

# International Standards and National Specificities in Large Economies: USA, China and EU

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## Abstract

*International Standards have seen for the past decades one of the most pronounced increases in adoption and usage across the globe. As International Standards become not only an indicator of the quality of economic processes deployed, their spread signals the level of integration in the world markets as they align to common practices. In this paper, I explore the dynamics of International Standards' adoption over the past decade, and the way in which these have been developed and adopted. I focus especially on regional differences, in the case studies of the largest economies today: USA, China and the EU. I show how sometimes national standards prevail over international standards, and how this is an instrumental tactics for meeting protectionist objectives. A specific case study in the field of international standardization studies the medical standards that benefit from the additional oversight of an International Organization (i.e. World Health Organization (WHO)). WHO has provided unitary guidelines of implementation across the globe, and has furthered significantly the homogeneity in this particular field.*

**Keywords:** International Standards; globalization; developed economies; USA; China; EU;

**JEL Codes:** F23; I18; L15; P52;

## 1. Introduction

*“A key issue for the economic development and for performance of organizations is the existence of standards. As their definitions and control are source of power, it seems to be important to understand the concept and to wonder about the representations authorized by the concept which give their direction and their legitimacy.” (Bredillet, 2003, p.2)*

The International Organization for Standardization (ISO), founded in 1947 and headquartered in Geneva Switzerland is the world's largest developer of voluntary quality standards, both industrial and commercial. More than 130 permanent employees and members from 161 countries form 783 technical committees and subcommittees responsible for the elaboration and revision of over 22,000 International Standards covering almost all aspects of quality, manufacture and technology.

With every standard answering the key question “What is the best way to do something?” many companies rely on ISO standards to increase productivity, lower cost and maintain quality and safety for products and services. This also enables companies to access international markets, ISO being the common denominator for businesses that are aware of the importance of quality in today's global economy.

ISO's most popular standards are: ISO 9001 Quality management, ISO 14000 Environmental management, ISO 15189:2012 Medical laboratories, ISO/IEC 17025 testing and calibration laboratories, ISO 26000 Social responsibility, ISO 31000 Risk management, ISO 50001 Energy Management. International Standards have not only

multiplied over the course of the years, but have also increased in complexity. As the process of developing such standards becomes more comprehensive, we can see an increasing consideration for health, safety, sustainable development and environmental protection.

In this paper, I look at several aspects related to International Standards. I present below an assessment of international and national standards from the perspective of their formulation and implementation. Then, I compare the geographical and sectorial spread of international standards' adoption.

## 2. Literature Review

In an important analysis on the economics of standards' adoption across the globe, Bredillet (2003) explains how changes in the quality of international standards across time are only a reflection of the evolution of various conventions that support them. They further explain that these changes or improvements take form under the pressure of factors concerning the markets (i.e. extensive growth vs. intensive growth, penetration by change of rules etc.), as well as factors that concern the companies that employ such standards (i.e. resistance to change, resilience, adaptive behaviour etc.). Essentially, as Bredillet shows the ultimate goal of international standards, as well as any improvements these may suffer across time, is to maximize relative coherence and the factor of performance (and profit implicitly).

Walter (2008) explores the adoption of international standards in the financial sector of East Asian economies after the 1997-1998 crisis, and shows how such initiatives are limited to mere formalism and not substantive compliance, in the absence of support from domestic actors (i.e. politicians, regulatory institutions, companies). While this study is not focused specifically on ISOs that are the focus of the present article, we can easily see that the outside pressure to comply with specific guidelines is only limited in the absence of domestic buy-in. Greenstein and Stango (2006) point out the strong link between international standards and national and international public policies.

As showed in previous publications (Volintiru, 2017; Volintiru, 2018) the main drivers for private agents to adopt ISO certification is the dual pressure from outside the company—regulatory provisions (i.e. it becomes mandatory to have ISO certification in order to access public funds or subsidies), and from inside the company—performance improvement through the implementation of the sector specific Standard's provisions and processes. A series of evaluations of the effects of ISO adoption on performance have indeed showed a positive effect (Sun, 2000; Singels *et al.*, 2001; Rahman, 2001; Terziovski and Power, 2007).

Drezner (2001, p.53) explains how an *“implicit assumption of most policy analysts and some academics is that globalization leads to a convergence of traditionally national policies governing environmental regulation, consumer health and safety, the regulation of labour, and the ability to tax capital”*. His study points to the fact that this is not always the case, and it is not always implicit that structural factors embedded in the global market can induce policy convergence (Drezner, 2001), but he admits that specific motivations do exist to support convergence of international regulations (which admittedly includes international standards).

In this article, I explore the international coverage of International Standards and for this I have to account for the complexity of inter-dependencies in the international market. In addition to the above-mentioned drivers for standards adoption in a given economy, the globalized economy provides an additional third incentive: trade.

In a landmark study on the economics of international standards, Blind (2004) makes a similar argument to mine, that one of the main driver of international standards' adoption is the firm as the main agent whose willingness to implement the process can make a significant difference in terms of large-scale adoption and implementation. He goes on to show that certification promotes trade (Blind *et al.*, 2018).

Compliance with international standards in order to penetrate targeted markets is known in the literature as the "California effect" (Vogel, 1997). According to Vogel (1997), trade can help with the adoption of importing countries' regulatory standards by exporting countries. His assessment is particularly focused on environmental standards, which are generally perceived as supplementary costs of compliance by economic agents.

Prakash and Potoski (2006, p.235) test the proposition of Vogel (1997) concerning the transnational diffusion of international standards through economic incentives derived from trade relations. Drawing on a panel of 108 countries over the course of seven years, they show that trade linkages can encourage the adoption of environmental international standards (i.e. ISO 14001), the condition being that a countries' major export markets had previously adopted this voluntary regulation.

Overall, there are several common elements in the existent propositions of the academic literature. Firstly, with regards to international standards, we must account for three drivers of compliance: firm performance targets, domestic regulatory provisions, and regulatory standards in partnering markets. The latter aspect leads me to the second element that the literature is engaging: to what extent globalization helps or hinders international standardisation and policy convergence? Essentially there are two approaches. On one hand, some argue that there is a race to the bottom, and economic agents will avoid markets with complex regulatory conditions. On the other hand, others argue that it is in fact a process of diffusion of national and international norms and regulations, as exporting countries adopt the regulatory provisions of their main trading partners. I support the second approach, as studies show a circular relationship between trade and international regulation to be mutually enforcing (see for the positive effects of trade on policy converges Vogel (1997), Prakash and Potoski (2006), and for the positive effects of international standards' adoption on trade (see Blind *et al.*, 2018).

### **3. Methodology**

In this article, I refer to International Standards as a means of investigating national approaches to economic integration. I compare the usage of national versus international standards in some of the world's largest economies. The case studies selected here are: United States of America (USA), European Union (EU), and China.

I use statistical data provided by the International Standardization Organization (ISO) that is collected through its encompassing Survey of Management System Standard Certifications across the globe, in between 1996-2016. This is the best data base available to us to assess the level of adoption in different countries, at different times. This descriptive statistical analysis reflects not only the "market" of international standards'

adoption (i.e. direct transactions between companies and certified providers), but also larger implications of economic recipes of development.

The hypothesis of this analysis is that the more international standards prevail over national standards, the more likely it is that the respective market is (or wants to be) highly integrated in the world economy. National standards, much like any technical barriers out there, can be an effective way to protect a market from foreign competitors that would have a harder time obtaining the needed certifications as opposed to domestic suppliers.

I also make use of extensive qualitative evidence on what the process of standards' adoption implies, the dynamics of the international market and its relationship with international standards, as well as national specificities on Standardisation Agencies and due process.

#### **4. International Standards' versus National Standards**

According to the International Standardization Organization (ISO), a standard is “*a document, established by a consensus of subject matter experts and approved by a recognized body that provides guidance on the design, use or performance of materials, products, processes, services, systems or persons*” (ISO, 2017).

International standards are often a reflection or collection of national standards. As countries have their own national authorities in charge of the development and implementation of standards, these institutions have gradually become members of the International Standardization Organization (ISO). According to ISO, the national authorities in charge of standardization generally have all of the following roles (ISO, 2017):

- to publish, and sometimes write, their own national standards;
- to represent their country in regional and international standard-setting fora;
- to hold a reference library of national, regional and international standards;
- to sell copies of standards.

Some national accreditation bodies also offer conformity assessment services such as accreditation, certification or other commercial activities (ISO, 2017).

Genschel (1997) has explained two decades ago how the distribution of standard setting to a multitude of competing standards organizations is both stable and efficient. Previous assessments (Bredillet, 2003) have identified some differences between the general principles upon certain sets of standards rests (see Table 1). As such, for the American National Standards Institute (ANSI), we can see as the founding principles: openness (i.e. any materially affected and interested party has the ability to participate), balance (i.e. consensus body shall be representative of the members and affected parties), due process (i.e. all objections shall have an attempt made toward their resolution, and right to appeal), and consensus (i.e. more than a majority but not necessarily unanimity).

**Table 1. Comparative Assessment of Main Principles of Standards’ Development**

American National Standards Institute (ANSI)		International Standards Organization (ISO)	
OPENNESS	Any materially affected and interested party has the ability to participate.	CONSENSUS	The views of all interests are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organizations.
BALANCE AND LACK OF DOMINANCE	Consensus body shall be representative of the members and affected parties.	INDUSTRY - WIDE	Global solutions to satisfy industries and customers worldwide.
DUE PROCESS	All objections shall have an attempt made toward their resolution. Interests who believe they have been treated unfairly shall have a right to appeal.	VOLUNTARY	International standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place.

Source: Holtzman (1999) in Bredillet (2003), adapted by the author.

Similarly, for ISO standards we can identify the following principles: consensus (i.e. the views of all interests are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organizations), industry – wide coverage (i.e. global solutions to satisfy industries and customers worldwide), and a voluntary nature (i.e. international standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place).

The American National Standards Institute (ANSI) is a private organization that oversees the implementation of consensus standards in the US. As a founding member of ISO, ANSI does not write standards. It gives accreditation to companies using as referential standards developed by other international standards organizations, government agencies and companies with representative experience in different fields of business.

**Table 2. Equivalent Versions of American and International Standards**

International (ISO)	American National Standard
ISO 9001: Quality management systems—Requirements	ASQ/ANSI/ISO 9001:2015: Quality management systems - Requirements
ISO 14001: Environmental management systems— Requirements with guidance for use	ASQ/ANSI/ISO 14001:2015: Environmental management systems - Requirements with guidance for use
ISO 19011: Guidelines for auditing management systems	ASQ/ANSI/ISO 19011:2011: Guidelines for auditing management systems
ISO 31000: Risk management principles and guidelines	ANSI/ASSE Z690.2-2011: Risk Management Principles and Guidelines (U.S. Adoption of ISO 31000:2009)
ISO 26000: Guidance on social responsibility	ASQ/ANSI/ISO 26000-2010(E): Guidance on social responsibility
Statistics standards: sampling by attributes	ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes

Source: asq.org

Certain ISO standards have American versions (same or adapted content). The United States' standardization system recognizes and respects the fact that there are many International standard bodies in charge of developing standards and that no single method of standards development can satisfy the needs of all sectors: "The complexity of the U.S. standardization and conformity assessments system is balanced with its flexibility. It is an outstanding example of how a strong, dynamic partnership between government and the private sector can help the nation achieve its economic and societal goals" (ANSI, 2017).

The Standardization Administration of China (SAC) is the national accrediting body that is in charge of management, supervision and overall coordination of national standardization work in China. Founded in April 2001 by the State Council of China, the SAC is responsible of representing China within the International Organization for Standardization (ISO). The China National Certification and Accreditation Administration (CNCA) is responsible of managing and implementing compulsory certification and testing nationwide, including the China Compulsory Certification (CCC) system. Both SAC and CNCA are under the supervision and administration of the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ).

Standards in China are divided into four major categories: national standards, regional standards, industry standards and enterprise standards for national companies. National standards can be either mandatory (technical regulations for products and services) or voluntary. In any case, they supersede international standards.

China recently suspended labelling requirements that would otherwise affect the €80 million-worth EU cosmetics exports. In order to comply with the national Chinese standards, many imported products have to get the China Compulsory Certification (CCC) mark before being commercialized on the Chinese market. Beyond this certification, there are other labelling requirements that companies have to fulfil, such as having specific information on the outside packaging of the products in Chinese. When European companies are faced with the need to put local languages on their packaging, they usually prefer to simply place an additional sticker ("over-stickering") before exporting, instead of creating an entirely new packaging for the targeted market. When China introduced special requirements for new packaging in 2016, this posed a significant challenge to some EU exporting companies of small sizes. European exporters reported a 10% increase in the number of trade barriers they encountered in 2016, and the 36 obstacles created in that year alone are estimated to have had a negative impact of €27 billion on EU exports.

According to the 2017 DIN Report on China's Standardization Reform, there is need of reforming the standardization environment in order to align it to the International Standardization Bodies. These changes include use of international ISO/IEC standards instead of own national standards, A coherent collection of mandatory standards, involvement of all relevant stakeholders in the standardization process, transparent guidelines for non-Chinese companies and copyrights of ISO, IEC and European standards.

While strong economic reasons exist for setting compatible international standards, the standard-setting process in the European Union is often used more as a competitive tool than as a means of expanding networks and markets internationally (Austin and Milner, 2001; Mattli, 2001).

Sometimes, as in the case of the European Union, in certain countries we find not only international or national standards, but also some form of regional regulations to which

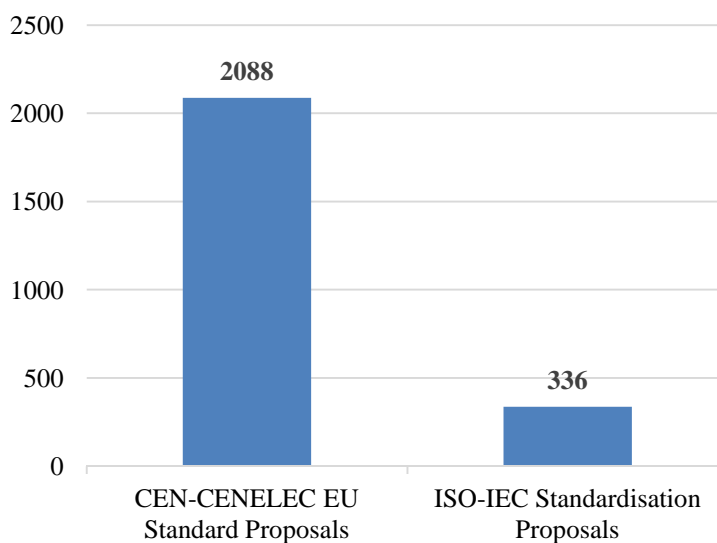
companies must adhere. These are also developed and implemented via a specialised institutional body or authority. In the case of the European Union, we have the European Committee for Standardization (CEN). In such a case, the national accreditation bodies have to be simultaneously members of the regional organization (i.e. European Committee for Standardization - CEN), and the international organization (i.e. International Standardization Organization - ISO). Other regional organizations that play an important role are the Pan American Standards Commission (COPANT) in Latin America which comprises a total of 32 national authorities (i.e. National Accreditation Bodies) in the region, and the Pacific Area Standards Congress (PASC) comprising 24 national authorities, including the United States of America (USA) and China.

The European Committee for Standardization (CEN), alongside the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI), are recognized by the European Union as European Standardization Organizations. The legal framework for this cooperation is set out in EU Regulation 1025/2012, which entered into force on 1 January 2013. This is what is essentially referred to as the European Standardization System (ESS). The European Committee for Standardization (CEN) is also committed to supporting the international standardization system, and cooperates closely with the International Organization for Standardization (ISO) through the Vienna Agreement (1991).

Standardization is a cornerstone of the European Innovation Policy, in terms of technology. It is seen by Borrás (2003) as one of the main policy instruments at EU level towards the development of an innovation-friendly regulatory framework (Table 3).

As shown by Figure 1, in 2017 a total of 2088 EU Standard Proposals were put forward by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). By comparison, the International Standardization Organization (ISO) put forward only 336 Standardization Proposals in the same year.

**Figure 1. Relevant International Standardization Activity in the European Union (2017)**



Source: European Committee for Standardization (CEN)

**Table 3. Action plan of the European Standardization System (ESS) for 2018**

#	CE Policy Priorities	Foreseeable Actions in the European Standardization System (ESS)
1	<b>Digital Single Market Strategy</b>	<ul style="list-style-type: none"> <li>improve the quality of fixed and wireless/mobile services including in industrial networks;</li> <li>establishing standards facilitating the development of 5G technological advances in the 26 GHz band (24.25 – 27.50 GHz) and higher mm-wave bands;</li> <li>improve railway radio communication systems, the exchange of data for passengers and schedules, and IT security;</li> <li>increase interoperability and easy data-sharing between operators across value chains, notably on product lifecycle management and logistics</li> </ul>
2	<b>Energy Union Strategy</b>	<ul style="list-style-type: none"> <li>establish new sensors and measurement methods to assess ambient air quality;</li> <li>monitor ammonia (HN3), chlorine and chlorine dioxide emissions to the air and emissions of hydrogen fluoride or total gaseous fluorides from industrial sectors;</li> <li>reduce the energy consumption of computers, displays, servers and data-storage devices, commercial refrigeration, electric motors, fans, lighting products, household cold appliances, standard air compressors, machine tools and external power supplies;</li> <li>improving the energy performance of buildings' heating and cooling systems by providing adequate information to the end-consumers on the energy efficiency of and the renewable use in district heating and cooling systems;</li> <li>support an increase of the proportion of ethanol in petrol from 10 % to 20/25 %, thus providing vehicle manufacturers with opportunities to optimise the combustion process, allowing lower fuel consumption and further reducing emissions of CO<sub>2</sub> and other pollutants;</li> <li>facilitate global action to reduce greenhouse gas emissions and fuel consumption; foster cooperation with non-EU regions and countries; and</li> <li>increase the deployment of green infrastructure, particularly in relation to physical building blocks and procedures.</li> </ul>
3	<b>Internal Market Strategy (with a Strengthened Industrial Base)</b>	<ul style="list-style-type: none"> <li>strengthening the role of CESNI, European Committee for Inland Navigation Standards, for the development of technical standards for inland navigation vessels;</li> <li>match European global navigation satellite system products with end-user applications;</li> <li>increase the interoperability of Galileo services with the aviation market;</li> <li>standardize public procurement bidding systems, platforms, forms and data;</li> <li>harmonize safety standards for 3D printers, robots, autonomous vehicles, wind turbines, automated machines and food machines;</li> <li>strengthen safety and performance requirements for medical devices and for in vitro diagnostic medical devices;</li> <li>update hygiene and safety requirements and test methods for construction products in contact with water;</li> <li>support work on the essential requirements for unmanned aircraft;</li> <li>update safety standards on civil explosives in line with technology developments;</li> <li>establish new technical specifications for interoperability relating to rail system infrastructure and rolling-stock subsystems;</li> <li>protect humans from cancer and other health effects of polycyclic aromatic hydrocarbons, by determining their migration from plastic and rubber;</li> <li>establish minimum requirements for improving the health and safety protection of workers potentially at risk from an explosive atmosphere; and</li> <li>improve consumer safety.</li> </ul>
4	<b>Justice and Fundamental Rights</b>	<ul style="list-style-type: none"> <li>establish requirements for detection equipment, in areas other than aviation, to protect citizens from terrorist attacks.</li> </ul>
5	<b>EU as a Global Actor</b>	<ul style="list-style-type: none"> <li>support Member States' efforts to develop joint defence capabilities while fostering a competitive and innovative industrial base.</li> </ul>

Source: European Commission (2017a)



The European Commission uses the process of standardization to support the implementation of its main priorities across the Member States. From innovation to smart specialization, there are different fields in which the European Union is developing its own standardization proposals and processes in addition to those of the International Standardization Organization (ISO).

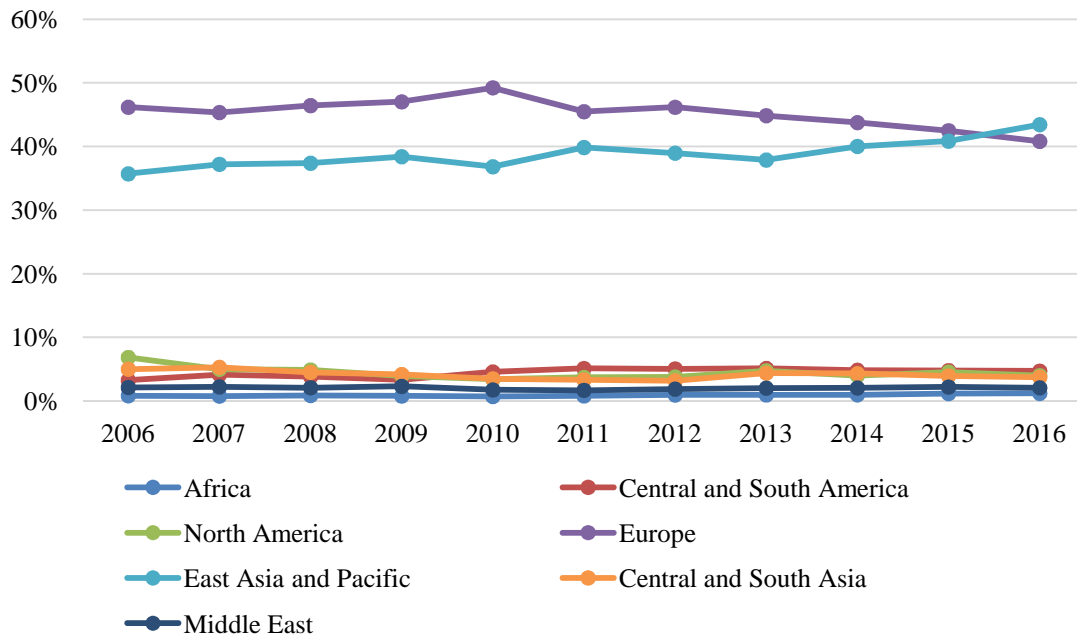
As previously mentioned, the EU Regulation no. 1025/2012 is the reference legislative document with regards to the European Standardization System, and according to it the primary objective of standardization is „*the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply*” (OJEU, 2012). The same document goes on to specify that „*European standards play a very important role within the internal market, for instance through the use of harmonized standards in the presumption of conformity of products to be made available on the market with the essential requirements relating to those products laid down in the relevant Union harmonization legislation*” (OJEU, 2012).

According to the European Commission, a harmonized standard is “*a European standard developed by a recognized European Standards Organization (i.e. CEN, CENELEC, or ETSI), and it is created following a request from the European Commission to one of these organizations; manufacturers, other economic operators, or conformity assessment bodies can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation*” (European Commission, 2017b).

## **5. Comparative Assessments of International Standards’ Adoption across the World**

The degree to which international standards have been adopted throughout the world varies from region to region, and from country to country. Looking at the number of international standards adopted in each of the world regions between 2006 and 2016, Europe and East Asia regions lead the ranking. For the most part of this decade, Europe has been the region with the largest share of ISO certifications in the world. In 2010, in Europe alone, one could find a half of the global number of ISO certifications (see Figure 2). It is only recently that Europe has been surpassed by the East Asia and Pacific region, with a total share of 43.4% of global ISO certifications in 2016. In the same year, Europe amounted to 40.8%.

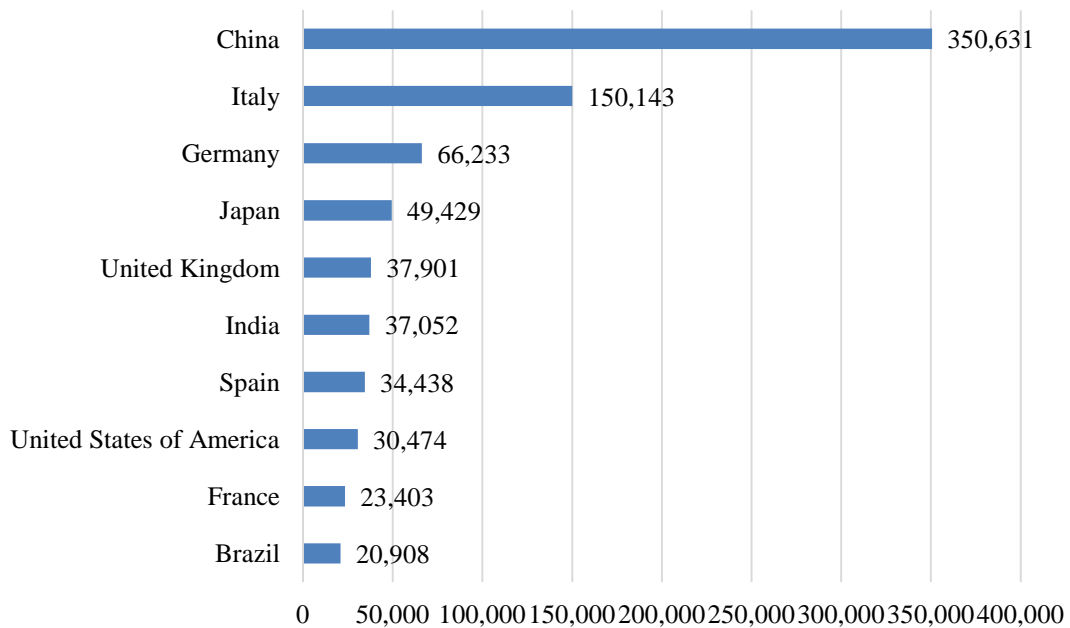
**Figure 2. Regional Shares of ISO Certification (%) (2006-2016)**



Source: data collected through the ISO Survey of Management System Standard Certifications (1993-2016), adapted by the author

The spectacular almost ten percentage points growth of the East Asia and Pacific region between 2006 and 2016 was mainly driven by the large number of ISO certifications implemented in China annually. In 2016, the number of ISO certifications implemented in China was so large that its level was comparable to that of the following top markets in the world taken together (see Figure 3).

**Figure 3. Countries with Largest International Standards Adoption in the World (2016)**

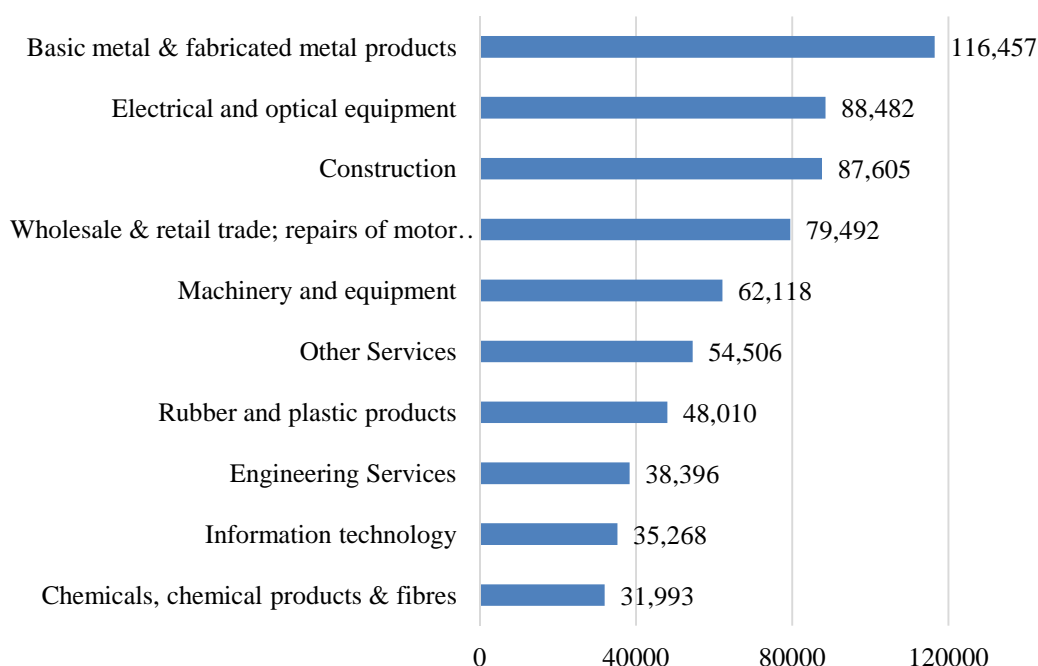


Source: data collected through the ISO Survey of Management System Standard Certifications (1993-2016), adapted by the author

China is by far the largest market in the world in terms of International Standards’ adoption. In 2016, we can see that it is only in this country that over 350,000 ISOs have been adopted, in comparison to the second largest market Italy that stands at only less than half of this figure, with a little over 150,000 ISOs being adopted here. Further down the top-ranking markets for International Standards adoption, Germany had approximately 66,000 ISOs adopted, and Japan approximately 49,000 ISOs. United Kingdom, India, Spain and USA all had in between 30,000 and 40,000 ISOs adopted in 2016, while France had approximately 23,000 ISOs, and Brazil only 20,000 ISOs.

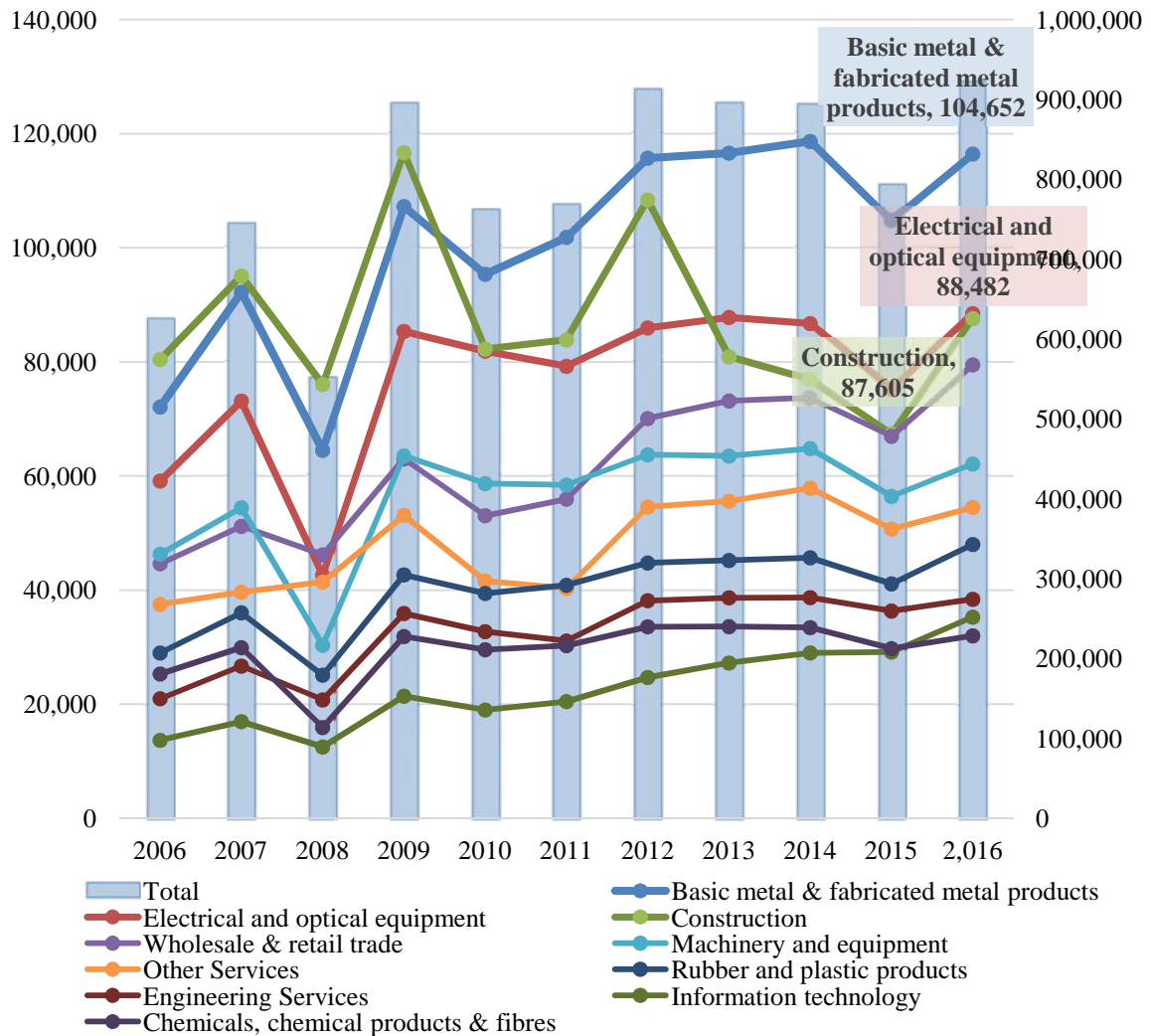
I also compare the level of International Standards adoption across economic sectors (see Figure 4). The main industrial sectors with ISO certification in 2016 were: metal and metal products—over 100,000 ISO certifications implemented worldwide, electrical and optical equipment, and the construction sector—over 80,000 ISO certifications implemented worldwide. While these three sectors have been dominant in international certification for the entire 2006-2016 decade, we can see below that there is significant fluctuation. They all had a significant increase from 2008 to 2009 (see Figure 5), and at that point the construction sector was the largest economic sector that used ISO certifications in the world. It has subsequently decreased in absolute size, leaving the metal and metal products to dominate this ranking. Other important sectors for ISO are: retail, machinery and equipment, engineering services, or IT.

**Figure 4. Industrial Sectors with Largest International Standards Adoption in the World (2016)**



Source: data collected through the ISO Survey of Management System Standard Certifications (1993-2016), adapted by the author

**Figure 5. Evolution of International Standards Adoption in Industrial Sectors (2006-2016)**



Source: data collected through the ISO Survey of Management System Standard Certifications (1993-2016), adapted by the author

## 6. International Standards for Medical Laboratories

I turn to the case study of international standards in the field of medical laboratories as an illustrative case study of harmonization across countries through the involvement of a dedicated international organization: World Health Organization (WHO). While international standards are in general under the oversight of the dedicated IO—International Organization for Standardization (ISO), the case of the medical laboratory standards shows that ISOs can be significantly furthered in terms of adoption and implementation by a dedicated sectorial IO. WHO provides unitary guidelines for the multitude of relevant international standards in the field of medical laboratories (see below). Some countries implement these standards through national agencies, others

through other bodies. This multitude of national regulators is possible due to the unitary umbrella of the coupled efforts of ISO and WHO in this field.

In the medical field, accreditation has been traditionally done domestically by each country. This is obviously connected to the large state ownership in this field. USA has for example multiple Agencies in charge of hospital accreditation. Medical laboratories however are a distinctive breed. Given that there is a growing tendency to have private service providers in this field, international standards were quicker adopted than national ones.

There are several International Standards concerned with medical laboratories that illustrate perfectly the extent to which national and international regulations have to be aligned. Firstly, ISO 17025 (General requirements for the competence of testing and calibration laboratories) was the first international standard (published in 1978) that proposed a laboratory quality management system. It is composed of general requirements for the competence, impartiality and consistent operation of laboratories. With its latest 2017 version, ISO 17025 is applicable to all organizations performing testing and calibration laboratory activities, regardless the field of research or number of employees.

**Table 4. International Standards for Medical Laboratories**

No.	Code	Name
1	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
2	ISO 15189	Medical laboratories – particular requirements for quality and competence
3	ISO/IEC 17043	Conformity assessment – general requirements for proficiency testing
4	ISO 13528	Statistical methods for use in proficiency testing by interlaboratory comparison
5	OECD GLP	OECD principles on good laboratory practice
6	ISO Guide 34	General requirement for the competence of reference material producers
7	ISO 8402	Quality management and quality assurance – vocabulary
8	ISO 19011	Guidelines for quality and/or environmental management system auditing
9	ISO 9001	Quality management systems – requirements

Source: WHO (2011)

Since 1988 a national regulation created expressly for medical laboratories and known as the Clinical Laboratory Improvement Amendments (CLIA) was enacted in the USA. CLIA is a national regulation but also a basis for accrediting laboratories worldwide. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing performed on humans in the USA through the Clinical Laboratory Improvement Amendments (CLIA). This covers approximately 260,000 laboratory entities according to Datema *et al.* (2012).

Secondly, ISO 15189 (Medical Laboratories – Particular requirements for quality and competence) with its 2012 version is the most widely used clinical laboratory standard. It was published for the first time in 2003 and it is now at its third revision, ISO 15189:2012 can be used by medical laboratories in developing their quality management systems and assessing their own competence according to ISO. It can also be used for recognizing the competence of medical laboratories by authorities and accreditation bodies.

According to the World Health Organization Report (2011) on the implementation of international standards in laboratories, there are several important steps to be taken at national level according to an agreed implementation plan drawn up by the national laboratory focal point, in consultation with the National Laboratory Coordinating Committee (Table 5). WHO accounts for the facts that „some countries may wish to develop national laboratory quality standards appropriate for each level of the health-care system, based on the regional standards” (2011, p.27).

**Table 5. Steps to be Taken in Implementing Laboratory Quality Standards at National Level**

Step No.	DESCRIPTION
1	Obtain national consensus for agreed standards by peer review.
2	Obtain approval for agreed standards by the appropriate national authorities.
3	Draw up an implementation plan with short-term, medium-term and long-term objectives, activities and timelines, and indicative annual budgets.
4	Identify appropriate implementing agencies (the government, nongovernmental agencies, and other partners including the private sector), and sensitize them to the plan and their possible contributions.
5	Sensitize participating institutions and health facilities.
6	Use or amend existing guidelines, checklists, SOPs, record forms and recording formats, appraisal forms, audit checklists, etc.; or develop country-specific documents.
7	Establish national procedures for laboratory networking and referral of samples.
8	Draw up detailed annual operational plans with budgets.

Source: WHO (2011)

## 7. Conclusion and Recommendations

In this article, I present the global dynamics of the international standardization process, and I analyse the variations. I look at these variations both from a qualitative perspective, and a quantitative perspective. In doing so, I show the extent to which international standards can be regarded as an indicator of internationalization of a given market, and the extent to which national, regional, and international standards can contribute to growth and development.

In the first empirical section, I present the qualitative traits that can be attributed to standardization in the main markets in the world today: United States of America, China, and the European Union. There is significant overlap between the guiding principles of both national and international standards, as proven by the comparison between American National Standards Institute (ANSI) and the International Standardization Organization (ISO). There is also a reflection of economic ambitions in the design and activity of regional (in the case of the European Union), or national (in the case of China), standardization institutions.

In second part of this article I show the extent to which the phenomenon of international standardization has increased over the course of the last decade across countries, and across economic sectors. While the dynamics of international standard adoption show reactivity to broader economic circumstances, such as the economic crisis of 2008, we see that the more integrated in the world economy certain markets try to be, the more international standards are being adopted. An example of exponential growth and the country with the largest number of international standards being adopted is currently China, and the East Asia and Pacific region.

Finally, the last part of this article takes the case study of medical laboratory international standards to show the process through which national and international standards are

being aligned. I therefore show in the present article not only the dynamics of international standards adoption in the world today, but also how important the institutional alignment between national and international authorities is. As such, we can see the process of standardization as a reflection or indicator of the larger process of economic integration at the world level.

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