22 December 2011

Screening report

Iceland

Chapter 1 – Free Movement of Goods

Date of screening meetings:

Bilateral meeting only: 7-8 December 2010

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. This principle is enshrined in the Treaty on the Functioning of the European Union (TFEU), in particular Articles 34 to 36, 114(4) to 114(9) and 346 to 348, as interpreted in the case law of the Court of Justice, as well as Commission Directive 70/50/EEC and interpretative communications. 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. Adequate administrative arrangements need to be put in place to apply the information exchange procedures laid down in Regulation 764/2008/EC 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 need to 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) or the "new and global approach" (imposing general product requirements).

New and global approach product legislation includes the areas of non-automatic weighing instruments and measuring instruments, 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-relating products (ERP), radio and telecommunications terminal equipment (R&TTE).

Old approach product legislation covers the areas of motor vehicles, chemicals, pharmaceuticals, cosmetics, legal metrology and pre-packaging, textiles, footwear labelling, and crystal glass.

A series of **procedural measures** also requires 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, Directive 91/477/EEC on the control of the acquisition and possession of weapons and Directive 93/7/EEC on cultural goods.

The EU *acquis* in this area has been complemented by the adoption of Regulation 765/2008 of 9 July 2008 on accreditation and market surveillance and by Decision 768/2008 of 9 July 2008 on a common legislative framework for the placing of products on the market. Regulation 765/2008 requires alignment of legislative and administrative provisions and to set up and maintain a policy, infrastructure and activities on market surveillance for products manufactured within or imported into the EU. Decision 768/2008 does not create any new direct obligations until incorporated into sector legislation.

Most of the *acquis* on free movement of goods is covered by the EEA Agreement. All new relevant Community legislation is regularly incorporated into the Agreement and thus applies throughout the EEA.

II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

This part summarises the information provided by Iceland and the discussion at the screening meeting. Iceland indicated that it can accept the *acquis* regarding 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

The legal basis for the free movement of goods is found in Articles 11 to 13 of the EEA Agreement. These provisions prohibit quantitative restrictions on imports and exports and measures having equivalent effect and provide for derogations. The EEA Agreement has been given legal status by Act No. 2/1993 on the European Economic Area. Therefore, regarding the general principle of free movement of goods, Icelandic legislation is generally in line with Articles 34 to 36 of the Treaty on the Functioning of the European Union.

Further rules in the legislation on technical issues are generally found in the sector specific legislation and rules adopted by the relevant ministries in order to transpose EU Directives. Act No 91/2006 on measurements, national standards and official weighing instruments and Regulation No 431/1994 on construction products are examples of such rules.

Implementation capacity (including administrative capacity)

In terms of administrative capacity, Iceland informed that it transposes into Icelandic law the EEA rules and regulations and that according to the EFTA Surveillance Authority it has been able to do so in a satisfactory way with the given resources.

II.b. Horizontal measures

Standardisation

Icelandic Standards (ÍST) is the national standards body of Iceland. It is an independent association whose role is to publish Icelandic standards and to represent Iceland in international and regional standards bodies, according to Act No 36/2003 on standards and Icelandic standards.

Iceland informed that as of the 1st of December 2010, 22.620 European standards were transposed as Icelandic standards; therefore almost 100% of European Standards by CEN[1], CENELEC[2] and ETSI[3] are transposed in Iceland.

Icelandic Standards has currently nine staff members. The number of staff and the financing of the institute are considered by Iceland to be adequate.

[1] European Committee for Standardization
[2] European Committee for Electro-technical Standardization
[3] European Telecommunications Standardisation Institute

Icelandic Standards (ÍST) is a full member of CEN and CENELEC and an associate member of ETSI. Also, Icelandic Standards (IST) is a member of ISO[4] and an associate member to IEC[5].

For a number of "New Approach" sectors, Iceland is publishing, in accordance with the requirements of EU legislation, the lists of harmonised European standards as transposed into Icelandic standards. However, for a number of areas (e.g. medical devices), lists of harmonised European standards and their updates are not regularly published.

Accreditation

The main principles of Council Regulation No 765/2008, Chapter II, Accreditation, are implemented by Act No 24/2006 on accreditation. The Act applies to accreditation services, the evaluation of designated bodies and the evaluation of good laboratory practices, other than the evaluation of pharmaceutical laboratory practices.

ISAC (Icelandic Board for Technical Accreditation) is the National Accreditation Body in Iceland; It is a full member of EA (European co-operation for Accreditation) and participates in its activities on a regular basis. Because of the small size of the Icelandic economy, Iceland did not consider it viable to establish a separate entity to offer accreditation services. Therefore, ISAC is a division of the Icelandic Patent Office where it was moved from the Consumer Agency with the Act on accreditation. At present there is one permanent staff in ISAC. Valid accreditations are at present 49 within 34 companies and covering 12 technical fields. Conformity assessment bodies are: Testing laboratories (8) (legal metrology, foods and clinical testing), Inspection Bodies (40) (motor vehicles, food establishments, market surveillance, lifts, ships, playgrounds, tachometers and electrical installations) and Certification Bodies (1) (organic products).

According to Act No 24/2006 on accreditation, Icelandic Accreditation (ISAC) is responsible for the designation of Conformity Assessment Bodies (CABs). Usually CABs are required, according to special sector legislation, to ascertain the necessary competencies to be able to perform conformity assessment, according to the respective modules applicable to the particular product in question. ISAC has, in line with the afore-mentioned Act, the responsibility to evaluate and ascertain competencies of applicants to become designated bodies. ISAC evaluation procedures are based on the ÍST EN ISO IEC 17000 series of standards.

Due to Iceland's small economy, products are mainly produced abroad and imported. The market for conformity assessment bodies is very small. Therefore, for a number of regulated areas (e.g. machinery) Iceland has not designated Conformity Assessment Bodies.

According to Iceland, Act No 24/2006 on accreditation is, in principle, subject to some further necessary adjustments, in line with Regulation 765/2008/EC. A peer review of ISAC is under preparation. Iceland stated that administrative capacity in the field of accreditation will continue to be built up in the near future.

From its establishment, ISAC has had a contract of cooperation with SWEDAC - the accreditation body in Sweden - for the assessment of laboratories. UKAS, the accreditation

[4] International Standardisation Organisation
[5] International Electro-Technical Commission

body in the UK, has asked for an agreement with ISAC in line with the European cooperation for Accreditation cross frontier policy and EU Regulation 765/2008.

Conformity assessment

Conformity assessments are referred to in sector specific legislation implementing EU Directives in various fields. Furthermore, Regulation No 957/2006 implemented EU Decision 93/465/EEC concerning the modules for various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization Directives.

In sector specific legislation according to sector specific EU Directives, it is also stipulated that the relevant Ministries are to notify bodies entrusted for conformity assessments in their respective sector specific areas.

Iceland stated that the conformity assessment procedures are generally in line with the provisions of Council Decision 768/2008/EC since this Decision applies the principles of Decision 93/465/EEC which is already implemented in Iceland by Regulation No 957/2006.

Iceland indicated that Decision 768/2008/EC will be fully implemented when the act will be incorporated into the EEA Agreement. Foreign reports are recognised if they are of trustworthy origin and presented in a language understood by the recipients in Iceland (normally English and/or Nordic languages other than Finnish).

Metrology

Act No 91/2006 on measurements, national standards and official weighing instruments, is the legal basis for metrology in Iceland, i.e. legal metrology as well as industrial metrology and calibrations.

Council Directive 80/181/EEC on units of measurement, as amended by Council Directives 85/1/EEC, 89/617/EEC and 1999/103/EC, has been transposed by Regulation 128/1994/IS as amended, but Directive 2009/3/EC has not yet been transposed.

According to Regulation 128/1994/15, the Consumer Agency is the National Standard Institute and is the responsible authority in the field of legal metrology. In addition, according to the Act, the Agency shall ensure accredited calibration services, which are necessary for legal metrology, and shall ensure service in the field of industrial metrology. The Agency can provide for calibration services that are necessary for trade and businesses in Iceland. The calibration services of the Consumer Agency are accredited by UKAS (United Kingdom Accreditation Service).

Market surveillance

According to existing Icelandic legislation, producers, importers and distributors can only place safe products on the market. In addition, in accordance with sector legislation transposing the *acquis*, they have to ensure that the products are in conformity with legal requirements, including ÍST EN Standards, as the case may be, or if not, be able to demonstrate compliance with essential requirements of the respective rules and legislation. Products bearing the CE marking enjoy the presumption of conformity according to EU legislation on the free movement of goods.

Act No 134/1995 on Product Safety and Official Market Control implements Directive 2001/95/EC on General Product Safety and contains main provisions concerning market surveillance of consumer product that do not fall under the scope of specific legislation as well as being complementary to sector specific legislation. The penalty according to Act No 134/1995 on Product Safety and Official Market Control is imprisonment of up to two years, unless other legislation provides for more serious penalties.

The Consumer Agency has the general responsibility for market surveillance according to Act No 134/1995, on product safety, as well as the national co-ordination of activities of other market surveillance authorities in special areas of the *acquis*.

The Consumer Agency is also the RAPEX (rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices) contact point in Iceland and the competent authority for market surveillance of various products, such as toys, certain electrical equipments (LVD), measuring instruments, etc.

In 2011, Iceland developed a Market Surveillance Programme in accordance with Article 18(5) of Regulation (EC) No 765/2008 covering market surveillance activities from a horizontal and sector point of view.

Regulation No 237/1996 implemented EU Regulation No 339/93/EEC on checks for conformity with the rules on product safety in the case of products imported from third countries. This EU Regulation has been repealed and replaced by Regulation 765/2008 of 9 July 2008 on accreditation and market surveillance. The Customs Directorate of Iceland is the main executive body. Cooperation between the Customs Directorate and the sector authorities will be further developed in 2011 in accordance with the afore-mentioned Regulation 765/2008.

Iceland stated that the entire text of Regulation 765/2008/EC would be transposed with an Act to be adopted by the Icelandic Parliament as Annex to the Icelandic law. Furthermore some changes are foreseen to Act No 134/1995 that at present are considered necessary to make certain clarifications in order to have a complete market surveillance system covering all products either under the General Products Safety Directive (non harmonised area) or under the Regulation 765/2008 (harmonised area). An example in this respect is that, according to provisions of Regulation No 765/2008, Member States have the responsibility to ensure annually that a National Market Surveillance Plan (NMSP) is put together and communicated to the Commission. In this case a legal text providing that the Consumer Agency will have the obligation to collect and coordinate plans of other national authorities and draw up the NMSP and communicate that to the Commission will be added to Act No 134/1995. Other similar modifications of the current legal text of Act No 134/1995, as amended, may be necessary and will be considered when Regulation No 765/2008 is implemented after its inclusion to the EEA Agreement and transposition in Iceland. It is expected that this will occur before the end of 2011.

II.c. New and global approach product legislation

Legal metrology: non-automatic weighing instruments; measuring instruments

Regulation No 465/2007 transposed Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments (MID). The aforementioned Directive was amended by Directive 2009/137/EC which has not been transposed yet. The legal basis for the 465/2007

Regulation is Act No 91/2006 on measurements, national standards and official weighing instruments. The system of approvals for the instruments allows manufacturers to choose among various procedures on conformity assessment according to the provisions of the Directive. Certificates of conformity to the MID Directive are valid throughout Europe, including Iceland.

Furthermore, Regulation 616/2000 on non-automatic weighing instruments implemented Directive 90/384/EEC, codified by Directive 2009/23/EC on non-automatic weighing instruments.

In Iceland type approval of instruments would either follow the afore-mentioned rules on non-automatic weighing instruments or, in case of automatic weighing instruments, the more recent rules of the Measuring Instruments Directive.

The competent department in Iceland is the Consumer Agency.

Low voltage equipment (LVD)

Regulation No 264/1991 on electrical equipment, as amended by Regulations No 458/1992 and 543/1993, transposed Directive 73/23/EEC. Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits has been transposed in Iceland with the ministerial Regulation No 678/2008 which has Act No 146/1996 as its legal basis. The system of conformity assessment follows the rules and modules as laid down in the Directive. The Icelandic Fire Authority is responsible for implementation of LVD in Iceland. Market surveillance is under the authority of the Iceland Fire Authority and the Consumer Agency.

Act No 146/1996 applies to high voltage equipment and power plants, as well as installations. Supervision of high voltage and installations is under the auspices of the Icelandic Fire Authority as of 1 July 2009 when this unit was transferred from the Consumer Agency to the Fire Authority. The administration and responsibility for Act No 146/1996 was also moved to the Ministry of the Environment.

A new Act on construction works was adopted in December 2010. According to this new Act the Fire Authority has the obligation in respect to surveillance of buildings and construction works at state level and its name as of 2011 is the Construction Authority. The Consumer Agency is however the competent authority for market surveillance of LVD products on the consumer market that are not intended to be part of fixed installations According to Iceland this division of tasks is mentioned in Act No 146/1996 but not clearly defined. It is however more clearly defined in Regulation No 678/2009.

As of 2011 a new authority, the Iceland Construction Authority, has overtaken the responsibilities of the Iceland Fire Authority, including responsibilities in this particular field. Iceland Construction Authority is responsible for market surveillance of electrical equipment, including equipment falling under the scope of the LVD, intended to be permanently fixed to buildings, i.e. having a fixed connection to the electrical installation of buildings or built into or bolted or otherwise fixed to fixtures or building parts, as well as electrical equipment intended for industrial and commercial use.

Main responsibility for market surveillance and LVD products lies with the Consumer Agency since the subject of market surveillance in this field is mostly LVD products intended

for use by consumers. Financial and human resources of both the Construction Authority and the Consumer Agency as regards LVD will be addressed. The Ministry of Interior and the Ministry of the Environment have the responsibility to ensure clear and transparent transposition of the provisions of the LVD. Further clarification and necessary amendments to the legal environment with relevant changes to the ministerial decrees or Regulations, and/or legislation if necessary falls within the responsibility of the aforementioned Ministries.

Electromagnetic compatibility (EMC)

Regulation No 270/2008 on electromagnetic compatibility transposed Directive 2004/108/EC on electromagnetic compatibility (EMC). The system of conformity assessment procedures follows the rules and modules as laid down in the Directive. The Icelandic Construction Authority and the Consumer Agency are responsible for the market surveillance.

Toys

Regulation No 408/1994 on toys and dangerous imitations transposed Directive 88/378/EEC as amended by Directive 93/68/EEC. Iceland has not yet informed the Commission about the transposition of Directive 2009/48/EC on toys safety.

Machinery

Rules No 761/2001 on machinery and other equipments transposed Directive 98/37/EC on the approximation of the laws of the Member States relating to machinery.

The Machinery Directive 2006/42/EC was transposed by the Ministry of Social Affairs and Social Security on 29 December 2009 by Regulation 1005/2009. The conformity assessment procedures follow those as laid down in the aforementioned Directive.

The Regulation is implemented by AOSH (Administration of Occupational Safety and Health) through inspections and market surveillance.

Noise emissions by outdoors equipment

Rules (IS) No 279/2003 on noise pollution of the environment resulting from the use of technical equipment designed for outdoor use transposed Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors, as amended by Directive 2005/88/EC. Directive 2005/88 was transposed by Rules (IS) No. 279/2003, as amended by Rules (IS) No. 1136/2008.

The scope of the legislation covers equipment and tools for outdoor use with the exception of cars, trains, equipment especially designed for the police, etc.

Iceland has no domestic production of such products. It relies purely on imports and is concerned mostly with market surveillance for imported products.

Lifts

Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts was transposed by the Ministry of Social Affairs and Social Security by Regulation No. 570/2000 as further amended by Regulation No. 341/2003 and Regulation No. 1003/2009.

Further amendments of the Lifts Directive 95/16/EC introduced by Machine Directive 2006/42/EC were transposed by Regulation 1003/2009.

The scope of the Regulation is lifts for persons, persons and goods, or goods only – that is if the carrier is accessible and with controls in reach.

Iceland has designated one Notified Body operating in the lifts sector.

Personal protective equipment (PPE)

Directive 89/686/EC on personal protective equipment (PPE), as amended by Directives 93/68/EEC, 93/95/EEC and 96/58/EC, is transposed in Rules 501/1994 and in Regulation No 635/1999 on personal protective equipment for private use. The supervision of Rules 501/1994 falls under the auspices of the Administration of Occupational Safety and Health in Iceland (AOSH). According to Article 16 paragraph 2 of the aforementioned Rules the AOSH has delegated the market surveillance of PPE for private use to the Consumer Agency which is responsible for general product safety issues and is also the competent authority for various other new-approach directives, e.g. toys, LVD on consumer markets, etc.

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

Regulation No 77/1996 concerning equipment and protective systems intended for use in potentially explosive atmospheres transposed Directive 94/9/EC of the same name. The system of conformity assessment procedures follows the rules and modules as laid down in the Directive.

The Regulation provides the regulatory framework for equipment use and operation in the main explosive atmosphere establishments and sites in Iceland, such as fuel (oil and gas) installations. The Iceland Construction Authority is responsible for the market surveillance.

Medical devices

The Act on Medical Devices No 16/2001 represents the framework and legal base for implementation of Directive 90/385/EEC. Furthermore, it enables the Government to implement further directives with a regulation.

Directive 93/42/EEC was transposed first in 1994 by Regulation 368/1994. Regulation 892/2004 on Medical Devices in 2004 transposes Directives 93/42/EEC, 2000/70/EC, 2001/104/EC and 2003/12/EC, and the amendment in 2006 transposes Directives 2003/32/EC and 2005/50/EC.

The new Regulation 943/2010 on Medical devices issued in December 2010 transposes the abovementioned Directives and Directive 2007/47/EC.

Directive 90/385/EEC was transposed by Regulation 476/1994. The new Regulation on active implantable medical devices was published in December 2010 and further transposes Directives 93/68/EEC and 2007/47/EC.

Directive 98/79 was transposed by Regulation 936/2011.

From the 1st of May 2011 the Icelandic Medicines Agency is the competent authority for medical devices and is responsible for surveillance of the safety of medical devices and it co-operates with the Consumer Agency regarding market surveillance.

Gas appliances

Directive 2009/142/EC (which codified Directive 90/396/EEC on Appliances burning Gaseous Fuels) was transposed by the Ministry of Social Affairs and Social Security by Rules No. 108/1996. Iceland still needs to provide information as to the used gas types, according to Article 2.2 of the Directive.

Pressure vessels

The Pressure Equipment Directive 97/23/EC was partly transposed by the Ministry of Social Affairs and Social Security by Rule No. 571/2000. Iceland stated that this transposition needs to be completed. All Pressure Equipment under the scope of the Directive shall be CE-marked. Surveillance of the market is performed by AOSH inspectors.

Rules No 99/1996 on simple pressure vessels transposed Directive 87/404/EEC on the harmonisation of the laws of the Member States relating to simple pressure vessels, codified by Directive 2009/105/EC

Pressure equipment is not manufactured in any quantity in Iceland. Therefore, market surveillance mostly refers to imported pressure equipment.

AOSH has cooperated with the other Nordic countries through NTM (Nordic and Baltic Pressure Equipment Authorities). In 2008-2009 there was cooperation through the Nordic Council of Ministers on Market Surveillance. AOSH receives RAPEX announcements through the Consumer Agency.

Cableway installations

Regulation No 668/2002 on cableway installations designed to carry persons transposed Directive 2000/9/EC of the same name. The system of conformity assessment procedures follows the rules and modules as laid down in the Directive.

Construction products

Iceland stated that Regulation No 431/1994 on construction products as amended by Regulation No 557/2008 transposed Directive 89/106/EEC relating to construction products as amended by Directive 93/68/EEC. However, Annex IV of the above-mentioned Directive has not been completely transposed.

A new Regulation issued by the Ministry of the Interior was published in December 2010. The Regulation contains an update to the list of standards referred to in the Directive. New Act on Construction No 160/2010 provides a new legal basis for the market surveillance of construction products and the implementation of EU legislation. According to the new legislation the Iceland Construction Authority is the competent authority for the market surveillance of construction products.

As a new Regulation 305/2011/EU on Construction Products has been adopted and is already in force in the EU since April 2011, the Directive 89/106/EEC will be fully abolished by 1 July 2013.

Recreational craft

Regulation No 168/1997 on leisure boats, with subsequent amendments, transposed Directive 94/245/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, as well as amending Directive 2003/44/EC.

Eco-design requirements for energy-relating products (ERP)

Act No 42/2009, on the eco-design of products that use energy, transposed Directive 2005/32/EEC for the setting of eco-design, amending Directive 92/42/EEC and Directives 96/57/EEC and 2000/55/EEC. According to the afore-mentioned Act, the Minister of Industry can lay down further rules for the implementation of the Act, including rules on type approvals. These implementing Regulations have not been adopted yet.

The new Eco-design Directive 2009/125 has not yet been incorporated into the EEA Agreement and has therefore not yet been transposed in Iceland.

The particular Eco-design implementing Regulations have not yet been implemented in Iceland since they are not yet incorporated into the EEA Agreement, but this incorporation is expected, according to Iceland, in late 2011.

Radio and telecommunications terminal equipment (R&TTE)

Act No 81/2003 on Electronic Communications (section XII) and Regulation No 90/2007 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, transposed and implemented Directive 1999/5/EC.

Explosives for civil uses

Regulation No 684/1999 on explosives, with subsequent amendments, transposed Directive 93/15/EEC and Directive 2004/57/EEC. Weapons Act No 16/1998 is the general legal basis for explosives for civil use. A licence from the Police Commissioner of the Capital Area is required for imports or production in the course of professional duties. The Administration of Occupational Safety and Health in Iceland assesses whether explosives satisfy the standards of Directive 93/15EEC.

II.d. Old approach product legislation

Emissions of pollutants from non-road mobile machinery engines

Regulation No 465/2009 on gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, transposed Directive 97/68/EC, as well as amending Directives 2001/63/EC, 2002/88/EC and 2004/26/EC.

Automotive sector

The Road Traffic Directorate is the type approval authority for motor vehicles. However, as there is no construction of motor vehicles in Iceland, it has never issued neither a component approval nor a whole vehicle type approval. The Road Traffic Directorate in cooperation with other Nordic countries (Norway, Sweden, and Finland) runs a project called Nor-Type. The purpose of Nor-Type is to register technical information from type-approval documents for use in the vehicle-register database in each participating country.

This registration covers all M1 vehicles but the plan is to register also N1 and L3e category. Iceland is responsible for running the operation on a daily basis. Registration of type-approved vehicles is based on EU legislation. For single vehicle registration Iceland accepts valid Certificates of Conformity or component approvals based on EU, ECE and FMVSS.

Iceland has fully transposed Directive 70/156/EEC with Regulation No 822/2004 on design and equipment of motor vehicles, giving preference to EU type approval of vehicles based on the above-mentioned Directive and subsequent amendments.

Directive 2007/46/EC of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (repealing Directive 70/156/EEC) has not yet been transposed by Iceland. Norway has asked for an adaptation text which has led to a delay in incorporating the Directive into the EEA Agreement. According to the Directive, stricter rules will apply as regards EU type approval of vehicles. Iceland plans to revise the current Regulation on Design and Equipment of motor vehicles to adjust it to Directive 2007/46/EC.

Iceland stated that it intends to become a party to the UNECE 1958 Agreement as well as the 1998 Agreement, probably before the end of 2011. With reference to the UNECE 1958 Agreement, Iceland does not intend to accede to any Regulation to which EU Member States have not acceded. Iceland has so far neither ratified the 1968 Vienna Conventions on Road Traffic, nor the one on Road Signs and Signals.

Iceland stated that Directive 2002/24/EC on the type-approval of two or three-wheel motor vehicles and Directive 2003/37/EC on type approval of agricultural or forestry tractors have been implemented with Regulation No 822/2004.

Iceland is aware that the placing on the market in Iceland of vehicles other than those based on the EU *acquis* will not be possible in the future.

Chemicals

Limitations, classification, packaging and labelling (REACH, CLP/GHS)

Icelandic chemicals legislation is divided into two main acts: Act No 52/1988, on toxic and dangerous substances and Act No 45/2008 on chemicals and preparations.

Act No 52/1988 forms the basis for implementing European legislation on chemicals; over 100 Icelandic regulations have been set mainly to implement different EU Directives and Regulations. These include the Dangerous Substances Directive 67/548/EEC, Dangerous Preparations Directive 1999/45/EC, Council Regulations on new and existing substances (793/93/EEC and others), Directive 76/769/EEC on limitations of marketing of substances and preparations, Directive 76/768/EEC on cosmetics, Directive 98/8/EC on biocides and Regulation no 648/2004/EC on detergents.

Act No 45/2008 was set as a basis for implementation of the REACH Regulation (EC) 1907/2006 in 2008. REACH entered into force in Iceland in June 2008 and is implemented by Regulation No 750/2008 on registration, evaluation, authorisation and restrictions of chemicals. The procedure for transposing amendments to the REACH-Regulations and implementing legislation in Iceland is to publish them in annexes to Icelandic Regulation no 750/2008. This applies for Regulations (EC) No. 1907/2006, 340/2008, 134/2009, 771/2008, 987/2008, 552/2009, 276/2010 and Directive 2006/121/EC. Other REACH EU-Regulations still await incorporation into the EEA Agreement and translation into Icelandic before they can be transposed into Icelandic law.

Iceland has set up a national helpdesk to answer questions from Icelandic manufacturers, importers and downstream users. As regards inspection and enforcement, local health authorities carry out inspections of substances on the market and of producers holding operating permits issued by these authorities. The Environmental Agency carries out inspections of large producers and companies it issued permits to. As to penalties for non-compliance with the REACH Regulation, Iceland has in place a "catch-all" provision that can be used for all violations of requirements. Iceland is represented in the FORUM and Help-Net and in the Member State Committee. Iceland has not yet nominated members for the Risk Assessment Committee or the SEAC committee. The Icelandic authorities do not have the in-house capacity to evaluate substances on the EU rolling action plan or to prepare and submit dossiers for identification of substances of very high concern and foresee that they will rely on external experts for assistance. To prepare in the REACH Committee for the comitology procedure, Iceland indicated that it lacked the human resources, but explained that it was considering participating upon accession. As to the building of capacity to participate in the Partner Experts Groups and technical subgroups, Iceland indicated it had not been able to participate in these due to limited administrative resources.

All substances and preparations must be classified and labelled according to Regulation No 236/1990 on classification, labelling and treatment of toxic and dangerous substances. This Regulation is based on EU legislation on classification and labelling (67/548/EEC and 1999/45/EC). Substances and preparations which are classified must be labelled in Icelandic.

Regulation No 1272/2008/EC on classification, labelling and packaging of substances and mixtures (GHS Regulation) will be implemented in Iceland as part of the EEA Agreement in 2012.

The Environment Agency is the competent authority for implementation and enforcement of the REACH Regulation in Iceland. Within the Agency there are 1,25 full-time equivalent units designated for the work of implementing and enforcing REACH. Around three persons in the Agency are handling REACH issues on a regular basis.

Local health authorities carry out inspections of substances and preparations on the market and also with producers holding operating permits issued by them. The Environment Agency carries out inspections of large producers and companies who have operating permits issued by the Agency. The Environment Agency also acts as an overall coordinator for enforcement and inspections, and supplies information and training for health inspectors.

Detergents

Regulation No 708/2008 implemented Regulation (EC) No 648/2004 on detergents. The same applies to Regulation no. 907/2006/EC (annex II to 708/2008) and Regulation 551/2009/EC

which was annexed to Regulation 833/2010 which amends Regulation 708/2008. The Regulations are set with a base in Icelandic Act no 45/2008 on substances and mixtures.

Fertilisers

Regulation No 630/2007 on inorganic fertilisers implemented Regulation (EC) No 2003/2003 relating to fertilisers, as well as amending Regulations (EC) No 886/2004, 2076/2004 and 162/2007.

According to Article 3 of Regulation No 630/2007 and Article 9 of Regulation No 398/1995, Iceland prohibits cadmium content in fertilisers higher than 50 mg of cadmium per kg of phosphorus.

Commission Regulation (EC) No 1107/2008, amending Regulation (EC) No 2003/2003 will be transposed in Iceland following incorporation into the EEA Agreement.

Drug precursors

Work is in progress in preparing amendments to Regulation No 233/2001 on narcotic drugs and psychotropic substances and other controlled substances, in accordance with Commission Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) 273/2004, and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Good laboratory practice (GLP)

According to Act No 24/2006 on accreditation, Iceland Accreditation (ISAC) is responsible for the evaluation of GLP and also for routine inspections.

Although ISAC has been entrusted with the responsibility of assessment of GLP, Iceland stated that no application for this type of assessment has been received so far.

Pharmaceuticals

Regulation No 950/2008 implemented Regulation (EC) No 273/2004 on drug precursors. Active pharmaceutical ingredients need to be manufactured according to Good Manufacturing Practices (GMP) which, according to Iceland, is in accordance with the present EU legislation.

As part of the EEA, Iceland has implemented most of the acts regarding medicinal products for human and veterinary use. Pharmaceutical Act No 93/1994 is the general framework and legal base regarding medicinal products and contains rules concerning marketing authorisations for medicines in Iceland in collaboration with regulatory authorities in the EEA, control and surveillance of the pharmaceutical industry in Iceland, and rules on pricing of medicinal products.

Iceland approves medicinal products by issuing a marketing authorisation (MA) according to current EU legislation, i.e. for centrally authorised products, Iceland issues a MA within a month from the Commission's approval, and for decentralised products MAs are issued via the mutual recognition procedure or the decentralised procedure. Through the Icelandic Medicines Agency, Iceland is fully represented in the scientific committee of the European Medicines Agency and in the network of EEA Heads of Medicines agencies.

Iceland stated that the structure of the Pharmaceutical Act needs to be revised, some aspects need to be clarified and some elements are missing in particular some definitions.

Iceland informed that the pharmaceutical package from 2004 was transposed by Regulation 141/2011 and Regulation 142/2011.

Being a small market Iceland's access to medicines is affected by the high costs of authorisation and translation; and given the limited volume of sales on the Icelandic market, these results in entry barriers and high costs for pharmaceutical products.

Cosmetics

Regulation No 758/2003 on Cosmetics, with subsequent amendments, fully transposed the European Cosmetics Directive 76/768/EEC with subsequent amendments, except for amending Directive 2008/88/EC which was transposed with Regulations 879/2009. The same rules apply in Iceland as in the EU for the production and marketing of cosmetics. According to these rules cosmetic products need to be labelled either in Icelandic, English, or any other Nordic language except for Finnish. The labelling needs to be in indelible, easily legible characters and with visible lettering. Cosmetics in spray cans need to be labelled in Icelandic, according to Regulation No 236/1990 on classification, labelling and treatment of toxic and dangerous substances.

The Environment Agency of Iceland is the competent authority and is responsible for implementation and coordination of enforcement of the regulations on cosmetics. Local health authorities are responsible for market surveillance, while the Environment Agency receives RAPEX notifications from the Consumers Agency and forwards them to the local health authorities.

Legal metrology and pre-packaging

Directive 76/211/EEC and Directive 2007/45/EC have been transposed by Regulation No 437/2009 on pre-packaging and e-marking.

Iceland stated that Directive 75/107/EEC on bottles used as serving containers was transposed by Regulation 130/1994/IS by a direct reference without any modifications. Following the same method, various old approach Directives have also been implemented on the basis of regulations and administrative provisions of the Ministry or the Consumer Agency.

The following Council Directives were implemented by Regulation 130/1994/IS by a direct reference without any modifications:

1. 71/347/EEC – mass of grain
2. 71/349/EEC – calibration of the tanks of vessels
3. 75/107/EEC – bottles used as serving containers
4. 76/765/EEC – alcohol meters and alcohol hydrometers
5. 76/766/EEC – alcohol tables
6. 86/217/EEC – tyre pressure gauges for motor vehicles

The Consumer Agency as competent authority is entrusted with making decisions on the type approval for old approach Directives according to the afore-mentioned Regulations and the general provisions in Regulation 129/1994 concerning this issue. Iceland is a signatory to the

TAA Agreement (Trade Agreement Act) of WELMEC (European cooperation in legal metrology) regarding instruments outside the scope of EEC Directives.

Periodical legal verifications of instruments are outsourced and carried out by accredited testing laboratories according to an agreement and mandate from the Consumer Agency and relevant regulations, as applicable. The Consumer Agency is however the supervisory authority in this area and responsible for all administrative measures concerning legal re-verifications of measuring instruments.

In addition to the requirement to use legal measuring instruments, checks are to be carried out by the competent departments on the premises of the packer/importer as well as market surveillance of e-marked pre-packages as regulated according to the pre-packages Directive as transposed by Regulation No 437/2009, on pre-packaging and e-marking.

Aerosol dispensers (ADD)

Regulation 98/1996, on aerosols transposed Directive 75/324/EEC relating to aerosol dispensers. The Regulation is currently updated following the Commission Directive 2008/47/EC.

Crystal glass

Rules No 382/2007 on the composition, production qualities and marking of crystal glass transposed Directive 69/4943 on the approximation of the laws of the Member States relating to crystal glass.

The Consumer Agency is responsible for market surveillance.

Textiles

Iceland has transposed the EU Directives relating to textiles on the basis of Act N° 57/2005. The Consumer Agency has issued and published the following acts: Rules N° 408/2007, Advertise N°1047/2008, Rules N° 295/2010, Rules N° 829/2010, Advertise N° 892/2010

Footwear

Rules No 391/2007 on the labelling of materials used in the main components of footwear transposed Directive 94/11/EC relating to labelling of the materials used in the main components of footwear for sale to the consumer. The Consumer Agency is responsible for market surveillance.

Return of cultural objects

Directives 1993/7/EEC, 96/100/EC and 2001/38/EC/199 on the return of cultural objects unlawfully removed from the territory of a Member State have been incorporated into the EEA Agreement and have been transposed in Iceland by means of Act No 57 /2011 on the export of cultural goods and the return of cultural goods to other countries.

Firearms

Main elements of Directive 91/477/EEC on weapons as amended by Directive 2008/51/EC are already included in the Weapons Act of 1998. According to Iceland, the transposition will be further completed by a new bill which is expected to be introduced into the legislative procedure by spring 2012.

II.e. Procedural measures

Notification procedures

Iceland has transposed the provisions of Directive 98/34/EC through Act No 57/2000 on the exchange of information on technical regulations on goods and services, which lays down a procedure for the provisions on information in the field of technical standards and regulations and on rules on information society services. The provisions of this Act are based on Directive 98/34/EC, but depart from it as to the type of reaction and the possibility to request an urgency procedure.

The Consumer Agency in Iceland is the national contact point for this notification procedure. However, Iceland stated that it does not participate directly in the 98/34 Committee but is represented by the EFTA Surveillance Authority.

Iceland periodically notifies, through the EFTA Surveillance Authority, certain draft technical regulations to the Commission.

Directive 98/34 was incorporated into the EEA Agreement. However, the rules on notification of technical regulations do not apply in exactly the same way in Iceland as in the EU Member States. Iceland is aware of the need to change the procedure by the date of accession.

III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY

Overall, as an EEA member, Iceland has already attained a high level of alignment and implements a substantial part of the *acquis* in this chapter. Given this level of alignment, Iceland should have few difficulties implementing the additional *acquis* by the time of accession.

Overall, Iceland has the necessary implementing capacity. Where specialised experience is not available in given areas, Iceland has sought cooperation with the EU Member States. However, Iceland will need to participate in relevant sector fora of implementation established at EU level, and there is a need to improve administrative capacity in some areas.

III.a General Principles

Iceland has reached a high level of alignment and applies most of the *acquis* in the field of free movement of goods. Transposition of relevant EU legislation by Iceland has been ensured following the inclusion of the *acquis* into the EEA Agreement. However, in some cases, Iceland has yet to transpose recently adopted EU legislation.

III.b Horizontal measures

European standards have been implemented as national standards. Icelandic authorities will have to address the issue of a policy with regard to the publication of references of harmonized standards in the area of 'new approach' Directives. Regulation 765/2008 and Decision 768/2005 need to be fully implemented. With regard to market surveillance, it is

important that relevant competent authorities will organise and carry out market surveillance activities and have at their disposal the necessary and appropriate competence, power and resources to act in accordance with Regulation (EC) 765/2008. In the area of accreditation, Iceland needs to ensure the operability of its accreditation body, unless it decides to have recourse to the national accreditation body of another Member State.

Directive 2009/3/EC relating to units of measurement needs to be transposed.

III.c New and global approach product legislation

Iceland has implemented EU legislation with a few exceptions. These exceptions refer mainly to the more recently adopted acts of EU legislation which so far have not been incorporated in the EEA Agreement. Iceland is aware of these cases and needs to undertake the necessary work of transposition by the time of accession.

Furthermore, regarding Directive 97/23/EC on pressure equipment, the existing transposition needs to be completed.

Iceland's national legislation transposing Directive 2006/95/EC on low voltage equipment needs be reviewed with a view to clearly differentiate between equipment subject to the Low Voltage Directive and other non-harmonized equipment. Iceland needs to separate the relevant Icelandic provisions that transpose provisions of the LVD from Act No 146/1996 and from Regulation No 678/2009. This would allow to better distinguishing in view of enforcement between harmonised and other provisions on high voltage and fixed electrical installations of buildings.

The transposition by Iceland of Directive 89/106/EEC on construction products needs to be further reviewed in view of its completeness. Moreover, Iceland will need to transpose by the time of accession the new Regulation 305/2011/EU on Construction Products. The Commission services will need to continue monitoring and assessing progress in this area.

III.d Old approach product legislation

Iceland has reached a good level of alignment in the area of relevant sector legislation with a few exceptions.

The transposition of the legislative framework in the automotive sector needs to be completed. Iceland needs to make sure that by the time of accession, only those vehicles and components in conformity with the EU *acquis* can be placed on the market and that the entire *acquis* has been fully transposed and implemented. This includes the setting up of administrative capacity to deal with the obligations detailed within the safeguard clauses in each framework directive.

Iceland will also have to finalise the transposition of REACH amendments and step up administrative capacity for REACH.

Iceland will need to finalise the implementation of Regulation EC No. 2003/2003 on fertilisers. The Commission has taken note of the fact that Iceland prohibits cadmium content in fertilisers higher than 50 mg of cadmium per kg phosphorus. This national limit of composition conflicts with the "free movement" clause in Article 5 of Regulation 2003/2003/EC. Upholding this national limit would require derogation from the *acquis*.

Two additional amendments to technical progress i.e. Commission Regulation (EC) No. 1020/2009 and Commission Regulation (EU) No. 137/2011 were published in the EU OJ since 2008; they will have to be transposed and implemented by Iceland by the time of accession.

With regard to GLP compliance monitoring, it would be advisable for Iceland to enter into a formal agreement with one of the established EU GLP monitoring authorities in line with OECD Guidance document [http://www.oecd.org/dataoecd/35/9/36922870.pdf] and inform the Commission about the conclusion of such agreement. Examples for countries having done so are Malta (agreement with Ireland), Luxemburg (agreement with Belgium) and Cyprus (agreement with Greece).

The transposition into the Icelandic legal order of the *acquis* in the area of pharmaceuticals will have to be completed. The structure of the Pharmaceutical Act needs to be revised, some aspects need to be clarified and some elements are missing, in particular some definitions.

In the area of legal metrology and pre-packaging all the Council Directives, except for Directive 75/107/EEC on bottles used as serving containers, have been repealed by Directive 2011/17/EU, which Iceland will need to transpose.

III.e Procedural measures

Iceland will have to fully transpose Directive 98/34/EC on the exchange of information on technical regulations on goods and services by the date of accession.