

# Screening report

## Montenegro

### Chapter 1 – Free Movement of Goods

**Date of screening meetings:**

Explanatory meeting: 14-17 January

Bilateral meeting: 4-6 March 2013

## I. CHAPTER CONTENT

The **general principle** of the free movement of goods implies that products must be traded freely from one part of the Union to another. The free movement of goods has been a key element in creating and developing the internal market. This principle is laid down by Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union (TFEU), preventing Member States from adopting and maintaining unjustified restrictions on intra-EU trade.

The TFEU provisions do not preclude prohibitions justified on grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, or the protection of industrial and commercial property, as well as other mandatory requirements recognised by the Court of Justice (e.g. protection of the environment). Such prohibitions must, however, remain proportionate and must not amount to arbitrary discrimination or a disguised restriction on trade between Member States.

Measures having equivalent effect to a quantitative restriction are prohibited subject to a limited and restrictive set of exceptions. This notably implies the elimination of technical barriers to trade and the compliance with the principle of mutual recognition. Sufficient administrative arrangements are foreseen to be put in place to apply the information exchange procedures laid down in Regulation (EC) No. 764/2008 and in the “strawberry” Regulation (EC) No 2679/98.

In a number of sectors the general principle is complemented by a harmonised regulatory framework. **Horizontal measures** define the quality infrastructure which Member States should put in place in areas such as standardisation, conformity assessment, accreditation, metrology and market surveillance.

The harmonised European product legislation, which needs to be transposed by each Member State, represents the largest part of the *acquis* under this chapter. It is based on the “old approach” (imposing precise product specifications) and the “new and global approach” (imposing general product requirements).

**New and Global Approach product legislation** covers low voltage equipment (LVD), electromagnetic compatibility (EMC), toys, machinery, lifts, noise emissions by outdoors equipment, emissions of pollutants from non-road mobile machinery engines, personal protective equipment (PPE), equipment and protective systems intended for use in explosive atmospheres (ATEX), medical devices, gas appliances, pressure vessels, cableway installations, construction products, recreational craft, eco-design requirements for energy-related products (ErP), and radio and telecommunications terminal equipment (R&TTE). **Old Approach product legislation** covers the areas of motor vehicles, chemicals, pharmaceuticals and cosmetics.

A series of **procedural measures** also require sufficient administrative capacity in order to be properly applied. These include a notification procedure in the field of technical standards and regulations laid down in Directive 98/34/EC as amended, Regulation (EEC) No 339/93 on *External border* checks related to product safety, Directive 91/477/EEC on the control of the acquisition and possession of weapons, legislation on crystal glass, footwear, textile labelling, pricing of medicinal products and Directive 93/7/EEC on cultural goods.

## II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

This part summarises the information provided by Montenegro and the discussion at the screening meeting. Montenegro indicated that it can accept the *acquis* regarding the Free Movement of Goods and that it does not expect any difficulties to implement the *acquis* by the time of accession.

## **II.a. General Principles**

### Legislative alignment

Montenegro stated that it intends to analyse its national legislation in order to align it with Articles 34-36 TFEU, but it also indicated that it does not yet have an elaborated timetable for this alignment. Montenegro considers that it does not have measures in place to prevent the import of industrial products based on price. Applicable legislation in Montenegro allows for free fixing of prices for all products with two exceptions: fuel (liquid oil-based fuel and electrical energy) and pharmaceutical products. Prices of liquid oil-based fuel are governed by the Regulation on the Method of Setting Maximum Retail Prices of Oil Derivatives (Official Journal (OJME) of Montenegro, No. 73/10) whereas prices of pharmaceutical products are set by the Law on Drugs (OJME 56/2011), and the resulting Regulation on Criteria for Setting Maximum Prices of Drugs (OJME 50/2007 & 62/2010).

Montenegro stated that its Law on Foreign Trade (OJME 28/04 & 37/07) stipulates that the government shall establish, maintain and make public an Export and Import Control List containing information on goods whose import and export are unrestricted, as well as information on goods whose import or export are subject to restrictions under this Law. Further control lists are made with regard to the Law on Foreign Trade in Weapons, Military Equipment and Dual-Use Goods and the Law on Export Control of Dual-Use Goods.

Montenegro also stated that its legislation, as regards the sale of certain goods, does not include measures that discriminate against persons that are not established or located in the country or that make it obligatory to store products on any grounds. The veterinary, sanitary and phytosanitary policies contained in national laws, regulations or administrative provisions do not include any measures which make it an obligation to have storage facilities in Montenegro.

Montenegro also indicated that industrial products are not subjected to any additional customs or other controls prior to marketing. Montenegro also stated that its legislation does not contain any provision which subject imported products to controls, other than those inherent in customs clearance procedures that are not carried out on domestic products.

The Montenegrin Law on Technical Requirements for Products and Conformity Assessment lays down the consumer information that has to be stipulated on a product, including the name of the producer or the importer and their address, and instructions and other prescribed documents and information on the product's safety in Montenegrin language. Article 4 of the Montenegrin Law on General Product Safety stipulates that when assessing the safety, the labelling of products, possible warnings and instructions for use and other information about the product shall be taken into account. This is also regulated by the Montenegrin Law on Consumer Protection

Montenegro indicated that it does not have a "Buy Montenegrin" campaign, nor does it provide any incentives for buying national products. However, in 2009, the Chamber of Economy of Montenegro registered the collective "GOOD FROM MONTENEGRO" trademark with the Agency for Intellectual Property of Montenegro (protected by WIPO).

Montenegro stated that it does not have any procedures in place with regard to parallel imports. As regards barriers to trade in Montenegro the Decree on the recognition of documents and the conformity mark stipulates the method for recognizing documents and conformity marks aimed at eliminating technical barriers to trade.

### Implementation capacity (incl. administrative capacity)

Montenegro informed that it has appointed the Department for Quality Infrastructure under the Sector for Internal Market and Competition of the Ministry of Economy as the contact point for technical regulations for both the WTO and the EU. Competent ministries use the internal

notification procedure and prescribed forms to inform the contact point about preparation and/or adoption of the technical regulations under their competence.

In several areas Montenegro acknowledged that the competent authorities currently do not have a sufficient number of trained staff. It also reported staffing and financial issues with regard to some of the structures necessary to actually implement the relevant acquis.

## **II.b. Horizontal Measures**

### Standardisation

Montenegro stated that the legal framework for standardisation consists of the Law on Standardization (OJME 13/08), and the national standards body is the Institute for Standardisation of Montenegro (ISME), established in 2007. Its main tasks are to develop standards, to provide information and build up relations with EU bodies and other stakeholders. It follows the rules of international and European standards organizations as well as World Trade Organization (WTO) Code of Good Practice.

ISME follows the work of the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) committees. It is an affiliate member of CEN and CENELEC since 2008 & 2009 respectively, but not yet a full member. It is not yet member of the European Telecommunications Standards Institute (ETSI) either. ISME works on regional cooperation with similar bodies in the region. It has technical agreements with the German, British and French standards bodies, and plans similar relationships with Turkish and US institutions. Under Montenegrin law EU and related standards are the basis for adoption of Montenegrin standards.

By the end of February 2013, ISME had issued 9,620 Montenegrin standards and related documents (it stated that 7,145 are identical to CEN standards (74.25%), 2,150 to CENELEC standards (22.34%), and 236 identical to ETSI standards (2.45%). ISME notifies CEN & CENELEC and it has standstill procedures if necessary. To date ISME has notified 47.35% of CEN and 34.77% of CENELEC standards. According to Montenegro, ISME currently has 22 employees, though its target foresees 32 employees.

### Conformity assessment

Montenegro stated that the regulatory framework for conformity assessment (CA) is not fully approximated via Montenegrin national legislation. Currently the Montenegrin Law on Technical Requirements for Products and Conformity Assessment (OJME 53/11) lays down the form, content and appearance of the conformity mark. It is the basis for prescribing technical requirements for products and for transposing the Directives under the new and sectoral approach. It also aligns Montenegrin legislation to several provisions of Decision 768/2008/EC on a common framework for the marketing of products and Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.

Montenegro stated that the current law stipulates that CA may be performed by a producer or by an authorised or designated body, and that procedures are established by technical regulations or standards referred to in the technical regulation. It also stipulates that CA may be performed by using one or several CA procedures or by an appropriate combination of the procedures in accordance with a separate technical regulation. It also defines the minimum requirements to be met by a CA body in order to be designated or authorised to perform conformity assessment, whereas separate technical regulations may establish additional requirements for designation or authorisation.

According to Montenegro, a large body of implementing legislation needs to be adopted in this area. Montenegro stated that respective drafts will be submitted to the Government for adoption and publication procedure by mid-2014. The Law on Technical Requirements for Products applies to all products whose safety requirements are not defined by specific technical regulation. Until all EU Old and New Approach Directives are approximated into Montenegrin law it applies Article 6 of its Product Safety Law (OJME 48/08) to enable its market surveillance bodies to assess goods, and uses harmonised standards as a conformity assumption.

Montenegro stated that its legislation already allows the use of CE marking for manufacturers to apply the mark to Montenegrin goods exported to the single market in the EU. However, Montenegro acknowledges that its legislation must be amended to ensure that the CE marking is used in a way that is aligned to the relevant EU legislation.

#### Accreditation

Montenegro stated that its regulatory framework in this area consists of the Law on Accreditation (OJME 54/2009) and a Decision on the establishment of the Accreditation Body of Montenegro (OJME 21/07) as the only national accreditation body. Accreditation is also prescribed by the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements through the procedure of designating/authorising conformity assessment bodies. Montenegro stated that it evaluates the competence of conformity assessment bodies based on accreditation certificates.

The Accreditation Body of Montenegro (ATCG) has its own statute, and Montenegro stated that its general and internal documents are designed to be consistent with the relevant *acquis* and European Accreditation Cooperation (EA) rules. It is a non-profit organisation with its own permanent staff, and external evaluators are engaged when needed. The ATCG register includes 19 accredited conformity assessment bodies: 14 test laboratories, 1 calibration laboratory, 3 inspection bodies, and 1 certification body.

The ATCG cooperates with the European Association (EA), and has been a full member since November 2011, is an associate member of the International Laboratory Accreditation Cooperation since 2009, and cooperates with accreditation bodies in other countries in the region via bilateral agreements. It participates in working groups of the EA, and is a full member in all technical committees.

#### Metrology

According to Montenegro, the Law on Metrology (OJME 79/08) is the basis of the metrology system in terms of legal metrology. The Bureau of Metrology is responsible for legal metrology and, inter alia, ensures the application of legal units of measurement in Montenegro. It is an independent governmental body supervised by the Ministry of Economy, established in September 2006 by the Government of Montenegro.

The Bureau is a member of several regional and international metrology organisations. It has received considerable EU support, and has founded several laboratories. It collaborates in EU MED programme activities. It performs type approvals and the verification of legal measuring instruments, and calibration of instruments and standards in the frame of founded laboratories. It has founded the laboratory for mass, temperature, length, pressure, volume, time and frequency, electrical quantities and electrical power. Montenegro stated that the measuring capacities of the laboratory are of varying levels – for three (mass, laboratory and length) it has already implemented a quality system in line with international standards, while for the others this process is in progress.

Montenegro stated that it has adopted implementing legislation which have aligned its national legislation EU Directives on Legal Measuring Units, Pre-packaged Products and Bottles used as

Measuring Containers. Montenegro further stated that these pieces of national implementing legislation may be reviewed following their implementation. In addition, in June 2013, national implementing legislation (rulebooks) were adopted (OJME 29/13) that transpose EU directives on Measuring Instruments (MID) and on Non-Automatic Weighing Instruments (NAWI).

#### Market surveillance

Montenegro stated that its legal framework for the safety and compliance of products currently relies on the Law on General Safety of Products (OJME 48/08), and that this Law stipulates the obligations of the customs authority and the market surveillance authority. In 2011 Montenegro also adopted a Law on Market Surveillance and a Law on Inspection Surveillance. It also relies on the Montenegrin Law on Technical Requirements for Products and Conformity Assessment for products under New Approach directives.

According to Montenegro, its procedural and organisational legislation in this area includes laws on Public Administration, on Market Inspection, on General Administrative Procedure and on Offences. Market surveillance provisions are also stipulated in specific sector legislation, while laws on Standardisation, Accreditation, and Metrology impact on the quality infrastructure for market surveillance. Montenegro stated that it foresees to further align its legal framework in this area with the *acquis* via new laws on General Product Safety and on Market Surveillance. The latter will foresee a product contact point, and the control of third country products. Montenegro expects that both laws will be drafted by the end of 2014.

In 2012 15,000 dangerous products were identified, and Montenegro reports a good response from businesses. Some products were temporarily recalled from the market, including lamps children, light chains, bikes, and hairdryers. The number of published notifications on dangerous consumer products is rising, and recall data is published in Montenegrin newspapers.

Responsibility for market surveillance covers a range of institutions, including the Administration for Inspection Affairs of Montenegro. The 2012 Market Surveillance Programme covered 17 types of products under the competence of six inspection bodies. Montenegro's Market Surveillance Coordination Body has been in place since October 2010. It is responsible for the coordination and cooperation between market surveillance bodies, supports harmonized market surveillance planning, analyses segregation of duties, and monitors implementation. The Administration for Inspection Affairs was established in 2012. It includes most of the inspectorates responsible for market surveillance, which facilitates cooperation between inspections. It has 12 inspectorates, with 52 inspectors.

#### Notification procedures

Montenegro stated that its Decree on the Notification of Technical Regulations, Standards, Regulations on Information Society Services and Conformity Assessment Procedures (OJME 11/13) aligns its legislation with the requirements of Directives 98/34/EC on Information Society services and 98/48/EC (amending Directive 98/34/EC). Montenegro also stated that Article 33 of its Law on Technical Requirements addresses technical regulations that do not have a basis in international standards or can be a barrier to trade.

The scope of the Decree covers technical regulations, standards, regulations on information society services and conformity assessments procedures. It establishes enquiry points including a national standardisation institute. Stakeholders, including standardisation institutions in EU Member States, are involved in the notification of standards and may signal that unnecessary barriers have been introduced.

#### External border checks

According to Montenegro, its Law on General Safety of Products is aligned to Regulation (EEC) No. 339/93. Article 15 of this law stipulates the obligations of the customs authority and the

market surveillance authority. With regard to the co-ordination between national market surveillance authorities and customs authorities on product conformity and safety checks at borders the Market Surveillance Coordination Body involves coordination and cooperation of surveillance bodies and customs authorities, and a Memorandum on Cooperation between the Administration for Inspection Affairs and the Customs Administration has been signed. A joint working group has been established to enable future joint activities to contribute to product conformity and safety checks in the most simple and effective way, together with the expert support from an EU project.

### **II.c. New and Global Approach Product Legislation**

Montenegro stated that the framework legislation for alignment with the *acquis* under the New Approach consists of its Law on Technical Requirements for Products and Conformity Assessment and its Decree on the form, content and appearance of a mark of conformity and its Decree on the recognition of documents and the conformity mark.

New Approach sectors where Montenegro indicated that this legal framework applies includes low voltage equipment, electromagnetic compatibility, toys, machinery, lifts, personal protective equipment, equipment and protective systems intended for use in potentially explosive atmospheres, and simple pressure vessels.

Montenegro acknowledged that the competent authorities currently do not have a sufficient number of trained staff with regards to many of the areas covered by the *acquis* under the New Approach, and that there are also resource constraints with regards to the bodies that ensure the implementation of the relevant legislation.

#### Low voltage equipment (LVD)

Montenegro stated that it has producers who place products covered by the Low Voltage Equipment Directive (2006/95/EC) on the internal market of the EU. It has established that there are no significant stocks of this type of products in Montenegro. The responsible government body is the Ministry of Economy. Montenegro indicated that the specific implementing legislation necessary for alignment has not yet been adopted.

Montenegro indicated that implementation shall be ensured by the competent inspection authorities of the Administration for Inspection Affairs, in cooperation with the coordination committee for market surveillance. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Electromagnetic compatibility (EMC)

Montenegro stated that its Law on Electronic Communications (OJME 50/2008, 70/2009, 49/2010, & 32/11) and Rulebook on Electromagnetic Compatibility (32/12) is aligned with Directive 2004/108/EC. This came into force on 1<sup>st</sup> January 2013. Montenegro has a small number of producers of such equipment, but it currently does not plan to establish a conformity assessment body in this sector.

The Administration for Inspection Affairs/Market Surveillance Department/Market Inspection is in charge of the implementation of the provisions of the law and implementing legislation. Currently if relevant equipment meets Montenegrin standards it is considered compliant, and products in question can be delivered to the market if they conform to the requirements of this law.

#### Toys

The competent authority is the Ministry of Health of Montenegro. Montenegro indicated that preparatory work to align its legislation with Directive 2009/48/EC has started, but no specific

date has yet been foreseen for adoption. Montenegro stated that it currently has a wide range of existing legislation in this area.

Toys placed on the Montenegrin market are currently inspected by sanitary inspectors and tested in two laboratories appointed to test them. The Administration for Inspection Affairs performs market surveillance in the area of toy safety. It has by 15 inspectors, who also perform other duties within their jurisdiction.

#### Machinery

Montenegro stated that it does not have production capacities in this area. There are no significant stocks of this type of products in Montenegro. The responsible government body is the Ministry of Economy, Department for Industry and Entrepreneurship, which is working on the adoption of the necessary specific implementing legislation. Montenegro stated that it currently has no plans to set up conformity assessment Bodies in this area.

#### Noise emissions by outdoors equipment

Montenegro stated that its Law on Environmental Noise (OJME 28/11) is partly aligned with Directive 2000/14/EC. The Montenegrin Ministry of Sustainable Development and Tourism (Department for Environment) is competent for the transposition of the Directive and plans to adopt the relevant implementing legislation necessary for alignment by the end of 2014.

According to Montenegro, market surveillance for the implementation will be performed by the Administration for Inspection Affairs in cooperation with the coordination committee for market surveillance. The Administration for Inspection Affairs has 7 persons conducting the surveillance of products in this field. Montenegro indicated that there are no manufacturers of these products or their components in Montenegro. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Lifts

Montenegro stated that there are currently no producers of lifts or of their components in Montenegro. Over the last three years the numbers of lifts installed in Montenegro were 85 in 2010, 63 in 2011 and 111 in 2012. Montenegrin legislation is not yet aligned with the *acquis*. It also stated that it is currently in the process of transposing Directive 95/16/EC into its national legislation via implementing legislation, which will replace up to eight previous pieces of implementing legislation relevant to lifts.

The implementation of the legislation transposing Directive 95/16/EC will be performed by the Administration for Inspection Affairs and the Housing Inspection. Market surveillance will be performed by the same bodies. The current level of resources available for this work are 9 inspectors of safety at work, and 2 housing inspectors. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Personal protective equipment (PPE)

There are currently no producers of Personal Protective Equipment in Montenegro. Montenegrin legislation is not yet aligned with the *acquis*. Implementation will be ensured by the competent inspection authorities of the Administration for Inspection Affairs. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

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

Montenegrin legislation is not yet aligned with the *acquis*. According to Montenegro, preparation of the specific legislation has not yet started.

Implementation of the legislation necessary to align with the *acquis* will be ensured by the competent inspection authorities of the Administration for Inspection Affairs, in cooperation

with the coordination committee for market surveillance. The electro-energetic inspection employs two persons, and there is one person in the mining inspection who conducts the surveillance of products related to explosive atmosphere equipment. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

### Medical devices

Montenegrin legislation is not yet fully aligned with the *acquis*. Montenegro stated that its current legislation consisting of the Law on Medical Devices (OJME 79/04) and the Law on Changes and Amendments to the Law on Medical Devices (OJME 53/09) is partially in line with the *acquis*. Montenegro stated that it foresees that further alignment will require the adoption of a fully compliant law and implementing legislation on classification. It also stated that it plans implementing legislation on the vigilance of medical devices.

Montenegro has an Agency for medicines and medical devices. This Agency is responsible for medicines, medical devices and narcotic substances. It also maintains registers of manufacturers and wholesalers, and registers of the importation of medical devices and of specialised stores for the retail of medical devices. Only persons entered into the register can market and import medical devices. The Agency also maintains a register of medical devices.

According to Montenegro, all wholesalers have to register with the Agency for medicines and medical devices, even if they are registered elsewhere. Montenegro envisages a suspensive clause whereby, if Montenegro accedes to the EU, such double registration will no longer apply to bodies registered in other EU Member States.

### Gas appliances

Montenegro does not have any manufacturers of gas appliances. Montenegrin legislation is not yet aligned with Directive 2009/142/EC. Montenegro stated that the preparation of the specific implementing legislation has been suspended, given that the directive is currently under review.

The competent authority for transposing the Directive into the national legislation of Montenegro is the Ministry of Economy. Implementation will be the responsibility of the Ministry of Economy and the Administration for Inspection Affairs. The Thermo-energetic Inspection currently has 1 person performing the oversight of products in the market related to pressure equipment and gas appliances. Montenegro intends to set up conformity assessment bodies in this sector. It has identified one body that could satisfy the criteria for nomination.

### Pressure Equipment

Montenegro does not have any manufacturers of pressure equipment. Montenegrin legislation is not yet aligned to the *acquis* (Directive 97/23/EC). The competent authority is the Ministry of Economy. Implementation will be the responsibility of the Ministry of Economy and the Administration for Inspection Affairs. Montenegro signalled that it intends to set up conformity assessment bodies in this area, and has identified two bodies that could satisfy the criteria for nomination.

### Simple Pressure Vessels (SPVD)

Montenegro does not have any manufacturers of simple pressure vessels. Montenegrin legislation is not yet aligned with the *acquis*. The competent authority is the Ministry of Economy. The specific implementing legislation is under preparation.

According to Montenegro, implementation will be the responsibility of the Ministry of Economy and the Administration for Inspection Affairs. Montenegro intends to set up conformity assessment bodies in this field. It has identified one body that could satisfy the criteria for nomination in this sector.

### Aerosol dispensers

Montenegro does not have any manufacturers of aerosol dispensers. Montenegrin legislation is not yet aligned with the *acquis*. Montenegro stated that it intends to align with Directive 75/324/EEC, as amended by Commission Directive 94/1/EC and Commission Directive 2008/47/EC, on aerosol dispensers. The competent authority is the Ministry of Economy.

The respective implementing legislation is expected to enter into force by the end of 2013. The competent authorities in charge of implementation of provisions of the Directive are the Ministry of Economy and the Administration for Inspection Affairs, in cooperation with the Coordinating body for market surveillance.

### Cableways

Montenegro stated that it intends to align its legislation in this area with Directive 2000/9/EC on cableways. It does not produce any cableways, but it has a relatively large number of cableway installations, notably in tourist areas.

Montenegrin stated that its legislation is not yet aligned with the *acquis*. Montenegro plans to adopt a Law on Safety and Interoperability on the Railway in late 2013 and after that a Regulation on Cable Cars. The responsible authorities are the Ministry of Transportation and Maritime Affairs and the Inspection for Railway Transport.

Market surveillance will be ensured by the Inspection for Railway Transport and the Administration for Inspection Affairs, in cooperation with Coordination body for market surveillance. The Ministry of Transport and Maritime Affairs has 10 inspectors performing oversight of products in the market, related to motor vehicles, recreational craft and cableways. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

### Construction products

Montenegro's construction sector represented around 5% of its GDP in 2010 and 2011. It has a small number of companies manufacturing construction products, but most construction materials, especially finishing materials, are imported. However, it possesses a wide selection of minerals that can be used in the manufacture of construction materials.

Montenegro stated that it intends to align its legislation with the Construction Products Regulation (EC) No. 305/2011. The Ministry of Sustainable Development and Tourism of Montenegro is the competent ministry. It has now started the preparation of legislation to align with the Construction Products Regulation, part of which is foreseen to be in place during 2013.

Montenegro foresees that implementing legislation will be adopted one year after the entry into force of this legislation. Implementation will be performed by the Administration for Inspection Affairs, in cooperation with the coordinating body for market surveillance. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

### Recreational craft

Montenegro stated that it does not have production capacities in this field except for individual boat builders. It intends to fully align its legislation in this area and considers that some of the measures contained in Directive 94/25/EC are reflected in its legislation. However, the current Montenegrin laws in this area only apply to recreational craft over 7 metres.

The Ministry of Transport and Maritime Affairs, Sector for Maritime Affairs, Maritime Safety Administration is the authority in charge of transposing Directive 94/25/EC into national legislation. The Maritime Safety Administration and the Administration for Inspection Affairs will ensure market surveillance.

Montenegro stated that it also plans to amend the laws on maritime and inland navigation and the law on the prevention of pollution to make them fully compliant with EU legislation. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Eco-design requirements for energy-related products (ErP)

Montenegro stated that the Law on Energy Efficiency (Article 36) introduced a legal basis for establishing the framework for eco-design of energy-related products. However this law was prepared in accordance with the previous EU Directive 2005/32/EC (Energy-using Products). Montenegro stated that legislation in this field is not yet aligned to the *acquis*. The competent authority for transposing the Eco-design Directive 2009/125/EC for energy-related products into the national legislation is the Ministry of Economy. It stated that it now plans to align with EU legislation by 1<sup>st</sup> January 2016.

Implementation will be the responsibility of the Ministry of Economy and the Administration for Inspection Affairs, which has 52 staff to perform a wide variety of inspections. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Radio and telecommunications terminal equipment (R&TTE)

Montenegro stated that it does not have any manufacturers in this area. Montenegro stated that it has almost entirely aligned its legislation on Radio and Telecommunications Terminal Equipment with Directive 1999/5/EC via implementing legislation (Rulebook on radio and telecommunications terminal equipment, OJME 32/12) which came into force on 1<sup>st</sup> January 2013, based on the following legal acts: Laws on Technical Requirements for products and Conformity Assessment Requirements (OJME 53/11), and on Electronic Communications (OJMEs 50/2008, 70/2009, 49/2010, 32/11). However, Montenegro acknowledged that further implementing legislation is necessary, which is planned to be adopted in 2014. The responsible legislative authority is the Ministry for Information Society and Telecommunications.

The Montenegrin Agency for Electronic Communications and Postal Services is responsible for publishing the interface to public electronic communications networks which are applied in Montenegro, and for giving an opinion on the possibility and requirements for marketing and use of radio equipment that does not use radio-frequencies in accordance with the national plan. It is also responsible for managing the radio frequency spectrum in Montenegro. The Agency has designated one person to be in charge of these activities.

Market surveillance is conducted by the Administration for Inspection Affairs/Market surveillance Department/Inspectorate for communications and postal services. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

If an RTTE product meets Montenegrin standards and it is deemed compliant it can be freely placed on Montenegrin market. If equipment does not use radio-frequencies in accordance with the national plan there is 30 day process to approval. A product can only be banned if it could cause harmful interference to the spectrum poses a threat to human health or does not effectively uses the spectrum.

#### Explosives for civil uses

Montenegro considers that its Law on Explosive Substances (OJME 49/08) is partially compatible with Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses. It does not cover conditions for sales, and other aspects covered by the above mentioned Directive. The current law also does not foresee identification codes. Montenegro stated that it intends to amend the law to establish a higher level of harmonization. The law is planned to be adopted by the end of 2013.

The Ministry of Interior of Montenegro is competent authority. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

Implementation will be ensured by the Administration for the Inspection Affairs in cooperation with the coordination committee for market surveillance. The Administration for the Inspection Affairs currently has 8 inspectors, who are responsible for the inspection of explosive materials, explosives for civilian use, pyrotechnic devices, and flammable materials, liquids and gases.

Montenegro stated that it intends to adopt implementing legislation which foresees registries of the use of such products. The Ministry of Interior and the police monitor and record transport and trade of these products, and issue approvals and licences. The police control the transport of these goods via the Law on Border Controls, and can perform inspections and seize forbidden substances.

#### Pyrotechnic articles

Montenegro stated that its Law on explosive substances is partially compatible with Directive 2007/23/EC on the placing on the market of pyrotechnic articles. It does not cover the obligations of manufacturers, importers and distributors, the categorization of pyrotechnics, the age limit for the use of pyrotechnics, or the terms of sale of pyrotechnics. Montenegro intends to make amendments to the existing law to establish a higher level of harmonization. An amendment is planned to be adopted by the end of 2013. The Ministry of Interior is competent for the transposition of this Directive. Implementation will be ensured by the competent inspection authorities of the Ministry of Interior in cooperation with the coordination committee for market surveillance. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

### **II.d. Old Approach Product Legislation**

Montenegro acknowledged that the competent authorities currently do not have a sufficient number of trained staff with regards to many of the areas covered by the *acquis* under the Old Approach, and that there are also resource constraints with regards to the bodies that ensure the implementation of the relevant legislation.

#### Motor vehicles

Montenegro stated that neither cars nor their components are built in Montenegro; it imports all new and used cars and components. Montenegro does not have a motor-vehicle importers association. Montenegro plans to align its legislation with the *acquis* through its Law on Road Traffic Safety (OJME 33/2012), its Law on Technical Requirements for Products and Conformity Assessment and rules on technical requirements. The Law on Road Traffic Safety is foreseen to enter into force by the end of 2013.

According to Montenegro, its current legislation requires vehicles to meet Euro 3 environmental criteria and other EU requirements, and to have a vehicle audit and inspection. If a car meets the requirements it is homologated for being placed on the Montenegrin market and the relevant certificate is issued. Type homologation for new vehicles has only recently been implemented in Montenegro.

Montenegro stated that it currently has some exceptions to the obligation for homologation (including diplomatic cars, vehicles destined for museums, for sports use, military vehicles, special vehicles, machinery, donated vehicles, and cars for disabled persons). Market surveillance is foreseen to be provided by the Inspection for Road Traffic and the Administration for Inspection Affairs. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

Montenegro declared that it will fully align with the EU motor vehicle type approval legislation by the time of accession, and this without requesting any transitional period or derogation. Furthermore, Montenegro also declared that it will not accede to any UNECE regulation under the 1958 Agreement to which the EU has not acceded.

#### Emissions of pollutants from non-road mobile machinery engines

Montenegro stated that neither such equipment nor their components are built in Montenegro, but that Montenegro imports new and used equipment, which have to meet certain existing requirements. The legal framework under which Montenegro plans to align with the *acquis* consists of its Law on Road Traffic Safety (OJME 33/2012), its Law on Technical Requirements for Products and Conformity Assessment and rules on technical requirements. According to Montenegro, implementing legislation necessary to fully align with the *acquis* in this area remains to be adopted.

Montenegro stated that its current legislation regarding Emissions of pollutants from non-road mobile machinery engines requires such equipment to meet Euro 3 environmental criteria and other EU requirements, and to have a vehicle audit and inspection. There is a Montenegrin institution that performs these checks. If the equipment meets the requirements it is homologated for being placed on the Montenegrin market and a relevant certificate is issued.

Montenegro stated that market supervision is foreseen to be provided by the Inspection for Road Traffic and the Administration for Inspection affairs, and that it currently has no plans to set up conformity assessment bodies in this area.

#### Chemicals – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Montenegro stated that it has no manufacturers of chemicals, but stated that it is aware that REACH (the *acquis* covering Registration, Evaluation, Authorisation and Restriction of Chemicals as provided by the Regulation (EC) No 1907/2006 and a number of amendments and implementing legislation) applies to the whole supply chain including down-stream users and distributors. The Montenegrin Ministry of Sustainable Development and Tourism is competent for drafting the legislation in this area and for the supervision of its implementation. Montenegro stated that its Law on Chemicals (OJME 18/12), which entered into force in March 2013, partly aligns its legislation to REACH. In Montenegro, the Environmental Protection Agency maintains a register of chemicals.

Montenegro is planning to nominate bodies for control of meeting essential requirements of REACH in terms of the safety of products in this field which are placed on its market. The market surveillance in this field will be provided by the Administration for Inspection Affairs and the coordination committee for market surveillance. The Administration for Inspection Affairs has ecological and health-sanitary inspectors, responsible for the surveillance in this field. Montenegrin legislation provides for a system of sanctions (fines).

However, there is a difference between REACH and Montenegrin rules on the obligations of registration of substances of the manufacturers and importers of chemicals. REACH provides that for the substances produced or imported into the EU in quantities of 1 tonne or more per year per company, manufacturers and importers need to demonstrate that they have appropriately identified and managed the risks by means of a registration dossier submitted to the European Chemicals Agency (ECHA). In Montenegro the registration obligation concerns chemicals manufactured in quantities of 100 kg or more. As REACH fully harmonises the provisions on restrictions of chemicals at the EU level, the Montenegrin legislation needs to be aligned accordingly with REACH provisions.

Montenegro stated that it plans the adoption of further national implementing legislation in order to gradually align with REACH requirements.

### Chemicals (Classification, Labelling and Packaging, CLP)

Montenegro stated that intends to align its legislation with Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures within the framework of the Montenegrin Law on Chemicals. While the body text of the CLP Regulation was implemented, its annexes still required implementation through national legislation. Montenegro announced that the drafting of the national legislation was expected to be accomplished by the end of 2013. The Montenegrin Ministry of Sustainable Development and Tourism is competent for drafting the legislation in this area as well as the supervision of its implementation.

The Environmental Protection Agency is responsible for gathering relevant information relating to the classification of chemicals and on the health effects of mixtures, as well as for the exchange of information and for the approval for the use of alternative chemical names. According to Montenegro, enforcement is carried out by the Administration for Inspection Affairs. It has ecological and health-sanitary inspectors, responsible for the surveillance in this field. Montenegrin legislation provides for a system of sanctions (fines).

### Detergents

Montenegro stated that its Law on Chemicals (see above) is partly aligned to the *acquis* on detergents (including Regulations (EC) 648/2004, 259/2012, 551/2009, and 907/2006) is. Montenegro indicated that it does not have any detergent manufacturers.

The Montenegrin Ministry of Sustainable Development and Tourism is competent for drafting the legislation in this area as well for the supervision of its implementation. According to Montenegro, market surveillance will be provided by the Administration for Inspection Affairs and the coordination committee for market surveillance. The Administration for Inspection Affairs has ecological and health-sanitary inspectors, responsible for the surveillance in this field. Montenegro stated that it intends to authorise laboratories to check the compliance of detergents with Regulation (EC) No. 648/2004 and its Annexes.

### Fertilisers

Montenegro stated that it does not have any fertiliser producers. Montenegro stated that its Law on Plant Nutrition Products (OJME 48/07 & 76/08) is partly aligned to Regulation (EC) No. 2003/2003 on fertilisers is the. It also stated that there are no differences in requirements between Regulation (EC) 2003/2003 and its Law on Plant Nutrition.

However, Montenegro indicated that the Law on Plant Nutrition Products incorporates national provisions relating to other types of fertilisers such as organic fertilisers, microbiological fertilisers, soil refinement substances and substrates, so it goes beyond the scope of Regulation (EC) No. 2003/2003. The Ministry of Agriculture and Rural Development of Montenegro is the administrative authority responsible for creating policy and adopting regulations in the field of plant nutrition products.

Montenegro also stated that it foresees to adopt implementing legislation on Good Agricultural Practices to introduce EU best practices into the country. Its implementing legislation on special conditions on plant regulation also applies and Montenegro stated that its legislation is aligned with some REACH registration aspects and limitations of chemical products. It is also relevant to explosives, as fertiliser components can be used for making explosives. In Montenegro there is a specific procedure to put fertilisers on the market; Montenegro stated that it would like to invest in this area to ensure that safety aspects are respected to the extent possible.

The Montenegrin Phytosanitary Administration is the public administration authority in charge of the implementation of regulations relating to mineral fertilisers. It also performs controls at the border, both for imports and products in transit. There are specific border points that are the

only entry points for these products. If all aspects are compliant, the import is authorised, if not the product can be tested. If suspicions are confirmed the product is marked “import prohibited”. The Administration for Inspection Affairs performs market surveillance of plant nutrition products through its phytosanitary inspectors.

#### Drug precursors

Montenegro stated that it does not produce substances that can be used in the production of narcotic drugs and psychotropic substances. Montenegro stated that its Law on the Control of Production and Trade of Substances that can be used to Manufacture Narcotic Drugs and Psychotropic Substances (OJME 83/09) of 14 December 2009 is partly aligned to Regulation (EC) 273/2004 on drug precursors. According to Montenegro, implementing legislation establishing a list of substances that can be used in the production of narcotic drugs and psychotropic substances (OJME 55/10) will be adopted by the end of 2014. The competent authority is the Ministry of Health.

Montenegro stated that the aim of its Law on the Control of Production and Trade of Substances that can be used to Manufacture Narcotic Drugs and Psychotropic Substances is to monitor and control production and trade of these substances to protect life and health, and it divides them into three categories: category 1 is main narcotic raw material, category 2 is implementing narcotic raw materials, and category 3 is narcotic raw material that can be replaced by others. This classification is performed by the Ministry of Health as proposed by the Agency for Medicines and Medical Devices and by the Police. The Ministry of Health or its agency retains all the relevant data on these licences. It also informs competent authorities in third countries in cases of export. For transit permissions sent to applicant and customs authorities are required to be returned within 15 days of trade.

Montenegro stated that a legal entity with a licence has to provide an annual report to the Ministry of Health or the Agency each year, and it has to inform the Ministry of Health of any unusual orders or thefts. Implementation of the Regulation will be done by the Administration for Inspection Affairs for market surveillance, in cooperation with the coordinating body for market surveillance, Customs Administration and the Ministry of Interior. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Good laboratory practice (GLP)

Montenegro stated that its Law on Medicines, published on 25 November 2011 (OJME 56/11) is partly aligned to the *acquis* with regard to GLP for medicinal products for human and veterinary purposes via the adoption of implementing legislation under the framework of; it plans to have implementing legislation in place by the end of 2014 to align with the *acquis*.

Montenegro stated that its Law on Chemicals (see above) is partly aligned with the *acquis* with regard to GLP for toxicological and eco-toxicological chemicals tests. Montenegro stated that its current Law on Medicines gives a definition of GLP and foresees that it is obligatory for a medicine (both human and veterinary) to undergo pharmacological-toxicological testing in accordance with the GLP before being placed on the market.

The provisions of the Directives in terms of Good Laboratory Practice Principles, details of the national GLP compliance programme, and measures necessary for verification of compliance with the principles of GLP, have not yet been introduced into Montenegrin legislation. Montenegro stated that its Law on Medicines foresees that the Guidelines on Good Laboratory testing will be adopted and published.

A GLP compliance monitoring authority has not yet been established in Montenegro. Montenegro stated that it needs to strengthen its administrative capacities in this area. With regard to GLP for toxicological and eco-toxicological chemicals tests Montenegro stated that the

remaining provisions will be aligned with the *acquis*. Implementing legislation on guidelines and requirements for the GLP, and on more detailed content of the application and GLP certification is planned. Montenegro indicated that it has yet to align with the *acquis* for GLP relevant to cosmetics or food additives.

For GLP for medicinal products for human and veterinary use the competent authority for the transposition is the Ministry of Health. For GLP for toxicological and eco-toxicological chemicals tests the competent authority is the Ministry of Sustainable Development and Tourism.

Market surveillance will be provided by competent inspection authorities. Non-clinical chemical tests are performed to evaluate the chemicals and assess the risk of their potential danger to life and human health and the environment. However, there are no laboratories in Montenegro that do non-clinical testing at the moment. Montenegro intends to set up conformity assessment bodies in this field.

### Pharmaceuticals

Montenegro stated that it has partly aligned with the *acquis* in this area. The legislative framework in the area of medicinal products in Montenegro is the Law on Medicines (see above) and seven adopted pieces of implementing legislation. Montenegro acknowledged that a set of Decrees, Regulations and Guidelines need to be adopted in order to align its legislation with the *acquis*.

Montenegro considers that harmonised areas include the deadlines for placing on market (210 days). There is a fast track procedure for EU registered medicines (150 days). Montenegro does not have National Guidelines on quality, safety and efficacy of medicines so it uses EU ones. According to Montenegro, market exclusivity for innovative medicines are in line with the *acquis*. Montenegro stated that it is also harmonising its legislation in the area of documentation; the register can be accessed on agency web site.

Montenegro's Law on Medicines foresees the conditions for registration. Montenegro considers that its marketing authorisation is partially harmonised - authorisation can be revoked if a product is not placed on the market within 3 years. With regard to manufacturing the Agency is competent to issue licenses. Montenegro still needs to adopt implementing legislation for some aspects.

Montenegro stated that with regards to wholesale some requirements exist but that implementing legislation remains to be adopted. Labelling has to be in accordance with authorisation and include an information leaflet/label. Implementing legislation on labelling has not yet been adopted in this area.

With regard to pharmacovigilance some measures are in place, but this is a rather new activity in Montenegro. A national notification system is in place and Montenegro is a full member of the WHO UMC since 2009, but implementing legislation has not yet been adopted. With regard to advertising, only the advertising of prescription medicines is allowed to health care professionals. With regard to falsified medical products Montenegro considers that its legal definition is in line with WHO rules.

In terms of administrative capacity the Ministry of Health has 11 staff (4 full time) working in this area. The Agency for Medicines and Medical Devices is competent for human and veterinary medicinal products, performing competences set in the Law on Medicines. There are 26 staff in the Agency for Medicines and Medical Devices and 8 staff in the veterinary administration working in this area.

Under the Law on Medicines the Agency for Medicines and Medical Devices is authorized to issue licenses for manufacturing, for wholesalers, and GMP certificates. It monitors the

consumption of medicines in Montenegro (according to WHO ATC/DDD and financial parameters). The Agency started issuing marketing authorization for human medicines in 2009.

According to Montenegro, 65% of all registered medicines in Montenegro are generic and 35% are innovative, currently there are 27 licensed wholesalers for human medicines, and 2 licensed domestic manufacturers, both producing generic medicines. Licenses for the wholesale of medicines containing narcotic substances are issued separately, in line with Montenegro's Law on the prevention of drugs abuse, and 9 wholesalers have so far obtained this license. There are no licensed manufacturers of veterinary medicinal products or medicinal premixes in Montenegro, all such products are imported.

### Cosmetics

Montenegro stated that it has not yet harmonised its legislation with the Cosmetics Directive 76/768/EEC. The current Montenegrin legislation is a law dating from 1991, and some provisions of the general Product Safety law are also applicable. Current implementing legislation foresees three classifications of cosmetics. Montenegro stated that in Montenegrin law cosmetics have to be marketed in the original packaging of the manufacturer, which has to contain certain data. It also stated that in Montenegrin law cosmetics cannot adversely affect health.

In Montenegro the Department of Health supervises the production, importation and trade of cosmetic products. It has begun preparations for harmonisation, deemed necessary for the free circulation of safe cosmetic products and for effective supervision. Monitoring is carried out by 15 sanitary inspectors, who also oversee other areas of competence including toy safety. In Montenegro, two laboratories perform quality control and health and safety testing: the Institute of Public Health of Montenegro in Podgorica (microbiological, physical and chemical testing) and the Center for Eco-Toxicological Research in Podgorica (physical and chemical testing).

## **II.e. Procedural Measures**

### Transparency in relation to pricing and reimbursement of medicinal products

Montenegro stated that its Law on Medicines and the Decree on criteria for setting maximum prices of medicines (OJ 50/2007 & 62/2010) is partly aligned with the *acquis* with regard to transparency in relation to pricing and reimbursement of medicinal products. Montenegro also stated that it also foresees to adopt a new Decree on criteria for setting the maximum prices of medicines.

Data on consumption of medicines in Montenegro is collected and processed by the Agency for Medicines in line with the Law on Medicines. The Agency for Medicines and Medical Devices will establish maximum prices for the medicines for human use which are covered by the National Health Insurance Fund, planned to start in 2013.

There are currently two lists for medicines in Montenegro: List "A" covers medicines that are issued at the expense of the Health Insurance Fund, list "B" covers medicines that are issued at the expense of the Health Insurance Fund and that also have the approval of the Commission for medicines of the Fund.

The current Law on Medicines does not set any penalties in case of non-compliance with the determined maximum price. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

### Crystal glass

Montenegro does not have any domestic manufacturers of glass products. Montenegro intends to align its legislation with the *acquis*, and the relevant implementing legislation is planned to be

drafted in 2014. The Administration for Inspection Affairs will ensure market surveillance in cooperation with the Market Surveillance Coordination Body. Montenegro intends to set up conformity assessment bodies in this field.

#### Textiles

Montenegro does not have any domestic manufacturers of textiles. Montenegro stated that it foresees that appropriate implementing legislation will be created to align with Regulation (EU) 1007/2011. Montenegro stated that the Administration for Inspection Affairs will ensure market surveillance in cooperation with the Market Surveillance Coordination Body. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Footwear

Montenegro does not have any domestic manufacturers of footwear. Montenegro stated that it foresees that appropriate implementing legislation will be created to align with the respective provisions of Directive 94/11/EC. Montenegro stated that this implementing legislation will be drafted by the end of 2013. Montenegro stated that the Administration for Inspection Affairs will ensure market surveillance in cooperation with the Market Surveillance Coordination Body. Montenegro stated that it currently has no plans to set up conformity assessment bodies in this area.

#### Notification procedures

Montenegro stated that its Decree on the notification of technical regulations, standards, regulations on information society services and conformity assessment procedures (OJME 11/13) is fully aligned with the requirements of Directives 98/34/EC and 98/48/EC. Article 33 of this Law addresses technical regulations that do not have a basis in international standards or can be a barrier to trade.

The scope of the Decree covers technical regulations, standards, regulations on information society services and conformity assessments procedures. It establishes enquiry points including a national standardisation institute, and estimates that most of the provisions of the Directives are included in the Decree. With regard to the notification of standards stakeholders are involved, including Standardisation Institutes in EU Member States. Stakeholders can notify unnecessary barriers where they consider that these have been introduced.

#### External border checks

According to Montenegro, its Law on General Safety of Products harmonises its legislation with the *acquis*. Article 15 of this law stipulates the obligations of the customs authority and the market surveillance authority.

With regard to the co-ordination between national market surveillance authorities and customs authorities on product conformity and safety checks at borders the Market Surveillance Coordination Body involves coordination and cooperation of surveillance bodies and customs authorities, and a Memorandum on Cooperation between the Administration for Inspection Affairs/Market Inspection and the Customs Administration has been signed. A joint working group has been established to enable future joint activities to contribute to product conformity and safety checks in the most simple and effective way, together with the expert support from an EU project.

#### Firearms

The production of weapons in Montenegro is authorised for weapons producers possessing safe storage facilities - there is currently such one manufacturer. Montenegro stated that it plans to adopt a Law on Weapons in 2013 in order to partly harmonise its national legislation with the *acquis*. The law will also enable the owners of prohibited weapons to hand them in, and for

owners without weapons possession documents to submit an application without the obligation to prove the weapon's origin under certain conditions.

However, the following aspects still need to be integrated into law: the obligation to mark transferred weapons for easy identification, the European weapons pass, and the exchange information with other country in regard to weapons transfer. It also plans to adopt a law on the production of weapons.

The Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods covers foreign trade in controlled goods (arms, military equipment, and non-military lethal goods). Montenegro stated that it is drafting a new Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods to further harmonise its legislation with the *acquis* for adoption in the third quarter of 2013. The current Law on Weapons (OJME 49/04, 49/08 & 20/11) lays down the categories of firearms that can be acquired and possessed by private persons and that are either prohibited or subject to authorisation or declaration. Implementation will be ensured by the Ministry of Economy.

Montenegro's stated that its Decision on establishing the national control list of arms and military equipment (OJME 52/12) is fully harmonized with the European List of Arms and Military Equipment. Montenegrin border control and international border police cooperation (based on international treaties) is performed in accordance with the Law on Border Control, which is implemented by the police.

Article 6 of the Montenegrin Law on Foreign Trade in Arms, Military Equipment and Dual-Use Goods and the Decision on establishing the list of non-military lethal goods weapons, ammunition, and energy material (OJME 66/10) is harmonized with the relevant EU Regulation. Foreign trade in such goods may be conducted by persons (physical and legal) previously registered in the Register kept by the competent authority (the Ministry of Economy of Montenegro).

#### Cultural Goods

Montenegro has not yet harmonised its legislation relating to Directive 93/7/EEC.

### **III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY**

Montenegro's legislation is partially in line with the *acquis* in Chapter 1, Free Movement of Goods. Implementing structures have been established or identified in several sectors. Montenegro has also produced plans for alignment in many areas. However, Montenegro needs to build up its administrative capacity and staffing levels in several sectors to ensure the effective implementation of the *acquis*.

Montenegro needs to amend its legislation to ensure that there is no legal ambiguity with regard to the use of CE marking. Montenegro has not aligned its legislation with Articles 34-36 TFEU. Its current legislation is only partly aligned with the *acquis* on metrology and market surveillance.

Montenegro's standardisation body (ISME) needs to become a full member of CEN and CELENEC. It has also established an Accreditation Body of Montenegro, but its application for European Accreditation Multilateral Agreement has not yet been submitted.

Specific sectoral implementing legislation is sometimes being developed in parallel with the basic framework legislation, such as for medical devices. However, in some cases Montenegro's current basic framework legislation needs to be adapted to the *acquis*, such as in the areas of cosmetics or explosives, before specific sectoral implementing legislation can be drafted.

### III.a. General Principles

Montenegro has not aligned its legislation with Articles 34-36 TFEU and it does not yet have an elaborated timetable regarding the adoption of the legislation and implementation/enforcement capacity in order to ensure this alignment. Montenegro needs to analyse national legislation in order to harmonise gradually with Articles 34-36 TFEU, and to identify outdated technical and other requirements for products which are not in line with the *acquis* and the need for mutual recognition clauses in individual regulations. The building-up of institutions and their role in the system will also have to be defined.

However, Montenegro stated that under some elements of its legislation it has established Export and Import Control Lists containing information on goods whose import and export are unrestricted. The Commission notes that, in principle, these lists should not exist as, although Article 36 TFEU provides for exceptions to the free movement of goods, such exceptions cannot normally be construed as covering whole product classes. Even if such were the case, special legislation (e.g. in the case of illegal drugs) would be needed to define the exception.

### III.b. Horizontal Measures

Montenegro has reached a reasonable level of alignment with the *acquis* on standardisation and accreditation.

As regards metrology and market surveillance in particular Montenegro's legislation is partly in line with the *acquis*. A standardisation body (ISME) has been established since 2007 and it is issuing Montenegrin standards. However, ISME will need to decide how it intends to deal with new ETSI harmonised standards. It also needs to become a full member of CEN and CELENEC. ISME finds it hard to establish technical committees due to the small size of the Montenegrin market. Montenegro needs to increase the number of employees and the volume of funding necessary for the operation and development of ISME.

Montenegro's legislation is not fully aligned with the regulatory framework for conformity assessment. The metrology laboratories have yet to be accredited, and the strategy for metrology development adopted.

The Accreditation Body of Montenegro is established, has a good level of cooperation in the region, and is a member of EU and international bodies. However it needs to ensure better cooperation with national authorities and with stakeholders, and to clarify how it evaluates the competence of conformity assessment bodies. Moreover its application for European Accreditation Multilateral Agreement has not yet been submitted, and the status remains unchanged. Montenegro now has 19 Conformity Assessment Bodies accredited (May 2013), but reports that interest in accreditation remains limited. Montenegro's requirements for the designation for the conformity assessment bodies need to be further clarified and specified.

Montenegro needs to further adapt its legal framework in the area of market surveillance via new laws on General Product Safety and on Market Surveillance. There is also the need to introduce a set of implementing laws on information exchange, as well as guidelines in this regard.

Montenegro needs to ensure that the use of the CE marking is not an obligation when they are put on the Montenegrin market, as this could result in legal ambiguity. The CE marking requirement can only be applied by either a Member State of the EU or a third country based on the EU's explicit agreement (e.g. EEA Agreement, EU-Turkey Customs Union). Montenegro needs to amend its legislation to ensure that there is no legal ambiguity.

Montenegro's Law on General Safety of Products aligns with Regulation (EEC) No. 339/93. But this regulation has been repealed and replaced by Regulation (EC) No. 765/2008, so its Law on

General Safety of Products will need to be amended or a new law adopted to align with the new Regulation.

### **III.c. New and Global Approach Product Legislation**

Montenegro has reached a reasonable level of legislative alignment in the areas of Electromagnetic compatibility (EMC), and Radio and Telecommunications terminal equipment (R&TTE).

Montenegrin legislation is partially aligned with the *acquis* on Medical Devices, and Eco-design for energy-using products.

The level of legislative alignment is limited as regards Low Voltage equipment (LVD), Toys, Machinery, and Noise Emissions by outdoors equipment, Lifts, and Recreational Craft.

Montenegrin legislation is not in line with the *acquis* on Personal Protective Equipment (PPE), Gas Appliances (GAD), Pressure Equipment, Simple Pressure Vessels (SPVD), Equipment for Explosive Atmospheres (ATEX), and Cableways.

Issues to be addressed include the application of planned new legislation on Lifts with regard to old lifts.

Other issues are the application of the Construction Products Legislation (concerning the application of specific provisions), Recreational Craft (with regard to the difference in the definition of boats between Montenegrin and EU legislation).

Montenegro needs to strengthen its administrative capacity in the relevant ministries and also in the Agencies and other bodies that ensure implementation, both to ensure alignment and also to ensure the implementation of legislation once aligned to the New Approach *acquis*.

### **III.d. Old Approach Product Legislation**

Montenegro has reached a reasonable level of legislative alignment in the areas of Drug Precursors.

Montenegrin legislation is partially aligned with *acquis* in the area of chemicals including REACH (however, there is notably a difference between REACH and Montenegrin rules on the obligations of registration of substances and this needs to be aligned), CLP, detergents, and fertilisers, GLP, and pharmaceuticals.

The level of legislative alignment is limited as regards explosives for civil use, crystal glass, textiles, footwear and firearms.

Montenegrin legislation is not in line with the *acquis* on cosmetics, emissions of pollutants from non-road mobile machinery engines, and on motor vehicles.

Issues to be addressed include type approval for motor vehicles, and the application of national fertiliser legislation to types of fertilisers not covered by the *acquis*. Montenegro also needs to strengthen the administrative capacity in the ministries and in the other bodies respectively responsible for the alignment and the implementation of its legislation with regard to Old Approach *acquis*.

### **III.e. Procedural Measures**

Montenegro's legislation is partially in line with the *acquis* on firearms and on external border checks. Montenegro plans to start to analyse its national legislation in order to harmonise it gradually with Articles 34-36 TFEU. However, Montenegro does not yet have an elaborated timetable for both the legislation and the implementation/enforcement capacity. As regards

external border checks, further work needs to be done to make product conformity and safety checks more effective.