CONFERENCE ON ACCESSION TO THE EUROPEAN UNION – CROATIA –

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CONF-HR 9

ACCESSION DOCUMENT

Subject:	EUROPEAN UNION COMMON POSITION Chapter 1: Free movement of goods

EUROPEAN UNION COMMON POSITION

(Revision of CONF-HR 18/08)

Chapter 1: Free Movement of Goods

This position of the European Union is based on its general position for the Accession Conference with Croatia (CONF-HR 2/05), and is subject to the negotiating principles endorsed by the Accession Conference (CONF-HR 5/05), in particular:

- any view expressed by either party on a chapter of the negotiations will in no way prejudge the position which may be taken on other chapters;

- agreements - even partial agreements - reached during the course of the negotiations on chapters to be examined successively may not be considered as final until an overall agreement has been established;

as well as to the requirements set out in points 13, 16 and 26 of the Negotiating Framework.

The EU underlines the importance for Croatia of compliance with the Stabilisation and Association Agreement as well as the Accession Partnership, which constitute basic elements of the pre-accession strategy.

The EU encourages Croatia to continue the process of alignment with the *acquis* and its effective implementation and enforcement, and in general to develop already before accession, policies and instruments as close as possible to those of the EU.

The EU notes that Croatia, in its addendum (CONF-HR 1/10) to its position (CONF-HR 7/08) accepts the *acquis* under chapter 1 as in force on 1st January 2010, and that Croatia declares that it will be ready to implement it by the date of its accession to the European Union, while requesting a transitional measure.

General principles

The EU takes note of the significant progress achieved in the implementation of the Action Plan for compliance with Articles 28 to 30 of the EC Treaty (Articles 34 to 36 of the TFEU), amending or repealing legal acts containing restrictions to free movement of goods and introducing the mutual recognition clause. Out of the 78 legal acts identified as containing provisions which represent measures limiting free movement of goods, 62 have been amended or repealed and 7 have been amended in order to include the mutual recognition clause, in line with Regulation (EC) No 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. In one case the measure having equivalent effect has been considered justified on the basis of Article 36 of the TFEU. This fulfils the requirements of the third closing benchmark as set out in the EU common position (CONF-HR 18/08).

The EU takes note of the actions undertaken by Croatia to strengthen its administrative capacity, in particular by increasing the staffing levels at the Department of Internal Market Co-ordination in the Ministry of Economy, Labour and Entrepreneurship (MELE). The EU underlines that, from the date of accession, Croatia needs to ensure that the principle of mutual recognition will be applied and that no measures having an equivalent effect to quantitative restrictions exist. When ensuring that the principle of mutual recognition will be applied, the EU invites Croatia to continue to take into account Regulation (EC) No 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

The EU invites Croatia to keep it regularly informed of the developments and steps undertaken as regards further alignment of its legislation on general principles to the *acquis*.

Horizontal measures

The EU takes note that Croatia has made good progress with the alignment in the field of horizontal legislation. The EU takes note of the adoption of key framework legislation, notably the new Act on Technical Requirements for Products and on Conformity Assessment (January 2010), the Act on Amendments to the Accreditation Act (July 2009) and the State Inspectorate Act (October 2008), in addition to the Act on Amendments to the Metrology Act (already adopted in October 2007). The EU notes that the administrative capacity with regard to horizontal measures is in place. These developments fulfil the requirements of the second closing benchmark on progress towards alignment of horizontal legislation as set out in the EU common position (CONF-HR 18/08). The EU invites Croatia to continue its efforts to complete the legislative alignment process, particularly in deleting the few still existing discrepancies with the *acquis* and in terms of the required bylaws. When further aligning the horizontal legislation Croatia should continue taking into account the Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and, whenever possible, the *sui generis* Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products.

As regards standardisation, the EU takes note of the adoption by Croatia of nearly all European standards. The Croatian Standards Institute (HZN) is a member of CEN and CENELEC since January 2010. The EU takes note of the actions undertaken by Croatia to strengthen its administrative capacity, in particular to increase the staff of the Croatian Standards Institute (HZN). The EU underlines the importance for Croatia to continue such efforts to reinforce the administrative capacity in this field.

On conformity assessment, the EU takes note that the new Act on Technical Requirements for Products and Conformity Assessment was adopted in January 2010. The EU invites Croatia to proceed with the adoption of related implementing legislation.

With regard to accreditation, the EU takes note of the adoption of the Act on Amendments to the Accreditation Act (July 2009) and of the Act on Amendments to the Statute of the Croatian Accreditation Agency (HAA) (July 2009) and of the progress made in further staffing the HAA. It takes note of the steps undertaken to conclude the EA multilateral agreements for accreditation of conformity assessment bodies and to continue the efforts for strengthening the administrative capacity of the HAA so as to ensure full implementation of the *acquis* by the date of its accession to the EU.

As regards metrology, the EU notes that the alignment with the *acquis* in this field is advanced. The EU takes note of the formal establishment of the Croatian Metrology Institute (HMI) in June 2008 as well as the adoption of the Law ratifying the Metre Convention in December 2008. While the Croatian State Office for Metrology (DZM) maintains the responsibility for legal metrology (adoption of regulations and supervision of implementation), the preparations for transferring responsibility for scientific metrology (measurement standards and traceability) to the HMI are advancing. As regards administrative capacity in the metrology sector, the EU takes note of the actions undertaken by Croatia to increase and train staff at the DZM and at the HMI. The setting up of the infrastructures of the DZM is advancing, with the designation of two laboratories in the field of chemistry, a National Laboratory for Humidity and a National Laboratory for Ionising Radiation. The EU reminds Croatia that the transfer of responsibility for scientific metrology to the HMI needs to be completed as it is important that the chain of traceability be moved at the national level through accredited testing laboratories to the industry, in time for accession.

With regard to market surveillance, the EU notes the progress made in the administrative capacity of the State Inspectorate (SI) and enforcement measures. A new State Inspectorate Law on the organisation and role of the State Inspectorate was adopted in October 2008, abolishing pre-market approval requirements and conferring necessary powers to the market surveillance inspectors. A new Regulation on the System for Rapid Exchange of Information on products presenting risks for consumer health and safety (RAPEX) was adopted (March 2009) and will enter into force upon accession. The State Inspectorate is the RAPEX contact point.

With the actions taken by Croatia to increase the administrative capacity, notably of the HZN, HAA, HMI, DZM and SI, the requirements of the fourth closing benchmark on administrative capacity to implement and enforce the legislation in all horizontal areas affecting the free movement of goods as set out in the EU common position (CONF-HR 18/08) are considered fulfilled.

The EU invites Croatia to keep it regularly informed of the developments and steps undertaken as regards further alignment of its legislation on horizontal measures to the *acquis*.

New and global approach product legislation

As regards the new and global approach product legislation, the EU takes note that Croatia has made good progress towards transposition of the EU *acquis,* notably in the area of low voltage equipment, recreational craft, machinery, radio equipment and telecommunications terminal equipment, electromagnetic compatibility, safety of toys, cableway installations, pressure equipment and simple pressure vessels, noise emissions by equipment for use outdoors, eco-design requirements for energy-using products, explosives for civil uses, pyrotechnic articles, and medical devices. The EU takes note of the establishment of an overall timetable for the completion of alignment in those areas where further work is necessary. The EU invites Croatia to continue the transposition of the EU *acquis* in this area, with particular regard to equipment and protective systems intended for use in potentially explosive atmospheres, construction products, eco-design requirements for energy-using products, gas appliances, pressure equipment and simple pressure vessels, machinery, non-automatic weighing instruments, measuring instruments, personal protective equipment, medical devices, pyrotechnic articles and safety of toys. With these developments, the requirements of the second closing benchmark for alignment of New and Global Approach product *acquis* as set out in the EU common position (CONF-HR 18/08) are considered fulfilled.

The EU invites Croatia to keep it regularly informed of the developments and steps undertaken as regards further alignment of its legislation on new and global approach product legislation to the *acquis*.

Old approach product legislation

As regards the old approach product legislation, the EU takes note of Croatia's good progress towards the transposition of the EU *acquis* notably in the area of pharmaceuticals (medicinal products for human use and veterinary medicinal products), motor vehicles, cosmetic products, pre-packaging, emissions of gaseous and particulate pollutants from engines installed in non-road mobile machinery, crystal glass and chemicals (including drug precursors, detergents and fertilisers). The EU takes note of the establishment of an overall timetable for the completion of alignment in those areas where further work is necessary. The EU encourages Croatia to pursue its efforts in order to complete legislative alignment with particular regard to textiles, footwear, pre-packaging and aerosol dispensers. With these developments, the requirements of the second closing benchmark for alignment of old approach *acquis* as set out in the EU common position (CONF-HR 18/08) are considered fulfilled.

As regards pharmaceutical products, Directive 2001/83/EC, as amended, has been transposed into Croatian legislation, notably into the Medicinal Products Act (June 2007), the Ordinance on the method for classification of medicinal products, and the prescription and dispensing of medicinal products (October 2005), the Ordinance on good practice in wholesale distribution of medicinal products (February 2005), the Ordinance on the method of advertising medicinal and homeopathic products and medical devices (May 2005), the Ordinance on quality control of medicinal products (April 2005), the Ordinance on good manufacturing practices for medicinal products (June 2009), the Act on Amendments to the Medicinal Products Act (April 2009), the Ordinance on Amendments to the Ordinance on the procedure and method for granting marketing authorisation for medicinal products (December 2009) and the Ordinance on pharmacovigilance (September 2009). The EU invites Croatia to align the provisions on data exclusivity and on the absence of financial interests in the pharmaceutical industry as regards the employees of the Agency for Medicinal Products and Medical Devices, by accession at the latest. The EU also notes that Croatia has adopted two Ordinances establishing the procedures and criteria for the determination of prices and the inclusion of medicinal products in the reimbursement lists (December 2009). The adoption and entry into force in January 2010 of these acts provide for alignment with the procedural obligations of Directive 89/105/EEC.

The adoption of the above legislation fulfils the requirements of the first closing benchmark as set out in the EU common position (CONF HR 18/08). Nevertheless, the EU invites Croatia to ensure that any future revision of its pharmaceutical pricing and reimbursement system complies with the provisions of Directive 89/105/EEC and will monitor the situation in this respect.

The EU notes that Croatia has withdrawn its request for a transitional period of three years from the date of Croatia's accession to continue not applying Directive 2001/83/EC on the community code relating to medicinal products for human use, as amended, in relation to the application of data exclusivity (8+2+1) provisions.

The EU notes that Croatia has reduced its request for a transitional period from five to four years from the date of Croatia's accession to continue not applying Directive 2001/83/EC on the community code relating to medicinal products for human use, as amended, in relation to the upgrading of marketing authorisations and documentation for medicinal products registered in Croatia. The EU considers that a transitional period of four years from the date of Croatia's accession, for those products which are listed in Croatia's position CONF-HR 7/08 ADD 1, is acceptable. The EU recalls that marketing authorisations covered by this derogation shall not benefit from mutual recognition in the Member States before these products have been authorised according to Directive 2001/83/EC, as amended.

As regards Regulation (EC) No 1907/2006 (REACH), Croatia has adopted the implementing Act (April 2008), which will enter into force upon accession. Croatia is advanced with preparations for implementation of the REACH Regulation in particular as concerns its effective participation in the mechanisms established by the Regulation, such as the organs and committees of the European Chemicals Agency. The EU notes that Regulation (EC) No 1907/2006 is also addressed under chapter 27 Environment.

The EU invites Croatia to keep it regularly informed of the developments and steps undertaken as regards further alignment of its legislation on old approach product legislation to the *acquis*.

Procedural Measures

With regard to procedural measures, alignment is advanced. The EU takes note of Croatia's transposition of the procedures set forth in Directive 98/34/EC, as amended by Directive 98/48/EC, through the adoption of a new Regulation on notification procedures in the field of standards, technical regulations and regulations on information society services (February 2009).

As regards external border checks, the EU notes that Croatia has prepared the procedures manual for border work, which needs to be finalised and adopted, has concluded the Integrated Border Management Agreement to promote intra-agency cooperation, has continued the implementation of its Integrated Border Management Strategy and Action Plan and has initiated measures for the proper implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products, including staff training.

As regards firearms and cultural goods, the EU takes note of the good progress in legislative alignment and in the strengthening of the administrative capacity to implement the legislation.

The EU invites Croatia to continue its efforts to complete transposition, in particularly to fully transpose Directive 98/34/EC, as amended by Directive 98/48/EC, and Directive 91/477/EEC, as amended by Directive 2008/51/EC, set up the relevant administrative structures, including the Central Contact Point, and to provide for the necessary IT infrastructure and staffing.

The EU invites Croatia to keep it regularly informed of the developments and steps undertaken as regards further alignment of its legislation on procedural measures to the *acquis*.

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In view of all the above considerations, the EU notes that, at this stage, this chapter does not require further negotiations.

Monitoring of progress in the alignment with and implementation of the *acquis* will continue throughout the negotiations. The EU underlines that it will devote particular attention to monitoring all specific issues mentioned above with a view to ensuring Croatia's administrative capacity to implement the legislation in the field of free movement of goods. Particular consideration needs to be given to the links between the present chapter and other negotiation chapters. A final assessment of the conformity of Croatia's legislation with the *acquis* and of its implementation capacity can only be made at a later stage of the negotiations. In addition to all the information the EU may require for the negotiations in this chapter and which is to be provided to the Conference, the EU invites Croatia to regularly provide detailed written information to the Stabilisation and Association Council on progress in the implementation of the *acquis*.

In view of all the above considerations, the EU will, if necessary, return to this chapter at an appropriate moment.

Furthermore, the EU recalls that there may be new *acquis* between 1st January 2010 and the conclusion of the negotiations.