

8 September 2006

Screening report

Croatia

Chapter 1 – Free Movement of Goods

Date of screening meetings:

Explanatory meeting: 16-20 January 2006

Bilateral meeting: 13-17 February 2006

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 EC Treaty, in particular Articles 28 to 30, 95(4) to 95(9), 296 to 298, as interpreted in the case law of the European 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 should be put in place to apply the information exchange procedures laid down in Decision 3052/95/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 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) or the “new and global approach” (imposing general product requirements).

New and Global Approach product legislation covers 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-using products (EUP), and 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, wood classification and crystal glass.

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

II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

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

Croatia indicates that it can accept the *acquis* regarding Free Movement of Goods. Croatia indicates that it does not expect any difficulties to implement the *acquis* by accession, except for the following:

- complying, upon accession, with data exclusivity provisions requiring a period of ten years (currently in Croatia 6 years is required);

- upgrading in time for accession the marketing authorisations of existing products not authorised on the basis of the requirements foreseen by the Community *acquis*.

II.a. General Principles

Legislative alignment

Croatia has initiated an internal screening of its domestic legislation in the light of Articles 28-30 EC, as interpreted by the ECJ case law and Commission interpretative documents. So far the analysis of three laws has been completed.

Croatia legislation allows for exceptional price control measures but does not apply it at present to industrial goods.

Provisions regarding import and export licenses are contained in a regulation based on the Trade Act. These currently apply to goods considered as sensitive, e.g. for environmental or security reasons.

No horizontal legislative provisions have been identified, which would make market access conditional upon the existence of an agent or representative established in Croatia. Specific requirements for storage facilities are indistinctly applied to domestic and imported goods on the basis of health and safety considerations (e.g. petroleum, food or medicinal products).

Horizontal legislative provisions under the Consumer Protection Act require all consumer information regarding a product to be provided in the national language and script, alongside any other languages. The use of easily understandable pictogrammes or foreign words is not considered equivalent. The act also provides for obligatory marking of the country of origin, as well as of the names and seat of the importer.

The Croatian Chamber of Economy has conducted a “Buy Croatian” campaign in 1997 and interrupted it at the beginning of 2005. At the end of 2005 a new campaign was launched "Produce and Buy Quality Products" which advertises quality products instead of explicitly domestic ones.

Parallel imports are not subject to specific restrictions.

As regards technical barriers to trade, a number of mandatory standards are still in place. The principle of mutual recognition is not yet enshrined in the legislation.

Croatia intends to continue the internal screening of its legislative measures which might be in breach of Articles 28–30 EC. Croatia plans to complete the screening of measures falling under State administrative bodies by the end of 2006. No particular target intermediate or completion dates have been provided for measures under other public entities such as local authorities.

Croatia plans to modify its import and export license regime so as to limit it to cases regulated at international level, e.g. the Basel or Montreal conventions. The revision of the Trade Act will rule out the application of licenses in trade with the EU as from accession. No particular date has been provided for its adoption. The revision of the Consumer Protection Act, planned for the 3rd quarter of 2006, will reduce the scope of mandatory provisions concerning labelling and marking.

The inventory of mandatory standards and restrictive technical regulations should last a year. Croatia is still considering options for the introduction of mutual recognition clauses in its

legislation, i.e. in framework or in sector legislation. No particular date has been provided in this respect.

Implementation capacity (incl. administrative capacity)

The central administrative authority is the Ministry of Economy, Labour and Entrepreneurship.

A regulation of July 2005 foresees the creation of a Department for Coordination of the Internal Market within the Ministry. The new structure is meant to steer all activities related to this *acquis* chapter, including the internal screening of legislation in the light of general principles. This department is currently staffed with one head and 2 professionals.

The Department plans to recruit two further professionals in the course of 2006, and more in the future.

Croatia has not yet identified a contact point for the information exchange procedure under Decision 3052/95/EC on measures derogating from the free movement of goods. For the “strawberry” Regulation (EC) No. 2679/98, the Department for Coordination of the Internal Market will become the contact point upon accession.

II.b. Horizontal Measures

Standardisation

The legal framework for standardisation in Croatia consists of the Standardisation Act of 2003, the Decree on the Establishment of the Croatian Standards Institute of October 2004, and on the rules on membership in the Croatian standards institute as well as its statute.

The national standards body is the Croatian Standards Institute (HZN). It operates since July 2005 as an autonomous public institution following the splitting up of the standardisation, accreditation and metrology functions. Most of the HZN income originates from the State budget. A more limited share is made of membership fees and sale of standards or services.

Members have been admitted since September 2005. A founding General Assembly was foreseen in early 2006, following which the composition of the Administrative Board could be reviewed and the Director General appointed on a permanent basis. The HZN employs 46 staff, operates its own infrastructure, and maintains a website as well as various publications.

The HZN is a member of the International Organization for Standardization (ISO), the International Electro-technical Commission (IEC) and the European Telecommunications Standards Institute (ETSI). It is an affiliate member in the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Croatia participates in 3 ISO Technical Committees (TCs) and 6 IEC TCs.

The HZN’s 172 TCs mirror 60 to 80% of international and European work in ISO, IEC, CEN, CENELEC and ETSI. SME participation in the Croatian standardisation work is high. Croatia considers consumer and environmental NGO participation still low yet. The HZN is striving to increase NGOs’ interest in standardisation.

The Croatian Standards Institute has so far transposed about 66.6 % of the CEN and CENELEC standards, mostly by adopting the drafting language version, occasionally by translating them into Croatian.

HZN does not yet have a target date for its application for full CEN/CENELEC membership. According to Croatia, compliance with the Nine Conditions for full membership depends largely on the speed of withdrawal of mandatory standards from the technical legislation, which will follow from alignment on the *acquis*.

Conformity assessment

The legal framework for conformity assessment in Croatia consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and of the Ordinance on the Form and Use of Conformity Mark of 1998, as amended.

The Act notably outlines procedures for assessing conformity, which mirror some of the modules described in Decision 93/465/EEC. These become effective in each sector once further legislation is adopted in line with the *acquis*. In the meantime earlier provisions on pre-market mandatory certification continue to apply, even if foreign test reports may be recognised in certain conditions. 44 such technical regulations are still in force in areas covered by the New Approach directives.

Ministries are responsible for designating conformity assessment bodies (CABs). The criteria for ascertaining their competences are defined in the sector legislation. According to the Accreditation Act, accreditation remains a voluntary process, distinct from the authorisation given by the relevant Ministry by designating a CAB. The ministries ascertain the competence of a CAB themselves, if they have qualified staff to perform this assessment. If not, the Croatian Accreditation Agency is consulted to assess a CAB before taking the decision on the designation. Croatia estimates its total number of testing laboratories at 400 and inspection bodies at 200. The current number of CABs active in Croatia is 33.

Provisions foresee the mandatory use of CE marking, which will be triggered upon accession or upon the conclusion of a mutual recognition agreement with the EU. In the meantime the so called 'C marking' applies as an interim solution. The legislation contains requirements to provide the technical files in the Croatian language and to specify the origin of the products.

A separate regulation on market surveillance contains a safeguard clause foreseeing the withdrawal of compliant products that are nonetheless found to endanger health and safety.

Some of the manufacturer responsibilities are defined in the Obligations Act, as amended in 2004. Manufacturer's general product liability remains to be further established, since the importer is currently held responsible for aspects covered in the manufacturer's declaration of conformity.

Draft amendments to the Technical Requirements for Products and Conformity Assessment Act were drafted in 2004. Croatia plans to prepare new draft amendments, in accordance with its 2006 National Programme for Integration into the EU. The presentation of the bill to government is foreseen in 2006.

Accreditation

The legal framework for accreditation in Croatia consists of the Accreditation Act of 2003, the Decree on the Establishment of the Croatian Accreditation Agency of October 2004, and of the Statute of the Croatian Accreditation Agency of June 2005.

The national accreditation body is the Croatian Accreditation Agency (HAA). It has operated since July 2005 as an independent and non-profit public institution exercising a public authority function. The HAA receives income from the State budget. The HAA employs 17

permanent staff and draws expertise from assessors and experts. Croatia considers that its accreditation system, based on the EN 45000 and ISO 17000 standard series, is operational. Croatia indicates that accreditation is performed on the basis of the qualification criteria laid down in Croatian standards transposing harmonised EN standards. It has so far accredited 66 bodies, of which 43 testing laboratories, 7 calibration laboratories and 9 inspection bodies.

The HAA is an associate member of the International Laboratory Accreditation Cooperation (ILAC). It is also a full member of the European Co-operation for Accreditation (EA) since November 2005.

Accreditation is not mandatory for conformity assessment bodies (CABs) in Croatia, but is considered as the most appropriate means to assess competence. The Croatian Government will further reflect the role of accreditation in the procedure of designation, and future notification, of CABs.

In 2006, the Croatian Accreditation Agency plans to complete the upgrading of its infrastructure, to update its quality management documents, to train assessors and establish technical committees. It also plans to raise the number of permanent staff to 20 by the end of 2007.

The HAA plans to apply for the EA Multilateral Agreements (MLAs) signatory status in 2006/2007, starting with calibration, testing, inspection and certification for quality management systems.

Metrology

The legal framework for metrology in Croatia consists of the Metrology Act of 2003.

The State Office for Metrology (DZM) is responsible for legal metrology. It has operated as an autonomous public authority since July 2005. The DZM employs 118 staff, of which 76 experts. The Office's incomes originate partly from the State budget, partly from verification and testing services. The DZM runs laboratories in Zagreb, Rijeka, Split and Osijek. It also performs verification and testing, and includes a Metrological Inspection which inspects instruments in use. 7 inspectors are currently employed, and their number should reach 20 in 2007.

The DZM is a member of the International Organization of Legal Metrology (OIML) and the European Collaboration in Measurement Standards (Euromet). Croatia is an associate member in the General Conference on Weights and Measures (CGPM). It expects to become an affiliate member of the European Cooperation in Legal Metrology (WELMEC) in 2006.

The DZM also oversees scientific metrology policy on an interim basis through its Department for Fundamental Metrology, until the Croatian Metrology Institute (HMI) is established. In particular, the DZM ensures measurement traceability and holds the State measurement standards for mass and density, while others are held in the other National Calibration Laboratories at the University of Zagreb, the Shipbuilding Institute and the Rudjer Boskovic Institute. Most are accredited by peers in the EU. Traceability to BIPM measurement standards is also generally available.

Croatia plans to separate scientific metrology from legal metrology functions. Croatia indicates it needs to change the existing Law on Metrology in order to establish the HMI as a separate public institution outside the existing State Office. The HMI would be organised as a decentralised organisation federating the various institutes active in this field. The proposal

for the new Law will be drafted by mid 2007 and after adoption by the Croatian Parliament, the establishment of the HMI as a separate public institution could start by the end of 2007.

Market surveillance

The legal framework for market surveillance in Croatia is based on a series of specific laws. Division of work is based on the Act on the Organisation and Scope of Central State Administration Bodies. Sanctions in this area are in most cases applied by reference to the Misdemeanour Act of 1992, as amended.

Most market surveillance activities are performed by the State Inspectorate, an autonomous central State administrative body established in 1997 under the Ministry of Economy, Labour and Entrepreneurship. The legal framework for its activities is the Act on the State Inspectorate of 1999, as amended. Certain product groups fall under the responsibility of other bodies, notably the Sanitary Inspectorate, the Telecommunications Inspection and the Building Inspection. The various bodies exchange information on their findings and meet at regular intervals to discuss annual and monthly planning of inspection campaigns. Overall, there currently is no body with lead responsibility over market surveillance in Croatia.

The State Inspectorate employs a total of 958 staff, of which 358 market inspectors, mostly university graduates. Its head is the Chief Inspector, appointed by the Government. In May 2005 a government regulation reorganised the market surveillance functions, with six specialised departments in the head office. The State Inspectorate is organised into headquarters in Zagreb, five regional offices, and 38 branch-offices reporting to these offices. The Sanitary Inspectorate employs in total 257 inspectors of which 173 graduates. The Telecommunication Inspection employs one inspector with university degree.

The Croatian market surveillance authorities do not possess their own laboratories; where a product is suspected of non-compliance, third party laboratories are contracted to determine compliance. Market surveillance is financed by the State budget. There is no mechanism for supplementary financing if budgets are exceeded. Market surveillance authorities in Croatia generally do not have the power to impose administrative penalties on miscreants; this can be done only by a court. However, inspectors of the State Inspectorate have the authority to impose fines on the spot stipulated by a specific law. Moreover market surveillance authorities can impose a number of corrective measures such as provisional bans or market withdrawals.

56 product groups, of which 22 relate to foodstuffs, are subject to pre-market assessment by the State Inspectorate. This applies to importers and domestic producers for the first import or the first placing on the market of a given product. The adoption of legislation in line with the *acquis* requires new means and methods of market surveillance. A gap analysis has been performed, in the light of an analysis of market structure. It revealed that the system is not sufficiently fit for purpose.

Croatia intends to increase education and specialised training for inspectors and to develop and implement, in the coming years, a strategy for market surveillance in the field of industrial products.

II.c. New And Global Approach Product Legislation

Legal metrology: non-automatic weighing instruments; measuring instruments

The legal framework in this area is based on the Metrology Act of 2003. An ordinance of 2005 regulates non-automatic weighing instruments (NAWI), which Croatia considers to be fully in line with the directive. As regards measuring instruments, 14 ordinances are in place, which Croatia considers to be partially in line with the directive, as they include most essential requirements but not all conformity assessment modules.

Croatia plans to bring the Metrology Act into compliance with both directives by the end of 2006. It plans to issue 9 new ordinances during the second half of 2006 with the aim of achieving full implementation of the measuring instruments directive at the end of 2007.

The competent authority is the State Office for Metrology.

Croatia has not yet identified potential Notified Bodies and does not envisage to have any for NAWI. The DZM still performs inspection of measuring instruments in use. This should be examined during the preparation of the Decree on the Reorganisation of DZM in 2006.

Market surveillance is performed by the State Inspectorate. No particular information was provided as regards their activity in this sector.

Low voltage equipment (LVD)

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and an ordinance of 2005. The ordinance, which will enter into force on 1 January 2007, will repeal the existing mandatory certification requirements and pre-market controls. Croatia considers its legislation to be in line with the directive. The ordinance also regulates the use of products.

339 harmonised EN standards have been adopted as Croatian standards in this area. The ordinance presumes conformity when these Croatian standards are fulfilled.

Croatia is preparing guidelines for the implementation of the ordinance. The guidelines will clarify in particular the functioning of the conformity assessment procedures and of market surveillance.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Croatia has identified six testing laboratories which could potentially meet the criteria for designation as Notified Bodies. Two have applied for accreditation. Croatia is aware that the directive does not foresee the intervention of NBs in conformity assessment in this sector except in a case when the product has been challenged to be non-compliant with the Directive.

Market surveillance is performed by the State Inspectorate. No particular plans were highlighted for adjusting to the abolition of pre-market controls.

Electromagnetic compatibility (EMC)

The legal framework in this area consists of the Telecommunications Act of 2003 and two ordinances of 2004 and 2005. Croatia considers that this legislation is partially in line with the directive, in particular in terms of scope and of conformity assessment.

Some of the harmonised EN standards have been adopted as Croatian standards in this area.

Croatia plans to fully align its legislation in this sector in the medium term.

The competent authority is the Ministry of Sea, Tourism, Transport and Development.

One testing laboratory has applied for accreditation in this sector.

Market surveillance of electrical and other technical equipment is performed by the Ministry of the Sea, Tourism, Transport and Development as well as the State Inspectorate. Croatia sees the need to strengthen the skills of the market surveillance staff before pre-market controls can be waived in this area.

Toys

The legal framework in this area consists of the Act on Health and Sanitary Inspection of Foodstuffs and General Use Products of 1997, as well as an ordinance of 2004. Croatia considers that the level of alignment of this legislation with the directive is limited, in particular in terms of scope, essential safety requirements, conformity marking, EC type examination procedures, and notification criteria.

Croatia indicates that all harmonised EN standards have been adopted as Croatian standards in this area.

Croatia plans to align its legislation on the basis of a new parliament Act on General Use Items, currently in parliamentary procedure, and of a new ordinance on safety of toys to be issued on that basis in 2007. The competent authority is the Ministry of Health and Social Welfare.

Croatia envisages to set up Conformity Assessment Bodies and to designate a Notified Body in this sector. The criteria remain to be determined.

Market surveillance is performed by the Sanitary Inspection of the Ministry of Health and Social Welfare. The Border Sanitary Inspection performs surveillance upon imports, and the Sanitary Inspection performs field inspections. Additional inspectorates are competent for electrical aspects (low voltage and EMC).

Machinery

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and an ordinance of 2005, to enter in force on 31/03/2006. Croatia considers its legislation to be in line with the directive, although importer responsibility should be distinguished from the responsibilities of the manufacturer with respect to the self-declaration of conformity.

Croatia is preparing guidelines for the implementation of the ordinance. The guidelines will clarify in particular the functioning of the conformity assessment procedures and of market surveillance. Clarification of the responsibilities of the importer requires amending the Act on Technical Requirements for Products and Conformity Assessment.

Croatia indicates that one third of the harmonised EN standards have been adopted as Croatian standards in this area. No particular target dates have been provided in this respect.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Croatia envisages setting up Conformity Assessment Bodies, with a view to designating them as Notified Bodies in this sector. An inventory and needs assessment study are ongoing for that purpose.

Market surveillance is performed by the State Inspectorate, as well as the Building Inspection and the Labour Inspection, which verify the machinery incorporated in construction works during construction or subsequent use. Croatia foresees the need to clarify the division of responsibilities between market surveillance inspectors, building inspectors and labour inspectors.

Noise emissions by outdoors equipment (Old Approach directive containing New Approach elements)

The legal framework in this area consists of the Noise Protection Act of 2003. No measure implementing the directive is in place yet.

Croatia plans to issue an ordinance for that purpose by the 1st quarter of 2007.

The competent authority is the Ministry of Health and Social Welfare.

Croatia envisages setting up Conformity Assessment Bodies, with a view to designating them as Notified Bodies in this sector, given that the directive requires the involvement of CABs at production stage.

Market surveillance will be performed by the State Inspectorate.

Emissions of pollutants from non-road mobile machinery engines (Old Approach directive)

Croatia does not have specific legislation in this area.

The legal basis will be provided by the Environmental Protection Act to be adopted in 2006. Alignment will take place by means of secondary legislation planned for 2007.

The competent authority is the Ministry of Environmental Protection, Physical Planning and Construction.

Croatia has identified a testing laboratory which could become a Conformity Assessment Body for type examination.

No particular arrangements are foreseen for market surveillance.

Lifts

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and an ordinance of 2005, to enter in force on 31/03/2006. Croatia considers its legislation to be in line with the directive. The ordinance also regulates maintenance, checks and rescue.

Croatia is preparing guidelines for the implementation of the ordinance. The guidelines will clarify in particular the functioning of the conformity assessment procedures and inspection.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Croatia has identified three laboratories which could potentially meet the criteria for designation as Notified Bodies in this sector. One inspection body has applied for accreditation. Public funding has been earmarked to upgrade these laboratories.

Market surveillance is performed by the State Inspectorate, as well as the Building Inspection, and the Labour Inspection which intervene during construction or subsequent

use. Croatia is aware that market surveillance inspectors must order remedial measures rather than withdrawal whenever technically feasible.

Personal protective equipment (PPE)

The legal framework in this area consists of the Act on Safety and Health Protection at the Workplace of 1996 as well as a series of ordinances. This legislation regulates PPEs used at work and not the consumer market.

Croatia has drafted a new ordinance in order to reach full alignment, which is planned for adoption in the 3rd quarter of 2006.

250 of the harmonised EN standards have been adopted as Croatian standards in this area. Preparations are ongoing for the remaining standards, but no target date has been set yet.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

A number of testing laboratories are active in this area. Croatia does not foresee the need to designate any Notified Bodies.

Market surveillance is performed by the State Inspectorate. The labour inspectors also verify the conformity of products with technical requirements.

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

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and an ordinance of 2005. Croatia considers its legislation to be largely in line with the directive, with some differences with respect to part of the markings, installation responsibilities, and slight differences in scope.

No particular plans have been outlined for full alignment.

Croatia indicates that all harmonised EN standards have been adopted as Croatian standards in this area.

The competent authority is the Ministry of Interior.

The former Agency for Explosive Atmospheres Hazardous Areas has been identified as a potential notified body in this sector. It has applied for accreditation

Market surveillance is performed by the Ministry of Interior and the State Inspectorate, department for electro-energetics and mining.

Medical devices

The legal framework in this area consists of the Act on Medicinal Products and Medical Devices of 2003 as well as a series of ordinances issued in 2005. Croatia considers this legislation partially in line with the directives. Essential requirements have generally been incorporated but there remain differences, notably as regards the conformity assessment procedure and pre-market controls. Directives on reclassification of breast implants, reclassification of hip, knee and joint replacements, medical devices which incorporate stable derivatives of human blood or human plasma or medical devices utilising substances of animal origin have not been transposed yet.

Croatia plans to amend the Act and one of the ordinances in order to reach full alignment by end 2007.

A small share of the harmonised EN standards have been adopted as Croatian standards in this sector. Preparations are ongoing, but no target date has been provided.

The competent authority is the Ministry of Health and Social Welfare.

The Agency for Medicinal Products and Medical Devices keeps a register of medical devices.

The Agency currently assesses conformity including testing. Croatia anticipates the need to entrust independent bodies with this task.

Market surveillance is performed by the Pharmaceutical Inspection. The Agency maintains and disseminates vigilance data. Croatia foresees the need to strengthen its market surveillance capacity in parallel with legislative alignment.

Gas appliances

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and an ordinance of 2005, to enter in force on 31/03/2006. Croatia considers its legislation to be in line with the directive, although importer responsibility should be distinguished from producer liability.

Croatia is preparing guidelines for the implementation of the ordinance. The guidelines will clarify in particular the functioning of the conformity assessment procedures and of market surveillance. Clarification of the importer liability question requires amending the Act on Technical Requirements for Products and Conformity Assessment.

79 of the harmonised EN standards have been adopted as Croatian standards in this sector. Preparations are ongoing, but no target date has been provided.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Croatia has identified two laboratories which could potentially meet the criteria for designation as Notified Bodies in this sector. Neither has applied for accreditation yet. Public funding has been earmarked to upgrade laboratories.

Market surveillance is performed by the State Inspectorate.

Pressure vessels

The legal framework in this area consists of the Act on Technical Requirements for Products and Conformity Assessment of 2003 and two ordinances of 2005, to enter in force on 31/03/2006. Croatia considers its legislation to be partly in line with the directive on pressure equipment and fully in line with the directive on simple pressure vessels, although there are requirements to provide the technical files in the Croatian language and to specify the origin of the products as well as problems in the scope of importer's responsibilities. The directives on aerosol dispensers and on transportable pressure vessels are not yet adopted.

Croatia is preparing guidelines for the implementation of the ordinance. It plans to issue the guidelines and three further ordinances by the 1st quarter of 2007 to implement fully the directives in this sector.

113 of the harmonised EN standards have been adopted as Croatian standards in this sector. Preparations are ongoing, but no target date has been provided.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Croatia has identified an inspection laboratory which could potentially meet the criteria for designation as a Notified Body in this sector. It has not applied for accreditation yet. Public funding has been earmarked to upgrade it.

Market surveillance is performed by the State Inspectorate.

Cableway installations

The legal framework in this area consists of three ordinances of 1979 and 1986 and 1991 respectively based on the Railways Act of 1974, the Standardisation Act of 1977, and the Sports Act of 1990.

Croatia plans to adopt a Cableway Installation Act by the end of 2007, on the basis of which subordinate legislation would be adopted in 2008 for full alignment with the directive in this area.

25 harmonised EN standards have so far been adopted as Croatian standards.

The competent authority is the Ministry of Sea, Tourism, Transport and Development.

No potential notified bodies have been identified so far in this area.

There is currently no central authority performing market surveillance in this area. Implementation of existing regulations is currently performed at local level.

Construction products

The legal framework in this area consists of the Building Act of 2003 as well as a horizontal ordinance of 2005 based on the former act, as well as of the Act on Technical Requirements for Products and Conformity Assessment of 2003. Croatia considers its legislation to be partially in line with the directive, although the Building Act covers construction methods in addition to materials, and pre-market control continues to apply to some product groups on a transitional basis.

Croatia plans to split the Building Act so as to cover construction products in a separate act. It plans to adopt two further horizontal ordinances based on the Building Act in order to reach full alignment with the directive.

Croatia has issued technical regulations for cement, concrete structures (including concrete, reinforcing steel, aggregates, additives, pre-fabricated products), and thermal protection and energy-saving. About 150 harmonised EN standards have been adopted as Croatian standards in this area, of which approximately 45 are referred to in technical regulations.

Croatia plans to continue progressively issuing product technical regulations implementing the EC ones, and adopting the related harmonised EN standards, between 2006 and the end of 2007.

The competent authority is the Ministry of Environmental Protection, Physical Planning and Construction.

Croatia has identified several Conformity Assessment Bodies. 15 have been accredited. One body has been designated as an Authorised Body for cement and further bodies could potentially be designated for thermal insulation, ETICS and reinforcing steel.

Market surveillance is performed by the State Inspectorate. Building inspectors ensure surveillance of construction works. Croatia anticipates the need to strengthen its capacity in this respect.

Recreational craft

The legal framework in this area consists of the Maritime Code of 2004, an ordinance of 2005, and technical rules of 2005, as well as a circular of the Croatian Register of Shipping (CRS) regarding the certification procedure during the transition period until accession or until the entry into force of a mutual recognition agreement. This legislation includes provisions on the safe operation of crafts. Croatia considers its legislation to be in line with the directive, except for conformity assessment procedures which are not fully incorporated for the time being, mandatory compliance with standards, and the lack of free choice for manufacturers to choose the conformity assessment body.

Croatia plans to reach full alignment by accession or by the entry into force of a mutual recognition agreement.

All harmonised EN standards have been adopted as Croatian standards.

The competent authority is the Ministry of Sea, Tourism, Transport and Development, which delegates the definition of implementing rules to the CRS.

The CRS has been designated as the sole competent body allowed to assess conformity with the technical requirements. It is accredited for QMS and inspection. Croatia plans to allow other bodies to operate by accession or upon the entering into force of a mutual recognition agreement.

Market surveillance is performed by the State Inspectorate. Further checks are performed upon registration.

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

Croatia does not have specific legislation in this area.

Croatia plans to transpose the directive through a regulation based on the energy-saving legislation for household appliances after the EU has adopted implementing measures concerning the directive.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

No particular arrangements are foreseen for market surveillance.

Radio and telecommunications terminal equipment (R&TTE)

The legal framework in this area consists of the Telecommunications Act of 2003 as well as the Act on Technical Requirements for Products and Conformity Assessment of 2003, and two ordinances. Croatia considers its legislation to be partially in line with the directive, in particular as regards the conformity assessment modules, the criteria and procedures for designating notified bodies and the pre-market controls.

Croatia plans to bring its legislation in line with the directive by accession.

The publication of the list of relevant Croatian standards adopting the harmonised EN standards is ensured by the Croatian Telecommunications Agency.

The competent authority is the Ministry of Sea, Tourism, Transport and Development.

The Croatian Telecommunications Agency, which is an independent regulatory body operating under the administrative surveillance of the Ministry, has been designated as the competent body to assess conformity, pursuant to the Telecommunications Act.

Market surveillance is performed by the Ministry of Sea, Tourism, Transport and Development and the State Inspectorate. Croatia anticipates the need to reinforce its capacity in this respect.

II.d. Old Approach Product Legislation

Motor vehicles

The legislative framework in the area of type approval of motor vehicles consists of the Decision of 1994 on Succession to the 1958 Geneva Agreement and annexed 49 UNECE Regulations, the Standardisation Act of 1996 and the Road Safety Act of 2004. This is complemented by the Ordinance on the Vehicle Approval System of 1996, the Ordinance on Essential Requirements for Agricultural and Forestry Tractors of 2002 and a series of specific ordinances. Croatia considers its legislation on type approval to be partially in line with the Community law, since 67 directives have been transposed so far.

Croatia plans to incorporate 4 further directives in 2006, 24 more in 2007 and the remainder soon after in order to reach full alignment. This will allow for granting as from the date of accession EC type-approvals for vehicles, systems, separate technical units and components.

The competent authority is the State Office for Metrology (DZM), Vehicle Approval Department, which is staffed with 4 employees.

The DZM relies on the Croatian Centre for Vehicles for inspection and for supervision of the network of 56 technical inspection stations. In the case of tractors, similar tasks are delegated to the University of Zagreb Office of Agriculture Mechanisation.

Croatia foresees the need to upgrade the technical services to the ISO 17025 standards. Given that its domestic production is limited to trailers, Croatia plans to partly rely on technical services based in current EU countries for approval of systems and components.

Chemicals

Limitations, classification, packaging and labelling

The legal framework in this area consists of the Chemicals Act of 2005 and a series of ordinances of 1999, 2001, 2002, 2003 and 2005. Croatia considers its legislation to be partly in line with the *acquis*, notably a number of national labelling requirements are more stringent.

Croatia plans to adopt new ordinances with a view to reach full alignment based on the forthcoming REACH package.

The competent authority is the Ministry of Health and Social Welfare.

The Croatian Institute of Toxicology is in charge of recording safety data sheets.

Market surveillance is performed by the Sanitary Inspection.

Detergents

The legal framework in this area consists of an ordinance of 2004. Croatia considers its legislation to be in line with the regulation only with regard to the labelling and marking of ingredients.

Croatia plans to reach full alignment with the adoption by the end of 2006 of a new ordinance based on the upcoming Act on General Consumption Items. The ordinance will cover both consumer and industrial use detergents.

20 of the EN standards in this area have been adopted as Croatian standards.

The competent authority is the Ministry of Health and Social Welfare.

Market surveillance is performed by the Sanitary Inspection of the Ministry of Health and Social Welfare. The Border Sanitary Inspection performs surveillance upon imports, and the Sanitary Inspection performs field inspections. Additional inspectorates are competent for other aspects (Environmental Inspection and State Water Directorate).

Fertilisers

The legal framework in this area consists of the Act on Fertilisers and Soil Improvers of 2003, as well as two ordinances of 1991. Croatia considers its legislation to be partly in line with the regulation, notably as regards limits on heavy metal and ammonium nitrate contents.

Croatia plans to adjust its legislation by accession in order to make way for the regulation as far as EC fertilisers are concerned.

The competent authority is the Ministry of Agriculture, Forestry and Water Management.

Market surveillance is performed by the Agriculture Inspection. The inspection relies on its own laboratories for testing. Croatia anticipates the need to improve its capacity in that respect.

Drug precursors

The legal framework in this area consists of the Act on Combating Narcotic Drug Abuse of 1991, the regulation on goods subject to export and import licenses of 2003, and medicinal and chemical product legislation. Croatia considers its legislation to be partly in line with the regulation.

Croatia plans to amend its legislation in order to reach full alignment, in particular to remove medicinal products from the scope, free intra-Community trade of category 3 substances and separation of intra- and extra-Community trade conditions.

The competent authorities are the Ministry of Economy, Labour and Entrepreneurship, and the Ministry of Health and Social Welfare. They issue licenses for export, import and transit of respectively toxic and medicinal precursors and other precursors.

The Sanitary Inspection performs checks on permits. The Croatian National Toxicology Institute processes annual reports provided by licensed companies. The Ministry of Economy, Labour and Entrepreneurship processes half-annual reports on precursor transfers, based on single transfer licenses and reports from licensed companies and customs.

Explosives for civil uses (New Approach directive)

The legal framework in this area consists of the Act on Explosive Substances of 2004 as well as three ordinances of 2005. Croatia considers its legislation to be largely in line with the current directives.

Croatia plans to amend its legislation in order to achieve full alignment, notably as regards the form for intra-Community transfers and the coverage of pyrotechnic articles.

35 harmonised EN standards have been adopted as Croatian standards in this area.

The competent authority is the Ministry of the Interior.

At present, there are two institutions acting as Conformity Assessment Bodies in Croatia.

Market surveillance is performed by 26 inspectors, 4 of whom are assigned to the Ministry and the others to the local and regional police units.

Good laboratory practice (GLP)

The legal framework in this area consists of the various basic acts regulating chemicals, human use and veterinary medicinal products, pesticides, food additives and biocides. Croatia considers its legislation to be largely in line with Directive 2004/10/EC following adoption of an Ordinance on GLP of May 2006. It considers its legislation to be partly in line with the other directives, in particular since animal feed additives, cosmetics, detergents and fertilisers are not covered.

Croatia plans to issue further ordinances to reach full alignment.

The competent authority is the Ministry of Health and Social Welfare.

Croatia still has to establish a GLP monitoring system.

Pharmaceuticals

Community codes relating to medicinal products for human use and veterinary medicinal products; centralised procedure for authorisation of medicinal products; good clinical practice; orphan medicinal products; good manufacturing practice and colouring matters

The legal framework in this area consists of the Act on Medicinal Products and Medical Devices of 2003, the Act on Veterinary Medicinal Products of 1998, as well as a series of ordinances. Croatia considers its legislation relating to medicinal products for human use to

be partly in line with the directives. The EC review of the pharmaceutical *acquis*¹ adopted in 2004 is not fully incorporated. Moreover there are no provisions in the legislation that foresee, as from accession, the immediate recognition of centrally-authorised medicinal products or products authorised in all other Member States through mutual recognition or decentralised procedures. Croatia indicates that an ordinance of 2004 enables the Ministry of Health to determine simplified requirements for marketing authorisation of medicinal products authorised in some EU Member States and of centrally-authorised products, which need to be relieved in order to ensure full alignment. In addition, Croatia considers its legislation relating to *veterinary medicinal products* to be in need of substantial improvements to be in line with the Community *acquis*

Croatia plans to adopt new legislation in order to reach full alignment by accession. However, it anticipates difficulties in complying with data exclusivity provisions requiring a period of ten years.

The competent authorities are the Ministry of Health and Social Welfare and the Ministry of Agriculture, Forestry and Water Management.

Marketing authorisation is under the responsibility of the Croatian Agency for Medicinal Products and Medical Devices, except for veterinary medicinal products for which it is the Ministry of Agriculture, Forestry and Water Management. The Agency also supervises the pharmaco-vigilance network. Croatia anticipates the need to strengthen the capacity of the Agency.

Croatia anticipates difficulties in upgrading in time for accession the marketing authorisations of existing products on the Croatian market that are not authorised on the basis of the requirements of the Community *acquis*.

Market surveillance is performed by the Pharmaceutical Inspection, except for veterinary medicinal products for which it is the Veterinary Inspection.

Croatia anticipates the need to strengthen off-shelf inspection by the Pharmaceutical Inspection, as well as its capacity to monitor good clinical practices and good manufacturing practice.

Transparency in relation to pricing and reimbursement of medicinal products

The legal framework in this area consists of the Act on Medicinal Products and Medical Devices of 2003 and an ordinance adopted on that basis, the rules of procedures of the Croatian Institute for Health Insurance (HZZO) as well as the Act on Compulsory Health Insurance of 2001. Croatia considers its legislation to be broadly in line with the directive and the EC Treaty principles.

¹ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products
Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use
Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

According to Croatia, the legislation contains provisions on deadlines for decisions, on precise criteria for pricing and reimbursement decisions, on the obligation to provide grounds for refusals and provisions specifying means of redress. Medicinal products reimbursement and pricing decision are valid for a year and require full applications for renewal.

Croatia plans to adopt a regulation based on the Act on Compulsory Health Insurance in order to reach full legislative alignment in this area.

The competent authority is the Ministry of Health and Social Welfare. The Croatian Institute for Health Insurance (HZZO) is responsible for issuing the reimbursement and pricing lists.

No specific mechanism for remedies applies in this area. In accordance with the General Administrative Procedures Act, appeals against HZZO decisions must be filed first with the HZZO itself. The Ministry of Health and Social Welfare is the second-level instance to appeal to. A further appeal may be filed with the Administrative Court against the decisions of the Ministry.

Cosmetics

The legal framework in this area consists of the Act on Health and Sanitary Inspection of Foodstuffs and General Use Products of 1997, as well as an ordinance of 2004, as amended. Croatia considers its legislation to be partially in line with the directives, in particular as regards the list of authorised ingredients. Main differences include the addition of a category of “special purpose cosmetics”, the requirement that importers provide evidence that such special purpose cosmetics are marketed in the manufacturer country, the absence of the manufacturer obligation to provide the evidence of safety, animal testing, and the list of authorised ingredients.

Croatia plans to align its legislation on the basis of a new parliament Act on Common Use Products, to be presented to the Government in June 2006.

The competent authority is the Directorate for Sanitary Inspection within the Ministry of Health and Social Welfare. It has delegated responsibilities regarding notification to the Croatian National Institute of Public Health.

Market surveillance is performed by the Border Sanitary Inspection and by the County Sanitary Inspection.

Legal metrology and Pre-packaging (Old Approach directives)

The legal framework in this area is based on the Metrology Act of 2003 as well as a series of ordinances and regulations. Croatia considers its legislation on units of measurement, alcohol meters, hydrometers and tables, as well as pre-packaging, to be fully in line with the related *acquis*. There is no Croatian legislation on the standard mass per volume of grain or of calibration of ship tanks. Croatia considers its legislation to be partially in line with the other directives in this area.

Croatia plans to bring the Metrology Act in compliance with the *acquis* directive by the end of 2006.

The competent authority is the State Office for Metrology (DZM).

In addition to policy responsibilities, it performs type approval of products and pre-packaging. The DZM Metrology Inspection performs inspection of measuring instruments in use. It also controls pre-packed products before they are placed on the market. It may suspend the use of an instrument or the marketing of pre-packed product until deficiencies are corrected.

Market surveillance is performed by the State Inspectorate. No particular information was provided as regards its activity in this sector.

Crystal glass

The legal framework in this area consists of the Consumer Protection Act and of the Act on Technical Requirements for Products and Conformity Assessment of 2003, as well as an ordinance issued in 2005. Croatia considers its legislation to be in line with the directive.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

Market surveillance is performed by the State Inspectorate.

Textiles

The legal framework in this area consists of the Consumer Protection Act and of the Act on Technical Requirements for Products and Conformity Assessment of 2003, as well as a series of ordinances that entered into force in January 2006. Croatia considers its legislation to be largely in line with the directives. Main differences relate to labelling requirements as well as the recent amendments to the directives.

143 EN standards have been adopted as Croatian standards.

Croatia plans to ensure alignment through amendments to the Consumer Protection Act and subsequent amendments to the ordinances.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

One laboratory has so far applied for accreditation for testing in the area of textiles. Four further laboratories could potentially perform testing in this area.

Market surveillance is performed by the State Inspectorate.

Footwear

The legal framework in this area consists of the Consumer Protection Act and of the Act on Technical Requirements for Products and Conformity Assessment of 2003, as well as an ordinance issued in 2005. Croatia considers its legislation to be in line with the directive.

17 EN standards have been adopted as Croatian standards.

The competent authority is the Ministry of Economy, Labour and Entrepreneurship.

One laboratory has so far applied for accreditation for testing in the area of footwear.

Market surveillance is performed by the State Inspectorate.

Wood classification

The legal framework in this area consists of the Act on Classification of Wood in the Rough of 2004 as well as two ordinances of 2005. Croatia considers its legislation to be in line with the directive.

The competent authority is the Ministry of Agriculture, Forestry and Water Management.

Croatia has designated two testing laboratories and one inspection body to do testing and product certification in this area.

Market surveillance is performed by the State Inspectorate and the Forestry Inspection.

II.e. Procedural Measures

Notification procedures

The current Croatian legislation does not provide a legal framework for transposing the acquis in this area. Currently Croatia participates in the WTO-TBT procedures..

Croatia intends to reach alignment by 2007 with the directive through amendments to the Act on Technical Requirements for Products and Conformity Assessment, planned for 2006, on the basis of which a regulation will be adopted by the end of 2006 on notification procedures in the field of standards, technical regulations and conformity assessment procedures. The regulation will include an obligation to notify to the EC, determine the scope of measures to be notified, foresee stand-still periods as well as impact assessment requirements. Croatia also considers amending, if necessary, the Act on the State Administration System.

The contact point for the procedure will be established at the Ministry of Economy, Labour and Entrepreneurship.

Croatia anticipates the need to establish an IT system and to allocate and train additional staff.

External border checks

The legal framework in this area consists of the Act on General Product Safety of 2003 and of the State Inspectorate Act. The General Product Safety Act lays down a general requirement of safety for products placed on the market. Croatia considers its legislation to be partially in line with the regulation. Customs have to transmit to the State Inspectorate a specific form for 56 groups of products, which are verified after customs clearance and prior to placing on the market. The time frame for the checks is not specified.

The competent authority for border checks is currently the Customs Administration.

Croatia plans to task, upon accession, the State Inspectorate with the responsibility for border safety checks required by Article 1 of Regulation (EEC) 339/93. It also plans to bring its system into line with the regulation through the implementation of a market surveillance strategy.

Firearms

The legal framework in this area consists of the Weapons Act of 1992 and the State Border Surveillance Act of 1995, both as amended, as well as a set of ordinances. Croatia considers its legislation to be partially in line with the directive. The period during which arms dealers

must keep records, the European firearms pass, and the concept of intra-EC transfers remain to be included and the weapon classification need to be adjusted.

Croatia intends to reach full alignment through a new Weapons Act, the draft of which has been presented to Parliament in June 2006.

The competent authority is the Ministry of Interior.

Cultural goods

The legal framework in the area covered by Directive 93/7/EEC consists of the Act on the Protection and Preservation of Cultural Objects of 1999, as amended, and the Ordinance on determining cultural objects considered to be a national treasure of the European Union of 2004. Croatia considers its legislation to be in line with the directive.

The competent authority is the Ministry of Culture. Its Department for Movable and Non-material Cultural Heritage and regional Conservation Departments, as well as the Zagreb City Office for the Protection of Monuments and Culture are responsible for implementation. They perform their task in cooperation with the Ministry of Interior and the Customs Administration.

III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY

The Croatian legislation is partially in line with the *acquis* in Chapter 1, Free Movement of Goods. Implementing structures have been established in most sectors but need to be completed and further upgraded, especially as regards the horizontal measures.

Croatia has produced plans for alignment in many areas. However, these plans do not cover the general principles deriving from Articles 28-30 EC. Several sectors are not adequately covered by alignment plans. Target dates for the legislation are not coordinated with the steps necessary to build up the necessary implementing structures. Sector legislation is developed without prior completion of the basic framework. The latter is needed in particular for the proper operation of the conformity assessment procedures and in order to complete the segregation of tasks between regulatory, standardisation, accreditation, metrology, conformity assessment and market surveillance functions.

III.a. General Principles

Croatia has reached a reasonable level of alignment with the general principles deriving from Articles 28-30 EC and related ECJ case law as far as price control regimes or parallel imports are concerned. The Croatian legislation is partially in line with the general principles as regards import and export license regimes, trade legislation, consumer information provisions and technical barriers to trade. Further alignment is needed e.g. in the field of packaging and packaging waste. Croatia's level of alignment with mutual recognition provisions is limited.

Croatia has recently initiated an internal screening of its legislation and administrative practices in the light of Articles 28-30 EC. A limited set of provisions have been examined so far. A target date has been set for State administrative bodies but without intermediate dates. No target dates have been defined for this purpose for other public entities such as local authorities. The department responsible for steering and supporting efforts within the governmental bodies has rather limited resources.

III.b. Horizontal Measures

Croatia has reached a reasonable level of alignment with the *acquis* on standardisation and accreditation. The Croatian legislation is partially in line with the *acquis* on conformity assessment, metrology and market surveillance.

Issues to be addressed, depending on the sectors, include in particular the withdrawal of mandatory standards and of pre-market mandatory certification, completing conformity assessment procedures and clarifying the roles of conformity assessment and notified bodies, distinguishing accreditation and designation of NBs, avoiding conflicts of interest between regulatory, certification and market surveillance activities, differentiating the liability provisions applying to the manufacturers, importers and distributors respectively.

Reasonable progress has been made in developing the necessary implementing capacity for standardisation and accreditation. It remains essential to complete the segregation of tasks between regulatory, standardisation, accreditation, metrology, conformity assessment and market surveillance functions. The separation of scientific metrology functions from legal metrology one has yet to start. Adjusting the conformity assessment infrastructure and the market surveillance activities to the requirements deriving from the New and Global Approach is a major challenge.

Croatia has outlined plans for alignment in this area. However, plans regarding the removal of mandatory standards and mandatory certification procedures are not fully coordinated with the sector legislation and with the upgrading of the conformity assessment infrastructure, with the market surveillance activities or with the adoption of EN standards. Furthermore, the adoption of crucial amendments to the framework Law on Technical Requirements for Products and Conformity Assessment has been postponed several times since December 2004, since when Croatia has carried on issuing implementing legislation based on the same framework. Delays have also affected the plans to segregate the different tasks.

III.c. New And Global Approach Product Legislation

Croatia has reached a reasonable level of legislative alignment in the areas of gas appliances, machinery and explosives for civil uses. The Croatian legislation is partially aligned with the *acquis* on legal metrology, low voltage electrical equipment, electro-magnetic compatibility, equipment for use in potentially explosive atmospheres (ATEX), lifts, personal protective equipment, medical devices, pressure vessels, construction products and radio and telecommunications terminal equipment. The level of legislative alignment is limited as regards safety of toys and insufficient as regards recreational crafts. The Croatian legislation is not in line with the *acquis* on eco-design requirements for energy-using products and cableway installations.

Issues to be addressed, depending on the sectors, include in particular aligning the scope of transposition measures with some directives so as to avoid confusion between marketing and use of products, adopting all essential requirements. A number of gaps are related to shortcomings regarding the horizontal measures.

Croatia has outlined target dates for legislative alignment in a majority of sectors, which as such seem feasible. However in many cases those plans are not coordinated with the necessary changes in the framework legislation, the adoption of harmonised EN standards as Croatian standards and the upgrading of the quality infrastructure as well as of the market surveillance activities.

III.d. Old Approach Product Legislation

Croatia has reached a good level of legislative alignment in the areas of crystal glass, footwear and wood classification. The legislative alignment in the area of textiles is reasonable. The Croatian legislation is partially aligned with the *acquis* on motor vehicles, limitations, classification, packaging and labelling of chemicals, detergents, fertilisers, drug precursors, good laboratory practices, the Community codes on medicinal products for human use, the *acquis* on orphan medicinal products, good manufacturing practice, colouring matters, cosmetics, legal metrology and pre-packaging. The level of legislative alignment is limited as regards transparency in relation to pricing and reimbursement of medicinal products. The Croatian legislation is not in line with the *acquis* relating to veterinary medicinal products and the amended pharmaceutical *acquis* of 2004 is not introduced. The Croatian legislation is also not in line with the *acquis* on noise emissions by outdoor equipment, and emission of pollutants from non-road mobile machinery engines.

III.e. Procedural Measures

Croatia has reached a reasonable level of alignment in the cultural goods. Croatia's legislation and institutions are partially aligned with the *acquis* on firearms and external border checks. The Croatian legislation and institutions are not in line with the *acquis* on notification procedures (directive 98/34 as amended).

The plans put forward by Croatia for alignment in the area of firearms appear feasible. As regards the notification procedure and the external border checks, Croatia's plans are directly related to those regarding the horizontal measures and call for the same comments.