Measurement technology: an effective strategy for international trade

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Focusing the European single market, this study addresses the significance of metrology and metrology-related functions (standards, conformity assessment and accreditation) for international trade. The paper highlights the most relevant results of the thorough revision of the European regulation for the free movement of goods, which aims to remove the still existing obstacles for the free circulation of products within the Community and to enhance the protection of legitimate interests like health, safety and environment. In this context, this study proposes a survey to be conducted among internationally recognized experts in metrology and regulation to assess the effectiveness of the applicable European legislation. Indeed, its recent revision represents an opportunity to improve the diffusion of key metrology concepts and the urgent need to diffuse metrology culture to increase the level of awareness, efficiency and transparency of the regulatory scheme for the benefit of all parts involved.

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NOMENCLATURE

CIPM = International Committee of Weights and Measures EU = European Union GDP = Gross Domestic Product ILAC = International Laboratory Accreditation Cooperation MRA = Mutual Recognition Arrangement NMI = National Metrology Institute OIML = International Organization for Legal Metrology WELMEC = European Cooperation in Legal Metrology WTO = World Trade Organization

1. Quality infrastructure and international trade

In the context of trade globalization, the economic success of a country depends essentially on its participation in international trade flows. Considering the important role of technology-intensive products in international trade, the development of the national *quality infrastructure* constitutes an important factor to increase competitiveness. The term *quality infrastructure* denotes the institutional arrangement necessary to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and conformity assessment (testing, certification and labeling) services. They are essential to improve the quality of products and to promote competitiveness through an adequate use of metrology (correctness of measurements) and the suitable application of conformity assessment based on harmonized technical and regulatory procedures and standards.

Facing the worldwide formation of economic blocs and conquest of foreign markets, the logic that guides today's business transactions is based on the *certified* quality of products and services. Furthermore, the quality of a product will not be accepted unless the services, processes and professionals involved in the certification process comply to certain standards or regulations, too. Exporters from countries that do not count with an internationally recognized quality infrastructure face high additional costs due to different regulatory requirements in different markets. And these costs, originated by redundant (usually unnecessary) tests, can easily turn products uncompetitive in global markets. Therefore, an appropriate technological infrastructure is an indispensable tool for the international economic insertion of a country, helping exporters to overcome their technical (and financial) inabilities to comply with regulatory requirements. This is particularly accomplished by demonstrating that equivalent quality infrastructure schemes are applied to perform the conformity assessment of products eligible to

circulate between trade partner countries. These schemes are crucial to ensure legitimate compliance with requirements for safety, consumer protection and environmental concerns. In this sense, quality infrastructure becomes a central issue for the integration of partner countries participating in common markets and in the international trading system.

In this context, the joint availability of all components of quality infrastructure is indispensable, since the above functions are closely related and interdependent. Standardization allows companies to leverage their engineering resources by providing technical input for manufacturing procedures. Once a standard is established, the industry benefits as a whole rationalizing manufacturing processes and reducing associated production costs. As a result, end users may access higher quality products for a lower price. While standards are an efficient means to codify and disseminate technical information throughout the economy, metrology confers reliability and credibility to measurements. Their adequate use has a pronounced value for manufacturers aspiring to world market status. Making an adequate use of industry standards and metrology, companies can realize many benefits if their products and services are qualified by recognized conformity assessment procedures. Moreover, government bodies and regulators must rely on laboratory testing results to base their decisions. Accreditation (by ILAC signatories) is the confidence (voluntary) scheme internationally practiced aiming to ensure that the laboratory has achieved a prescribed level of technical competence to perform specific types of testing, measurement and calibration activities. Thus, laboratories should be capable of producing data that are accurate, traceable and reproducible; i.e.: measurement results that have an adequate level of confidence. This is how quality infrastructure contributes to regulation as it provides the conditions that allow trade partners to compete fairly in a global economy promoting domestic, regional and international trade while reducing expenses, improving quality assurance and marketing goods and services.

2. The European regulation for the free movement of goods

The increasing economic integration is closely related to a more effective integration of technical regulation at international and regional level. Regarding the European regulation for the free movement of goods in the single market, the European Union's approach was based on the principle of mutual recognition and harmonization of national technical regulations. However, regulatory harmonization was accomplished to cover a vast amount of technical details for each product, which hindered free trade within the single market. Considering the difficulties arising from this system, a new regulatory strategy was adopted in 1985: the Council Resolution 85/C 136/01 establishing the *New Approach* – a new legal framework for the harmonization of national regulations regarding industrial products. ¹ The adoption of this new technique of regulatory

harmonization is explained by the "urgent need to solve the present situation regarding technical barriers to trade and dispel the consequent uncertainty for economic operators" [1]. In 1989, the *New Approach* was complemented by the Council Resolution 90/C10/01 concerning the *Global Approach* for conformity assessment². It was introduced in order to ensure the free movement of goods in the single market and the protection of the general interest. The adoption of the New and Global Approaches enhanced the development of European companies through the establishment of a more integrated, more competitive and more innovative economic environment. It enabled the realization of economies of scale through the formation of a broader market and encouraged European companies to invest in product innovations. Thus, it improved efficiency and dynamism of the European economy and generated economic growth.

Despite the enormous efforts made, the single market still offered opportunities that had not been materialized. According to the European Commission, further improvement was necessary to maximize the potential of the single market, its attractiveness to foreign investors and its position as a global leader in developing and implementing standards and technical regulations [2]. And more, it was essential to demonstrate a greater sensitivity regarding the concerns of European citizens (specifically regarding product safety) and to consider important changes in the overall context, as the enlargement of the European Union. These circumstances led to the recent revision of the New and Global Approaches, aiming to respond appropriately to the weaknesses identified in the complex and participatory revision process. A revision that led to the adoption of the so-called New Regulatory Framework, consisting of several legislative measures published in the Official Journal of the European Union in August 2008, applicable to Member States since January 2010.

2.1 Main shortcomings of the European regulatory scheme

The European technical regulation for the free movement of goods in the common market has faced significant difficulties in application and enforcement. These are due to undesirable differences in administrative procedures and unbalances of the quality infrastructure in place at the national and commercial laboratories in operation in each Member State. Concerning the first, the difficulties refer to non-uniform interpretation and application of requirements throughout the EU, especially in conformity assessment and accreditation schemes. As to the latter, traceability still remains a

¹ Compared to the *Old Approach*, the Council Resolution 85/C136/01 of May 1985 established the basis for the *New Approach*, a new logic of regulatory strategy which introduced the essential (mandatory) security requirements in the European directives. The purpose of this change was to ensure a high level of protection of the public interest while adding more flexibility to legislation.

The directives based on the *New Approach* refer mainly to European harmonized standards, whose compliance involves a *presumption of conformity* with the applicable essential requirements. This is how the right for the free movements of goods can be granted. Nevertheless, preserving the voluntary character of harmonized standards, manufacturers are free to choose any other technical solution to demonstrate compliance with the essential requirements defined in the directives.

 $^{^2}$ The Council Resolution 90/C10/01 of December 1989 established the conditions for the *Global Approach*; i.e.: to assess conformity through appropriate procedures (modules), which are defined according to the type of risk related to the products. In the context of the *Global Approach*, the CE-marking is a key element to certify that the marked products have undergone the applicable conformity assessment procedures and were considered compliant to the essential requirements.

challenge as companies demand traceability of measuring and test equipment to national standards by means of calibration to ensure that manufactured parts be interchangeable and fit the purpose. Furthermore, the interaction of metrology -which enables all functions of quality infrastructure- with technical regulation is deficient. Difficulties to express measurement uncertainties or the unavailability of appropriate measurement equipment and methods still represent problems which are not properly considered when establishing technical regulation requirements. Lack of metrological awareness amongst regulators and insufficient harmonization of best practices for metrology policy and implementation are to be criticized. Full harmonization of the best practices associated with the functions of quality infrastructure seems to be the main challenge to be overcome by the EU Member States. The basic elements of quality infrastructure are not always understood and applied in the same way within the European Union. The harmonization between 27 Member States is certainly not a trivial undertaking considering the differences in economic development, the country's traditions in organizing their quality infrastructure, cultural and linguistic differences, availability of budgetary funds and the country's capacity to attract foreign direct investments.

2.2 Corrective measures adopted

The creation of an internal market without barriers for the free movement of goods is one of the main objectives of the EU. Considering the appointed shortcomings of the current European regulatory scheme, the New Regulatory Framework was adopted on 23rd of June 2008 to be enforced since January 2010. The legal texts adopted are 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 [3] and Decision N° 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products [4]. This Framework aims to improve conditions for the free movement of goods in a thorough harmonized context and to guarantee a higher level of protection of public interest when compared to the previous scheme. It builds upon existing systems to introduce clear Community policies to strengthen the application and enforcement of internal market legislation. It provides support for the application of the CE marking, clarifies its meaning and sets out simple common definitions of terms which are sometimes used differently. It strengthens quality and confidence in conformity assessment activities through reinforced and clearer rules on requirements for the designation of notified bodies, including the (almost) compulsory use of accreditation regardless its voluntary character. It enhances accreditation through the strengthening of the peer evaluation system; limits cross-border accreditation within the EU and officially recognizes accreditation as a service of general interest provided by a public authority. It enhances market surveillance with the aim to guarantee that national market surveillance authorities in fact should have the power, resources and knowledge required for an adequate performance of their tasks. These improvements are introduced through improvements in communication and coordination between market surveillance authorities and harmonization of differing

approaches (proactive vs. reactive) between Member States.

Essentially, these are the measures related to conformity assessment, accreditation and market surveillance introduced by the *New Regulatory Framework*. They aim to remove still existing obstacles for the free circulation of products within the Community and to enhance the protection of legitimate interests as human health and safety, environment. Surprisingly, in spite of the metrology deficiencies identified in the revision process of the *New and Global approaches*, no specific corrective measures for metrology were acknowledged in the *New Regulatory Framework*. Likewise, not for standards either. Although not explicitly quoted, it is however important to bear in mind that metrology and standards are major concepts that are inherently reflected in the other functions of quality infrastructure already discussed.

3. Proposal for the assessment of the regulatory scheme

In the light of the functions of quality infrastructure, a survey is proposed [5] to assess the effectiveness of the regulatory scheme ruling the free movement of goods within the European market. The opinion poll shall take into account the views of international experts (knowledgeable in the European legislation) who work in key areas of the quality infrastructure; i.e.: metrology, standards, accreditation, conformity assessment, regulation and market surveillance.

3.1 The proposed structure of the survey

The proposed instrument for data acquisition is a structured questionnaire acknowledging 10 conceptual questions related to standards, metrology, conformity assessment, technical regulation, accreditation and market surveillance. This questionnaire shall forward the following main statements (admitting closed-ended answers structured in the options *I agree*, *I disagree* and *no opinion*).

<u>Main statement on standards</u>: European harmonized standards reflect a key element of the New and Global Approaches. However, there exist several weaknesses concerning the European standardization process.

<u>Main statement on metrology</u>: Adequate concepts of metrology are not always taken into consideration during the process of development and application of standards and technical regulations.

<u>Main statement on conformity assessment (addressed to notified</u> <u>bodies)</u>: The effectiveness of the new and global approaches depends on the actual performance of notified bodies, uneven across the EU.

<u>Main statement on conformity assessment (addressed to the CE-marking)</u>: The CE-marking is an important mechanism for the free circulation of goods and consumer protection in the EU. However, there exist several deficiencies concerning its effectiveness.

<u>Main statement on accreditation</u>: Accreditation was introduced into the New Approach to overcome deficiencies in the work of conformity assessment bodies. Even so, accreditation is performed with different degrees of rigour in the EU, which negatively affects the effectiveness of the New Approach.

<u>Main statement on the proposed corrective measures for</u> <u>accreditation</u>: The revision of the New Approach (enforced from January 2010 onwards) will considerably improve the effectiveness of accreditation in the EU.

<u>Main statement on market surveillance</u>: Market surveillance is an essential tool for the enforcement of the New Approach Directives. Ruled by different degrees of rigour in the EU, it may create unequal conditions for economical operators and jeopardize product safety.

<u>Main statement on the proposed corrective measures for market</u> <u>surveillance</u>: The revision of the New Approach (enforced from January 2010 onwards) will considerably improve the effectiveness of market surveillance in the EU.

<u>Main statement on the interaction of key actors</u>: The collaboration between market surveillance authorities, national accreditation bodies and notified bodies should guarantee the effectiveness of the applicable regulatory scheme. However, several weaknesses remain.

<u>Main statement on the effectiveness of the New Regulatory</u> <u>Framework</u>: The revision of the New Approach (enforced from January 2010 onwards) is strong enough to overcome already identified weaknesses.

Furthermore, to increase the scope of answers and collect a greater variety of data, these statements shall be unfolded in a multiple choice format and include fields for optional comments.

3.2. The expected outcome of the survey

The proposed survey shall be conducted with two specific purposes: (i) to promote the discussion of shortcomings related to the then applicable regulation (*new and global approaches*) and (ii) to contribute to the analysis of legislative measures adopted in the context of the *New Regulatory Framework* conceived to mitigate the detected deficiencies. Data tabulation and discussion of each one of the questions raised shall lead to a comprehensive analysis of the essence of the New and Global Approaches and their respective reviews. Considering that regulatory principles and practices must be continuously developed to meet the evolving needs of economy and society at large, the outcome of this survey aims to subsidy the ongoing revision process of the applicable European regulation.

4. Measurement technology as a strategy for international trade

Measurement technology is a main component of quality infrastructure and constitutes a valuable tool for trade operations. The proliferation of free trade agreements enlarging the EU (and leading to more countries acceding to the World Trade Organization, WTO) will continue to increase the volume of cross-border trade that, in turn, drives metrology. Trade attracts foreign investments, guarantees

access to new technologies, develops technical expertise and generates revenue. Trade is crucial too for establishing business confidence and strengthening economic growth. Because metrology -a sort of an "invisible technology" acting behind the scenes- is neither easily quantifiable nor its benefit immediately perceived by common citizens and governments; it lacks general understanding regardless its economic relevance. The link between global trade and the role played by metrology, standards and conformity assessment in export competitiveness is still largely misunderstood. And mechanisms by which the functions of industrial technology contribute to the establishment of confidence in measurements and the lessening of technical barriers to trade are often misconstrued. Over the years, the importance of the national quality infrastructure - a public good from the standpoint of public economics theoryhave been underestimated in the development of economic policies to which trade is an essential component. But it was only a decade ago that the International Committee of Weight and Measures (CIPM), supported by directors of the national metrology institutes (NMIs) from thirty-eight Member States of the Metre Convention and representatives from two international metrology-related organizations (OIML and ILAC), introduced a comprehensive scheme to establish the equivalence of national metrology systems. This became the basis for the CIPM Mutual Recognition Arrangement (CIPM-MRA) conceived and implemented at that time but still undergoing improvements ever since.

Metrology induces an economic impact as it is almost impossible to describe anything without referring to weights and measures. In fact, accurate measurements impact on modern society and constitute an essential component to support trade while promoting innovation, economic growth and welfare. Results of a study developed for the European Commission [6] quantifies the economic impact of measurement activity in the European Union to almost € 230 billion of directly estimable benefits. This economic return is equivalent to 2.7% of EU GDP with a benefit to cost ratio of nearly 3:1. The study emphasized that this positive impact of measurement is particularly significant in highly industrialized countries e.g.: in Germany it accounts to 4.7% of the GDP. This is why no economy can underestimate the importance of adopting and implementing internationally recognized and accepted metrology, standardization, accreditation and conformity assessment practices for economic growth.

5. Conclusions

Measurement technology provides a vital link to global trade, market access and export competitiveness as it reduces unnecessary barriers to trade and contributes to consumer confidence in product safety. Despite this fact, awareness of the importance of accurate measurements is still unsatisfactory among practitioners, regulators and legislators. There is an increasing need for proactive cooperation and information exchange between national metrology institutes (NMIs) and metrology stakeholders (regulators, industry, universities etc.) covering a wide range of measurement needs. Generally speaking they still lack appreciation and understanding of basic concepts of measurement accuracy and measurement uncertainty. A more effective collaboration³ between metrologists and regulators could help to replace the unambiguous simplicity of the "yes/no" answers requested by the international trade judicial system; a more useful metrology fundamentals could certainly avoid financial losses and misfortunes inherent to wrong decisions associated to trade.

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³ In some countries and regions, promotion of closer interaction between technical regulation and metrology is developed by national or regional legal metrology organizations. Existing organizations like WELMEC (European Cooperation in Legal Metrology) or projects like RegMet (Improving dialogue between EU Regulatory Bodies and National Metrology Institutes, 2000-2003) serve a useful purpose as they create a forum for relations between involved actors and represent a possibility to establish general awareness for the significance of metrology.