

# **Screening report**

## **Serbia**

### **Chapter 1 – Free Movement of Goods**

**Date of screening meetings:**

Explanatory meeting: 17-20 June 2014

Bilateral meeting: 9-12 September 2014

## 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 and chemicals<sup>1</sup>.

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, legislation on the trade in weapons, defence products, crystal glass, footwear, textile labelling, pricing of medicinal products and Directive 2014/60/EU on cultural goods.

## II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

This part summarises the information provided by Serbia and the discussion at the screening meeting. Serbia 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.

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<sup>1</sup> Pharmaceuticals and cosmetics are covered under Chapter 28.

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

### Legislative alignment

Serbia stated that its legislation is partly aligned with Articles 34-36 TFEU. It is currently preparing a methodology in order to ensure full alignment. It expects to finalise this preparation phase during 2014, to adopt Action plan in 2015 and implement the resulting action plan in the period 2015-2018.

Applicable legislation in Serbia allows for free fixing of prices for all products apart from those covered by the following exceptions: the Serbian Law on Medicines and Medical Devices, its Tobacco Law and its Law on Excise Tax.

Serbia stated that its Arms and Military equipment control list, adopted by the Government of the Republic of Serbia in July 2014 is fully harmonised with the EU Common Military List adopted by the Council on 17 March 2014. With regard to explosives for civil use and pyrotechnic articles Serbia indicated Directives 2014/28/EU and 2007/23/EC are not transposed in national legislation.

Serbia also stated that some of its legislation includes measures that make it obligatory to appoint a representative or to provide storage facilities, notably its Law on explosive substances. Serbia also has provisions which allow only traders holding a production licence or wholesale licence to import in the following laws: on Manufacturing and Sale of Narcotic Drugs; on Tobacco; and, with regards to precursors, on Substances Used in Illicit Production of Narcotic Medicines and Psychotropic Substances. For chemicals Serbia stated that it requires legal entities and entrepreneurs to hold a permit for placing of particularly hazardous chemicals on the market. It stated that the import of chemicals is in not limited, nor conditioned by holding of a production or wholesale license, and that it is considering the repeal of the above stated provisions of the Law on Chemicals.

The Serbian Law on Technical Requirements for Products and Conformity Assessment is the general legal basis for the adoption of technical regulations in Serbia, except for a few specific cases where technical requirements are laid down in specific laws. Serbia acknowledged that some areas of this law differ from the *acquis*, and stated that further alignment is planned.

The Serbian Law on Trade and the Law on Health & Safety of Products of General Use include an obligation to label the origin of the goods in question (a "Made in ..." label). The Law on Consumer Protection and the Law on trade provide that goods in retail have to be with a declaration in Serbian language, in Cyrillic or Latin alphabet. Serbian legislation also includes restrictions on advertising or use with regard to tobacco, alcohol, and games of chance.

Serbia indicated that it does not have a "Buy Serbian" campaign, nor does it provide any incentives for buying national products. It also stated that it does not have any procedures in place with regard to parallel imports.

As regards barriers to trade Serbia indicated that for imported industrial products covered by its legislation on low voltage equipment (LVD), electromagnetic compatibility (EMC), telecommunications terminal equipment (R&TTE) and partly for machinery safety (MD), importers have to provide a confirmation of conformity at the border, before importing the goods in question.

### Implementation capacity (incl. administrative capacity)

Serbia indicated that it has set up a Negotiation Group for this Chapter (NG1) as the main body for co-ordination and the forum for the free movement of goods. It is coordinated by the Ministry of Economy, Sector for Quality Infrastructure and Products Safety on the Market (formerly the Sector for Free Movement of Goods and previously the Sector for Quality Infrastructure) which

consists of the Department for Notification, Projects and Registers (including the group for Removing of Barriers in Non-harmonized Area and Registers and a Group for Notification of Conformity Assessment Bodies and Projects), a Group for Metrology, the Department for Technical Regulation and Conformity Assessment (including a Group for the New Approach Technical Regulations and a Group for the Old Approach Technical Regulations and Non Harmonised Area) and the Group for Policy of Accreditation and Standardisation.

Serbia signalled that in some areas it needs to strengthen its administrative capacity, such as with regard to the Road Traffic Safety Agency (RTSA), and to expand training on market surveillance. However it also signalled that the market surveillance budget is being under pressure due to budget restrictions. For example, with regard to Market Surveillance on Toys, the expected budget 2012-2013 was not provided, and budgetary limitations have impacted on the provision of the necessary administrative capacity regarding REACH.

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

### Standardisation

Serbia states that its national legal framework for standardisation is partly aligned with the relevant *acquis*. It plans for full alignment through amendments to its Law on Standardisation (planned to be in place by the end of 2014) and by a revision to its Regulation on the Manner of Providing Information and Notification of Technical Regulations, Conformity Assessment and Standards (planned to start in 2015).

The Institute for Standardisation of Serbia (ISS) is a public institution. Its role is to be the national standards body in the Republic of Serbia. ISS follows the work of the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), the International Organization for Standardisation (ISO) and the International Electrotechnical Commission (IEC) committees. It is not yet a full member of CEN and CENELEC but participates in many of their technical committees; it plans to gain full membership by 2016. It has established an integrated Quality Management System (QMS) (ISO 9001) and Information Security Management System (ISMS) in 2010.

Serbia stated that by September 2014 ISS had adopted around 95% of all CEN/CENELEC EN and also of CEN/CENELEC Harmonised Standards, 100% of ETSI (the European Telecommunications Standards Institute) Harmonised Standards and 16% of all ETSI Standards. It has withdrawn 12,000 conflicting and obsolete national standards. There are a few national technical regulations referring to the national standards (e.g. civil engineering, electrical engineering, railways) that are not held by ISS. ISS applies the CEN/CENELEC Notification and standstill procedure, and performs trainings for its Technical Committee members at least twice a year in line with CEN/CENELEC good practice. Serbia stated that ISS currently has 62 employees and an IT system that can fulfil the requirements of CEN/CENELEC.

### Conformity assessment

The legal framework for conformity assessment (CA) in Serbia consists of its Law on Technical Requirements for Products and Conformity Assessment, its Regulation on Manner of Performing Conformity Assessment, Content of the Documents of Conformity, and Shape, Outline and Content of Mark of Conformity, its Rulebook on the Manner of Affixing Marks of Conformity on Products, and Use of Marks of Conformity, and its Regulation on the Manner of Recognition of Foreign Documents of Conformity and Marks of Conformity.

Serbia stated that its regulatory framework for CA is partly aligned with the *acquis*. With regard to the recognition of foreign CA results Serbian legislation foresees a ministerial level decision on accepting foreign certificates if they a) provide at least equivalent level of protection as per

Serbian legislation, and b) have been assessed by Conformity Assessment Bodies (CABs) that have equivalent level to Serbian one. With regard to the distinction between the authorisation and designation of Conformity Assessment Bodies this law allows the Serbian state to issue the conformity assessments in some areas, such as motor vehicles. With regard to Conformity Marking, Serbian legislation provides that the Serbian conformity mark is in force, and that the CE mark will be applied on the date of accession or if Serbia signs an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with the EU. Serbia has not yet envisaged transitional provisions for products that will be placed on the market before an ACAA comes into force/before accession and it acknowledged that it will now have to consider transitional provisions in this regard.

Serbia stated that under its current legislation the entity responsible for affixing the conformity mark is determined by the relevant technical legislation. Depending on the case, this is done by either the manufacturer or an authorised representative or in exceptional cases the importer - Serbia acknowledged that the latter provision is not fully in line with the *acquis*. In case of incorrect conformity marking the Market Surveillance Authority can require corrective actions, impose restrictions or prohibition of placing the product on the market or withdrawal of the product from the market.

### Accreditation

Serbia stated that its regulatory framework in this area consists of the Law on Accreditation. This confers the authority to perform accreditation activities to the Accreditation Body of Serbia (ATS), as the sole accreditation body in the country. Serbia stated that the Law on Accreditation is aligned with the provisions dealing with accreditation of Regulation (EC) No 765/2008 which sets out the requirements for accreditation and market surveillance relating to the marketing of products.

The 2006 Serbian Act on Establishment defined ATS as an independent and non-profit institution. ATS determines the competence of Serbian CABs (conformity assessment bodies), lays down and publishes the Rules of Accreditation, keeps a public register of accredited CABs, participates in the work of international and European organisations for accreditation, and promotes the importance and role of accreditation. ATS currently has 36 permanent employees, 59 Lead Assessors, 114 Technical Assessors in testing labs and 125 Technical Experts. It intends to reinforce its administrative capacity by recruiting five more staff members. With regard to products covered by the New Approach directives, at the time of the screening Serbia had granted accreditation to 23 designated bodies: in the areas of lifts (four), medical devices, (four), electrical equipment designed for use within certain voltage limits (four), low-voltage products (two), pressure equipment (eight) and personal protective equipment (one).

In 2012, ATS signed an EA (European Co-operation from accreditation) Multilateral Agreement EA MLA) for the following fields: testing (including medical labs), calibration, inspection, and product certification. In 2014, a new EA MLA was signed to include certification of management systems and certification of persons, and co-operation with accreditation bodies in other countries in the region via bilateral agreements.

### Metrology

According to Serbia the basis of its metrology system in terms of legal metrology is the Serbian Law on Metrology, 17 basic bylaws and 14 rulebooks. The main institution for metrology in Serbia is the Directorate of Measures and Precious Metals (DMDM), which is a governmental body supervised by the Ministry of Economy. DMDM is a member of European Association of National Metrology Institutes (EURAMET), European Association for Chemical Measurements (EURACHEM), European metrology program for innovation and research (EMPIR), the

International Organization of Legal Metrology (OIML), and an associate member of the European Co-operation in Legal Metrology (WELMEC).

DMDM performs conformity assessment of measuring instruments, type examination and type approval, verification of measuring instruments for which the authorised bodies do not exist, metrology supervision and market surveillance of measuring instruments and pre-packed products, and testing of pre-packed products and measuring bottles. It has 110 employees, including 69 engineers and scientists.

According to Serbia its legislation is partly aligned with the *acquis* with regard to Metrology. Alignment measures currently planned include alignment with Directive 2014/31/EU for non-automatic weighing instruments and Directive 2014/32/EU for measuring instruments. It also plans to align with Directives 75/324/EEC and 2008/47/EC for aerosol dispensers, revise the Law on Metrology and relevant bylaws. Serbia foresees the above-mentioned alignment in the period 2015-2018. DMDM also envisages increasing its administrative capacity by recruiting further employees.

### Market surveillance

Serbia stated that its legal framework for the safety and compliance of products, its Law on Market Surveillance which lays down the horizontal framework for Market Surveillance, is partly aligned with Regulation (EC) No 765/2008. Serbia stated that this law aligns with the main obligation and application of market surveillance principles, that it defines the role of the Market Surveillance authorities in Serbia, in particular with regard to the implementation of activities and measures of market surveillance and the jurisdiction of certain market surveillance authorities, the co-operation between market surveillance and customs authorities, information exchange and communication with stakeholders, planning and monitoring the activities of market surveillance, and co-ordination in the field of market surveillance.

Serbia stated that other laws are also relevant (see under Conformity Assessment), and that its Law on Market Surveillance does not exclude measures foreseen under its general product safety legislation (the Serbian Law on – NB: The General Product Safety (and the General Product Safety Directive were screened under this chapter28Chapter 28), which has by-laws for the implementation in this areachapter28). The Ministry of Trade, Tourism & Telecommunications, the Ministry of Health, the Ministry of Labour and Social Policy, the Ministry of Construction, Transport and Infrastructure, the Ministry of the Interior, the Ministry of Agriculture and Environmental Protection, the Ministry of Economy, and the Ministry of Mining and Energy have responsibilities for market surveillance. In September 2014 the Market Inspection Sector had 463 employees and 100 market inspectors in charge of control in the field of compliance and safety of products. In 2012, 2,858 inspections were performed in Serbia, leading to 463 cases of elimination of irregularities/inadequate consumer information and 156 withdrawals/recalls.

### Notification procedures

Serbia stated that its legal framework with regard to Notification is partly aligned with Directive 98/34/EC by a Serbian Regulation on the manner of providing information and notification of technical regulations, conformity assessment and standards which also lays down a procedure for the provision of information in the field of technical standards and regulations. This legislation is being redrafted in order to align it with Regulation (EU) No 1025/2012. Serbia acknowledged that this re-drafting is necessary to enable the Commission and Member States to react under Directive 98/34/EC as in some cases a technical regulation could already adopted at the time of notification (for example by-laws [rulebooks] adopted under an urgency procedure), which explains the reasons for the urgency of the measures taken (i.e. the adoption of Serbian technical regulations)

The scope of the current Serbian Regulation covers technical regulations (TR), conformity assessment procedures and standards for all industrial and agricultural products, including fish products, except those that are made primarily for the protection of workers in the use of a product. It also applies to technical regulations for Information Society services, with the exception of technical regulations containing rules regarding radio broadcast services, television broadcasting services, telecommunication services, and financial services.

#### External border checks

Serbia stated that its Law on Market Surveillance is aligned with Regulation (EC) No 765/2008. This law allows for direct co-operation and communication between market surveillance authorities and the Customs Administration, which can inform the market surveillance authorities about imports blocked. If the Customs Administration is not informed about the activities taken by market surveillance authorities within three days, blocked imports are to be released if there are no other constraints for their release. If the market surveillance authorities find that a product is dangerous, they may ban its circulation on the Serbian market.

Serbian sectoral legislation is not aligned with the *acquis* with regard to border controls on industrial products covered by the legislation on low voltage equipment (LVD), electromagnetic compatibility (EMC), telecommunications terminal equipment (R&TTE) and on machinery safety. These are subjected to additional customs or other controls prior to marketing importers in that importers have to provide a certificate of conformity (known in Serbia as a "Confirmation of Conformity") at the border, before importing the goods in question.

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

The framework legislation for alignment with the *acquis* under the New Approach in Serbia is its Law on Technical Requirement for Products and Conformity Assessment. The technical level of alignment is most frequently ensured by by-laws (rulebooks) adopted by the Minister responsible in accordance with the law mentioned above, apart from cases where specific product legislation (sectorial laws and implementing bylaws) is adopted (notably Toys, Chemicals, Measuring Instruments, and Non-automatic weighing instruments). Other relevant framework legislation includes that listed above with regard to Conformity Assessment and to Standardisation. Serbia signalled concerns regarding the capacity and resources of some line ministries in charge of adopting and implementing technical legislation.

There are a number of cases with regard to New and Global Approach *acquis* where Serbia imposes additional customs or other controls prior to marketing imported goods, where importers have to provide a certificate of conformity (known in Serbia as a "Confirmation of Conformity") at the border before importing the goods in question.

#### Low voltage equipment (LVD)

Serbia stated that its legislation is partly aligned with the *acquis*. Differences with regard to the *acquis* include provisions on Confirmation of conformity, pre-market control, the use of the Serbian Conformity Marking, and the obligations of importers. These products are subjected to additional controls prior to marketing in that importers have to provide a certificate of conformity (known in Serbia as a "Confirmation of Conformity") at the border before importing the goods.

Serbia 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. The government body responsible for transposition and implementation is the Ministry of Economy. The Ministry for Trade, Tourism and Telecom, Sector for Market Inspection, is responsible for enforcement (market surveillance).

### Electromagnetic compatibility (EMC)

Serbia stated that its legislation is partly aligned with the *acquis*. Differences with regard to the *acquis* include provisions on Confirmation of conformity, pre-market control, the use of the Serbian Conformity Marking, and the obligations of importers: these products are subjected to additional customs or other controls prior to marketing in that importers have to provide a certificate of conformity (known in Serbia as a "Confirmation of Conformity") at the border before importing the goods.

Serbia stated that it has producers who place products on the market that are covered by Directive 2004/108/EC. The government body responsible for transposition and implementation is the Ministry of Economy. The Ministry for Trade, Tourism and Telecommunications, Sector for Market Inspection, is responsible for enforcement (market surveillance).

### Toy safety

Serbia stated that its legislation is not aligned with the *acquis*. Serbia's legal framework in this area includes its Law on Health Safety of Products of General Use, which covers children toys – items for general use, clearly intended for children up to 14 years to play (Articles 3 and 4), so the coverage of Serbian legislation is not the same as the *acquis*. Serbia stated that it has recognised that alignment with the *acquis* is necessary to enable the free movement of safe toys, as well as an efficient system to protect the health of children. A task force has been formed to draft new legislation that will align with the requirements of the *acquis* in order to achieve a high level of protection of the health and safety of children. The authority responsible for both alignment and market surveillance is the Serbian Ministry of Health.

Currently, before customs clearance for toys, the importer is obliged to submit to the sanitary inspector a written request and documentation of relevance for determining health safety at the place of customs clearance. The inspector approves by written decision the import of health safe toys, or bans the import of health unsafe toys, within three days from the official control enforcement. Serbia stated that it has limited production capacity in this area.

### Machinery

Serbia stated that its legislation is partly aligned with the *acquis* via its Rulebook on machinery safety which entered into force on 20 March 2010, under the framework of the Serbian Law on Technical Requirements for Products and Conformity Assessment. It had a transition phase until 20 March 2012.

Serbia signalled differences with the *acquis* concerning the a certificate of conformity (known in Serbia as a "Confirmation of Conformity"), a document of conformity introduced into Serbian technical legislation that accompanies four groups of machinery placed on the market in Serbia, defined in Article 11 of the Rulebook. The request for the Confirmation of conformity is submitted to a designated body that reviews the technical documentation, establishes whether machinery complies with the essential requirements, and then issues the Confirmation of conformity for compliant machinery. The use of the Serbian conformity mark is also obligatory. The Rulebook foresees that these national additions shall cease to apply upon the signing of the ACAA agreement or Serbia's accession to the EU.

These products are also subjected to additional customs clearance prior to placing on the market. Importers have to provide a certificate of conformity (known in Serbia as a "Confirmation of Conformity") at the border (see above). Serbia acknowledged that is not in line with the *acquis* and that it will reconsider these provisions in near future.

There are Serbian producers in this sector, some of which export. The responsible government body is the Ministry of Economy, sector for quality infrastructure. Market Surveillance

responsibilities are split between the Ministry of Labour, which inspects the use of machines, and the Ministry of Trade, Tourism and Telecommunications.

#### Noise emissions by outdoors equipment

Serbia stated that its legislation is not yet aligned with the *acquis*. Serbia adopted a Rulebook on noise emissions by equipment for use outdoors in 2013. This Rulebook shall start to apply as of 1 July 2015. However, there are some open issues which might delay its full implementation, including the fact that the Institute for Standardisation of Serbia has not yet adopted more than half of the standards mentioned in the noise test codes. Serbia also has concerns about the readiness of its industry for the application of the Rulebook, and it has yet to decide who shall collect noise data.

There are some Serbian manufacturers in this area. ATS has accredited six laboratories for performing noise tests. The government body responsible is the Ministry of Economy. Market surveillance shall be performed by the Ministry of Trade, the Ministry of Agriculture and Environmental Protection and local authorities, co-ordinated by the Council for the safety of products.

#### Lifts

Serbia stated that it has partly aligned its legislation with the previous Directive (95/16/EC) by adopting the Rulebook on safety of lifts, which came into force on 6 January 2011, under the framework of the Serbian Law on Technical Requirements for Products and Conformity Assessment. Serbia plans to align with the new Lifts Directive (2014/33/EU) by the end of 2016.

However, differences between Serbian legislation and the *acquis* concern additional national provisions regarding special and additional special requirements for the inspection of existing ("old") lifts in use. These foresee annual inspection of all lifts by a CAB designated for the inspection of lifts, including checks that existing lifts comply with special requirements. Additional inspections take place upon basic changes to a lift, when the lift is put into service after an accident, or upon the request of the surveillance authorities. The Rulebook also foresees transitional conformity mark provisions in that the use of the Serbian conformity mark is obligatory, until the signing of an ACAA or Serbia's accession to the EU.

There are a number of manufacturers of lifts and lift components in Serbia. The ministry responsible is the Ministry of Economy, Department for Technical Regulations and Conformity Assessment; Market Surveillance is performed by the Ministry of Trade, Tourism and Telecommunications. Inspections of lifts in use (including existing lifts) are performed by the Ministry of Construction, Transport and Infrastructure for lifts in residential buildings and by the Ministry of Labour for the lifts in commercial facilities. There were six accredited and designated CABs for lifts in Serbia at the time of the screening meeting; there were no CABs for lift safety components.

#### Personal protective equipment (PPE)

Serbia stated that its Rulebook on Personal protective equipment, adopted in December 2011, is aligned with the *acquis* apart from the transitional conformity mark provisions which foresee that the use of the Serbian conformity mark is obligatory until the signing of an ACAA or Serbia's accession to the EU. There is one designated CAB in Serbia; three more are in the process of accreditation. The ministry responsible is the Ministry of Economy, while market surveillance is performed by the Ministry of Trade, Tourism and Telecommunications. There are some producers of Personal Protective Equipment in Serbia.

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

Serbia stated that its Rulebook on equipment and protective systems intended for use in potentially explosive atmospheres, which started to apply as of 1 January 2015, is partly aligned with the *acquis*. Differences with the *acquis* include transitional conformity mark provisions that foresee that the use of the Serbian conformity mark is obligatory, until the signing of an ACAA or Serbia's accession to the EU, and also that the Certificate of conformity (modules F or G) shall be issued by a Serbian designated CAB for equipment and components in certain equipment groups. Serbia stated that there is one Serbian CAB accredited and designated for ATEX products. The ministry responsible is the Ministry of Economy.

With regard to Market Surveillance the Mining Inspectorate had three inspectors – they are planning to hire three more. Other competent market surveillance authorities are: Ministry of Trade – Sector for Market Surveillance and Ministry of Labour – Labour Inspectorate. All these market surveillance authorities are co-ordinated by the Council for the safety of products. There are some producers of these products in Serbia.

### Gas appliances

Serbia stated that its legislation is not aligned with the *acquis* and that alignment has not yet started. The ministry responsible for legal alignment is the Ministry of Mining and Energy. The Ministry of Trade, Tourism and Telecommunications is responsible for market surveillance. There are no major manufacturers of gas appliances in Serbia.

### Pressure Equipment

Serbia stated that it has aligned its legislation with the *acquis* by adopting a Rulebook on Technical Requirements for the Design, Manufacture and Conformity Assessment of Pressure Equipment, applicable from 1 July 2012, apart from transitional conformity mark provisions that will cease to apply until the signing of an ACAA or Serbia's accession to the EU. The ministry responsible for legislation and market surveillance is the Ministry of Mining and Energy, which has 10 inspectors of pressure equipment. There are currently seven relevant designated CABs in Serbia, and about 10 major manufacturers of pressure equipment.

### Simple Pressure Vessels (SPVD)

Serbia stated that it has aligned its legislation with the *acquis* by adopting a Rulebook on technical requirements for the design, manufacture and conformity assessment of simple pressure vessels, applicable from 1 July 2012, apart from transitional conformity mark provisions that will cease to apply at the signing of an ACAA or Serbia's accession to the EU. The ministry responsible for legislation and market surveillance is the Ministry of Mining and Energy, which has 10 inspectors of pressure equipment. There are no designated CABs in Serbia, and no major manufacturers of simple pressure vessels.

### Aerosol dispensers

Serbian legislation is not yet aligned with the *acquis*. There is currently no Serbian national legislation in this area. Serbia stated that it plans alignment with the *acquis* by the end of 2015 by adopting a Rulebook on Aerosol dispensers under the framework of the Serbian Law on Technical Requirements for Products and Conformity Assessment. The Ministry of Economy is responsible for legal alignment; the Directorate of Measures and Precious Metals will be responsible for implementation and market surveillance. There are manufacturers in this area in Serbia.

### Cableways

Serbian legislation is not yet aligned with the *acquis*. There is currently no existing Serbian national legislation in this area that corresponds to the *acquis*. Serbia stated that it plans to adopt

a Law on Cableway Installations Designed to Carry Persons in the fourth quarter of 2015. The ministry responsible for legislation and market surveillance is the Ministry of Construction, Transport and Infrastructure. There are no designated CABs in Serbia, which has no major manufacturers of such equipment.

### Construction products

Serbian legislation is not yet aligned with the *acquis*. Serbia stated that it intends to align its legislation with the *acquis* by the end of 2016. The ministry responsible for legal alignment is the Ministry of Construction, Transport and Infrastructure, which also ensures market surveillance for construction products. Serbia stated that it currently does not have sufficient staff to meet all the inspection needs in this area.

Serbia stated that it has 64 CABs in the area of construction products. Serbia's construction sector is important to its economy; it employed 5.58% of the Serbian workforce in 2013. Serbia stated that there are three cement plants, 210 companies producing concrete and a large number producing mortar on its territory. There are also 118 companies producing bricks, tiles and backed clay products, mostly for export.

### Recreational craft

Serbia stated that it has adopted secondary legislation aligned with the *acquis* by a rulebook adopted on 22 December 2014, to be fully implemented by 2017. The ministry responsible for legal alignment is the Ministry of Construction, Transport and Infrastructure, which also ensures market surveillance. There are manufacturers in this sector in Serbia, mostly SMEs.

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

Serbia stated that its legislation is partly aligned with the *acquis*. Serbia adopted a Law on the Efficient use of Energy in 2013. This law specifies that products shall be placed on the market and put into service only if they comply with the eco-design requirements specified in a technical regulation, if the products' compliance has been verified by means of the prescribed attestation procedure and if the products are labelled in compliance with the regulation pertaining to the particular group of products.

Serbia also stated that, prior to placing a product on the market and prior to putting it into service, the compliance label shall be attached to the product in cases where the manufacturer or their representative has provided and delivered the product conformity declaration. In 2009 Serbia adopted a Law on Environmental Protection which includes provisions for an Ecological Label, which Serbia states corresponds to the EU Eco Label.

The ministry responsible for legal alignment with regard to eco-design for energy related products is the Ministry of Mining and Energy. The Ministry of Trade, Tourism and Telecommunications is responsible for market surveillance. The Ministry responsible for Environmental Protection is responsible for the environmental requirements for products, and the Ecological Label. Serbia stated that it plans to start work on further alignment with the *acquis* in early 2015.

The Serbian Law on Efficient Use of Energy prescribes the obligation for labelling and other standard product information on consumption of energy and other essential resources for energy-related products. Serbia has also adopted a Decree on the types of energy-related product requiring the labelling of energy consumption and other essential resources. This prescribes the types of energy-related products, the deadlines of the introduction of mandatory energy efficiency labels and inspection of the implementation of regulations on labelling. The Ministry of Trade, Tourism and Telecommunications is responsible for market surveillance.

Seven rulebooks have been adopted that lay down the energy labelling obligations per product sector, respectively covering household refrigerating appliances, televisions, electrical lamps and luminaries, electric ovens, air conditioners, household dishwashers, and household washing machines. These rulebooks entered into force in March 2014, and apply from June 2014. The ministry responsible for legislation is the Ministry of Mining and Energy.

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

Serbia stated that its legislation is partly aligned with the *acquis*. Serbia indicated that it adopted a Rulebook on radio equipment and telecommunication terminal equipment, which entered into force on 1 June 2012.

Specific divergences that Serbia acknowledged between its legislation and the *acquis* arise from lack of provisions in Serbian Law on Electronic Communications regulating the notification and publication of interface specifications by operators of public telecommunications networks, and of provisions in this Law regulating the obligation of economic operator to notify the national authority responsible for spectrum management of the intention to place on the market radio equipment using not harmonised RF bands.

Serbia signalled that it lacks a quality infrastructure system in this sector. It does not have the necessary accredited laboratories, and it lacks trained market surveillance staff – it has no specialised inspectors of such equipment. There are a small number of manufacturers in this sector in Serbia. Serbia plans further alignment with the *acquis* in the period 2016-2018. The ministry responsible for both legal alignment and market surveillance in this area is the Ministry of Trade, Tourism and Telecommunications.

#### Explosives for civil uses and Pyrotechnic articles

Serbian legislation is not aligned with the *acquis*. In Serbia, the field of explosives for civil use and pyrotechnic products is regulated by several laws dating from the 1970s & 1980s: a Law on trade of explosive materials, a Law on explosive substances, flammable liquids and gases, a Rulebook on Safety in the production of explosives and gunpowder, and a Law on the Transport of Dangerous Goods. Serbia plans to align with the *acquis* by the end of 2016 by adopting a Law on Explosive Substances and associated rulebooks. The ministry responsible for both legal alignment and market surveillance in this area is the Ministry of the Interior.

The Directorate for Preventive Protection is responsible for approving the production and transport of explosive substances and for control of the placing on the market of explosive substances, the purchase and use of explosive substances, and the control of the transportation of explosive substances, weapons, and ammunition. In Serbia there are six legal entities engaged in the production of explosives for civil use and two in the production of explosives for civil use and pyrotechnic articles, while 111 legal entities are engaged in the explosive substances trade.

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

#### Motor vehicles

Serbia stated that its legislation is not aligned with the *acquis*. Serbia's domestic legal framework has no legal acts that would ensure alignment with the *acquis*, even though it has a long experience of the implementation of Automotive Technical Requirements (of the European Union and the United Nations Economic Commission for Europe [UNECE])) and relevant technical services. Serbia plans to adopt a Regulation on Vehicle Approval, Equipment and Parts by the end of 2014, which would create a legal framework for alignment with the *acquis* in this area. It then plans with align to specific *acquis* via a series of rulebooks which it plans to adopt between 2015 and 2018.

The entity responsible for both legal alignment and market surveillance is the Serbian Road Traffic Safety Agency (RTSA). RTSA is the Approval Authority of Serbia for wheeled vehicles, equipment and parts according to the 1958 UN Agreement; it grants approval and authorises testing laboratories (technical services) pursuant to certain UN Regulations. New complete vehicles, new completed vehicles on WVTA approved chassis', and automotive equipment and parts are produced in Serbia. Serbia has adopted 57 UNECE Regulations and notified another 32, and it has seven laboratories in this area.

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

Serbia stated that its legislation is not aligned with the *acquis*. Serbia stated that there are no producers of such equipment on its territory. Serbia stated that it plans to adopt a Regulation on Vehicle Approval, Equipment and Parts by the end of 2014, which would create a legal framework for the alignment with the *acquis*. Serbia planned to align with the specific *acquis* via a series of rulebooks to be adopted between 2015 and 2018. However, it put these plans on hold due to the announcement of new EU *acquis* which is expected to replace the current Directive.

The entity responsible for both legal alignment and market surveillance in this area is the Serbian Road Traffic Safety Agency (RTSA). RTSA is the Approval Authority of Serbia for wheeled vehicles, equipment and parts according to the 1958 UN Agreement. Serbia also plans to increase its administrative capacity for market surveillance activities (with inspection functions), as well reinforcing co-ordinating activities between competent market surveillance authorities.

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

Serbia stated that it is partly aligned with REACH requirements. Serbia has been preparing for alignment with REACH for several years through a Serbian REACH & CLP (Classification, Labelling and Packaging) harmonised chemicals management system, which it considers is largely aligned with REACH requirements. While a REACH Implementing Act has not yet been enacted in the country, Serbia stated that REACH-aligned legislation has been in force in Serbia since 2009, and Serbian rulebooks and guidelines repeat the material contained in individual REACH provisions in detail (including REACH rules on Safety Data Sheets, and REACH bans and restrictions). Serbia plans to start drafting a Serbian REACH Implementing Act during 2015.

Although Serbian law does not yet provide for this, Serbia expects the ministry responsible to be the Environment Ministry. This ministry's Unit for Chemicals is foreseen to become the competent authority. Serbia estimates that it needs to allocate extra human resources and ensure further capacity building in order to implement REACH. Serbia estimates that its chemicals industry has a significant share of the national economy, with around 1,700 legal entities, mostly SMEs and micro-enterprises. 30,000 to 40,000 chemicals (i.e. substances and mixtures) (around 9,000,000 tons) have been placed on the Serbian market.

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

Serbia stated that it is partly aligned to CLP requirements. Serbia estimates that its chemicals industry has a significant share in national economy (see above). Serbia has implemented the CLP requirements through its 'Rulebook on classification, packaging, labelling and advertising of the chemical and certain article in accordance with Globally Harmonised System for Classification and Labelling of the UN' and 'Rulebook on the List of classified substances', but some sectoral legislation still needs to be aligned with CLP (notably legislation on control of major-accident hazards involving dangerous substances ("Seveso III")).

A CLP Implementing Act has not yet been enacted; Serbia stated that it plans to start drafting this during 2015. Serbia has not yet designated a competent authority for CLP, but it expects the Environment Ministry's Unit for Chemicals to assume this responsibility. Serbia also stated that it has not yet appointed a national poison control centre, but that it has a National Centre for

Poison Control, established by the Law on Protection of Health, and it foresees that this will be appointed by the CLP Implementing Law Serbia estimates that it needs extra human resources and further capacity building in order to implement CLP.

### Detergents

Serbia stated that its legislation is partly aligned with the *acquis*. The legislative framework in Serbia is its Law on Chemicals, and a Rulebook on Detergents that entered into application in June 2010. Serbia estimates that its legislation is aligned with regard to rules on biodegradability of surfactants, restrictions or bans of surfactants, and additional labelling of detergents. Serbia explained that some differences between Serbian legislation and the *acquis* are partly due to Serbia not being a Member State of the EU: there are no provisions regarding the duties of the Member States, Committee procedures, adaptation of annexes, free movement clause and safeguard clause in its national legislation, as they are not possible to implement in a non-EU country. Other differences between Serbian legislation and the *acquis* concern requirements for placing on the market, regarding provisions for placing on the market detergents containing surfactants failing to comply with the requirements for ultimate aerobic biodegradation, and regarding limitations on the content of phosphates and of other phosphorus compounds.

Serbia intends to align to limitations of phosphate and other phosphorous compounds content by the end of 2014, and a first draft of a Serbian Regulation on Detergents Implementing Act is planned for 2015. Serbia estimates that its detergents industry has a significant share of its chemicals industry, with about 300 legal entities (mostly SMEs and micro-enterprises), around 100 of which are manufacturers.

### Fertilisers

Serbia stated that it has aligned its legislation with the *acquis*. Relevant legislation includes its Law on Plant Nutrition Products and Soil Improvers, and Rulebooks on Conditions for Classification and Determining Quality of Plant Nutrition Products and Soil Improvers, Tolerances of Nutrients Content and Contents of Declaration and Method of Designation of Plant Nutrition Products, on Characteristics of Ammonium Nitrate Fertilizers with High Nitrogen Content, Boundary Values of Nitrogen and Methods of Testing Explosion Resistance, and on Methods of Testing Plant Nutrition Products and Soil Improvers.

The responsible authority in Serbia for legal alignment and implementation is the Ministry of Agriculture and Environmental Protection. It considers that it has sufficient resources for the implementation of Serbian legislation in this sector. Serbia has nine competent laboratories that check the compliance of fertilisers with the requirements of its current legislation. The annual production of fertilisers in Serbia in 2013 was 750,000 tons (5.6% higher than in 2012), and Serbia stated that its imports are higher than exports.

### Drug precursors

Serbia stated that it is partly aligned with the *acquis*. Relevant Serbian legislation includes a Law on Substances Used in Illicit Manufacture of Narcotic Drugs & Psychotropic Substances, a Rulebook on Form and Content of Authorisation for Import, Export and Transit of Category 1, Category 2, and Category 3, and Regulations on “Scheduled Substances” used in Illicit Manufacture of Narcotic Drugs & Psychotropic Substances.

At least two manufacturers on drug precursors are present in Serbia. In Serbia the import, export and transit of all three categories of drug precursors can only be undertaken with prior presentation of authorisation or approval. Production of or trade in drug-precursors of all three categories can only be performed by legal entities to whom the Ministry of Health has issued a license for manufacture and a license for trade. Substances that are not in the list of ‘Scheduled Substances’ are governed by the “Decision on determining goods for import, export or transit of

which certain documents are required”, and their import or export can only be carried out with prior presentation of an approval by the Serbian Ministry of Health.

Serbia stated that its legislation is aligned with EU Regulations (EC) No 111/2005 and (EC) No 273/2004. Further amendments to its legislation are foreseen between 2014 and 2016 to align with EU Regulations (EC) No 297/2009 and (EC) No 225/2011, amending (EC) No 1277/2005, (EC) No 1258/2013 amending (EC) No 273/2004, and (EC) No 1259/2013 amending (EC) No 111/2005. A Serbian Government Office for the Fight against Drugs was set up in July 2014, which regulates and co-ordinates drug policy. The Ministry of Health is in the process of establishing a National Monitoring Centre for Drugs and a National focal point.

#### Good laboratory practice (GLP)

Serbia stated that it is partly aligned with the *acquis*. Relevant Serbian legislation includes its Law on Medicines and Medical Devices, a Rulebook on the entry, content of the application and the costs of entry in the Register of laboratories that perform laboratory testing, and a Rulebook on the Good Laboratory Practice Certificate form, information entered into the Register of the issued certificates, and keeping the Register. Serbia has also issued Good Laboratory Practice Guidelines.

The ministry responsible for the inspections with regard to GLP, is the Ministry of Health. Serbia. In theory a GLP certificate is issued based on the request by the laboratory, performed inspection and final report, and it would be signed by the Minister of Health. The Ministry of Health should keep a register of issued certificates. At the moment the register is empty because so far there have not been any requests to issue a GLP certificate. Currently only one laboratory in Serbia is recorded in the register of GLP laboratories. At this time Serbia does not have a list of experts in this area. NB: Medical Devices were screened under Chapter 28.

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

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

Serbia stated that it is partly aligned with the *acquis*. Relevant Serbian legislation includes its Health Insurance Law, a Rulebook on conditions, criteria and procedure of products to be added and removed from the reimbursement list, and a Rulebook on Reimbursement list of medicines provided from compulsory health insurance. This last was adopted in 2014. It contains a list of medicines that are covered by compulsory health insurance (a list of essential medicines according to "The List of Essential Medicines" of the World Health Organization) of 2,349 medicines (of a list of around 4,500 medicines with an established wholesale price). The reimbursement list is drawn up in full at least once a year.

In order to ensure further alignment with the *acquis* Serbia plans to draft a new Law on Medicines and Medical Devices, which it expects to be adopted by the end of the 2014. One difference between the *acquis* and Serbian legislation concerns deadlines: in certain cases Serbian provisions contain deadlines for a decision on the fulfilment of conditions and criteria of up to 120 days from the date of submission of the complete application. Serbia acknowledged that this is not aligned with EU provisions, in which the maximum deadline is 90 days. Currently the draft Serbian law also does not align the deadlines in question with those of the *acquis*.

### Crystal glass

Serbia stated that its legislation is not aligned with the *acquis*. It adopted a Rulebook on the Marking of Crystal Glass in December 2014, which shall be apply as of January 1, 2018. This new Serbian Rulebook will lay down requirements for labelling of crystal glass products and requirements for determination of the chemical and physical characteristics (testing methods) of categories of crystal glass labelled in accordance with this Rulebook. The competent authority

for legal alignment, monitoring, and compliance is the Ministry of Economy. It intends to reinforce its personnel (to hire an extra employee) with regard to crystal glass (and also to textiles and footwear).

Serbia currently does not have any domestic manufacturers of crystal glass products. Market surveillance will be ensured by the Ministry of Trade, Tourism and Telecommunications. At this time there are no accredited laboratories in this area.

### Textiles

Serbia stated that its legislation is partly aligned with the *acquis*. A Rulebook on marking and labelling of textile products was adopted in January 2014, and it will come into force on 1 July 2015. The competent authority for legal alignment is the Ministry of Economy. The competent authority for market surveillance is the Ministry of Trade, Tourism and Telecommunications. There are around 100 trained inspectors in the area for technical conformity assessment and product safety, but only a few are trained to inspect textile products.

In Serbia there are around 1,550 companies operating in this sector, in textile yarn and fabric production and in the production of finished garments. There are 15 relevant CABs in Serbia at the time of the screening, out of which eight are testing laboratories and seven are inspection bodies for textile products. These CABs can be used by manufacturers, as well as by the market surveillance authorities, for the determination of textile fibre composition and compliance of the results with data on labels and markings on textile products.

### Footwear

Serbia stated that its legislation is partly aligned with the *acquis*. A Rulebook on marking and labelling of textile products was adopted in January 2014 and it enter into force on 1 July 2015. The competent authority for legal alignment is the Ministry of Economy. The competent authority for market surveillance is the Ministry of Trade, Tourism and Telecommunications. There are around 100 trained inspectors in the area of technical conformity assessment and product safety, but only a few are trained to inspect footwear products.

In Serbia there are around 500 companies operating in this sector, including footwear producers. There are 11 relevant CABs in Serbia at the time of the screening: seven inspection bodies for footwear products, and four testing laboratories. These CABs are used by manufacturers for testing the material used for the three main components of footwear as well as by the market surveillance authorities in Serbia.

### Defence products

Serbia stated that its legislation is partly aligned with the *acquis*. Current Serbian legislation in this area consists of several laws, including its Law on Production and Transfer of Arms and Military Equipment, its Law on Foreign Trade in Arms, Military Equipment and dual use goods, its Law on Export and Import of Dual Use Goods, its Law on Arms and Ammunition, its Law on the Prohibition of Development, Production, Stockpiling and Use of Chemical Weapons and Their Destruction, Law on the Transport of Hazardous Substances, Law on Chemicals, Law on Explosive Substances, Inflammable Liquids and Gases, Law on the Trade of Poisonous Substances, and its Law on Protection against Ionizing Radiation and on Nuclear Safety.

Serbia is in the process of drafting a new Law on the Production and Transfer of Arms and Military Equipment, and expects a new law on Export and Import of Arms and Military Equipment to enter into force shortly. Serbia also adopted a new National Arms and Military Equipment Control list in July 2014, which it estimates is fully harmonised with the EU Common Military List.

Serbia estimates that it is the biggest producer and exporter of weapons and military equipment in the region. Its Ministry of Defence has issued 58 licenses for the production of arms and military equipment as of May 2014, and, as of August 2014, 178 entities were registered in Serbia for the export and import of arms and military equipment.

Serbia only issues individual export licenses for defence products, and permits for transport and transit of arms and military equipment are also only issued individually. In Serbia such licenses are valid for a period of up to a year or, exceptionally (should the execution of the work in question last for over a year) a license may be issued for the time limit expected for the work to be completed as defined under the contract, but no more than up to 3 years. Serbian acknowledged that its legislation is different to the *acquis* with regard to licences, as the *acquis* also foresees global and general licenses.

Serbia stated that its definitions of defence-related products are aligned to that of the EU, as is the fact that in Serbia the transfer is based on the prior export license, as are the criteria implemented in issuing the license and export limitations. Serbia plans to fully align with the *acquis* by the date of its accession to the EU.

### Firearms

Serbia stated that its legislation is partly aligned with the *acquis*. The Serbian Law on Weapons and Ammunition defines acquisition, possession, carrying, trade, transportation, repairing and alternation of the weapons, weapon components and ammunition. Three rulebooks have been adopted under this law which regulate the methods of conducting training for the handling of firearms, and procedures for storing and safeguarding weapons and ammunition. The Serbian Criminal Code also contains provisions on the illegal manufacture, possession, carrying and trade in ammunition and explosive components. In June 2014 over a million weapons were registered in Serbia.

The Serbian Law on Testing, Marking and Labelling Firearms and Ammunition defines the conditions and methods of testing, marking and labelling of firearms, ammunition, weapon components and devices prior to their practical use and trade. Under this law a rulebook has been adopted which regulates the conditions and methods for testing, marking and labelling of firearms, ammunition, weapon components and tools, and their marking and labelling.

Serbia estimates that its legislation is aligned with the *acquis* with regard to the need to hold a license or permit to possess a weapon. It estimates that it is partly aligned with regard to the categories of weapon, but its legislation does not provide for convertible and dis-functional weapons, and is only partly aligned with regard to the definition of a dealer. Serbia acknowledged that its legislation is not aligned with the *acquis* with regard to the conditions for issuing a permit to possess a weapon, or with regard to collector's licences, brokers or the European Firearms Pass.

Serbia is planning a new Law on weapons and ammunition and drafting a new law on testing, marking and labelling of firearms, devices and ammunition and new rulebooks that it estimates would align to most aspects of the *acquis* apart from the European Firearms Pass, which it intends to incorporate into its legislation immediately before its accession to the EU.

### Cultural objects

Serbia stated that its legislation is not aligned to the *acquis*. Serbia estimates that it has no administrative, legal or political obstacles to the restitution of illicitly imported cultural objects. Serbia plans to align its national legislation with the *acquis* by the end of 2018.

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

Serbia's legislation is partially aligned with the *acquis* in Chapter 1, Free Movement of Goods. Implementing structures have been established or identified in several sectors. Serbia has also produced plans for alignment in many areas. In some sectors, such as with regard to Toys, Serbia needs to reinforce administrative capacity to ensure the effective implementation of the *acquis*.

Specific gaps remain to be addressed in relation to the amendments of the legal framework, including the co-ordination and planning of steps towards full alignment and ensuring sufficient administrative capacity. Serbia also needs to amend its legislation in several cases in order to remove additional customs or other controls prior to marketing imported goods, where importers currently have to provide a certificate of conformity at the border before importing the goods in question.

Serbia has not yet aligned its legislation with Articles 34-36 TFEU. Its current legislation is also only partly aligned with the *acquis* on metrology and market surveillance. It has established the Accreditation Body of Serbia (ATS), as the sole accreditation body in Serbia, and Serbia's standardisation body (ISS) has aligned Serbian standards to a large percentage of EU standards, though it is not yet a full member of CEN and CENELEC and its competences are not yet fully aligned with EU standardisation bodies.

Specific sectoral implementing legislation is sometimes being developed in parallel with the basic framework legislation, such as for weapons and ammunition and for testing, marking and labelling of firearms, devices and ammunition. However, in some sectors Serbia's current basic framework legislation needs to be adapted to the *acquis*, such as in the area of toys and of cableway installations, before specific sectoral implementing legislation can be drafted.

Serbia should adopt a strategy and an action plan in order to align with the *acquis* covered by the Chapter, including ensuring the necessary administrative capacity and the removal of the above-mentioned barriers to trade.

#### **III.a. General Principles**

Serbia needs to fully align its legislation with Articles 34-36 TFEU. To support this objective, Serbia should adopt a strategy and an action plan to analyse national legislation in order to align 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. In doing this Serbia will firstly need to perform an initial review of its legislation and administrative practices during the drafting of this action plan in order to identify areas that will potentially need further action. The build-up of institutions and their role in this system will also have to be defined.

#### **III.b. Horizontal Measures**

Serbia has reached a good level of alignment with the *acquis* on standardisation and accreditation, but it is not fully aligned. As regards metrology and market surveillance in particular Serbia's legislation is partly in line with the *acquis*. A standardisation body (ISS) is well established and it is issuing Serbian standards. However, ISS does not cover all of the sectors covered by standards bodies in the EU (including electro-magnetic standardisation), and it is not yet a full member of CEN and CENELEC.

Serbian legislation is not fully aligned with the *acquis* with regard to conformity marking. Under Serbia's current legislation the entity responsible for affixing the conformity mark is determined by the relevant technical legislation, which, depending on the cases, stipulates that it is to be

done by the manufacturer, by an authorised representative, but also by the importer, which is not in line with the *acquis*.

In many cases Serbian legislation stipulates that the Serbian conformity mark is in force, and that, as a transition measure, the CE mark will be applied on date of accession or if Serbia signs an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with the EU. However Serbia has not yet envisaged transitional provisions for products that will be placed on the market before an ACAA comes into force/before accession and it will now have to foresee transitional provisions in this regard.

Serbia needs to further align its legislation in the area of market surveillance, which is currently partly aligned with the *acquis*.

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

Serbia has reached a reasonable level of legislative alignment in the areas of Personal protective equipment (PPE), Pressure equipment, and Simple Pressure Vessels (SPVD).

Serbian legislation is partially aligned with the *acquis* with regard to Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX), Eco-design requirements for energy-related products (ErP) and Energy Labelling of products. Serbian legislation is also partially aligned with the *acquis* with regard to Low Voltage equipment (LVD), Electromagnetic compatibility (EMC), Radio Telecommunications terminal equipment (RTTE) and machinery. However, items imported in these last four sectors are subjected to additional customs or other controls prior to marketing in that importers have to provide the certificate of conformity at the border, before importing the goods in question. Serbia needs to remove such barriers to trade.

Serbian legislation is not in line with the *acquis* on Toy Safety, Medical devices, Gas appliances, Aerosol dispensers, Cableways, Construction products, Recreational craft, and Explosives for civil uses and Pyrotechnic articles. In some cases work on alignment is on-going, but in other cases (such as toys) only some initial work has been undertaken, and Serbia's administrative capacity also needs reinforcing in areas including toys.

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

Serbia has reached a reasonable level of legislative alignment in the area of Fertilizers.

Serbian legislation is partially aligned with the *acquis* in the areas of Chemicals – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Chemicals (Classification, Labelling and Packaging, CLP), Detergents, Drug precursors, and Good laboratory practice (GLP), although Serbia has not yet adopted a REACH Implementing Act or a CLP Implementing Act, a competent authority for REACH and CLP remains to be designated, and mutual recognition of GLP monitoring programmes remains to be implemented.

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

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

Serbian legislation is partly aligned with the *acquis* on Transparency in relation to Pricing and reimbursement of Medicinal Products, Defence products, and Firearms.

Serbian legislation is not aligned with the *acquis* with regard to Textiles and to Footwear, but Serbia intends to fully align by mid-2015 with regard to footwear, and to partly align (with the exception of one article) by the same time with regard to textiles. Serbian legislation is also not aligned with the *acquis* with regard to Crystal Glass or to Cultural Objects.