickel alloy coated steel with specified properties at low temperatures MEST EN 10222-3:2008 (en);
- 21) Steel forgings intended for operation under pressure - Part 4: Weldable fine grain steels with high tightening strength MEST EN 10222-4:2008 (en);
- 22) Stainless steel bars for operation under pressure MEST EN 10272:2008 (en);
- 23) Hot rolled weldable steel bars for operation under pressure with specified properties at high temperature MEST 10273:2008 (en);
- 24) Steel pipes for precision applications - Technical specifications for delivery - Part 4: Seamless cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-4:2008 (en);
- 25) Steel pipes for precision applications - Technical specifications for delivery - Part 6: Welded cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-6:2008 (en);
- 26) Copper and copper alloys - Seamless, round pipes for heat exchangers MEST EN 12451:2008 (en);
- 27) Copper and copper alloys - Rolled, finned, seamless pipes for heat exchangers MEST EN 12452:2008 (en);
- 28) Water tube boilers and auxiliary installations - Part 1: General MEST EN 12952-1:2008 (en)
- 29) Water tube boilers and auxiliary installations - Part 7: Standards for boiler equipment MEST EN 12952-7:2008 (en);
- 30) Water tube boilers and auxiliary installations - Part 8: Standards for liquid and gaseous fuel feeding systems for the boiler MEST EN 12952-8:2008 (en);
- 31) Water tube boilers and auxiliary installations - Part 9: Standards for pulverized solid fuel feeding systems for the boiler MEST EN 12952-9:2008 (en);
- 32) Water tube boilers and auxiliary installations - Part 10: Standards for safeguard against excessive pressure MEST EN 12952-10:2008 (en);
- 33) Water tube boilers and auxiliary installations - Part 14: Standards for flue gas DENOX-systems using liquefied pressurized ammonia and ammonia water solution MEST EN 12952-14:2008 (en);
- 34) Water tube boilers and auxiliary installations - Part 16: Standards for solid fuel combustion systems on screens and fluidized bed MEST EN 12952-16:2008 (en);
- 35) Shell boilers - Part 1: General MEST EN 12953-1:2008 (en);
- 36) Shell boilers - Part 2: Materials for parts of boilers under pressure and accessories MEST

- EN 12953-2:2008 (en);
- 37) Shell boilers - Part 3: Design and calculation for parts under pressure MEST EN 12953-3:2008 (en);
 - 38) Shell boilers - Part 4: Manufacturing and structure of boiler parts under pressure MEST EN 12953-4:2008 (en);
 - 39) Shell boilers - Part 5: Inspection during construction, documentation and marking of boiler parts under pressure MEST EN 12953-5:2008 (en);
 - 40) Shell boilers - Part 7: Standards for systems feeding liquid and gaseous fuels to boilers MEST EN 12953- 7:2008 (en);
 - 41) Shell boilers - Part 8: Standards for safeguard against excessive pressure MEST EN 12953- 8:2008 (en).

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Simple pressure vessels (SPVD)

a) short description and

Standards

In Montenegro, the following groups of standards dating from the period of former Yugoslavia still apply to pressurized equipment and gas equipment: JUS. M. E2; JUS. M. E3; JUS. M. E5; JUS. M. E6; JUS. M. E7; JUS. M. Z2; JUS. M. Z3; JUS. C. T3, as well as EN standards and ISO.

Harmonization of standards with EC standards

Following the Standardization Law (Official Gazette of Montenegro 13/08), the Decision on adopted Montenegrin standards in the area of pressurized equipment (Official Gazette of Montenegro 38/08 of 20 June 2008) was adopted. The following adopted Montenegrin standards regulate the area of pressurized equipment:

- 1) Pressurized Equipment - Part 5: Documentation on Compliance and Control of Materials MEST EN 764- 5:2008 (en);
- 2) Copper and copper alloys - Seamless, round copper pipes for water and gas in sanitary and heating applications MEST EN 1057:2008 (en);
- 3) Cryogenic vessels - Gas/material compatibility MEST EN 1797:2008 (en);
- 4) Mobile fire extinguishers MEST EN 1866:2008 (en);
- 5) Flat products made of steels for operation under pressure - Part 1: General requirements MEST EN 10028-1:2008 (en);
- 6) Metal products - Types of inspection documents MEST EN 10204:2008 (en);
- 7) Steel castings intended for operation under pressure MEST EN 10213:2008 (en);
- 8) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specific properties at indoor air temperature MEST EN 10216-1:2008 (en);
- 9) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Non-alloy and alloy steel pipes with specific properties at high temperatures MEST

- EN 10216-2:2008 (en);
- 10) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 3: Fine grain alloy steel pipes MEST EN 10216-3:2008 (en);
 - 11) Seamless steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Non-alloy and alloy steel pipes with specific properties at low temperatures MEST EN 10216-4:2008 (en);
 - 12) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 1: Non-alloy steel pipes with specified room temperature properties MEST EN 10217-1:2008 (en);
 - 13) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 2: Electric welded non-alloy and alloy steel pipes with specific properties at higher temperatures MEST EN 10217-2:2008 (en);
 - 14) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 3: fine grain alloy steel pipes MEST EN 10217-3:2008 (en);
 - 15) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 4: Electric welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-4:2008 (en);
 - 16) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 5: Submerged arc welded non-alloy and alloy steel pipes with specific properties at high temperatures MEST EN 10217-5:2008 (en);
 - 17) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 6: Submerged arc welded non-alloy steel pipes with specific properties at low temperatures MEST EN 10217-6:2008 (en);
 - 18) Welded steel pipes for operation under pressure - Technical specifications for delivery - Part 7: Stainless steel pipes MEST EN 10217-7:2008 (en);
 - 19) Steel forgings intended for operation under pressure - Part 1: General requirements for open die forgings MEST EN 10222-1:2008 (en);
 - 20) Steel forgings intended for operation under pressure - Part 3: Nickel alloy coated steel with specified properties at low temperatures MEST EN 10222-3:2008 (en);
 - 21) Steel forgings intended for operation under pressure - Part 4: Weldable fine grain steels with high tightening strength MEST EN 10222-4:2008 (en);
 - 22) Stainless steel bars for operation under pressure MEST EN 10272:2008 (en);
 - 23) Hot rolled weldable steel bars for operation under pressure with specified properties at high temperature MEST 10273:2008 (en);
 - 24) Steel pipes for precision applications - Technical specifications for delivery - Part 4: Seamless cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-4:2008 (en);
 - 25) Steel pipes for precision applications - Technical specifications for delivery - Part 6: Welded cold-drawn pipes for hydraulic and pneumatic power systems MEST EN 10305-6:2008 (en);
 - 26) Copper and copper alloys - Seamless, round pipes for heat exchangers MEST EN 12451:2008 (en);
 - 27) Copper and copper alloys - Rolled, finned, seamless pipes for heat exchangers MEST EN 12452:2008 (en);
 - 28) Water tube boilers and auxiliary installations - Part 1: General MEST EN 12952-1:2008 (en)
 - 29) Water tube boilers and auxiliary installations - Part 7: Standards for boiler equipment MEST EN 12952-7:2008 (en);
 - 30) Water tube boilers and auxiliary installations - Part 8: Standards for liquid and gaseous fuel feeding systems for the boiler MEST EN 12952-8:2008 (en);
 - 31) Water tube boilers and auxiliary installations - Part 9: Standards for pulverized solid fuel feeding systems for the boiler MEST EN 12952-9:2008 (en);
 - 32) Water tube boilers and auxiliary installations - Part 10: Standards for safeguard against excessive pressure MEST EN 12952-10:2008 (en);
 - 33) Water tube boilers and auxiliary installations - Part 14: Standards for flue gas DENOX-systems using liquefied pressurized ammonia and ammonia water solution MEST EN 12952-14:2008 (en);
 - 34) Water tube boilers and auxiliary installations - Part 16: Standards for solid fuel combustion

- systems on screens and fluidized bed MEST EN 12952-16:2008 (en);
- 35) Shell boilers - Part 1: General MEST EN 12953-1:2008 (en);
 - 36) Shell boilers - Part 2: Materials for parts of boilers under pressure and accessories MEST EN 12953-2:2008 (en);
 - 37) Shell boilers - Part 3: Design and calculation for parts under pressure MEST EN 12953-3:2008 (en);
 - 38) Shell boilers - Part 4: Manufacturing and structure of boiler parts under pressure MEST EN 12953-4:2008 (en);
 - 39) Shell boilers - Part 5: Inspection during construction, documentation and marking of boiler parts under pressure MEST EN 12953-5:2008 (en);
 - 40) Shell boilers - Part 7: Standards for systems feeding liquid and gaseous fuels to boilers MEST EN 12953- 7:2008 (en);
 - 41) Shell boilers - Part 8: Standards for safeguard against excessive pressure MEST EN 12953- 8:2008 (en).

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Cableway installations

a) short description and

Following the Directive **2009/9/EC on Cableway installations designed to carry persons**, 22 harmonized European standards have been transposed at the national level, i.e. 95.65% of all harmonized standards related to this Directive.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Construction products

a) short description and

Following the Directive **89/106/EEC on Construction products, 314** harmonized European standards have been transposed at the national level, i.e. 82.65% of all harmonized standards related to this Directive.

No body is currently authorized for assessment of harmonization. There are two certified laboratories in Montenegro for construction materials and their testing:

1. JSC Institute for Construction Materials, Geotechnical and Chemical Analyses, Nikšić, performs the testing of the following types of construction materials: stone, stone aggregate, cement, concrete, concrete curbs, concrete prefabricate products, concrete blocks, clay products and asphalt.
2. JSC Construction Supervision and Laboratory Testing, Podgorica, performs the testing of the following construction materials: concrete, asphalt and aggregate.

Market supervision for installable building materials is it currently performed by market inspectors, mostly relating to the proper declaring of products at sales points (warehouses, etc.).

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

- Recreational craft

a) short description and

The following Montenegrin standards are harmonized with EN and ISO standards:

| | | | |
|-------------------------|---|--------------------|---|
| MEST EN ISO 6185-1:2008 | Čamci na naduvavanje - Dio 1: Čamci sa maksimalnom snagom motora do 4,5 kW | EN ISO 6185-1:2001 | Inflatable boats - Part 1: Boats with a maximum motor power rating of 4,5 kW (ISO 6185-1:2001) |
| MEST EN ISO 6185-2:2008 | Čamci na naduvavanje - Dio 2: Čamci sa maksimalnom snagom motora između 4,5 kW i 15 kW | EN ISO 6185-2:2001 | Inflatable boats - Part 2: Boats with a maximum motor power rating of 4,5 kW to 15 kW inclusive (ISO 6185-2:2001) |
| MEST EN ISO 6185-3:2008 | Čamci na naduvavanje - Dio 3: Čamci sa maksimalnom snagom motora iznad 15 kW | EN ISO 6185-3:2001 | Inflatable boats - Part 3: Boats with a maximum motor power rating of 15 kW and greater (ISO 6185-3:2001) |

01 Free movement of goods

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|-------------------------|--|-----------------------------|---|
| MEST EN ISO 7840:2008 | Mala plovila - Vatrootporna crijeva za gorivo | EN ISO 7840:2004 | Small craft - Fire-resistant fuel hoses (ISO 7840:2004) |
| MEST EN ISO 8099:2008 | Mala plovila - Sistemi za prikupljanje sanitarnog otpada | EN ISO 8099:2000 | Small craft - Toilet waste retention systems (ISO 8099:2000) |
| MEST EN ISO 8469:2008 | Mala plovila - Crijeva za gorivo neotporna na vatru | EN ISO 8469:2006 | Small craft - Fire-resistant fuel hoses (ISO 7840:2004) |
| MEST EN ISO 8665:2008 | Mala plovila - Dvosmjerni brodski motori sa unutrašnjim sagorijevanjem - Mjerenje snage i deklarisanje | EN ISO 8665:2006 | Small craft - Marine propulsion reciprocating internal combustion engines - Power measurements and declarations (ISO 8665:2006) |
| MEST EN ISO 8666:2008 | Mala plovila - Osnovni podaci | EN ISO 8666:2002 | Small craft - Principal data (ISO 8666:2002) |
| MEST EN ISO 8847:2008 | Mala plovila - Kormilarski uređaj - Sistemi kablova i remenica | EN ISO 8847:2004 + AC:2005 | Small craft - Steering gear - Cable and pulley systems (ISO 8847:2004) |
| MEST EN ISO 8849:2008 | Mala plovila - Elektromotorne pumpe na jednosmjernu struju za ispušavanje prljavštine | EN ISO 8849:2003 | Small craft - Electrically operated direct-current bilge-pumps (ISO 8849:2003) |
| MEST EN ISO 9093-1:2008 | Mala plovila - Ventili i odvodi za vodu u trupu plovila - Dio 1: Metalni | EN ISO 9093-1:1997 | Small craft - Seacocks and through-hull fittings - Part 1: Metallic (ISO 9093-1:1994) |
| MEST EN ISO 9093-2:2008 | Mala plovila - Ventili i odvodi za vodu u trupu plovila - Dio 2: Nemetalni | EN ISO 9093-2:2002 | Small craft - Seacocks and through-hull fittings - Part 2: Non-metallic (ISO 9093-2:2002) |
| MEST EN ISO 9094-1:2008 | Mala plovila - Zaštita od požara - Dio 1: Plovila dužine trupa manje ili jednake 15 m | EN ISO 9094-1:2003 | Small craft - Fire protection - Part 1: Craft with a hull length of up to and including 15 m (ISO 9094-1:2003) |
| MEST EN ISO 9094-2:2008 | Mala plovila - Zaštita od požara - Dio 2: Plovila dužine trupa veće od 15 m | EN ISO 9094-2:2002 | Small craft - Fire protection - Part 2: Craft with a hull length of over 15 m (ISO 9094-2:2002) |
| MEST EN ISO 10087:2008 | Mala plovila - Identifikacija plovila - Sistem kodiranja | EN ISO 10087:2006 | Small craft - Craft identification - Coding system (ISO 10087:2006) |
| MEST EN ISO 10088:2008 | Mala plovila - Trajno ugrađeni sistemi za gorivo i fiksni rezervoari goriva | EN ISO 10088:2001 | Small craft - Permanently installed fuel systems and fixed fuel tanks (ISO 10088:2001) |
| MEST EN ISO 10240:2008 | Mala plovila - Uputstvo za upotrebu | EN ISO 10240:2004 | Small craft - Owner's manual (ISO 10240:2004) |
| MEST EN ISO 10592:2008 | Mala plovila - Hidraulični kormilarski sistemi | EN ISO 10592:1995 + A1:2000 | Small craft - Hydraulic steering systems (ISO 10592:1994) |
| MEST EN ISO 11105:2008 | Mala plovila - Ventilacija prostora za smještaj benzinskih motora i/ili rezervoara benzina | EN ISO 11105:1997 | Small craft - Ventilation of petrol engine and/or petrol tank compartments (ISO 11105:1997) |
| MEST EN ISO 11547:2008 | Mala plovila - Zaštita od puštanja pogona u rad | EN ISO 11547:1995 + A1:2000 | Small craft - Start-in-gear protection (ISO 11547:1994) |
| MEST EN ISO 11592:2008 | Mala plovila dužine trupa do 8 m - Određivanje maksimalne snage pogonjenja motora | EN ISO 11592:2001 | Small craft less than 8 m length of hull - Determination of maximum propulsion power |

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|--------------------------|--|-----------------------------|--|
| MEST EN ISO 11812:2008 | Mala plovila - Vodonepropusni kokpiti i brzoprazneći kokpiti | EN ISO 11812:2001 | Small craft - Watertight cockpits and quick-draining cockpits (ISO 11812:2001) |
| MEST EN ISO 12215-1:2008 | Mala plovila - Konstrukcija trupa i zahtijevane karakteristike - Dio 1: Materijali: Termoreaktivne smole, armiranje staklenim vlaknima, referentni laminat | EN ISO 12215-1:2000 | Small craft - Hull construction and scantlings - Part 1: Materials: Thermosetting resins, glass-fibre reinforcement, reference laminate (ISO 12215-1:2000) |
| MEST EN ISO 12215-2:2008 | Mala plovila - Konstrukcija trupa i zahtijevane karakteristike - Dio 2: Materijali jezgre za sendvič konstrukciju, ugrađeni materijali | EN ISO 12215-2:2002 | Small craft - Hull construction and scantlings - Part 2: Materials: Core materials for sandwich construction, embedded materials (ISO 12215-2:2002) |
| MEST EN ISO 12215-3:2008 | Mala plovila - Konstrukcija trupa i zahtijevane karakteristike - Dio 3: Čelik, legure aluminijuma, drvo, drugi materijali | EN ISO 12215-3:2002 | Small craft - Hull construction and scantlings - Part 3: Materials: Steel, aluminium alloys, wood, other materials (ISO 12215-3:2002) |
| MEST EN ISO 12215-4:2008 | Mala plovila - Konstrukcija trupa i zahtijevane karakteristike - Dio 4: Proizvodni prostor i proizvodnja | EN ISO 12215-4:2002 | Small craft - Hull construction and scantlings - Part 4: Workshop and manufacturing (ISO 12215-4:2002) |
| MEST EN ISO 12216:2008 | Mala plovila - Prozori, okna i vrata - Zahtjevi za čvrstoću i vodonepropusnost | EN ISO 12216:2002 | Small craft - Windows, portlights, hatches, deadlights and doors - Strength and watertightness requirements (ISO 12216:2002) |
| MEST EN ISO 13590:2008 | Mala plovila - Lična plovila - Zahtjevi za konstrukciju i instalaciju sistema | EN ISO 13590:2003 + AC:2004 | Small craft - Personal watercraft - Construction and system installation requirements (ISO 13590:2003) |
| MEST EN ISO 13929:2008 | Mala plovila - Kormilarski uređaj - Sistemi sa zupčastim prenosom | EN ISO 13929:2001 | Small craft - Steering gear - Geared link systems (ISO 13929:2001) |
| MEST EN ISO 14509:2008 | Mala plovila - Mjerenje zvuka koji emituju rekreaciona plovila na motorni pogon | EN ISO 14509:2000 + A1:2004 | Small craft - Measurement of airborne sound emitted by powered recreational craft (ISO 14509:2000 + A1:2004) |
| MEST EN ISO 14509-2:2008 | Mala plovila - Zvuk koji emituju rekreaciona plovila na motorni pogon - Dio 2: Ocjena zvuka upotrebom referentnog plovila | EN ISO 14509-2:2006 | Small craft - Airborne sound emitted by powered recreational craft - Part 2: Sound assessment using reference craft (ISO 14509-2:2006) |
| MEST EN ISO 14946:2008 | Mala plovila - Maksimalna nosivost | EN ISO 14946:2001 + AC:2005 | Small craft - Maximum load capacity (ISO 14946:2001) |

The following EN and ISO Standards shall apply until the adoption of relevant Montenegrin standards:

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|-----------------------------------|---|
| ISO 14945:2004; EN ISO 14945:2004 | Small craft - Builder's plate |
| EN ISO 15085:2003 | Small craft - Man overboard prevention and recovery |

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| ISO 11591:2000; EN ISO 11591:2000 | Small craft engine driven - Field of vision from helm position |
| ISO 12217-1:2002; EN ISO 12217-1:2002 | Small craft - Stability and buoyancy assessment and categorization Part 1: Non-sailing boats of hull length greater than or equal to 6 m |
| ISO 12217-2:2002; EN ISO 12217-2:2002 | Small craft - Stability and buoyancy assessment and categorization Part 2: Sailing boats of hull length greater than or equal to 6 m |
| ISO 12217-3:2002; EN ISO 12217-3:2002 | Small craft - Stability and buoyancy assessment and categorization - Part 3: Boats of hull length less than 6 m |
| ISO 12216:2002; EN ISO 12216:2002 | Small craft - Windows, portlights, hatches, deadlights and doors - Strength and watertightness requirements |
| EN ISO 15083:2003 | Small craft - Bilge pumping system |
| EN ISO 15084:2003 | Anchoring, mooring and towing - Strong points |
| ISO 15584:2001; EN ISO 15584:2003 | Small craft - Inboard petrol engines - Engine-mounted fuel and electrical components |
| ISO 16147:2002; EN ISO 16147:2002 | Small craft - Inboard diesel engines - Engine-mounted fuel and electrical components |
| ISO 14895:2000; EN ISO 14895:2003 | Small craft - Liquid-fuelled galley stoves |
| ISO 10133:2000; EN ISO 10133:2000 | Small craft - Electrical systems - Extra-low-voltage d.c. installations |
| ISO 13297:2000; EN ISO 13297:2000 | Small craft - Electrical systems - Alternating current installations |
| IEC 60092-507:2000; EN 60092-507:2000 | Electrical installations in ships - Part 507: Pleasure craft |
| ISO 8848:1990; EN 28848:1993 | Small craft - Remote steering systems |
| ISO 10592:1994; EN ISO 10592:1995 | Small craft - Hydraulic steering systems |
| ISO 9775:1990; EN 29775:1993 | Remote steering systems for single outboard motors of 15 kW to 40 kW power |
| ISO 10239:2000; EN ISO 10239:2000) | Small craft - Liquefied petroleum gas (LPG) systems |

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|---|---|
| ISO 8846:1990; EN 28846:1993 | Small craft - Electrical devices - Protection against ignition of surrounding flammable gases |
| ISO 11547:1994; EN ISO 11547:1995+A1:2000 | Small craft - Start-in-gear protection |

Testing, certification, assessment of conformity and certification are regulated under the Technical Regulations for Boat Construction of the Maritime Safety Department and Technical Regulations of the Maritime Safety Department for: I) Approval of manufacturers and service providers; and II) Generic product approval.

b) further evolution.

It is planned to prepare technical regulations whereby the standards for the manufacturing of small passenger vessels and commercial boats shall be applied.

- Eco-design requirements for energy-using products (EUP)

a) short description and

The line Ministry (Ministry of Economy), in cooperation with the Ministry responsible for environmental protection, stipulates general eco-design requirements for products and the conditions for putting energy-using products on the market, obligations of importers, procedure for conformity assessment and conformity markings, and other conditions that provide for application of eco-design requirements for products.

b) further evolution.

All measures concerning metrology, conformity assessment and market supervision shall be regulated under technical regulations relating to implementation of eco-design measures to be adopted by the line ministry following the entrance into force of the Law on Energy Efficiency.

- Radio and telecommunications terminal equipment (R&TTE)

a) short description and

Following the Directive **1999/5/EC** on **Radio and telecommunications terminal equipment**, **63** harmonized European standards have been transposed at the national level, i.e. 26.80% of all harmonized standards related to this Directive.

b) further evolution.

Simultaneously with the transposition of essential requirements of the applicable New Approach Directive, the corresponding EN standards shall be adopted as national standards through technical regulations. The line Ministry shall assess the need for possible notification of the Notification Committee by the competent body for conformity assessment of Montenegro and submit the request to the enquiry point. Accordingly, the line Ministry shall follow all recommendations from the Blue Guide and measures stipulated by the Law on Technical Requirements for Products and Assessment of Compliance with Set Standards.

PROCEDURAL MEASURES

A. Measures having an equivalent effect to quantitative restrictions

33. Do measures exist in the laws, regulations or administrative provisions adopted at national or local level on the production, distribution and marketing of food or industrial products:

a) Relating to the price of such products (e. g. fixing the prices above or below which the importation or marketing of a product is prohibited or restricted, laying down profit margins or other price components, etc.)?

In the market of Montenegro, prices are formed freely, except for specific medicines, oil and oil derivatives and coal.

Article 6 of the Law on Medicines (Official Gazette of the Republic of Montenegro 80/04 and 18/08) authorizes the Government to set maximum prices of medicines. Apart from that, price control applies only to medicines – imported or domestic – listed as medicines issued at the expense of the Health Insurance Fund.

In accordance with the Decree on the manner of identification of maximum retail prices for oil derivatives (Official Gazette of the Republic of Montenegro 52/02, 55/02, 23/03, 32/02 and 35/05), oil companies are obliged to respect maximum retail prices of oil derivatives. Maximum prices are based on actual costs and adjusted according to price movements in the world market, exchange rates, import customs duties, duties and tax, trading expenses, expenses of handling and storing, margins, etc.

As far as the coal is concerned, control of prices applies only to domestic production of coal which is supplied to the thermal power plant of Pljevlja. This measure is applied pursuant to the Energy Law (Official Gazette of the Republic of Montenegro 39/03 and 53/09). The coal intended for other customers or purposes is subject to no price regulation.

However, it is important to note that regulation of prices by the Government of Montenegro includes no discrimination between domestic and imported products.

b) Which require automatic or non-automatic import licences or permits for imported goods (e.g. licence for import of automobiles)?

The Law on Foreign Trade (Official Gazette of the Republic of Montenegro 28/04 and 37/07) and the Decree implementing the Law on Foreign Trade (Official Gazette of the Republic of Montenegro 52/04), Decision on control list for export, import and transit of goods (Official Gazette

of the Republic of Montenegro 45/07), Law on General Administrative Procedure (Official Gazette of the Republic of Montenegro 60/03) and the Law on Administrative Dispute (Official Gazette of the Republic of Montenegro 60/03) constitute general legal framework for the issuing of import permits. Additionally, depending on the type of products, permits are issued in accordance with the following regulations: Law on International Trade of Weapons, Military Equipment and Goods with Dual Application (Official Gazette of Serbia and Montenegro 7/05 and 8/05); Decree on assuming competence of authorities as stipulated by the Law on International Trade of Weapons, Military Equipment and Goods with Dual Application (Official Gazette of the Republic of Montenegro 40/06); Law on Environmental Protection (Official Gazette of the Republic of Montenegro 48/08); Law on the Elements of Environmental Protection (Official Gazette of Serbia and Montenegro 24/98); Law on Transportation of Hazardous Materials (Official Gazette of the Federal Republic of Yugoslavia 27/90); Law on the Production and Trade in Hazardous Substances (Official Gazette of the Federal Republic of Yugoslavia 15/95, 28/96 and 37/02); Law on the Protection from Ionizing Radiation (Official Gazette of the Federal Republic of Yugoslavia 46/96); Decision on placing specific species of plants and animals under protection (Official Gazette of the Republic of Montenegro 76/06); Law on the Production and Trade in Narcotic Drugs (Official Gazette of the Federal Republic of Yugoslavia 46/96 and 37/02); and Law on Veterinary Matters (Official Gazette of the Republic of Montenegro 11/04).

c) Which ban certain specific products (foodstuffs, including vitamins and other food supplements, and chemical substances)?

Article 14 of the Law on Foreign Trade (Official Gazette of the Republic of Montenegro 28/04) stipulates that goods which are illegal to trade in Montenegro shall not be imported. Moreover, pursuant to Article 30 of this Law, regardless of origin, Montenegro may ban an import of goods for the purpose of protection of national security, health and safety of human beings, plants and animals.

d) Which restrict or prohibit distant selling (mail order, internet sales) of certain products (pharmaceuticals, alcoholic beverages and others)?

No restriction or ban on distant selling of goods (mail orders, internet sales etc.) is stipulated under Montenegrin legislation.

e) Which make access to the domestic market conditional upon having an agent or representative in the territory of your country (e.g. legislation which provides for the sale of certain goods in your country subject to authorisation that may be obtained only by a person established there)?

Pursuant to Article 6 of the Customs Law (Official Gazette of Montenegro 21/08) a foreign person who has no seat or place of residence in Montenegro may participate in all customs procedures, including export and import. A foreign person participating in customs procedure must have a customs agent, either a company or an entrepreneur whose seat or place of residence is in Montenegro, and that is registered by the customs authority.

f) Which oblige importers to have storage facilities in the territory of your country (e.g. legislation applying only to imported goods which require these imported goods to be stored for some time before being marketed)?

Montenegrin legislation places no obligation on importers to have storage facilities in the territory of Montenegro, in the sense that imported goods have to be stored for a period of time before being placed on the market.

g) Which impose on the marketing of imported products conditions (relating in particular to shape, size, weight, composition, presentation, identification and packaging, labelling) that are different from those imposed on domestic products or which require or encourage the use of certain type of packaging (shape, size, composition) for the marketing of a certain product, whether domestic or imported (e.g. requirement that some goods may only be sold in a package with special form)?

Pursuant to Article 30 of the Law on Foreign Trade (Official Gazette of the Republic of Montenegro 28/04), conformity with the applicable technical regulations in Montenegro may be stipulated as a requirement for the import of goods. In that sense, mandatory criteria for placing goods into circulation are stipulated under technical regulations aimed to protect the safety, life, health and security of persons, plants and animals, and environmental protection. Technical regulations apply to goods of both domestic and foreign origin, and stipulate the characteristics, technical specifications, terminology, symbols, packaging, labeling, and also the process or method of production of goods.

h) Which oblige economic operators to label their product with the “Made in ...” marking (obligatory origin marking)?

Pursuant to Article 69 of the Law on Consumer Protection (Official Gazette of the Republic of Montenegro 26/07), goods in circulation has to be accompanied by a declaration in accordance with technical and other regulations and has to be consistent with the information contained in the declaration. Unless otherwise specified under the technical or other regulation, the declaration must, inter alia, contain the title and registered office of the manufacturer.

Additionally, Article 8 of the Rulebook on declaring and labeling packed food (Official Gazette of Serbia and Montenegro 04/04, 12/04 and 48/04) stipulates that a declaration on food package must, inter alia, include the country of origin ("made in ...") and the country from which the food item was imported ("Imported from...").

i) Which encourage or authorise the purchase (by individuals or public authorities) of domestic products alone or give preference to the purchase of such products in advertising campaigns (e.g. promotion actions with the participation of public authorities applying only to goods produced by producers in your country or from domestic raw materials)?

Montenegrin legislation includes no provisions that encourage or authorize purchase of domestic products alone or give preference to the purchase of such products over the imported products. In accordance with the principle of equal treatment, imported goods are treated equally as domestic goods in every sense of the word.

j) Which exclude imported products alone, in full or in part, from the possibility of using domestic facilities or equipment or which reserve the use of such facilities or equipment, in full or in part, for domestic products alone?

There are no such provisions in Montenegrin legislation.

k) Which subject imported products to controls, other than those inherent in customs clearance procedures, which are not carried out on domestic products (e.g. veterinary, sanitary, phytosanitary and other controls)?

Montenegrin legislation includes no measures of control other than those applicable to domestic goods. Since the Law on quality control and quality controls at the border went out of force, quality control is currently applied on the level of retail sales, including no discrimination between domestic and imported goods. In addition to previously explained measures for barrier removal (TBT measures), customs clearance procedure shall also include procedures related to veterinary, sanitary, phytosanitary and other measures (SPS measures) which are described more in detail in Chapter 12.

l) Which allow only traders holding a production licence or wholesale licence to import some goods (e.g. licensing system for the production and wholesale of some goods, which allow only the licence holder to import these goods)?

According to the Tobacco Law (Official Gazette of Montenegro 48/08), Law on Medicines (Official Gazette of the Republic of Montenegro 80/04), Law on Medical Devices (Official Gazette of the Republic of Montenegro 79/04), Law on the Production and Trade in Narcotic Drugs (Official Gazette of the Federal Republic of Yugoslavia 46/96 and 37/02), Law on Chemicals (Official Gazette of the Republic of Montenegro 11/07), Law on the Plant Nutrition Products (Official Gazette of the Republic of Montenegro 48/07), Law on the Plant Protection Products (Official Gazette of the Republic of Montenegro 51/08) and Energy Law (Official Gazette of the Republic of Montenegro 39/03), a license must be obtained for the performance of specific activities. Only licensed entities may be involved in trade of tobacco, medicines and medical devices, narcotics and poisons, fertilizers and pesticides, and in operative control of facilities, networks and equipment for generation, transmission, distribution, procurement and sale of energy.

m) Which create monopolies of sale of some goods (e.g. tobacco products, alcohol products, etc)?

There are no such provisions in Montenegrin legislation.

n) Which reserve certain trade names for domestic products alone and, if so, on what conditions (e.g. rules which reserve the use of a certain description to products prepared in your country from domestic raw materials)?

There are no such provisions in Montenegrin legislation.

34. Do you have any information on the number of times your authorities intervened to prohibit the marketing of products or withdraw products from the market for any reason over the last 2 years, e.g. health risk, incomplete labelling, inadequate consumer information, failure to comply with compulsory standards, etc.?

Market inspectors supervise the market of non-food products as authorized under special material laws and other regulations, in accordance with stipulated rules and procedures.

Supervision is performed ex officio, in accordance with annual work plan, operative monthly plans, on the basis of analysis of the situation in the market from the previous period, consumer complaints and following initiatives of other natural or legal persons, and other elements that may be useful for risk assessment, aimed to maximally improve the efficiency of control.

The table below include the data on the number of undertaken controls of products in the market, number of cases where some products were temporarily withdrawn from the market for not being properly labeled and declared or because those were accompanied by no supporting documentation:

| Market Inspectorate Data | 2007 | 2008 | Total: |
|---|--------|--------|--------|
| Number of inspection controls of goods in circulation | 20 583 | 19 050 | 39 633 |
| Products withdrawn from the market | 4 660 | 3 359 | 8 019 |
| Lacking proper declaration and accompanying documentation | 3 568 | 2 664 | 6 232 |
| Exceeded Date of Expiry | 405 | 43 | 448 |
| Not registered in business books | 687 | 652 | 1.339 |
| Temporarily: | 4 092 | 3 297 | 7 389 |
| Permanently: | 568 | 62 | 630 |

35. What are the general rules applicable in your country to non-food products? For example, is the marketing of products with a label and instructions written in a foreign language allowed? What particulars must be mentioned on the label of any industrial product intended for sale to consumers?

Non-food products on the market must be labeled and accompanied by the applicable supporting document (instruction for use, warranty, etc.) in accordance with special technical regulations that stipulate the requirements for particular products, i.e. in accordance with the Law on Consumer Protection (Official Gazette of the Republic of Montenegro 26/07 of 16 May 2007). Supporting documents and other information intended for customers must be translated into Montenegrin language (Article 82).

The Law on Consumer Protection (Article 69) stipulates the following:

- 1) Goods in circulation shall bear a declaration in accordance with technical and other regulations and shall correspond to the information from the declaration.
- 2) Unless otherwise stipulated by technical or other regulations, each declaration shall contain the following information:
 - a) Title or trade mark under which the goods are sold;
 - b) Title and registered office of the manufacturer;
 - c) Title and registered office of the importer and name of the country of origin, in case of imported goods;

- d) Data on quantity, composition, quality, type and model of goods, date of manufacturing and expiration, manner of utilization, conservation and storing of goods and warning of possible risks associated with regular and irregular utilization of goods, depending on the nature of goods.
- 3) Any removal or alternation of data from the declaration shall be prohibited.

B. Return of unlawfully removed cultural objects

36. Do you have legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State?

There are no such provisions in Montenegrin legislation.

37. What are the legal provisions ensuring the return of cultural goods in your country?

Those are the provisions of the Property Law.

38. If such legislation exists, what categories of cultural goods are covered?

All movable cultural goods are covered.

39. Which is the central authority, if any, responsible for dealing with the export of cultural goods and ensuring the return of cultural goods?

In accordance with the Law on the Protection of Cultural Heritage (Official Gazette of the Republic of Montenegro 47/91), approvals for the export of movable items of cultural heritage and moveable cultural goods are issued by the Ministry responsible for cultural activities, with prior consent of the National Institute for the Protection of Cultural Heritage.

40. Do you have any plans to modify the existing legislation? Please give details and timetables.

The legislation on cultural heritage is currently undergoing a reform conducted in accordance with the European and international standards, and best practices of the neighboring countries. In that sense the following draft laws have been prepared:

- Law on Cultural Goods;
- Law on Museums;
- Law on Archives;
- Law on Libraries,

The new laws are planned to be adopted until the end of 2009.

C. Control of the acquisition and possession of weapons

41. Do you have legislation providing for the control of the acquisition and possession of weapons? Please explain.

Montenegro has a law stipulating the control of acquisition and possession of weapons. Acquisition, holding, carrying, manufacturing, trade and transport of weapons and ammunition, as well as handling of weapons is regulated by the Law on Weapons (Official Gazette of the Republic of Montenegro 49/04; and Official Gazette of Montenegro 49/08) and the subsequent implementing regulations (Rulebook on forms of certificates on weapons and ammunition (Official Gazette of the Republic of Montenegro 2/05 and 35/08); Rulebook on spatial and technical requirements for safe production and storing of weapons and ammunition (Official Gazette of the Republic of Montenegro 2/05); Rulebook on forms and maintenance of records on weapons and ammunition (Official Gazette of the Republic of Montenegro 2/05); Rulebook on training program and qualification procedure for holding, carrying and proper usage of firearms (Official Gazette of the Republic of Montenegro 5/05)). These regulations apply to foreigners who are granted permanent residence or temporary residence for a period longer than one year, unless otherwise stipulated under international agreements. The Law on Weapons is not applicable to weapons and ammunition used by the Army of Montenegro, police, and other state administration bodies authorized to acquire and hold weapons under specific regulations, and also museum exhibits.

The foregoing Law on Weapons:

- 1) Identifies the meaning of weapons (firearm; air weapons; gas weapons; signalization weapons; fragmentation weapons; string weapons; cold weapons; major parts of weapons); provides classification of weapons according to specific uses and types (weapons for personal safety; hunting weapons; sports weapons; trophy weapons; old weapons and combined weapons);
- 2) Identifies the weapons whose acquisition, holding, carrying, manufacturing, repair, trade and transport is prohibited;
- 3) Identifies the weapons than may be freely acquired in the marking with no reporting obligation;
- 4) Identifies the weapons which may be acquired based on appropriate permit;
- 5) Places a ban on carrying weapons in public; and
- 6) Obligates the Ministry of Interior Affairs and Public Administration to maintain records on issued approvals for the acquisition of weapons and ammunition, issued gun certificates and permits to hold weapons, issued approvals to collect weapons, and on confiscated, found and surrendered weapons.

This Law regulates in more detail the following issues: acquisition, holding, carrying of weapons and ammunition and collection of weapons; handling weapons and ammunition; confiscation of weapons, ammunition and gun certificates; repair and modification of weapons; trade in weapons and ammunition; manufacturing of weapons and ammunition; transport of weapons and ammunition; shooting ranges as the facilities intended for sports and recreational shooting exercises; supervision and maintenance of records; and also stipulates fines in case of violation of this Law.

The Criminal Code (Official Gazette of the Republic of Montenegro 70/03, 13/04, 47/06 and Official Gazette of Montenegro 40/08) stipulates the following criminal offences: manufacture and acquisition of weapons and means intended for commission of a criminal offence (the person who acquires weapons, explosives, means required for their manufacturing or poison that is known to be intended for execution of criminal offences, or who manufactures such items or enables other person to acquire them shall subject to imprisonment from six months to five years; the person who manufactures or delivers to another persons any means for burglary or breaking in, being aware that this is intended for execution of criminal offence, shall be fined or sentenced to imprisonment of up to one year – Article 402); unauthorized keeping of wepoans and expolosives (the person who illegally manufactures, sells, procures, exchanges, carries or keeps firearms, ammunition or explosive substances, shall be sentenced to prison from three months to three years; the person

who illegally keeps, carries, manufactures, repairs, processes, sells, procures, exchanges, transports or otherwise releases into circulation firearms, ammunition, explosive substances, fragmentation or gas weapons, whose possession is prohibited for the citizens, shall be sentenced to prison from six months to five years; If the criminal offence includes a larger quantity of weapons or such means or the concerned weapon or other such means are of large destructive power, the offender shall be subject to prison sentence from one to eight years – Article 403).

42. Is there a legislation laying down the categories of firearms the acquisition and possession of which by private persons is either prohibited or subject to authorisation or declaration?

The Law on Weapons stipulates the types of weapons whose acquisition, possession, carrying manufacturing, repair, modification and transport is prohibited:

- 1) All types of automatic weapons,
- 2) Shoulder semi-automatic weapons with magazine capacity of more than six bullets, except for caliber 22 LR rifles;
- 3) All types of weapons with integrated silencer, silencers intended to use with firearms and silencer parts;
- 4) Telescopic sights with visible sights or with a device for electronic enhancement of visible or infrared sights;
- 5) Weapons intended for launching explosive projectiles;
- 6) Weapons in the shape of an object serving another purpose, so that its appearance is not recognizable;
- 7) Fragmentation weapons;
- 8) Ammunition mainly intended for armor piercing, ammunition with explosive, inflammable or poisonous projectiles;
- 9) Ammunition that was not cleared for putting into circulation according to special regulations;
- 10) Switchblades the blades of which are under the pressure of compressed springs, pivoting out of the handle when a button or lever is pressed, brass knuckles or throwing metal stars (Shuriken).

The Law on Weapons stipulates that firearms for personal safety (pistols and revolvers of caliber 5.6 mm and more), hunting weapons and sports weapons and crossbows of draw weight exceeding 45 kg (100 pounds), may be acquired only with prior approval issued by the Ministry of Interior Affairs and Public Administration. Firearms ammunition may be acquired by natural persons on the basis of firearm certificate.

Natural persons over the age of 18 may acquire the following items without approval:

- 1) Air weapons, signal weapons and signal weapons, bows, crossbows of draw weight lower than 45 kg (100 pounds), sprays that are scattering non-harmful substances, devices intended for salvation, devices for slaughtering of livestock and other similar devices intended for industrial and technical purposes, if those are acquired in accordance with the applicable regulations.
- 2) Weapons that are acquired and possessed as souvenirs and reproductions of weapons used for decorative purposes that cannot be fired or modified to fire bullets.
- 3) Replica weapons and other object intended for game from which can fire only bullets that reach kinetic energy of less than 9.5 joules, corks that cause a bang sound, etc.
- 4) Spear guns and other objects using spring force, strained rubber or pressurized gas to eject spears or harpoons intended for fishing only (underwater weapons).

43. If the legislation is in force:

a) Which categories of firearms are covered?

In accordance with the Law on Weapons, firearms include the following: all types of rifles, pistols and revolvers; all devices which, using the force of drag force of powder gasses, may eject through a barrel bullets, balls, shells, darts or any other projectile; hand or self-standing devices intended for causing a loud bang, constructed so that they cannot accommodate a whole charge, muzzle loaded with a specific amount of gunpowder and ignited by fuse, matchlock or flintlock mechanism. The foregoing firearms are hand or shoulder firearms and may have a repeating mechanism, semiautomatic or automatic.

The Law on Weapons identifies the following:

- 1) Firearms for personal safety (pistols and 5.6 mm caliber revolvers and higher);
- 2) Hunting firearms (shoulder firearms of various calibers with rifled and smooth bored barrels, acquired for hunting purposes);
- 3) Sport firearms (up to 12 mm caliber shoulder firearms; up to 8.61 mm or 0.338 inches caliber rifled barrels; up to 11.43 mm or 0.45 inches caliber hand firearms; pistols and revolvers of greater caliber adjusted for sports purposes; low-caliber rifles and pistols of caliber 5.6 mm, rim fired, etc.);
- 4) Combined firearms (weapons with two or more rifled or smooth bored barrels of different caliber);
- 5) Short firearms (firearms with barrel length of no more than 30 cm, and total length of no more than 60 cm);
- 6) Shoulder firearms (firearms with barrel length of more than 30 cm, and total length of more than 60 cm);
- 7) Automatic firearms (firearms where a single pull of the trigger results in firing several bullets);
- 8) Semiautomatic firearms (firearms which are after firing a single bullet ready for next firing following a single pull of the trigger, while it is possible to fire one bullet at a time), etc.

Fragmentation weapons include all types of bombs, mines, grenades and other devices equipped with explosive substances or detonator (weight, impact, pull, friction, chemical reaction, electrical energy etc.), which results in the release of energy and its fragmentation.

b) Which are the conditions necessary to be fulfilled in order to obtain the authorisation?

Issuing of approvals to natural persons

An approval for weapon acquisition may be issued to a natural person who meets the following criteria:

- 1) A person older than 21 years (exceptionally, an approval may be granted to a person of 18 years of age – police officers, professional army personnel, authorized customs officers, authorized persons in the authorities for enforcement of criminal sanctions, persons involved in the protection of persons and property in accordance with special regulations; shooters – members of sports shooting organizations and hunters – members of companies or entrepreneurs for the performance of professional duties);
- 2) A person who has never been convicted or against who no criminal proceedings have been initiated involving criminal offenses against the constitutional order and security of Montenegro, against humanity and other assets guaranteed by international law, criminal offences against life, body, property, and other criminal offences with elements of violence, out of greed or base motives;

- 3) A person who, during the previous three years before he or she submitted an application to be granted an approval to acquire weapons, had not been sanctioned or subject to criminal proceedings for a violation of public peace and order committed by firearms, and other violations stipulated by the Law on Weapons;
- 4) That there are no other circumstances that would indicate that such weapon may be misused, especially such as frequent and excessive drinking, seriously disturbed family relations, neighboring relations or relations at work, disciplinary violation of hunting regulations of sports shooting regulations, etc;
- 5) That he or she has a justifiable reason to acquire a weapon – in case of jeopardized personal safety (in case of weapon acquisition for personal protection – pistols and revolvers of caliber 5.6 mm and more); that he or she is a hunter (for the purpose of acquisition of hunting weapons – shoulder firearms of various calibers with rifled and smooth bored barrels acquired for hunting purposes, as hunting weapons are also considered as hand firearms used for mercy kill of wild game); and in case he or she is engaged in sport shooting (for acquisition of sport weapons – shoulder firearms of smooth bored barrels of caliber up to 12 mm, rifled barrels of caliber up to 8.61 mm, or 0.338 inches, hand firearms of caliber up to 11.43 mm, or 0.45 inches, pistols and revolvers of greater caliber adjusted for sport purposes, low-caliber rifles and pistols of caliber 5.6 mm, rim fired, with rifled or smooth bored barrels);
- 6) It was confirmed by medical examination that he or she was fit to possess and carry weapons (medical certificate is issued by the medical center designated by the Ministry of Health, which also regulates the procedure for conducting medical examinations, list of illnesses and health conditions that would make a person unfit for the possession and carrying of weapons, the procedure for management of records and medical documentation and contents of a certificate on conducted medical examinations);
- 7) That he or she is trained in handling weapons and knows regulations related to possession and keeping of weapons (these conditions are proved in the following manner: for hunting weapons - certificate of passed hunting exam; for sports weapons – certificate of sport shooting organization on active membership in sport shooting organization, and for hand firearms certificate of qualification for possessing and carrying and proper utilization of firearms, issued by the Ministry of Internal Affairs and Public Administration which also stipulates the program and method of qualification and taking exams).

Issuing of approval for weapon acquisition to companies and entrepreneurs

An approval to acquire firearms may be granted to the companies and entrepreneurs that are directly involved in physical protection activities and protection of objects as well as shooting organizations for performing their activities if they have ensured the premises for safe storing and keeping of weapons.

Decision Making

Once an application for the issuing of approval to acquire a weapon has been field, the Ministry establishes the level of compliance with the conditions for the issuing of an approval, and:

- If the conditions are met, an approval for weapon acquisition shall be issued and shall be valid for a period of six months following the date of issue (if it is not used within this time limit, it must be returned to the Ministry not later than within eight days following its expiration);
- If conditions are not met, it issues a decision rejecting the application against which an administrative dispute may be filed with the Administrative Court.

Obligations of traders in weapons and weapon certificate

An authorized weapons trader may sell weapons only to a person who has an approval for the acquisition of weapons and he or she is obligated to inform the Ministry of Interior Affairs and

Public Administration that a weapon was sold not later than within eight days following the sales transaction. The purchaser of a weapon is obligated, not later than within eight days, to file an application to have such weapon registered and a weapon certificate issued by the Ministry (weapon certificate for possession is issued to natural persons in possession of weapons for the purpose of personal safety, while a weapon certificate for possession and carrying of weapons is issued to the natural person for hunting and sports purposes).

c) What kind of information must be given in the declaration?

The form of an application for the issuing of an approval for the acquisition of firearms is stipulated by the Rulebook on forms of certificates on weapons and ammunition; the form consists of two pages and is of the following dimensions: 210x297.

On the first page the applicant fills in the following information: personal identification number; name and surname; place of residence and address; nationality; occupation; qualifications; title, place and registered address of the company where the natural person is employed; type of weapons for which the request is submitted; reasons for weapon acquisition (personal safety, property protection, sports and recreation, etc.), justification of reasons; date of submission of application and the applicant's signature.

The second page of the form is filled in by the authorized official of the Ministry, including the following information: the manner in which the decision was made (approval granted, approval rejected, request denied, procedure suspended), reasons for rejection of application, reasons for granting approval, date of decision, and title of the authority, register number and place of resolution.

44. Are there any special rules for collectors and bodies concerned with the cultural and historical aspects of weapons? If so must these collectors and bodies be recognised by the local authorities?

The Law on Weapons regulates the issue of trophy weapons (firearms and cold weapons that are preserved as souvenirs from wars and represent personal or family trophies for the owner) and antique weapons (weapons that are no longer in use, weapons of historical or cultural value, weapons that represents an integral part of national costume, weapons with flintlock, matchlock or cap lock firing mechanism and other firearms, other than military or police weapons that are overage and unused).

The Ministry of Interior Affairs and Public Administration issues a weapon certificate to the owner of a trophy weapon for an indefinite period of time. Weapon certificate cannot be issued to a person if any of the requirements are not met, which are considered to be an obstacle for the issuing approval for acquisition of weapons, as listed under the response 43 b (items 1-6). Utilization of trophy weapons as well as manufacturing and acquisition of the related ammunition is prohibited by the law.

A natural person may, not requiring an approval by the Ministry, acquire, collect and possess up to three pieces of antique weapons. For the purpose of acquisition, possession and placing more than three pieces of antique weapons, an approval of the Ministry shall be required and such person has to meet the applicable requirements (as in the response to question 43 b – items 1–5) and have adequate space for safe storage and possession of collected weapons. A natural person who was granted an approval to collect weapons may, in addition to antique weapons, also collect cold weapons, automatic and semi-automatic weapons that are no longer a part of an arsenal of armed forces or police, and are permanently disabled for use (permanently and fully filled in barrel or bullet chamber; in case of weapons where the barrel may be replaced without tools, such barrel must be permanently closed and attached to the weapon block). Antique weapons and weapons

that are possessed on the basis of approval to collect weapons, shall not be carried or used, and no ammunition shall be acquired, possessed or manufactured for such weapons.

Sports, shooting and hunting organizations and other companies and entrepreneurs that are registered for the performance of specific activities, shall keep records on the acquired weapons and ammunition, as well as on weapons and ammunition that are lent to use. Form of records is set by the Ministry.

Objects related to national ways of living and customs, historic events and phenomena and important persons, such as museum artifacts, are exhibited in museums or other premises ensuring the required protection of such artifacts in accordance with the Law on Museums.

45. Does the legislation, if any, exclude from its scope weapons and ammunition used for hunting or target shooting? If so, what rules are applied?

The issues on weapons and ammunition used for hunting and sport purposes are regulated under the Law on Weapons.

An approval to acquire a hunting weapon may be granted to a natural person involved with hunting activities, while a person practicing target shooting may be granted an approval to acquire a sporting weapon (more details provided under the response to question 43 b).

An approval to acquire firearms may be granted to companies and entrepreneurs that are directly involved in physical protection and protection of objects and goods and shooting organizations for the purpose of performing its professional activities, if those have ensured the premises for safe placement and storing of weapons.

For the weapons acquired on the basis of an approval, companies and entrepreneurs are issued a permit to possess a weapon.

Hunting weapons shall not be used outside of hunting areas, shooting ranges or other locations designated for practice shooting, and sporting weapons shall not be used outside shooting ranges or other locations designated for practice shooting. Outside hunting areas, shooting ranges or other location designated for shooting practice or competition, shoulder hunting and sport weapons may be carried only in canvases or boxes and unloaded, while the hand hunting and sporting weapons must be closed in canvases and locked in boxes where no ammunition shall be placed. Shooting organizations may lend weapons and ammunition to be used only by members of such shooting organizations while they are practicing shooting at shooting ranges, while a permit to transfer weapons and ammunition shall be issued to the person who is transferring the weapons.

In accordance with the Law on Wild Game and Hunting, wild game can be hunted by natural person holding a hunting permit and hunting certificate (a hunting permit is issued for each specific hunting area, while a hunting certificate is issued for all hunting areas in Montenegro). The mentioned documents are issued to a natural person, excluding foreigners, who passed the hunting exam and has a permit to carry hunting weapons and who is a member of the related hunting organization. Wild game may be hunted only with hunting weapons whose strength does not exceed the resistance of the actual wild game that is being hunted, and the Ministry of Agriculture, Forestry and Water Management, in agreement with the Ministry of Interior Affairs and Public Administration, issues more detailed regulations regarding the type and caliber of hunting weapons and minimum caliber and strength of bullets that may be used for hunting specific wild game.

46. Do you have any plans to modify the existing legislation? Please give details and timetables.

Law on Firearms was amended on 29 July 2008. No further amendments to the Law on Firearms are planned for the time being.

D. Checks for conformity with the rules on product safety in the case of products imported from third countries

47. Do you have legislation providing for conformity with the rules on product safety in the case of imported products? If so:

NO. All products in the market of Montenegro are treated equally – the principle of reciprocity and equivalence in terms of free movement of goods.

a) Since when has it been in force?

Montenegrin legislation on safety of products provides for equal treatment of national and imported products. Accordingly, it is not possible to specify an actual date of entrance into force of a special piece of legislation since the adoption of such a law would represent a trade barrier.

b) Please describe its broad outlines (which service is responsible for border controls and co-ordination regarding imported products, what is the procedure provided for, etc.?)

The Law on General Safety of Products transposes the Regulation (EC) 339/93 of the Council. Article 15 stipulates the obligation of competent customs authorities in the course of customs procedure to delay for three (3) days the release of products or parts/series of products into circulation and immediately notify the competent inspection authorities accordingly, where it is established that:

- Particular products or parts/series of products show specific characteristics that lead to justified doubt that those may represent serious risk for health and safety of consumers; or
- Particular products or parts/series of products are not accompanied by the appropriate certificates or are not properly labeled.

If the competent inspection authorities fail to undertake the applicable measures or notify the customs authority of undertaken measures within three (3) working days, the customs authority shall release the product or parts/series of products whose release was delayed into circulation, by all means provided that all other valid requirements are met.

Exchange of information among the authorities competent for market supervision is regulated by Article 13 of the mentioned Law, which further stipulates that information includes notification on:

- Application of protection clause within the meaning of Article 7 of the Law;
- Undertaken measures of competent authorities and conducted activities of manufacturers and distributors concerning the products representing a high risk.

List of Annexes:

Annex 14 - LAW ON ACCREDITATION, 6, 7,
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CONFORMITY ASSESSMENT OF
PRODUCTS WITH PRESCRIBED
REQUIREMENTS, 6

Annex 16 - LAW ON TECHNICAL
REQUIREMENTS FOR PRODUCTS AND