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***UEPLAC BACKGROUND PAPER TBT SPHERE IN UKRAINE
AFTER WTO ACCESSION AND TOWARDS THE FTA WITH THE
EU***

Background Paper

TBT Sphere in Ukraine after WTO accession and towards the FTA with the EU

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LIST OF ABBREVIATIONS

ACAA	Agreement on Conformity Assessment and Acceptance of Industrial Products
CAB	Conformity assessment body
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
EA	European Accreditation
EC	European Community
ENP	European Neighbourhood Policy
ETSI	European Telecommunications Standards Institute
EU	European Union
FTA	Free Trade Agreement
GPSD	EC Directive General Product Safety
MFN	Most Favoured Nation (in WTO Agreements)
MRA	Mutual Recognition Agreement
OIML	International Organisation for Legal Metrology
PCA	Partnership and Co-operation Agreement
PECA	Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products
RAPEX	Rapid Exchange of Information (within the GPSD)
SPS	Sanitary and Phytosanitary measures
TBT	Technical Barrier to Trade
WELMEC	European Co-operation in Legal Metrology
WTO	World Trade Organisation

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TBT Sphere in Ukraine after WTO accession and towards the FTA with the EU

Introduction

In the WTO terminology Technical Barriers to Trade (TBT) are part of the wider taxonomy of Non-Tariff-Barriers (NTBs)¹. In the EC Treaty, the corresponding generic concept applicable to the free movement of goods, beyond the completion of the Internal Market, between the EU Member States, is addressed under the wording of measures “having equivalent effects” to quantitative restrictions.

The TBT Agreement applies to all industrial and agricultural products (Article 1.3 TBT Agreement) except products covered by the SPS Agreement (measures on foodstuffs and feedstuffs of which the purpose relates to food safety or animal welfare).

Since its accession to the WTO on 16 May 2008, Ukraine is committed to comply with the rules laid down in the GATT and other multilateral WTO agreements such as the TBT and SPS Agreements. That was a prerequisite to start the negotiation of a Free Trade Agreement (FTA) with the European Union.

The FTA will cover a number of important areas, for example, Intellectual Property Rights, Competition and Public Procurement but the central discussion will focus on customs tariffs and TBT which impede trade facilitation between the EU and Ukraine.

This background paper has been requested by the State Department for Legislative Approximation at the Ministry of Justice of Ukraine (SDLA). It intends to provide in a single document the relevant set of tools used by the EU to ensure the free movements of industrial goods between the EU Member States and to facilitate market access in the relations with third countries. Allegedly, the SDLA will disseminate this information among the Ukrainian Agencies and line institutions which may have a stake in the TBT sphere of the future FTA.

Furthermore, since the EU has recently (June 2008) adopted a New Package on Internal Market comprising key elements of the horizontal framework required to ensure the free movement of goods, this paper takes also stock of the subsequent changes which should be reflected in Ukraine to allow, at least, the conclusion of an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA). This ACAA is envisaged in the Objective 30 of the EU-Ukraine ENP Action Plan, the roadmap for its conclusion has been agreed on 19 December 2005 and there are now clear indications that this ACAA will be further discussed to be annexed as a Protocol to the FTA.

Changes needed are not only related to the legal or institutional framework but also to measures of capacity building of the public and private actors involved in the regulatory chain of conformity assessment procedures. In particular, manufacturers have to be prepared to switch from a system where mandatory certification of products or processes is predominant to a system relying mostly on the use of voluntary standards and less descriptive technical regulations which set out only essential requirements to which standards have to conform.

¹ NTBs refers to the broad range of policies other than customs tariffs that have restrictive effects on the trade of goods and services and related factors of production.

To this extent, this paper could also contribute to the prioritization in the “Second Stage of the National Programme for Legislative Approximation” as far as industrial goods are concerned.

By no means, this background paper does not prejudice the scope of the points subject to discussion between the EU and Ukrainian Negotiators, nor does it anticipate the results of the EU-Ukraine Summit of 9 September 2008 on the content of the future “association” between the EU and Ukraine.

1. TBT sphere: a smooth path from WTO accession to FTA negotiation

1.1. Regional agreement vs WTO rules: complementarities

The FTA to be concluded between the EU and Ukraine is a regional economic agreement authorized by the Article 24 of GATT under certain conditions. Regional agreements set out rules that derogate to some extent to the principle of equal treatment (MFN) for all trading partners Members of the WTO. However, it has been observed by the WTO Secretariat (study carried out in 1995) that regional agreements encourage trade flow between groups of countries and that commitments undertaken by the parties to the agreements would not have been possible at that time on a multilateral basis.

The FTA EC-Ukraine will not threaten the rules of GATT but it will complement them. Thus, recitals or other provisions of the FTA or the ACAA will remind that both parties have obligations under the WTO and especially under the WTO Agreement on Technical Barriers to Trade.

1.2. Prevention of obstacles to trade in the TBT Agreement and the principles of the free movements of goods in the EU

The GATT contains only general and indirect references to barriers to trade in the Articles 3 (National Treatment on Internal Taxation and Regulation), 11 (General Elimination of Quantitative Restrictions) and 20 (General Exceptions).

It is not a coincidence that the plurilateral Agreement on Technical Barriers to Trade has been signed by 32 GATT Contracting Parties at the end of the Tokyo Round in 1979 before becoming, after the Uruguay Round, the current multilateral TBT Agreement 1994, while at the same time the European Economic Community was developing the new approach to technical harmonization and standardisation (Council Resolution of 7 May 1985).

The TBT Agreement and the EC New Approach derive from the same philosophy. There are therefore similar tools in the WTO and the EC to implement common principles. Mechanisms may however differ given the totally different legal contexts and because the more detailed rules applicable in the intra-community trade are enforced by the European Commission and the European Court of Justice and not by the Dispute Settlement Body of the WTO.

To show that the conclusion of a FTA with the EC implies only more concrete and more detailed commitments than those undertaken under the TBT Agreement, a brief parallel can be drawn between the provisions of the TBT Agreement (applicable to WTO Members) and the EC rules on free movement of goods (applicable to EU Member States).

The principle of non-discrimination and national treatment contained in the TBT Agreement (applicable also to conformity assessment procedures) is reflected in the EC Treaty with more stringent provisions.

The principle that legitimate objectives may authorize exemptions to the national treatment as far as the differentiation is proportionate to the objectives pursued, is also a principle of the EC law (stricter interpretation in the EC).

The TBT principle of the avoidance of unnecessary obstacles to trade is complemented by the harmonization of the technical regulations and the prohibition of measures equivalent to quantitative restrictions in the EC.

To ensure regulatory convergence, the TBT Agreement encourages the WTO Members to use existing international standards for their national regulations, whereas the EC strongly relies on the harmonised standards adopted by European standardisation bodies (with adoption of joint EN/ISO standards where ISO standards are compatible with EU specificities).

Article 2.7 of the TBT Agreement encourage the WTO Members “to give positive consideration” to accepting as equivalent ” technical regulations of other Members that fulfill the same policy objectives through different means. That is also the starting point of the principle of mutual recognition in the EC, based on the case-law *Cassis-de-Dijon*.

The rules under the article 5 and 6 of TBT Agreement grant a specific importance to the equal treatment in carrying out conformity assessment procedures (access for foreign operators, handling of applications, transparency, mutual recognition of results in the context of prior consultations to ensure confidence in testing and certification bodies or in the framework of Mutual Recognition Agreements). In the EU, conformity assessment procedures have been harmonized (by Directives) and they are now unified (by Regulations).

New national standards and technical regulations which do not conform to international standard and which may impact significantly the international trade have to be notified to the WTO Secretariat to allow for comments from WTO Members. Among the EU Member States, this transparency stems from the Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations².

2. Reference framework on the free movement of goods in the EU for regulatory convergence between the EU and Ukraine

2.1. Horizontal framework: New and Global Approach

2.1.1. Common features of the Community harmonization legislation under the New and Global Approach

The Council Resolution of 7 May 1985 on standardization and general guidelines for a new approach on technical harmonization³, followed by the White Paper of the European

² The exchange of information pursuant to the Directive 98/34 EC is mandatory for each new draft national standard or draft technical regulation. Since 1998, The mechanism covers also information society services. A standstill period for at least 3 months allows Member States and the European Commission to react.

³ Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

Commission of June 1985 on the Completion of the Internal Market has generated a considerable legislative work on the EU level.

The horizontal procedures applicable to the product-sector harmonization legislation are laid down in the Council Decision 93/465/EEC⁴. The main features of the system may be summarized as follows:

- The Community legislative harmonization under the New Approach is limited to essential health and safety requirements (or other requirement of public interest).
- Harmonised standards have to be adopted by the European standardisation organisations (CEN, CENELEC and ETSI) so as to comply with the essential health and safety requirements laid down in the Community harmonization legislation.
- The European Commission issue mandates for the elaboration of harmonized standards by the European standardisation organisations.
- The use by manufacturers of harmonized standards gives a presumption of conformity with the essential health and safety requirements.
- In the absence of harmonized standards, national standards of the EU Member States stay valid for the purpose of conformity assessment.
- Manufacturers may develop their own standards but before placing the related product on the market they have to demonstrate the standards conform to the essential health and safety requirements.
- Categories of products covered by the Community harmonization legislation are placed on the market with the CE marking. This marking indicates to consumers that the products comply with the essential health and safety requirements.
- CE marking may result from a self assessment of the manufacturers or from other conformity assessment modules with intervention of third parties (the module to be applied is determined by the product-sector legislation).
- Conformity assessment bodies (CABs) notified to the European Commission by the relevant public authorities to provide a specific range of services have to meet certain criteria concerning their independence, qualification and financial sustainability. As a result, notified CABs are allowed to be involved in the regulatory chain of conformity assessment in any EU Member State and tests or certificates of those CABs are recognized across the Community.

The Global Approach reproduces the same system but, generally, without CE marking.

2.1.2. Reform of 2008

Improvements and uniform practice of conformity assessment procedures have been proposed by the European Commission in 2007 and they have been approved in June 2008 under the form of two new pieces of EC legislation which replace the existing horizontal framework.

- The Regulation (EC) No 765/2008⁵ sets out the rules applicable to accreditation activities

⁴ Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the 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

⁵ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

and Chapter IV of the same Regulation covers the general principles of the CE marking. The corresponding provisions will be in force on 1 January 2010.

- The Decision No 768/2008/EC⁶ lays down the horizontal general framework for future legislation harmonising the conditions for the marketing of products. It replaces the Decision 93/465/EEC. Therefore the set of reference provisions for the existing sectoral legislation is applicable immediately.

In particular, the new EC rules provide for the following:

Accreditation

Each Member State appoints a single national accreditation body to perform accreditation of bodies involved in compulsory or voluntary conformity assessment procedures.

The national accreditation bodies is not authorized to compete with conformity assessment bodies, not does it compete with other national accreditation bodies.

As a matter of principle, a conformity assessment body requests accreditation with the national accreditation body of the Member State in which it is established. In certain cases, cross-border accreditation is possible, for example, where the national accreditation body of the country of establishment does not perform accreditation in respect of the conformity assessment activities for which accreditation is sought or where the national accreditation body referred have not successfully undergone peer evaluation in respect of the conformity assessment activities for which accreditation is sought.

The national accreditation body has to fulfill certain organizational requirements:

- independence from conformity assessment bodies it assesses and from commercial pressures;
- objectivity and impartiality of its activities;
- decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;
- safeguard of the confidentiality of the information obtained;
- efficient management and internal controls and publication of audited annual accounts; competent and sufficient staff who is documented and whose performances are monitored; measures taken to verify that conformity assessments are not burdensome for enterprises by taking account of the size of the enterprises, the structure of the sector in which operates, the degree of complexity of the product technology and the mass or serial nature of the production process.

National accreditation bodies are subject to peer evaluation by EA (European Co-operation for Accreditation).

Notifying authorities

⁶ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

The EC law prohibits conflict of interest and competition with conformity assessment bodies and requires organizational measures to ensure that a decision relating to the notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

Notified conformity assessment bodies

To ensure impartiality and competence of conformity assessment bodies the detailed requirements of the EC law include, inter alia, the following principles:

- prohibition of conflicts of interest (personnel responsible for carrying out the conformity assessment tasks, consultancy services) and of all pressures and inducements;
- qualification of the staff and procedures in place for the transparency and the ability
- of reproduction of the conformity assessment procedures adapted to the enterprise and the technology in question;
- remuneration of the top level management and assessment personnel cannot depend on the number of assessments carried out or on the results of those assessments.
- liability insurance (except where this liability is assumed by the State)
- professional secrecy;
- staff is familiarized with the EC legislation and is informed of the standardization activities along with the activities of the notified body coordination group established under the relevant Community harmonisation legislation.

Accredited in-house bodies which constitute a separate and distinct part of the enterprises and which do not participate in the design, production, supply, installation, use or maintenance of the products they assess may implement certain conformity assessment modules (modules A1, A2, C1 or C2) under certain conditions.

Conformity assessment procedures

The conformity assessment procedures used in the EC sectoral legislation are selected among a set of modules by taking into consideration the relevance of the module for the type of product, the risks posed by the product and the need to avoid too burdensome tasks in relation to the risks covered by the legislation concerned. Where third party involvement is mandatory, the manufacturer has a choice between quality assurance and product certification modules.

The range of procedures comprises the following:

Module A	Internal production control
Module A1	Internal production control plus supervised product testing
Module A2	Internal production control plus supervised product checks at random intervals
Module B	EC-type examination
Module C	Conformity to type based on internal production control
Module C1	Conformity to type based on internal production control plus supervised product testing
Module C2	Conformity to type based on internal production control plus supervised product checks at random intervals
Module D	Conformity to type based on quality assurance of the production process
Module D1	Quality assurance of the production process

Module E	Conformity to type based on product quality assurance
Module E1	Quality assurance of final product inspection and testing
Module F	Conformity to type based on product verification
Module F1	Conformity based on product verification
Module G	Conformity based on unit verification
Module H	Conformity based on full quality assurance
Module H1	Conformity based on full quality assurance plus design examination

CE marking

More legal certainty is given to the definition of the CE marking and the responsibility of the manufacturer who affixes the CE symbol on its products.

2.2. Horizontal framework: other pieces of the EC legislation

2.2.1. Calibration and testing: legal metrology

Legal metrology concerns the regulatory framework for measuring instruments for legal use. This activity is therefore involved in the measuring tasks required for the implementation of the conformity assessment procedures provided by the Community harmonizing legislation. The EC Directive 2004/22⁷ establishes the requirements that the devices and measurement systems have to satisfy. To this end it repeals a number of previous Directives on legal metrology and introduces the New Approach by providing for essential health and safety requirements, reference to harmonized standards, conformity assessment and CE marking. For non-automatic weighing machines, another New Approach Directive applies since 1990⁸.

Legal metrology authorities of the EU Member States participate in the European Co-operation for Legal Metrology (WELMEC) and are members of the International Organisation of Legal Metrology (OIML).

⁷ Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments. The Directive applies to the devices and systems with a measuring function defined in the instrument-specific annexes concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), heat meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

⁸ Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments.

There are also other classic Directives which apply to specific aspects of metrology:

Council Directive 71/347/EEC (measuring of the standard mass per storage volume of grain). Council Directive 71/349/EEC (calibration of the tanks of vessels). Council Directive 71/316/EEC (common provisions for both measuring instruments and methods of metrological control). Council Directive 74/148/EEC (weights of from 1 mg to 50 kg of above-medium accuracy). Council Directive 75/107/EEC (bottles used as measuring containers). Council Directive 75/443/EEC (reverse and speedometer equipment of motor vehicles). Council Directive 76/765/EEC (alcoholometers and alcohol hydrometers). Council Directive 76/766/EEC (alcohol tables). Council Directive 80/181/EEC (units of measurement).

2 2.2. Market Surveillance and General Safety of Products

The Directive 2001/95/EC on General Product Safety (GPSD) introduces a general obligation on the producers to place only safe products on the market. The main purpose is to ensure the safety of products regardless of the lack of standards or technical regulations applicable to the products in question.

The Directive applies in so far as there are no provisions with the same objective, nature or effect in other pieces of EC legislation. For example, it may cover the lacunae on specific aspect of safety not yet regulated by the existing product sector legislation.

Distributors and importers are required to contribute to this safety along the supply chain. The criteria for the assessment by the manufacturers or public authority of the safety of any product relate to the conformity with the following:

- specific rules of national laws in compliance with the EU legislation
- national standards transposing European standards
- other national standards
- recommendations by the regulatory authority (European Commission) setting guidelines on product safety assessment
- product safety codes of good practice in force in the sector concerned;
- the state of the art and technology;
- reasonable consumer expectations concerning safety.

Market surveillance authorities may order preventive or corrective measures in close collaboration with the economic operators concerned. Those measures have to be proportionate to the risk posed by the products (gradual enforcement). Recall or withdrawal of a product from the market is organized as a last resort .

The Directive sets up a rapid mechanism of exchange of information on dangerous products (RAPEX)¹⁰. This system managed by the European Commission on the basis of the notifications made by the EU Member States comprises a methodology for the evaluation of risks.

The existence of a market surveillance system is a condition for the correct implementation of the Directive 2001/95/EC on General Product Safety. Market surveillance refers also to the effective enforcement of the national legal measures implementing the EC Directives “New Approach” where the correct affixing of the CE marking on a wide range of industrial products is controlled by public authorities after the placing of the products on the market.

To reinforce the confidence into the Internal Market and to ensure a coherent implementation of market surveillance activities throughout the Community, the Regulation (EC) No 765/2008 establishes a Community market surveillance framework. Apart from rules on the obligations of

⁹ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety.

¹⁰ Some categories of products are not covered RAPEX because they are covered by specific and equivalent notification mechanisms established by the Community legislation:

- Pharmaceuticals covered by Directives 75/319/EEC and 81/851/EEC;
- Medical devices (covered by Directive 93/42/EEC), active implantable medical devices covered by Directive 90/385/EEC, in vitro diagnostic medical devices covered by Directive 98/79/EC;
- Food and feed covered by Regulation (EC) No 178/2002.

the Member States to organize and co-ordinate market surveillance activities, most of the provisions of the Regulations reflect the role and powers of market surveillance authorities in the Directive on the General Safety of Products.

For example, the idea of the proportionality of market surveillance measures is expressed as follows:

“Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.”

...

“Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.”

The Community Rapid Information System established by the Regulation makes also use of RAPEX.

An important component of the Regulation is the link made between market surveillance within the Internal Market and the Customs controls of products entering the Community market. To this end the Regulation incorporates the provisions of the Regulation (EEC) No 339/93 “on checks for conformity with the rules on product safety in the case of products imported from third countries”.

2.2.3. Liability for defective products

The Directive 85/374/EEC¹¹ establishes a regime of strict liability (liability without fault) of producers in case of damage caused by defective products. The products in question were originally industrial products (including processed food) but since the “mad-cow” disease, the scope of application of the Directive has been extended to primary agricultural products.

This liability does not preclude the joint and several liability of all the operators in the production chain (right of contribution or recourse).

The producer is exempt from liability in limited cases, for example where the defect causing the damage did not exist at the time when the product was put into circulation by him or where the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

When the injured person is at fault, the producer's liability may be reduced.

To strike a delicate balance between the interests of claimants, manufacturers and their insurers, the Directive provides for a time-limit of 3 years to seek for compensation and a € 500 threshold regarding damages suffered in order to avoid litigation in an excessive number of cases. Moreover, the EU Member States are granted the option to cap the amount of compensation (not below € 70 million for damage resulting from death or personal injury).

¹¹ Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999.

2.3. Sectoral legislation

The Community harmonization legislation for product-sectors is twofold.

A number of categories of products covered by Directives “New and Global Approach” set out essential health and safety requirements and specify the modules of conformity assessment to be used to check the product against the harmonized standards presumably compliant with the essential requirements of the Directives. Where appropriate, standards are updated by the European standardisation organisations.

Other Directives (and sometimes Regulations), under the so called “Old Approach”, define detailed technical specifications and testing requirements applying to specific products. Those Directives are amended regularly to be adapted to the technical progress.

The main product sectors covered by the “New and Global Approach” with requirements concerning the CE marking are as follows:

- Toys safety (Directive 88/378/EEC)
- Low voltage equipment – LVD (Directive 2006/95/EC)
- Electromagnetic compatibility - EMC (Directive 2004/108/EC)
- Simple pressure vessels (Directive 87/404/EEC)
- Pressure equipment (Directive 97/23/EC)
- Construction products (Directive 89/106/EEC)
- Machinery safety (Directive 98/37/EC)
- Personal protective equipment - PPE (Directive 89/686/EEC)
- Non-automatic weighing instruments (Directive 90/384/EEC)
- Measuring instruments (Directive 2004/22/EEC)
- Appliances burning gaseous fuels (Directive 90/396/EEC)
- Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (Directive 92/42/EEC)
- Explosives for civil uses (Directive 93/15/EEC)
- Equipment and protective systems in potentially explosive atmospheres – ATEX (Directive 94/9/EC)
- Recreational craft (Directive 94/25/EC)
- Lifts (Directive 95/16/EC)
- Cableway installations designed to carry persons (Directive 00/9/EC)
- Radio and telecommunications terminal equipment (Directive 99/5/EC),
- Medical devices: General Directive (93/42/EEC)
- Medical devices: In vitro diagnostic (Directive 98/79/EC)
- Medical devices: Active implantable (Directive 90/385/EEC)
- Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC)
- Energy efficiency requirements for ballasts for fluorescent lighting (Directive 2000/55/EC)
- Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof (Directive 96/57/EC)

Other Directives “Global Approach” may not have requirements on CE marking. The marking is sometimes represented by another compulsory symbol or a free symbol. For example, that is the case for the following areas:

- Packaging and packaging waste
- Interoperability of trans-European high-speed rail system
- Interoperability of trans-European conventional rail system
- Marine equipment
- Transportable pressure equipment

Beside the Directives “New and Global Approach” there are also “standards-receptive” Directives. They concern inter alia:

- Airborne noise emitted by household appliances
- Energy labelling of household appliances
- Waste electrical and electronic equipment
- General product safety

Old Approach Directives or Regulations cover mainly the following product sectors:

- Chemicals
- Fertilisers
- Pharmaceuticals
- Cosmetics
- Automotive industry
- Labelling of certain industrial products (textiles, footwear, crystal glass, etc) or foodstuffs to prevent deceptive practices.

2.4. Mutual recognition for industrial products not covered by the EC harmonization legislation

2.4.1. Principle of mutual recognition for the free movement of goods in the EU

In the context of the free movement of goods, the principle of mutual recognition has been settled by the case-law of the Court of Justice of the European Communities. The Court held through the combined interpretation of the articles 28 and 30 of the EC Treaty¹² that a Member State may not prohibit the sale on its territory of products which are lawfully marketed in another Member State except where restrictions are justified by overriding reasons of public interest and which are proportionate to the aim pursued¹³.

The overriding reasons of public interest of the article 30 of the EC Treaty are interpreted strictly. Given the teleological approach of the Court to interpret the EC legislation, they may however cover new areas of concern such as environmental protection.

Mutual recognition applies to products which are not yet regulated by the Community harmonisation legislation, or to aspects of products falling outside the scope of such legislation.

The Council Resolution of 28 October 1999 on mutual recognition recalled the principle to the EU Member States. Furthermore, the European Commission issued two Communications to streamline implementing measures required to comply with the principle¹⁴.

In parallel, the Decision No 3052/95/EC¹⁵ was adopted to monitor the correct implementation of the principle. Since, the scheme established by this decision was not sufficiently successful it

¹² Article 28 EC (ex Article 30 EEC): Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 30 EC (ex Article 36 EEC): The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

¹³ Initially, the Court stated in the famous case *Dassonville* (Judgement of the Court of 11 July 1974. *Procureur du Roi v Benoît and Gustave Dassonville*. Case 8-74): "*All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions*". More detailed considerations were introduced in a second fundamental judgment in the case "*Cassis de Dijon*" (Judgement of the Court of 20 February 1979. *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*. Case 120/78): "*Obstacles to movement within the Community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted in so far as those provisions may be recognised as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer*". (...) "*There is therefore no valid reason why, provided that they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other Member State; the sale of such products may not be subject to a legal prohibition on the marketing of beverages with an alcohol content lower than the limit set by the national rules*".

¹⁴ Communication from the Commission to the European Parliament and the Council. Mutual recognition in the context of the follow-up to the Action Plan for the Single Market. COM (1999) 299 final of 16.06.1999. Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (2003/C 265/02).

¹⁵ Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

was recently replaced by new mechanisms laid down in the Regulation (EC) No 764/2008¹⁶. This Regulation will apply from 13 May 2009.

2.4.2. EC Regulation No 764/2008

The purpose of the Regulation (EC) No 764/2008 is to introduce compulsory and transparent mechanisms to solve the problems that result from applying technical rules of a Member State to specific products lawfully marketed in another Member State. It does not prejudice the functioning of the measures based on the Directive on General Safety of Products or other measures authorized by virtue of other pieces of EC legislation.

Procedural rules

The procedure to be applied starts at an early stage of the decision making process concerning administrative measures¹⁷ which could hinder the free movement of products (including agricultural and fish products) lawfully marketed in another Member State.

The main stages are the following:

Evaluation made by the competent authority of the country of destination to determine whether or not to adopt a decision.

A written notice is sent to the economic operator. This notice states the technical or scientific elements available and overriding reasons of public interest for imposing national technical rules on the product or type of product in question and why less restrictive measures cannot be used. The notice informs also the economic operator of the time-limit to submit comments (not less than 20 working days).

The decision of the competent authority is taken within a period of 20 working days from the expiry of the time limit for the receipt of the comments from the economic operator. It is notified to the economic operator and to the European Commission and has to specify:

- the grounds on which it is based, including the reasons for rejecting the arguments of the economic operators;
- the remedies available to challenge the decision including the availability of non-judicial problem-solving mechanisms, such as the SOLVIT system¹⁸.

¹⁶ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 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.

¹⁷ The decision may relate to the following:

- the prohibition of the placing on the market of that product or type of product;
- the modification or additional testing of that product or type of product before it can be placed or kept on the market;
- the withdrawal of that product or type of product from the market.

¹⁸ SOLVIT is an Internal Market Problem Solving Network initiated by the Commission Recommendation of 7 December 2001 on principles for using "SOLVIT". This computerized network helps to find, free of charge, out-of-court and not binding solutions further to complaints by consumers and businesses regarding the incorrect application of internal-market legislation by public authorities. SOLVIT contact points are part of the public authorities of the member country in which they are located.

While applying this procedure, the competent authority of a Member State has to comply with the rules below:

- In the notice, or at any stage of the procedure the economic operator may be requested to provide easily accessible (principle of proportionality) relevant information concerning the characteristics of the product or type of product in question and the law applicable in the country of origin.
- Certificates or test reports issued by a conformity-assessment body accredited for the appropriate field of conformity-assessment activity must be accepted.
- Temporary suspension of the marketing of the product is not allowed, except where rapid intervention is required to prevent harm to safety and health of users.

The Regulation establishes also a mechanism of control by the European Commission: Member States produce a yearly report which contains at least the number of written notices sent to economic operators and decisions taken by the authorities including the grounds on which those decisions were based and the type of products concerned.

Product Contact Points

Having in view the implementation of the principles of administrative simplification, the Regulation provides for the establishment of a system of Product Contact Points.

The EU Member States may entrust this function to existing services within the public administration (for example, existing contact points established in accordance with other Community instruments and/or national SOLVIT centres) or to any other public or private organization (chambers of commerce, professional organisations, etc).

The duty of Product Contact Points is to provide, free of charge¹⁹ and within 15 working days of receiving any request from economic operators or competent authority of another Member State, concrete information concerning the national technical rules applicable to a specific type of product in the territory in which they are established. This information extends to the functioning of mutual recognition (procedure applicable, remedies, etc) including the particulars of the authorities responsible for supervising the implementation of the technical rules in question and means to contact those authorities directly.

To this end, Product Contact Points should have sufficient resources (adequate staff and equipment to perform the basic tasks). In addition they are encouraged to make the information available through a website and in other Community languages.

In the context of the EU policy on e-government²⁰, the European Commission could set up a telematic network between the Product Contact Points.

2.4.3. Mutual recognition clause in specific pieces of legislation of the EU Member States

¹⁹ For additional information, Product Contact Points may charge fees that are proportionate to the costs of this information.

²⁰ Decision 2004/387/EC of the European Parliament and of the Council of 21 April 2004 on the interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC).

The Council Resolution of 28 October 1999 on mutual recognition calls upon the Member States "to review and simplify the relevant national legislation and its application procedures, for example, by inserting appropriate mutual recognition clauses in relevant legislative proposals and improving national procedures for applying efficiently these clauses".

In the views of the European Commission, the presence of the mutual recognition clause in each relevant piece of national legislation is helpful for economic operators and national authorities because it gives legal certainty as for the procedure to be followed.

As often as possible the Commission quotes the Judgement delivered on 22 October 1998 in the case C-184/96 "foie gras" as a corner stone in the implementation of the principle of mutual recognition²¹. Indeed, further to one of the claims presented by the Commission, the Court stated:

"In the light of the foregoing considerations, it is declared that, by adopting the Decree without including in it a mutual recognition clause for products coming from a Member State and complying with the rules laid down by that State, the French Republic has failed to fulfil its obligations under Article 30 (now article 28) of the Treaty."

On the occasion of the seminars on mutual recognition implemented in the Candidate Countries to the 5th EU enlargement, the European Commission presented a standard clause worded as follows:

"The provisions of the legislation under...(sector concerned - include a non exhaustive list of the legal acts and regulations concerned) shall not impede the import, marketing and use of products legally produced and marketed in one EU or EEA Member State, provided they ensure an equivalent level of protection."

It was also exposed that the clause could be complemented with additional provisions:

- An explanation of the application of article 28 EC and the principle of mutual recognition.
- A provision that would make the application of the principle of mutual recognition applicable for certificates, tests, laboratories, etc.
- A non exhaustive list of the legal acts affected.

In its interpretative communication (2003/C 265/02), on "the practical application of mutual recognition", the European Commission provides also an example of a detailed mutual recognition clause (See Annex I to this Background Paper).

Other examples of mutual recognition clauses used by EU Member States are presented below. They are extracted from notifications made pursuant to the Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

Slovak Republic (Notification Number 2005/74/SK of 1 March 2005)

Draft Decree of the Ministry of the Economy laying down requirements for safety of textile fibres and yarns, textile, leather and clothing products made from textiles and leather intended for direct contact with skin (maximum values for hazardous chemical substances and products,

²¹ Page 17, First Report on the Application of the Principle of Mutual Recognition in Products and Services Markets. SEC (1999)1106 of 13.07.1999.

safety tests to be carried out by the manufacturer, importer or supplier).

A mutual recognition clause is included in Section 6 of the draft decree.

“The requirements laid down in the annex which do not emerge directly from the relevant European Community regulations covering the harmonised field shall not apply to products manufactured or marketed in a Member State of the European Union or marketed in accordance with the legislation of any of the states in the European Free Trade Association which are simultaneously contracting parties to the European Economic Area. This shall be the case assuming such products satisfy:

- a) technical regulations which are binding with respect to the manufacture or marketing or use of such products in any of these states,*
- b) technical standards or code of good practice issued by a national standards body or an entity of equivalent standing pursuant to the legislation and requirements of a state which is a contracting party to the European Economic Area,*
- c) international technical standards authorised for use in any of these states, or*
- d) traditional or innovative production processes used in any of these states in accordance with their legislation, for which there is sufficient detailed technical documentation showing that the product in question can also be assessed for a given usage if necessary on the basis of supplementary, but not product conformity, tests and assuming such legislation, technical standards, codes of good practice or processes guaranteeing a degree of protection of legally protected interests correspond to the degree of such protection in the Slovak Republic.”*

France (Notification Number 2007/614/F of 7 November 2007)

Draft Decree on electronic breathalyzers.

Article 3

I. – The electronic breathalyzers referred to in the first paragraph of Article 1 shall be designed and manufactured to guarantee the reliability of the measurements taken for the purposes of ensuring personal safety.

II. – The electronic breathalyzers referred to in the first paragraph of Article 1 must:

- Either pass tests laid down in standards whose references shall be published in the Official Gazette of the French Republic.*

The person responsible for the initial placing on the market of electronic breathalysers shall make documents available to the inspection authorities containing a detailed description of the equipment as well as the reports of tests, conducted for each model, certifying that the equipment conforms to the said standards, and the address of the places of manufacture or storage with a view to placing on the market.

- Or comply with a model that has been issued with an attestation of conformity with the requirements on the reliability of the measurements taken for the purposes of ensuring personal safety, following a type examination carried out by a French body or by a body in another Member State of the European Community or in a State signatory to the Agreement on the European Economic Area or Turkey, said body having been accredited - for the inspection of the products referred to in Article 1 of this Decree - in accordance with standard EN/ISO 17025 by the French Accreditation Committee (COFRAC) or by an accreditation body signatory to the multilateral agreement signed within the framework of European coordination of accreditation bodies.*

Article 5

The provisions of this Decree shall not, however, hinder the free movement of electronic breathalysers that conform to the technical standards or specifications or manufacturing processes laid down by the legislation of another Member State of the European Community or of a State signatory to the Agreement on the European Economic Area or Turkey, which provide a level of reliability suitable to ensure personal safety equivalent to that guaranteed by this Decree.

3. Mutual recognition of industrial products and conformity assessments in MRA concluded by the EU

3.1. Current situation

Within the objective of facilitating the trade of industrial products, Mutual Recognition Agreements between the EU and partner Countries concern the **recognition of tests reports certificates and marks of conformity in relation to the conformity assessment activities of each party**. The main focus is put on the **mutual recognition in product sectors governed by the New Approach Directives**. Exceptionally, the MRA may cover other areas of the EC legislation, for example “conformity assessment”²² in the field of Good Laboratory Practice for the assessment of chemicals²³ or in the field of Good Manufacturing Practice for pharmaceuticals²⁴.

The EU approach to conclude a MRA is developed in two directions. Either the EU seeks a legislative alignment concerning the technical requirements of the products subject to MRA or the MRA is designed under the concept of equivalence of regulatory objectives.

Legislative alignment is possible only where the parties to the MRA share the same political and strategic objectives of trade facilitation.

Equivalence implies the regulatory autonomy of the parties. On the one hand, mutual recognition could be applicable to product sector covered by legislation that is deemed equivalent. In this case the parties accept the results of conformity assessment procedures carried out by the recognized CABs against the requirements of the country of origin. On the second hand, mutual recognition could be applicable to product sectors where the legislation is not equivalent. In this case, the parties accept the results of conformity assessment procedures carried out by recognized CABs against the requirements of the country of destination.

The MRA between the EU and Switzerland makes use of the two mechanisms above.

²² In this case conformity assessment does not relate to evaluation against the background of safety requirements but against other practices. See for example the in the Chapter 14 “Good laboratory practice (GLP)” of the Annex to of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment : “For the purpose of this Sectoral Chapter, ‘designation of conformity assessment bodies’ means the procedure by which the GLP Monitoring Authorities recognise that test facilities comply with the GLP principles.”

²³ MRA with Israel, Switzerland and Japan.

²⁴ MRA with Canada, Japan and the USA

Legislative alignment entails always a long process but a MRA based on regulatory equivalence does not represent a miracle solution. Actually the **mechanism of equivalence is little used because it entails complicated negotiation and does not always ensure the smooth functioning of trade facilitation.**

First, the negotiation has to cover in detail each individual product sector. For each product sector, the parties have to identify the objectives of individual technical regulations and to agree thereafter the equivalence of those objectives. Lastly, they have to agree the proper mechanisms to ensure the mutual recognition.

Second, on the occasion of any substantial revision or updating of the technical regulations in question, the MRA is likely to be renegotiated²⁵.

According to an analysis of the European Commission based on the experience of current MRAs between the EU and third countries²⁶:

“Mutual Recognition Agreements (MRAs) should be negotiated only in cases where there is clear equivalence of respective rules and a real prospect of making them operate almost "automatically"(...). The "enhanced" type MRA (mutual recognition of certificates based on equivalent or common requirements) is the one offering the best prospects of implementation and trade facilitation. This is the type of MRA worth pursuing in the future.”

3.2. Structure of MRA – PECA - ACAA

Mutual Recognition Agreements (including PECAs²⁷ and ACAAs²⁸) have certain common features. Some of them are summarized below:

- Mutual recognition of the results of conformity assessment procedures carried out in accordance with Community and national law listed in the Annexes and with regard to the notified CABs listed in the Annexes as well.
- Flexibility of the scope of the Agreement. Fast track procedures to amend the Annexes (product sectors, legislation, designating authorities and notified CABs).
- Rules and procedure to restrict the marketing of a product covered by the Agreement in case of overriding reason of public interest (safeguard clause).
- Causes and consequences of the verification of the technical competence and compliance of a notified CAB by the other Party.

²⁵ For more detailed developments on this issue, see in particular the Commission staff working paper on implementing policy for external trade in the fields of standards and conformity assessment – a tool box for instruments. Document SEC(2001) 1570 of 28.9.2001.

²⁶ Commission Staff Working Paper SEC(2004)1072 of 25.08.2004 on Priorities for Bilateral/Regional trade related activities in the field of Mutual Recognition Agreements for industrial products and related technical Dialogue.

²⁷ Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) concluded with certain Candidate Countries to the 5th EU enlargement.

²⁸ Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs) concluded with Malta and pending for negotiation with SAA and a few ENP Countries.

- Agreements on conformity assessment concluded by either Party with a country which is not a Party to this Agreement does not entail an obligation upon the other Party to accept the results of conformity assessment procedures carried out in that third country, unless there is an explicit agreement between the Parties.
- Exchange of information and cooperation.

The Annexes to the Agreements specify the product sectors covered by the Agreement and, for each of them:

- Community and national law
- Notifying authorities
- Notified bodies
- Specific arrangements (for example, special rules, supplementary provisions, transitional arrangements)

3.3. Settlement of dispute

Any MRA envisages mechanisms for the settlement of dispute concerning the application of the Agreement. This mechanism is set out in the MRA itself or by reference to the provision on dispute settlement contained in a more general Trade Agreement concluded between the partner Countries. In MRAs and FTAs concluded by the EC, the dispute settlement is organized under a Joint Committee (amicable settlement through a political consensus between the parties). It may be also complemented by binding arbitration mechanisms.

With regard to the future FTA EU-Ukraine, the Confederation of European Business - BUSINESSEUROPE (voice of enterprises in the EU - formerly UNICE) suggests the following²⁹:

“The agreement with Ukraine should include a binding and effective bilateral dispute settlement mechanism with clear cut deadlines. This should be set up in analogy to the WTO mechanism or the mechanism enshrined in the FTA between the EU and Chile. Precise deadlines and retaliation as a means of last resort are key. BUSINESSEUROPE supports direct access by companies to the mechanism which is essential when dealing with a country whose judicial system is undergoing reforms.”

Against this background it will be noted that Dispute Settlement Procedure in the FTA Chili-EU is organized as follows:

Parties endeavour to reach a mutually satisfactory agreement on the dispute. If the matter is not resolved within 15 days after the Association Committee has convened, or 45 days after the delivery of the request for consultations within the Association Committee, a Party may request in writing the establishment of an arbitration panel. Within three days of the request for the establishment of the arbitration panel, three arbitrators are selected by lot by the chairperson of the Association Committee (on a list 15 arbitrators drawn by the Association Committee). Arbitrators are bound to comply with a Code of Conduct set out in an Annex to the Agreement. They serve in their individual capacities (specialized knowledge or experience in law,

²⁹ BUSINESSEUROPE position on an EU-Ukraine Free-Trade Agreement, 29 January 2008.

international trade or other matters relating to the Agreement) and cannot be affiliated with, nor take instructions from any Party. Each Party is committed to take the measures necessary to comply with the ruling of the arbitration panel.

4. Implications of the FTA for Ukraine in terms of future work for legislative approximation

4.1. Background

Completion of measures identified in the EU-Ukraine ENP Action Plan

Priorities for legislative approximation included in the EU-Ukraine ENP Action Plan remain valid. In fact the objectives 30 and 31 of the ENP-AP have already anticipated the main measures for the removal of TBT between the EU and Ukraine.

Most of those measures relate to the adoption of the institutional, legal and administrative measures - both horizontal and sectoral - to permit the conclusion of an ACAA.

- Harmonisation of the horizontal framework and sectoral legislation in priority sectors for possible inclusion of the product sectors in an Agreement on Conformity Assessment and Acceptance of Industrial products (ACAA).
- Revision of existing Ukrainian standards, providing for harmonization with international and European standards and for voluntary application.
- Institutional arrangements and capacity building to avoid the concentration of functions within a single institution and related conflicts of interest with regard to standardisation, accreditation and conformity assessment,
- Harmonisation of the legislation on liability for defective products and general product safety.
- Simplification of conformity assessment procedures for industrial products, in accordance with EU rules and practice.
- Development of market surveillance capacities of the Ukrainian institutions based on best practice of EU Member States.

Other measures pave the way of an enhanced regulatory convergence to facilitate the movement of goods.

- Prevention of quantitative restrictions.
- Harmonisation of import licensing and registration requirements with those of the EU.
- Review of national measures covering the weight, composition, labeling manufacture and description of products to remove discrimination against imported products.
- Nomination of a contact point to facilitate co-operation and improved information flow between the EU and Ukraine on national measures and obstacles that could hinder the movement of goods.

ACAA is central for Ukraine to have a stake in the Internal Market of the EU

The objective of the entry into force of an ACAA (presumably by the end of 2011) is central to facilitate the trade of industrial products in priority sectors. That is already an ambitious programme where it will be required from Ukraine the same efforts as those made by Candidate Countries at a late stage of the EU accession process.

Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) concluded with certain Candidate Countries to the 5th EU enlargement organized the recognition of conformity assessment certificates concerning several product sectors covered by New Approach Directives. Before the signature and the entry into force of those PECAs, Candidate Countries had to adopt the corresponding parts of the *acquis communautaire* (horizontal legislation and relevant sectoral legislation including the adoption of the related harmonized standards) as a basis for their own legislation. They had also to set up the proper quality infrastructure (membership of the European Standardisation bodies, accreditation of qualified laboratories and CABs) and undergo a peer review to assess the results obtained.

In a different legal context, the same is proposed to Ukraine. **That is clearly an “enhanced MRAs” to be based on common rules.**

Format of the negotiation indicates the purpose of a regulatory convergence for other product sectors

It flows from the format of the current negotiation of the FTA that the Parties intend to reach a regulatory convergence beyond the priority product sectors covered by the ACAA. Annexes to generic provisions of the FTA are going to list pieces of the EC legislation and related key measures (concrete objectives) where gradual convergence of Ukrainian legislation with community policies and legislation is sought. This exercise is going to drive a coherent and comprehensive process of prioritization which has not yet been experienced in Ukraine due to the lack of co-ordination of the institutions involved in the European integration process. This prioritization has to be based on realistic commitments on the results to be achieved within a certain timeframe (legal measures, capacity building measures, needs of EU assistance, impact on enterprises). The scope and degree of market access in the future FTA depends on what can be effectively implemented.

4.2. Legislative approximation

4.2.1. The baseline: legal and institutional changes in relation to the quality infrastructure

The three laws enacted by the Verkhovna Rada in May 2001 on standardization, conformity assessment and accreditation of conformity assessment bodies have been welcome as a step towards the principle of the quality infrastructure applied in the EU (modular approach).

Despite various amendments, this legal framework does not yet ensure the full compliance with the corresponding horizontal EC legislation that is necessary to conclude the ACAA. Another reason to revisit this legislation is the recent adoption of the Regulation (EC) No 765/2008 on the rules applicable to accreditation activities and CE marking and the Decision No 768/2008/EC on the notifying bodies, notified CABs and a new set of conformity assessment modules.

To ensure coherence and legal certainty, a number of laws or regulatory acts that refer directly or indirectly to the concept of standardization, conformity assessment and accreditation should be scrutinized as well. **One of the first results to be achieved is the separation of the regulatory, standardisation, and conformity assessment functions³⁰.**

With regard to market surveillance and the related aspect of general safety of products, worth noting several attempts to propose a law compatible with the Directive GPSD and the practice of market surveillance in the EU Member States. A recent draft law registered at the Verkhovna Rada under No 1365 of 17 January 2008 contains a number of convergence points with the Directive GPSD and is rather business-friendly but, like other previous or concurrent non-official versions, this draft law does not express sufficiently fundamental principles such as the graduation in the scale of remedial measures and the reference to standards or the state of art as a criterion (among others) to assess that a product is deemed safe. Moreover, the role of customs authorities to detect unsafe products imported in Ukraine is still overlooked.

There is also at least a non-official version of a draft law on market surveillance prepared by the State Committee of Ukraine for Technical Regulation and Consumer Policy (Derzhspozhyvstandart) and this text contains provisions on the liability for defective products. Unfortunately the authors do not reproduce strictly the provisions of the Directive 85/374/EEC that are necessary to strike a balance between the interests of the victim, the manufacturer and the insurer.

As a whole, this short description of the state of affairs suggests there are a lot of gaps to bridge in the horizontal legislative framework of Ukraine before making possible the signature of an ACAA.

4.2.2. Full legislative alignment to EC rules in priority sectors

The first product sectors to be covered by an ACAA are low voltage equipment, machinery, simple pressure vessels and electromagnetic compatibility. **Other product sectors might be added as far as the corresponding quality infrastructure is in place** at the planned time of entry into force of the related technical regulations.

³⁰ This separation of functions has been limited so far to accreditation activities. National Accreditation Agency of Ukraine was separated from the State Committee of Ukraine for Technical Regulation and Consumers Policy in July 2002.

In terms of legal drafting, the approximation of the legislation relating to New Approach Directives implies the essential health and safety requirements and the conformity assessment modules are reproduced strictly. For various reasons, law-makers in Ukraine add their own interpretation of the EC rules. As a result, it is advisable to review at least the technical regulations adopted in the four priority areas of the ACAA.

4.2.3. Gradual regulatory convergence towards other pieces of EC legislation

It belongs to the Negotiators of the FTA to define the scope and the pace of the regulatory convergence between the EU and Ukraine.

There are indications in the EU-Ukraine ENP-Action Plan that the **labelling** of product is an area of concern. Recent debates have suggested as well that the recognition of tests on chemicals carried out in Ukraine, based on **Good Laboratory Practice**³¹, would facilitate the compliance with the EC rules on chemicals³² by Ukrainian exporters.

To some extent, the methodology for product market and sector monitoring implemented by the European Commission³³ could help the Ukrainian policy makers to identify, more accurately than through empirical evidence, which are the priority product sectors.

Gradual regulatory convergence in the sphere of TBT means also the **implementation of good regulatory practice**. This point is an element of discussion during the triennial reviews of the operation and implementation of the WTO TBT Agreement. The TBT Committee considers that good regulatory practice helps to avoid unnecessary obstacles to trade and contributes therefore to the effective implementation of the disciplines of the Agreement by each Member. **Simplification, predictability, transparency, and accountability in the development of technical regulations are part of the process for the removal of TBT between the EU and Ukraine**. In this area, it seems that a considerable effort is still needed³⁴.

³¹ Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

³² That concerns in particular, but not exclusively:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

³³ See, "Guiding Principles for Product Market and Sector Monitoring", European Economy, Occasional Papers, number 34 and the Commission Staff Working Document SEC(2007) 1517 of 20.11.2007 on the results of a first sector screening accompanying the Communication from the Commission on a single market for 21st century Europe.

³⁴ See, for example, the results of recent international conferences:

International Conference On Technical Regulations in Ukraine – Urgent need for reform organized by the Committee for Entrepreneurship and Regulatory Policy with the support of the IFC on 23 April 2008. International

The last observation concerning regulatory convergence for trade facilitation in industrial products between the EU and Ukraine concerns an argument which is often put forward by certain Ukrainian stakeholders: some aspects of the Ukrainian framework on consumer protection and technical regulations would ensure a better level of safety than the EU rules.

Should this belief be demonstrated by scientific evidence or reports on casualties, the safeguards provisions in the GATT and the TBT Agreement do not impede the capacity of WTO Members to define their own level of safety for the trade in goods. In the EU context, it is the same but the application of the principle of proportionality is monitored more strictly.

In the context of far-reaching commitments to be included in a “FTA+”³⁵, it is assumed that the Agreement may contain provisions on the prohibition of “measures equivalent to quantitative restrictions”. In this case, the appreciation of the margin of discretion of the Ukrainian Authority to adopt more stringent measures in their technical regulations could be regulated by mechanisms similar to those envisaged in the article 95 of the EC Treaty (derogations to the Community harmonization legislation, granted to EU Member States under certain strict conditions).

4.2.4. Mutual recognition of industrial products non-regulated by the Community harmonization legislation

Reportedly, Ukrainian stakeholders would like to put forward a proposal concerning the introduction in the FTA of the principle of mutual recognition for goods not covered by the Community harmonization legislation.

There is at least one example where such a principle has been laid down in a MRA. In the ACAA of 2004 between the EC and Malta (just before the accession of Malta to the EU), the article 4 of the Agreement specifies:

“The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the Annexes on ‘Mutual acceptance of industrial products’, which fulfil the requirements for being lawfully placed on the market in one of the Parties, may be placed on the market of the other Party, without further restriction.”

Nevertheless, the Annex to which this article refers is empty.

It is not prohibited to think that the same provision could be negotiated between the EU and Ukraine and that a specific Annex could list the products to which this mutual recognition applies, even if the establishment of such a list would be complicated by the fact individual Member States may regulate products in non-harmonised sectors.

It has also to be borne in mind that the Directive on the General Product Safety would anyway apply in non-harmonised sectors.

Conference on Implementing Regulatory Reforms in Ukraine: Lessons learned from international and local practice organized on 18 September 2007 organised by the IFC/WB.

See also under the Chapter 2 “Reducing barriers to growth: the role of institutional and regulatory reform”, in the 2007 OECD report on Ukraine Economic Assessment.

³⁵ Terminology used by in several reports on the consequences of the future FTA.

As an alternative solution, the Parties to the FTA might agree mechanisms of mutual recognition of industrial products similar to those laid down in the Regulation (EC) No 764/2008.

4.3. Administrative capacity building supported by the EU funding to implement the FTA

As said previously, the exercise of legal drafting in the legislative approximation process represents only one side of the coin. The objective being the effective implementation of the *acquis* in the agreed priority sectors, the most difficult task is to ensure the functioning of the legislation by measures of administrative capacity building. This effort is due to be supported by the EU assistance.

In line with the new pattern of the EU assistance under the ENPI and the Paris Memorandum of May 2006, the EU and partner countries expect that Twinning and TAIEX activities together with direct funding (for example Sector Budget Support) are going to better impact the ownership and the efficiency of the EU assistance.

With regard to the capacity building in the field of TBT, two important twinning projects are currently implemented in Ukraine:

- Twinning project UA06/PCA/TR/07 - Strengthening Activities of The National Accreditation Agency of Ukraine.
- Twinning project UA06/PCA/TR04- Strengthening of Standardisation, Market Surveillance, Metrology and Legal Metrology, Conformity Assessment and Consumers Policy in Ukraine.

Their common purpose is to support the establishment of the quality infrastructure in relation to the conclusion of an ACAA between the EU and Ukraine. That includes, *inter alia*, support to the adoption of harmonized standards, support to the membership of the European Standardisation and Accreditation organisations, support to the reform of the institutional framework to prevent conflicts of interest between the bodies involved in conformity assessment activities.

Expected outputs of those twinning projects have to be considered to prioritise the legal and administrative measures needed to meet the objectives of the future FTA in the TBT sphere.

4.4. Costs and benefits for enterprises

A number of reports³⁶ have been commissioned to assess the costs and benefits of the future FTA between the EU and Ukraine. All of them intend to evaluate, at least globally, the impact of the reform of technical regulations towards the EU rules, in the case of Ukrainian enterprises.

³⁶ See, for example the following studies:

- Global Analysis Report for the EU-Ukraine Trade Sustainability Impact Assessment. ECORYSECORYS Nederland BV, June 2007 (study commissioned by the European Commission, DG-Trade).
- Free Trade between Ukraine and the EU: An impact assessment. International Centre for Policy Studies, Kyiv, 2007.
- Prospects for EU-Ukraine Economic Relations,. CASE Reports No. 66, Center for Social and Economic Research, Warsaw 2006, Małgorzata Jakubiak, Anna Kolesnichenko.

To sum up the main conclusions, it is observed that one of those studies³⁷ describes the general trend as follows:

“Despite definite short-term risks for such industrial sectors as machine-building, chemicals and light industry, the institution of an FTA+ between Ukraine and the EU will have a positive impact on the country’s entire economy in the medium and long term. Ukrainian companies will gain access to EU markets, provided that they meet EU standards and regulatory requirements. Meanwhile, the cost of instituting EU standards and re-equipping production facilities should be compensated through an inflow of investment capital from the EU”.

Another report³⁸ underlines:

“The assessment of the costs of harmonization is a very difficult exercise, both conceptually and technically. The conceptual difficulty is that from a long-term prospective many expenses on improvement of product safety, environmental quality, administrative procedures and the like are not costs, but rather investments, as they lead to improvement of the economic environment and quality of life. In the short-term, the expenses may be substantial, yet in the long term they will turn into benefits.”

More accurate data on the compliance costs for using the harmonized standards of the EU are displayed in the Global Analysis Report for the EU-Ukraine Trade Sustainability Impact Assessment produced by a private contractor³⁹. They refer to a survey conducted by CASE on non-tariff barriers faced by Ukrainian exporters to the EU. A table exposes the results of the survey.

Percentage of yearly production costs spent by Ukrainian exporters to the EU in order to ensure products compliance with the EU norms (reference year, 2006) would be, for example, the following:

- Manufacture of textiles: 2.3
- Tanning and dressing of leather; manufacture of luggage, and footwear: 5.3
- Manufacture of wood and of products of wood and cork: 20.9
- Manufacture of chemicals and chemical products: 5.5
- Manufacture of machinery and equipment: 4.4
- Manufacture of electrical machinery and apparatus: 11
- Manufacture of radio, television and communication equipment and apparatus: 10.
- Manufacture of medical, precision and optical instruments, watches and clocks: 20

³⁷ “The FTA+ impact on industry”, page 103 and subsequent of the report produced by International Centre for Policy Studies, Kyiv, in 2007 on the impact assessment of the FTA EU-Ukraine.

³⁸ Prospects for EU-Ukraine Economic Relations. CASE Reports No. 66, Center for Social and Economic Research, Warsaw 2006, Małgorzata Jakubiak, Anna Kolesnichenko.

³⁹ Global Analysis Report for the EU-Ukraine Trade Sustainability Impact Assessment. ECORYSECORYS Nederland BV, June 2007 (study commissioned by the European Commission, DG-Trade).

- Manufacture of motor vehicles, trailers and semi-trailers: 12.3

The figures above have to be interpreted cautiously because they have been made of a limited number of respondents.

UEPLAC IV (EU funded project active in the area of legislative approximation) has also conducted a survey in 2008 for the product sector low voltage equipment (LVD)⁴⁰. One of the results of the Regulatory Impact Assessment is presented below:

- CIS: Import of low voltage electric equipment to Ukraine from CIS countries is expected to decrease by 5% to 10% in the short term, because European conformity assessment procedures will be a barrier to trade for some CIS exporters. Export volumes to CIS are not expected to change as a consequence of LVD.

- EU: Import of low voltage electric equipment to Ukraine from EU countries is expected to grow by 1% to 2% in the short term, while export to EU countries should increase by 3% to 5% in the medium term as previous barriers to trade are removed and adaptation to new conformity assessment procedures takes place.

To some extent, the conclusion of this pilot case-study concerning the change in trade flows, stemming from the introduction in Ukraine of a system compatible with New Approach Directives, could be extended to other product sectors.

⁴⁰ Regulatory impact analysis of the introduction of the EC Low Voltage Directive into the Ukrainian legislation. Ukrainian-European Policy and Legal Advice Centre (UEPLAC), Kyiv, March 2008.

ANNEX

MODEL AND EXAMPLES OF MUTUAL RECOGNITION CLAUSES

Example 1

Commission Interpretative Communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (2003/C 265/02).

Example of a detailed mutual recognition clause:

“The requirements of this law do not apply to products lawfully manufactured and/or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in an EFTA State that is a contracting party to the EEA agreement.

If the competent authorities have proof that a specific product lawfully manufactured and/or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in an EFTA state that is a contracting party to the EEA agreement, does not provide a level of protection equivalent to that sought by this law, they may refuse market access to the product or have it withdrawn from the market, after they:

- have informed the manufacturer or the distributor in writing which elements of the national technical rules prevent the marketing of the product in question, and*
- have proved, on the basis of all the relevant scientific elements available to the competent authorities, that there are overriding grounds of general interest for imposing these elements of the technical rule must be imposed on the product concerned and that less restrictive measures could not have been used, and*
- have invited the economic operator to express any comments he may have within a period of (at least four weeks or 20 working days), before issuing an individual measure against him restricting the marketing of this product, and*
- have taken due account of his comments in the grounds of the final decision.*
- The competent authority shall notify the economic operator concerned of individual measures restricting the marketing of the product, stating the means of appeal available to him.”*

Example 2

Notification by France (Number 2008/126/F of 27 March 2008) of a draft Decree laying down the safety requirements to be met by goal frames and goals and amending the Sport Code.

This Decree lays down the safety requirements applicable to goal frames and goals for installation in France.. Goals manufactured according to standards (EN 748, EN 749, EN 750, EN 1270) or to a model covered by a certificate of conformity, granted following a type examination, by an accredited body, are deemed to meet these requirements.

Amendments to the regulatory part of the Sport Code:

“Article R 322-20. – It shall be prohibited to import, hold with a view to sale or distribution free of charge, place on sale, sell or distribute free of charge, rent or provide either free of charge or in return for payment goal frames that do not comply with the safety requirements laid down in this section. (...)

Article R 322-22 – Goal frames and goals shall be deemed to have met the safety requirements laid down in this section if they are:

1. manufactured according to the standards whose references are published in the Official Gazette of the French Republic.

The person responsible for the initial placing on the market of these products shall provide the authorities referred to in Article L 215-1 of the Consumer Code with a detailed description of the product, the means by which the manufacturer ensures that the manufacture conforms to these standards, the results of tests carried out on the basis of these standards and the address of the places of manufacture or storage with a view to placing on the market.

2. or they are manufactured according to a model that has been issued with a certificate of conformity with the safety requirements, said certificate having been issued following a type examination carried out by a body located in France or in another Member State of the European Community or by a State signatory to the Agreement on the European Economic Area or Turkey, said body having been accredited in accordance with standard EN/ISO 17025 and by the French Accreditation Committee (COFRAC) or by an accreditation body signatory to the multilateral agreement signed within the framework of European coordination of accreditation bodies for the inspection of goal frames and goals referred to in Article R 322-19 of this Code.

(...)

The provisions of this section shall not hinder the principle of free movement of goal frames and goals that conform to the regulations or standards or technical specifications or manufacturing processes of another Member State of the European Community, or State signatory to the Agreement on the European Economic Area or Turkey, which guarantee a level of safety equivalent to that guaranteed by this section.”

Example 3

Notification by Spain (Number 2002/306/E of 26 July 2002) of a draft Royal Decree adopting the quality standard for yoghurt.

"This provision shall not apply to products legally manufactured and marketed in the other Member States of the European Community nor to products originating from the EFTA countries, contracting parties to the Agreement on the European Economic Area (EEA).

The said products, provided that they do not pose a risk to health, within the meaning of Article 30 of the EC Treaty or Article 13 of the Agreement on the EEA, may be marketed in Spain with the description laid down in the legal provisions applicable in the Member State of the Community from which they originate or in the EFTA country which is a contracting party to the EEA agreement from which they originate, or failing that, with a description of the product and, if necessary, of its use, which is sufficiently precise to inform the buyer of its true nature so that they can distinguish it from products with which it could be confused. "

Example 4

Notification by Austria (Number 2001/191/A of 2 May 2001) of a draft Order from the Federal Minister for Labour and Economic Affairs amending the Order on drinking vessels (glasses)

"3. The following Section 7 shall be inserted in front of Section 8:

“Section 7. In a Member State of the European Union or the European Economic Area, drinking vessels which carry approved manufacturer’s marks are to be regarded as the equivalent of domestic marks if the

manufacturer can provide the Federal Office of Weights and Measures with proof that the mark has been registered abroad.”