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"The International Technical Standards in the Light of the WTO TBT Agreements and their Legal Effects in the United States and the European Union"

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A mio Padre,
la cui grinta e il cui coraggio,
a cinque anni dalla scomparsa,
non hanno smesso di illuminare
la nave della nostra famiglia.

A mia Madre,
per aver governato quella nave
come nessun comandante
avrebbe saputo fare.

« Patet omnibus veritas;
nondum est occupata;
multum ex illa etiam
futuris relictum est. »

LUCIUS ANNAEUS SENECA
Epistulae morales ad Lucilium
Lib IV, 33

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INTRODUCTION

Standardization, and the disparate number of effects it produces on our lives on a daily basis, is, perhaps, one of the legal phenomena which have, until recent times, most frequently been underestimated by the literature.[1]

The reach of standardization, particularly in a globalized world and in constantly more integrated economies, involves almost any and every product and service, from electronics to the management of chemical waste. This requires standards to be respected by producers and suppliers worldwide, in order that they achieve the best possible outcome available when their output is placed on the market.[2]

The need for standards in general is much debated by legal scholars,[3] particularly in the context of contemporary administrative law.[4] With the progressive decentralization of power,[5] the relationship between legal standards and pure rules acquires a considerable

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* The system of citations adopted for this thesis is the American Bluebook 19th Edition for Law Review, with minor differences.

[1] *See* ALBERTO PREDIERI, *Norme tecniche come fattore di erosione e di trasferimento di sovranità*, *in* STUDI IN ONORE DI FELICIANO BENVENUTI 1436 (Mucchi, 1996) (pointing out the disinterest of scholars towards the genesis and the effects of standardization).

[2] For some concrete examples of this influence, *see World Trade Report 2005 Exploring the links between trade, standards and the WTO*, WORLD TRADE ORGANIZATION, 35-42 (2005) *available at* http://www.wto.org/english/news_e/pres05_e/pr411_e.htm (stressing the impact of compatibility standards in the IT sector). For an analysis of the beneficial effects of standardization, *see, e.g.*, *Benefits of International Standards*, ISO, http://www.iso.org/iso/home/standards/benefitsofstandards.htm (last visited June 10, 2014).

[3] Technical standards are only a very limited part of the standardization phenomenon. *See generally* Sabino Cassese, *Global Standards for National Democracies?*, Rivista di diritto pubblico trimestrale 701, 701-720 (2011).

[4] *See* GIACINTO DELLA CANANEA & ALDO SANDULLI, GLOBAL STANDARDS FOR PUBLIC AUTHORITIES, IX-XII (Editoriale Scientifica 2013).

[5] *See* Jean-Bernard Auby *Is legal globalization regulated? Memling and the business of baking camels*, 4 Utrecht L. Rev., Dec. Issue 3 210, 211 (2008) ("Law-making processes are in a process of growing dispersion,

importance for the understanding of global governance and its tight liaison with constitutional democracies.[6]

Our legal analysis will focus on a specific kind of technical standards known as international standards, those which, as with the Agreement on the Technical Barriers to Trade [hereinafter "TBT"], are produced by bodies or systems that can be deemed to be international because of their openness to the "relevant bodies of at least all Members of the World Trade Organization" [hereinafter the "WTO"].[7]

In the first chapter, after setting the context of our analysis, we will deal with the definition of international standards recognized in the World Trade Arena, and the way in which it has been modified by the recent case law of the Appellate Body, the highest judicial organ of the WTO.

In the second chapter, we will formulate our hypothesis with regard to the international standards developers which satisfy the parameters dictated by the jurisprudence of the Appellate Body. This will focus primarily on the ISO/IEC system, the model of standardization followed globally and allegedly favored by the WTO; the American ANSI system; and some other prototypes that have been growing in importance during recent decades.

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while one can perceive that the distribution of roles between national authorities and international bodies, between public organs and private actors tend to blur increasingly").

[6] *See* Cassese, *supra* note 3, at 722-723 (pointing out that, although no global democracy exists, global administrations adopt a rather wide set of legal tools in order to promote democratic performance to local administrations).

[7] *See generally* Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1.2., 1869 U.N.T.S. 401 [hereinafter TBT].

In the third chapter, we will analyze the manner in which international standards have been received by the American and European public administrations, how they penetrate their respective administrative laws, and why some international standards may be said to qualify under one system but not the other.

Before tackling our discussion, however, it is worth making some preliminary considerations that will prove beneficial to our survey.

First, technical standards are normative instruments which defy a clear-cut definition, finding their place both in the realm of the law and the realm of science.[8] While our analysis will mostly deal with the concrete effects international standards have on the administrative laws of the American and European jurisdictions examined here, we should also be cognizant of the existing debate as to the concrete limits of the law. This is extremely relevant in our epoch of diverse forms of technocracy.[9]

[8] For a complete analysis of the dialectic existing between administrative law and other sciences, *see generally* MARCELLO CLARICH, MANUALE DI DIRITTO AMMINISTRATIVO, 16-36 (Il Mulino, 2013).

[9] *See, e.g.,* HARM SCHEPEL, THE CONSTITUTION OF PRIVATE GOVERNANCE: PRODUCT STANDARDS IN THE REGULATION OF INTEGRATING MARKETS 26 (Oxford and Portland Hart, 2005) (making reference to those theories that envisage the possibility of institutionalizing the dialogic framework involving science and politics); Thorsten Hüller & Matthias Leonhard Maier, *Fixing the Code? Global Food-Safety Governance Under Review*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 267, 281-285 (Oxford and Portland Hart, 2005); *See also* Antonio Iannuzzi, *Caratterizzazioni della normazione tecnica nell'ordinamento italiano. Il campo di analisi e di verifica della materia ambientale*, Studi parlamentari e di politica costituzionale 137, 138 - 139 (2006) (affirming that the continuous technological development is seriously limiting the actual space left to political determination); Martin Shapiro, *"Deliberative", "Independent" Technocracy v. Democratic Politics: will the Globe echo the E.U.?,* 68 Law & Contemp. Prob. 341, 343 – 344 (2005) (underlining how especially in the high-tech field politics is often forced to leave important politically-sensitive decisions to technique). For a complete analysis of this problem in relation to the SPS Agreement, *see* Elizabeth Fisher, *Beyond the Science/Democracy Dichotomy: The World Trade Organisation Sanitary and Phytosanitary Agreement and Administrative Constitutionalism*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 327, 327-332 (Oxford and Portland Hart, 2005).

Second, international standards and the way they are regulated are a direct manifestation of the so called "Global Administrative Law",[10] a set of norms, rules and standards which, born at the international level often without a precise hierarchy, can, and often do, profoundly influence the principles and dynamics of national administrations,[11] progressively eroding the regulatory autonomy of States.[12]

Third and conclusively, international standards bear a profound effect on international trade.[13] It is for this reason that the manner in which they are regulated on a global scale is often a point of contention among the most developed countries, those which contend to promote their respective models to achieve a comparative advantage in the dynamics of production and export.[14]

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[10] *See generally* Benedict Kingsbury, *The concept of "Law" in Global Administrative Law*, IILJ Working Paper 2009/1, 3, INSTITUTE FOR INTERNATIONAL LAW AND JUSTICE.ORG (Feb. 27, 2009), http://www.iilj.org/publications/2009-1Kingsbury.asp ("Global administrative law is emerging as the evolving regulatory structures are each confronted with demands for transparency, consultation, participation, reasoned decisions and review mechanisms to promote accountability."). *See also* Bernardo Giorgio Mattarella, *Umberto Borsi e il diritto amministrativo internazionale*, Rivista italiana di diritto pubblico comunitario 933, 937-939 (2005) (underlining the problems related to the denomination of "global administrative law" as opposed to other formulas such as "international administrative law").

[11] *See generally* Richard B. Stewart & Michelle Ratton Sanchez Badin, *The World Trade Organization and Global Administrative Law*, IILJ Working Paper 2009/7, 2-3, INSTITUTE FOR INTERNATIONAL LAW AND JUSTICE.ORG (Oct. 14, 2009) http://www.iilj.org/publications/2009-7Stewart-RattonSanchez.asp; Sabino Cassese, *Gamberetti, tartarughe e procedure. Standards globali per i diritti amministrativi nazionali*, Rivista di diritto pubblico trimestrale 657, 657-661 (2004) [hereinafter Cassese, *Gamberetti, tartarughe e procedure*]; Sabino Cassese, *Il diritto amministrativo globale: una introduzione*, Rivista di diritto pubblico trimestrale 331, 338 (2005) [hereinafter Cassese, *Il diritto amministrativo globale*] (pointing out the tendency of global administrative law, differently from traditional administrative law, to rise "from the neighborough").

[12] *See* Patrizia Nanz, *Democratic Legitimacy and Constitutionalisation of Transnational Trade Governance: A View from Political Theory*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 59, 65-67 (Oxford and Portland Hart, 2005) (stressing the ability of the WTO to intrude in the way social, environmental and tax policies among the others are regulated all over the world).

[13] For an economic and quantitative analysis of this relationship, *see generally* World Trade Report 2005, *supra* note 2.

[14] *See generally* ANDREW T. GUZMAN & JOOST H.B. PAUWELYN, INTERNATIONAL TRADE LAW 2ND EDITION, chapter 19 new edition (Wolters Kluver Law and Business, 2nd ed. 2012) (forthcoming).

This last concern will be taken into account at the present time, as the agenda of the Transatlantic Agreements proceeds towards the constitution of a free trade zone and a commercial partnership involving the United States and the European Union.[15]

[15] For an introduction to the argument, *see* Giulio Napolitano, *L'ora del diritto transatlantico: un'adeguata normativa per consolidare la partnership economica*, Il Sole 24 Ore, (Feb. 4, 2013). *See generally Reducing Transatlantic Barriers to Trade and Investment - An Economic Assessment In-depth study on the potential effects of the EU-US Transatlantic Trade and Investment Partnership*, (Mar., 2013), *available at* http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf (pointing out the necessity of building common standards between the EU and the U.S. in order to reduce barriers to trade). For further evidence on the argument it is possible to consult the Transatlantic Trade & Investment Partnership Agenda, *available at* http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152523.pdf (last visited May 28, 2014). Hitherto it is still uncertain what level of integration the two parties will reach. For a concise description of the possibilities at stake, *see generally* Sabino Cassese, *L'Unione Europea come Organizzazione Pubblica Composita*, Rivista Italiana di diritto pubblico comunitario 987, 987 (2001).

CHAPTER I:

DEFINING THE INTERNATIONAL TECHNICAL STANDARDS IN THE WTO ARENA: THE POSSIBLE IMPACT OF THE TUNA DOLPHIN II DECISION

I.1: INTERNATIONAL STANDARDS AS AN EXPRESSION OF THE INTERNATIONAL PRIVATE GOVERNANCE

In recent times, the preference commercial actors all over the world have expressed towards the use of technical standards has rarely been questioned. [16] The industrial manufacturing process as well as, in the last few decades, the supply of highly complex services in disparate fields[17] has started to demand an increasing amount of rules, codes, norms which have the major task of ensuring the safety, reliability and good quality of the products or services destined to be put on the market.[18] These rules are commonly called "standards".[19]

Standards have been defined in numerous ways. In the context of the World Trade Organization, a standard is a "document that provides rules, guidelines or characteristics for products or related processes and production methods and may also include or deal exclusively with terminology, symbols, packaging, marketing or labeling requirements as they apply to a product, process or production method".[20]

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[16] *See* PREDIERI, *supra* note 1, (pointing out the tendency of market economies to be colossal producers and consumers of technical norms).

[17] It should be reminded that this work focuses mostly on the standards taken into account by the TBT Agreement; hence, the international standards related to services will not be analyzed because they are not part of the so called "GATT aquis", but are covered in the "General Agreement on Trade in Services" [hereinafter GATS].

[18] For an analysis of the beneficial effects of standardization, *see* ISO, *supra* note 2; ASME, https://www.asme.org/shop/standards?cm_re=About%20ASME-_-GlobalHeader-_-Standards (last visited June 10, 2014). *See* SCHEPEL, *supra* note 9, at 5 (casting doubts on the concept of the "Invisible hand" that, according to some economists, should govern the market). *See also generally* NATALINO IRTI, L'ORDINE GIURIDICO DEL MERCATO (GLF editori Laterza, 2009).

[19] Some standards are however defined "codes". *See Boiler and Pressure Vessel Code 2013 Edition*, ASME, https://www.asme.org/shop/standards/new-releases/boiler-pressure-vessel-code-2013 (last visited June 15, 2014).

[20] Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1.2., 1869 U.N.T.S. 401 [hereinafter TBT].

If the use of technical standards in so relevant proportions is a phenomenon relatively new to the legal community, the reasons of the reliance on international standards date back to the Industrial Revolution and the first attempts to start mass production dynamics by the manufacturers. In that context, it soon became clear that in order to grant the interchangeability of the production inputs – one of the pillars of the functioning of whichever industry[21] – certain common rules had to be established and followed.[22]

To be relied upon, standards should be clearly stated and, necessarily, agreed upon by the industrial community, otherwise their efficacy would be somehow reduced if not completely destroyed. Since that time, this dialectic process – whose name is "standardization" – has developed its own codes and rules and, in addition to involving engineers, chemists, scientists and experts of many sorts, has called upon the very "players of the market" who are asked to make use of the standards they contributed to forge.[23]

Standardization as a legal phenomenon is progressively being understood as part of that trend of societies to shape their own normative context, alone or only slightly in conjunction with public powers.[24] Several authors commonly refer to this tendency as "Governing without Government",[25] expression which quite successfully condenses the tangible crisis of the government observed through the lenses of traditional legal categories –

[21] The automotive and the information technology (IT) industries represent a telling example.

[22] For a broader description of the historical roots of standardization, *see, e.g., La storia dell'UNI*, UNI, http://www.uni.com/index.php?option=com_content&view=article&id=1617&Itemid=1486 (last visited June 15, 2014) (tracing the history of standards back to the Ancient Egypt and Roman Empire).

[23] *See generally* Lawrence D. Eicher et Al., *Friendship among Equals, recollections from Iso's first fifty years* (ISO Central Secretariat, 1997), *available at* http://www.iso.org/iso/2012_friendship_among_equals.pdf .

[24] *See* Anna Moscarini, *Le fonti dei privati*, Giurisprudenza Costituzionale 1895, 1895-1896 (2010), (stressing how the identity between the State, the legal system and the monopoly of the sources of law envisaged by Hans Kelsen does not represent anymore a reliable model in order to understand the actual normative structure of globalized societies).

[25] *See, e.g.*, SCHEPEL, *supra* note 9, at 21.

accelerated by the ongoing process of globalization[26] – with the innate need of societies, at different levels, to be governed and to govern themselves.[27]

It has been wondered if the progressive decline in the rule making process experienced by "governments" – concept interpreted nowadays in a broader flavor than "State": entity endowed with legislative, administrative and judicial powers, competent to pose binding rules [28] – has been balanced by any like entity, capable of performing comparable tasks.

A deeper analysis of the legal fabric of the actual globalized legal arena discourages straightforward answers[29] but, nonetheless, warns that if "governments" still retain a relevant pole of the rule making process, "economic discourse" is often favored over law, [30] privileging normative procedures which incorporate and go beyond the traditional dynamics of public representation and constitutional democracy.[31]

Far from being regarded as a real surrender of the public to the private, of the "politics to the markets", this tendency may be appreciated as a "transformation" process,

[26] For an introduction to the problem, *see* Vincenzo Cerulli Irelli, *Verso la contrazione dell'area del pubblico*, in DALLO STATO MONOCLASSE ALLA GLOBALIZZAZIONE 25 , 25 (Giuffrè, 2000).

[27] *See, e.g.,* SCHEPEL, *supra* note 9, at 22 (quoting Alfred C. Aman, *The Limits of Globalization and the Future of Administrative Law: From Government to Governance*, 8 Ind J Glob L S 379, 391 (2001)). *See generally* Cassese, *Gamberetti, tartarughe e procedure*, *supra* note 11, at 657-660 (further examining the process of disintegration of the National State as an element of globalization).

[28] The judicial branch should be looked at carefully especially in common law jurisdictions, where courts have a well-known role as rule makers.

[29] *See* ALFRED C. AMAN, JR, THE DEMOCRACY DEFICIT: TAMING GLOBALIZATION THROUGH LAW REFORM, 132-134 (New York University Press, 2004).

[30] *Id.* For a complete analysis on the argument, *see generally* SABINO CASSESE, OLTRE LO STATO, 185-189 (Bari GLF editori Laterza, 2007).

[31] The lack of democracy sometimes attributed to the automatic use of technical standards in the drafting of technical regulations will be addressed thorough this paper and, more deeply, in the conclusion. For an introduction to the tendency of administrative law and administrative governance to develop hybrid public – private methodologies, *see generally* Sabino Cassese, *Tendenze e problemi del diritto amministrativo*, Rivista di diritto pubblico trimestrale 901, 904-912 (2004).

where the framework of the economic society itself spontaneously triggers the constructions of a new constitutional balance.[32]

This new balance, which sees the public and the private sectors becoming part of a joint dialogue more than the elements of a struggling competition,[33] is characterized by a reciprocal "borrowing of mechanisms and strategies" between the two systems.[34]

On one hand the public sector becomes progressively more akin to the private one through a constant process of "deregulation" and "privatization", making a wider use of contractual models and consensual procedures than it ever did in the past; on the other hand, the private sector, while keeping its peculiar dialectic framework, accepts to assume more constitutionally compatible forms and be constantly more involved in the rule making process, also through the performance of several administrative tasks.[35]

Hence, the traditional activity of government is abandoned in favor of a more fluid and flexible activity commonly defined as "governance",[36] where administrative decisions

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[32] *See* SCHEPEL, *supra* note 9, at 19-20. *See also* Damian Chalmers, *Administrative Globalisation and Curbing the Excesses of the State*, In CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 351, 355 (Oxford and Portland Hart, 2005) (underlining that markets nowadays develop their own institutions of rule, which act as surrogates for legal and political institutions).

[33] *See* SCHEPEL, *supra* note 9, at 19-20.

[34] *See generally* Sabino Cassese, *L'arena pubblica nuovi paradigmi per lo Stato*, Rivista di diritto pubblico trimestrale 601, 601-650 (2001) [hereinafter Cassese, *L'arena pubblica*]. *See also* Cassese, *Gamberetti, tartarughe e procedure*, *supra* note 11, at 664-667. *See also* Auby, *supra* note 5, at 211-212 (stressing the lack of legal hierarchies in the globalized era).

[35] *See* PREDIERI, *supra* note 1 (examining the crucial role of private bodies, endowed with "public munera", in the setting of technical norms); SCHEPEL, *supra* note 9, at 21 (quoting Paul Hirst, *Democracy and Governance, Debating Governance* 13, 28 (OUP, Oxford, 2000)). *But see* Sabino Cassese, *Le trasformazioni del diritto amministrativo dal XIX al XXI secolo*, Rivista di diritto pubblico trimestrale 27, 27-40 (2002) (warning that the privatization of administrative law takes place through the forms but not the substance of private law, while public administrations remain the responsible of the administrative procedures).

[36] *See, e.g.,* SABINO CASSESE, LA CRISI DELLO STATO, 3-4 (Bari GLF editori Laterza, 2002); *See* SCHEPEL, *supra* note 9, at 11; Cassese, *Gamberetti, tartarughe e procedure*, *supra* note 11, at 675. *See also* Walter Mattli & Tim Büthe, *Global Private Governance: Lesson from a National Model of Setting Standards in Accounting*, Law and Contemporary Problems 225, 225-230 (2005) (explaining the phenomenon of standardization through the

are taken at different levels and characterized by cooperation,[37] are neither necessarily binding nor conveyed through standardized sources of law.[38]

Standardization is a clear example of the profound mingling of competences that characterizes legal systems nowadays as well as the difficulty to clearly ascribe institutions and sources to the public rather than private sphere.[39] This can be shown by several aspects.

The first of these elements is the nature of standards bodies. They may be either public or private, even though they often borrow elements from both models, making any classification tough.[40] Second, they can be freely accessible[41] or be subject to several forms

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theory of principal-agent). *See* Paolo Cirielli, *L'armonizzazione tecnica nello spazio giuridico globale*, Rivista di diritto pubblico trimestrale 415, 438 (2008) (underlining the necessity of finding a way to control the activity of the agents-global regulators with respect to the principal-WTO).

[37] *See generally* Sabino Cassese, *Lo spazio giuridico globale*, Rivista di diritto pubblico trimestrale 323, 323-325 (2002). *See also* Edoardo Chiti, *La Normalizzazione*, in TRATTATO DI DIRITTO AMMINISTRATIVO, 4028 (Giuffrè Milano 2003) (analyzing the substantially discursive and interdependent structure of the normalization framework envisaged by the so called "New Approach" in the European Union).

[38] *See* Moscarini, *supra* note 24, at 1895-1901.

[39] Standardization bears also a considerable significance for its relationship with other branches of the law, such as IP, Tort, Antitrust and Constitutional Law. *See, e.g.*, Harm Schepel, *The Role of Standards in Regulatory Regimes*, Panel Discussion: Implementing the future WTO commitments on trade facilitation (Jul 5, 2010, Geneva) *available at* http://unctad.org/fr/Pages/MeetingsArchive.aspx?meetingid=; Rob Steele, *International Standards, ISO and the WTO*, Panel Discussion: Implementing the future WTO commitments on trade facilitation (Jul 5, 2010, Geneva) *available at* http://unctad.org/fr/Pages/MeetingsArchive.aspx?meetingid=.

[40] Interestingly, numerous standards bodies – today private associations – used to be public bodies. *See, e.g.*, *The history of CEN*, CEN, http://www.cen.eu/cen/products/en/pages/default.aspx (last visited June 15, 2014). *But see* Harm Schepel, *The Empire's Drains: Sources of Legal Recognition of Private Standardisation Under the TBT Agreement*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 397, 398 (Oxford and Portland Hart, 2005) [hereinafter Schepel, *The Empire's Drains*] (underlining how nowadays entirely public standards are few in number while entirely private standards are rather common).

[41] *See, e.g., How to join the American Water Works Association*, AWWA, http://www.awwa.org/membership/join.aspx (last visited June 15, 2014) (giving the possibility to join the association simply by paying the requested registration fee).

of restrictions.[42] Third, their product (the standards themselves) may be formally voluntary while bearing a certain level of imperativeness.

The imperativeness of standards can have many roots: the trustworthiness of the standard among the operators of a determined industry;[43] the influence of the manufacturer / producer of the standard on the market the standard itself is affecting;[44] finally, by means of certain normative provisions, which either mandate the use of the standards involved in a specific industry[45] or directly incorporate the standards into binding sources of law, more commonly known as "technical regulations",[46] endowing them with a substantially new public dress.[47]

Correctly, several authors have underlined how among the standards bodies all over the world a severe antagonism has started, which the most developed nations are willing to influence and even manipulate.[48]

Further element of complexity is the inner international character which distinguishes certain technical standards from others. This because if aspiring at huge levels of recognition

[42] A clear example is furnished by the so called "geographical membership" requirements. We will deal extensively with one of them discussed in the recent case law of the Appellate Body with regard to the Agreement on the International Dolphin Conservation Program (AIDCP).

[43] *See In the matter of* Mc Wane, Inc., and Star Pipe Product, Ltd., U.S. Federal Trade Commission, Docket n. 9351 2014 (briefly analyzing the widespread acceptance of the AWWA standards mentioned above by the industrial community worldwide).

[44] *See* PREDIERI, *supra* note 1, at 1437 (making the example of the widespread use of the standards imposed by IBM by several several competing manufacturers).

[45] *See* SCHEPEL, *supra* note 9, at 3.

[46] A further discussion related to the difference between standards and technical regulations will follow in the next paragraphs.

[47] *See* Cirielli, *supra* note 36, at 424-428. *See also* Chiti, *supra* note 37, at 4027-4030.

[48] *See, e.g.,* Robert Howse, *A New Device for Creating International Legal Normativity: the WTO Technical Barriers to Trade Agreement and "International Standards"*, In CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 383, 392 (Oxford and Portland Hart, 2005) (arguing that this rivalry may have a cause in the absence of a list of international standard-setting bodies in the TBT Agreement).

among market players is a permanent component of any standard, standards themselves can have ranges and targets which can be considerably different, being them local, national or international.[49]

The purpose of this thesis is to deal specifically with international standards, analyzing their function in the World Trade Organization under the "Agreement on Technical Barriers to Trade" (TBT Agreement).[50]

However, before analyzing international standardization in its normative context, a remark should be made with regard to the choice of the formula "International Standards" in the TBT Agreement.[51] The use of the adjective "International" could constitute a point of contention. If on one hand it correctly describes the typology of standards that have to be adopted by national legal systems for their technical regulations if they wish to benefit of the rebuttable presumption set forth in article 2.5 of the TBT,[52] on the other hand it might induce the legal practitioner to consider the standards debated as a product of the International Legal System.[53]

This second assumption is – at least in part – mistaken, considered that international standards constitute the final product of standard bodies which are often private bodies and

[49] The relevance of this element will be analyzed while discussing the recent developments offered by the Appellate Body in the Appellate Body Report, *United States–Measures Concerning the Importation, marketing and Sale of Tuna and Tuna Products*, WT/DS381/AB/R (*adopted* 13 June 2012) [hereinafter AB Report *U.S.-Tuna II*].

[50] *See generally* TBT Annex 3 "Code of Good Practice for the Preparation, Adoption and Application of Standards", lett. B.

[51] *See* TBT Preamble.

[52] We will deal with article 2.5 in paragraph I.3.

[53] TBT Annex 3 "Code of Good Practice for the Preparation, Adoption and Application of Standards", lett. B.

associations charged with public functions rather than real public bodies, no matter if nationally or internationally based.[54]

While the use of the periphrasis "global standards" is becoming very popular among legal scholars,[55] in spite of the difficulty to clearly define the adjective "global" in the legal context, a different terminology could have employed other adjectives; for instance, making use of the Latin words "ultra" or "supra" in conjunction with "national" in order to describe the non-domestic nature standards such as ISO or ASME possess.

It should be stressed that some authors have attributed the expression "supra" to legal regimes like the European Union where, in spite of the liaison existing between the European Institutions and the Member States, it can be said that the institution itself, in the person of the Commission, is a separate legal entity and can be imagined as being located "supra", at a level higher than the legal systems of the National States.[56] Interestingly, this school has also pointed out that global administrations like the United Nations often lack such separate and independent institutional structures, with several consequences on their role as international administrations.[57]

Alternatively and less radically, international standards could have been renamed as "private international standards", in order to stress their consensual-contractual nature.[58] This

[54] *See* Schepel, *The Empire's Drains* , *supra* note 40.

[55] *See generally* Stephanie Dagron, *Global harmonization through public-private partnership: the case of pharmaceuticals*, IRPA GAL Working Paper 2012/1, 9, IRPA (Dec. 31, 2011), http://www.irpa.eu/wp-content/uploads/2012/01/IRPA_WP_Dagron.pdf (pointing out how the guidelines of the ICH have reached the status of global standards).

[56] *See, e.g.,* CHITI EDOARDO & BERNARDO GIORGIO MATTARELLA, GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW 17-19 (Springer, 2011).

[57] *Id.*

[58] *See* Schepel, *The Empire's Drains*, *supra* note 40.

denomination has also the advantage of sharpening the difference between the standards involved in the TBT and the so called "private national standards": difference which will come in handy throughout the analysis of the case law of the Appellate Body of the World Trade Organization.

I.2: STANDARDIZATION IN THE CONTEXT OF THE WTO

Originating from the negotiations that took place between 1986 and 1994 and inheriting the legal framework of the old General Agreement on Tariffs and Trade (GATT) 1948,[59] the World Trade Organization (WTO) has since ploughed a considerable effort in order to boost the process of trade liberalization.[60]

The new global administration, which started its works on January 1995, did not only take over the GATT,[61] but grew considerably in terms of competences performed, adding to the original function of the previous body, the negotiation of tariffs lowering in the trade of goods, several other tasks related to a broader concept of trade.[62]

The role of the WTO in developing a global administrative law has been deeply analyzed by scholars. Especially through the activity of the Appellate Body, the judicial body of the World Trade Organization competent at hearing appeals from the panels instituted in order to settle those disputes that do not prove solvable by means of the negotiation process

[59] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

[60] *See generally* GUZMAN & PAUWELYN, *supra* note 14, at 83-89 (examining how the WTO was born to supersede many of the flaws of the original GATT structure).

[61] *Id.* (highlighting, for instance, the considerable improvements operated to the judicial mechanism of the WTO which have given rise to the judicial activity of the Appellate Body as we know it today).

[62] *Id.* For instance, nowadays the WTO constantly deals with services and intellectual property rights. *See generally* Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1.2., 1869 U.N.T.S. 401 [hereinafter TRIPS].

established in the Dispute Settlement Understanding,[63] several global administrative law principles have been spelled out and entered the administrative law of the national systems.[64]

Among the most classical examples of this process there is the now almost 20 years old decision in the *United States – Import prohibition of Certain Shrimps and Shrimps Products,*[65] where for the first time the Appellate Body, interpreting the chapeau of Art. XX of the General Agreement on Tariffs and Trade,[66] recognized due process, non-discrimination and transparency principles in the international arena as obligations the Member States had to comply with.[67]

With regard to our topic, it should be reminded what has been said with regard to the broader understanding of the concept of "trade" embraced by the WTO at the outset of its activity in 1995. If the GATT agreement was characterized by a major focus on the reduction of tariffs among the Member States, since the Kennedy Round and progressively more with the Tokyo Round the Member States started to negotiate and draft several side agreements

[63] *See* Dispute Settlement Understanding, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1.2., 1869 U.N.T.S. 401 [hereinafter DSU], art. 17.

[64] *See* Sabino Cassese, *La funzione costituzionale dei giudici non statali. Dallo spazio giuridico globale all'ordine giuridico globale*, Rivista di diritto pubblico trimestrale 609, 615-621 (2007) [hereinafter, Cassese, *La funzione costituzionale dei giudici non statali*] (underlining the capacity of the judges operating in the global arena to shape the principles of global administrative law, filling "the empty spaces" between the regulatory regimes). *See also* Cassese, *Gamberetti, tartarughe e procedure, supra* note 11 (explaining the functioning of the process through which due process principles enter national administrative laws by means of the decisions of international administrative bodies).

[65] Appellate Body Report *United States–Import prohibition of Certain Shrimps and Shrimps Products* WT/DS58/AB/R (*adopted* Nov. 6, 1998) [hereinafter AB Report *U.S.-Shrimps*].

[66] The first time the Chapeau of article XX was taken into account was in the very first case the Appellate Body had to deal with: Appellate Body Report *United States–Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (*adopted* May 20, 1996).

[67] AB Report *U.S.-Shrimps*. *See* Benedict Kingsbury, Nico Krisch, Richard B. Stewart, *The Emergence of Global Administrative Law*, IILJ Working Paper 2004/1, 36 - 37, INSTITUTE FOR INTERNATIONAL LAW AND JUSTICE (Jan., 2014) http://www.iilj.org/publications/2004-1Kingsburry..asp. *See also* DELLA CANANEA & SANDULLI, *supra* note 4, at 23 -24 (stressing how these violations were independent from the public policy reasons that brought the United States to implement the measures themselves).

which had a much broader object than the original tariff negotiation (from anti-dumping regulation to government procurement).[68] The Agreement on the Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures find their origins in this context.

With regard to the first of these agreements, since the very beginning of the Kennedy Round it became clear that the entire process of lowering tariffs and quotas (plus other less relevant forms of border measures) would have become completely useless in the event States would have been left free to implement internal forms of barriers to trade, making use of the regulatory powers they retained.[69]

Regulatory protection is the worst kind of protectionism according to trade scholars, because it increases the so called "deadweight" at the benefit of none: neither the importing States nor the exporting ones take advantage of a regulatory framework willfully discriminatory and protectionist in nature, instead of what happens with regard to tariffs and, more arguably, quotas, where some forms of economic benefit could take place for both importing and exporting States.[70]

The ancestor of the TBT Agreement was the "Standards Code". Approved by 43 Member States in 1979, it resembled the structure and the spirit of the actual agreement, even though its binding force was considerably weaker: possible disputes among States should have been solved through negotiation with the help of a technical expert group and – only at

[68] *See* GUZMAN & PAUWELYN, *supra* note 14, at 89.

[69] *See* Cirielli, *supra* note 36, at 417-423.

[70] *See* Dunkel Arthur & Roessler Frieder, *The Ranking of Trade Policy Instruments under the Gatt Legal System* (unpublished, excerpted in ANDREW T. GUZMAN & JOOST H.B. PAUWELYN, INTERNATIONAL TRADE LAW 2ND EDITION 89 (Wolters Kluver Law and Business, 2nd ed. 2012)).

a further stage – by means of a panel, required to decide with the consent of all the States part of the dispute itself.[71]

Nowadays, the TBT Agreement is fully encompassed in the "GATT aquis" and has not mere persuasive force.[72] From its opening it recognizes the validity of the standardization process in improving the efficiency of industrial production and its potential in the facilitation of international trade. It acknowledges the role played by standards in the harmonization process and the difficulties that less developed countries might encounter while complying with the international standards.[73]

Harmonization is one of the leitmotifs of the entire agreement. Even though the word "harmonization" does not compare thorough the articles of the TBT Agreement (this is a clear difference with the SPS Agreement, which encompasses a whole section dedicated to harmonization in article 3) [74] it expresses itself in at least three different ways: the harmonization of technical regulations, to which articles 2 and 3 are devoted; the harmonization of conformity assessment procedures, to which article 5 is devoted; the participation of the States in the process of standardization, to which article 4 is devoted and

[71] *See* Cirielli, *supra* note 36, at 421. *See also* Ingo Venzke, *Technical Regulations and International Standards: the EC-Trade Description of Sardines Case*, in GLOBAL ADMINISTRATIVE LAW: THE CASEBOOK, 10962 (Irpa 2012).

[72] *See* TBT Preamble.

[73] *See also* TBT art. 12 (establishing a different regime for developing country members). *See* also Martina Ghelarducci, *Suggestioni e contributi dell'ordinamento internazionale alla nascita ed alla elaborazione della categoria delle "norme tecniche"*, Studi parlamentari e di politica costituzionale 39, 41- 44 (2006) (pointing out that a complementary role of the TBT is the transfer of technology from developed to developing countries).

[74] This is not the only difference between the two Agreements. *See generally* Iraides Romero Montoya, Implementing the Uruguay Round Agreement in Venezuela: the Case of Agricolture, Rivista di diritto dell'Economia, dei Trasporti e dell'Ambiente (2006) *available at* http://www.giureta.unipa.it/3_PUBL_08_03_2006.htm (pointing out that "The TBT requirements can be expected to be significantly less rigorous than the requirements of the SPS Agreement"). For a complete analysis of the use and the meaning of the word "harmonization" in the TBT and the SPS Agreement, *see* KARSTEN ENGSIG SØRENSEN, LIBERALISING TRADE IN THE EU AND THE WTO, 259-266 (Cambridge University Press, 2012).

several other provisions are related.[75] All these provisions refer to the use of international standards but their effect is different.[76]

Before addressing each one of these provisions, it seems necessary to clearly distinguish international standards from technical regulations. This is perhaps even truer in the context of the WTO, where international standards are relevant not only if considered alone, but even more when taken into account as the basis for the drafting of technical regulations.[77]

Perhaps because of the differentiated use legislators have made of them thorough the history, technical regulations have been categorized in different ways over the years,[78] encompassing juridical norms with complex technical content, norms drafted by public bodies and non-mandatory rules and codes agreed upon by private associations (what we usually call standards).[79]

A complex debate has interested constitutional law scholars with regard to the proper genre to which technical regulations should be ascribed, whether their content is naturalistic or they can be compared with other norms endowed with prescriptive meaning. This debate goes beyond our analysis and will not be paraphrased in this work but should be borne in

[75] *See, e.g.*, TBT art. 2.6; 5.5.

[76] *See* Cirielli, *supra* note 36, at 422-423.

[77] *See* TBT art. 2.4. *See also* Stewart & Ratton Sanchez Badin, *supra* note 11, at 19 (claiming that in the event technical regulations are based on international standards they enjoy a real shield from legal challenge).

[78] *See* ALBERTO PREDIERI, *Le norme tecniche nello Stato pluralista e prefederativo*, in Il diritto dell'economia, 251 (pointing out the polysemous nature of the the expression itself).

[79] *See* Paola Biondini, *Approcci definitori alla "norma tecnica"*, Studi parlamentari e di politica costituzionale 31, 31-32 (1998).

mind while we address some of the more critical aspects of the interactions existing between technical standards and technical regulations.[80]

I.3: THE TBT LEGAL FRAMEWORK

In the context of the TBT Agreement, the crucial difference existing between technical regulations and standards is linked with their "voluntary" or "mandatory" character. This element has also shaped the structure of the agreement and the order in which the various provisions follow each other in that framework.[81]

Before conducting an overview of the problems that the definitions encompassed in the TBT Agreement present, especially in their relationship with the ISO/IEC Guide 2: 1991, it is useful to go over the provisions of the TBT, which mostly interests our analysis, focusing the attention on those provisions that present the major interpretative glitches.

Articles 2 and 3 of the TBT Agreement are completely dedicated to the preparation, adoption and application of technical regulations, respectively by Central Government Bodies and, on the other side, Local and Non-Government Bodies (the second group of these provisions mostly refers to the first one).

[80] For more details on the constitutional analysis of technical regulations as elaborated by the Italian doctrine, *see id*. at 32-36.

[81] A further discussion of this difference will be undertaken while we analyze the relationship between the definitions of "standards" accepted in the TBT Agreement and in the ISO/IEC Guide 2 in paragraph I.5.

Article 2 can be considered the heart of the whole Agreement for the relevance it has in dictating the terms of the harmonizing process the TBT aims at realizing and also for the frequent use made of it by the claiming parties in the dispute settlement context.[82]

It resembles in part some provisions of the GATT Agreement. It is endowed with a Most Favored Nation provision (2.1); it requires that technical regulations are not "more trade-restrictive than necessary" to fulfill certain legitimate objectives (objectives listed in a non-exclusive / open-ended list) (2.2); it mandates the use of the available international standards in the drafting of technical regulations by government bodies (2.4); it establishes a rebuttable presumption on the basis of which the technical regulations founded in accordance with the existing international standards are considered not to violate article 2.2, hence not to be "more trade restrictive than necessary" (2.5); it encourages Member States to fully participate in the process of standardization operated by appropriate international standardizing bodies (2.6); it sets a (rather weak) obligation for States to give "positive consideration" to equivalent technical regulations of other Member States (2.7).[83]

To favor the wider recognition of international standards, States are encouraged to state technical regulations in terms of performance rather than design or descriptive characteristics and are required to set up a transparency mechanism by means of which in the event a new technical regulation – potentially conflicting with international standards – is

[82] Both Peru and Mexico, in the two cases that will be discussed later, claimed a violation of art. 2, perpetrated, respectively, by the European Community and the United States.

[83] *See* Cirielli, *supra* note 36, at 437.

about to come into force, they have to inform the other Member States, which are allowed to make comments in writing and discuss them.[84]

Article 3 mandates that Member States oversee the respect of the core obligations set forth in article 2 by entities at lower levels of the constitutional hierarchy;[85] it holds Member States "fully responsible" for the respect of those obligations and, besides, for any action or measure they may take that can encourage local or non-governmental bodies not to comply with article 2.[86]

Turning to articles 5,[87] it should be reminded that this provision addresses the procedures for assessment of conformity by central governments. As for article 2, it is complemented by other two provisions, articles 7 and 8, which address the procedures for assessment of conformity by local government bodies and non-governmental bodies in a way similar to article 3.

The most relevant sections of article 5 for the purposes of our analysis are 5.4 and 5.5. The first of these two provisions resembles article 2.4: it mandates Member States to make use of relevant guidelines and recommendations issued by international standardizing bodies in the event these guidelines exist – or are about to be completed – when Member States are in the process of drafting conformity assessment procedures, except where such guides appear inappropriate to the Members for one (or more) of the reasons listed in article

[84] TBT art. 2.8; 2.9.

[85] TBT art. 3.1; 3.2.

[86] TBT art. 3.4; 3.5.

[87] The reason why we analyze before article 5 and then article 4 is because in our opinion article 4 constitutes one of those provisions in the agreement that suggest a methodology applicable to all provisions.

5.4.[88] On the other hand article 5.5, similarly to article 2.6, encourages Member States to actively participate in the process through which standardizing bodies set forth guidelines for the assessment of conformity.

It should be noted that article 5 lacks a presumption *iuris tantum* similar to the one of article 2.5.[89] The reason for this difference is unclear but the reading of article 5 may furnish a plausible answer. The procedures for the assessment of conformity are normally based on guidelines and recommendations, both documents which lack the normative character of international standards.

In conclusion, we should address the nature of Article 4. Article 4.1 dawns on the reader as a pretty weak provision, despite the use of the expression "shall". Member States are required to ensure that their central governmental standardizing bodies accept and comply with the "Code of Good Practice for the Preparation, Adoption and Application of Standards", reproduced in Annex 3 of the TBT Agreement and mostly directed to the standardizing bodies themselves.[90] Similarly to article 3, Member States are also required to guarantee that local standardizing bodies and non-governmental bodies abide by the Code and are responsible for any measure that could encourage deviation from the Code itself.

[88] TBT art. 5.4. Among the reasons that justify this deviation there are: national security requirements; the prevention of deceptive practices; protection of human health or safety; animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems. The list is not intended to be a closed one.

[89] *See also* Cirielli, *supra* note 36, at 437.

[90] TBT Annex 3 "Code of Good Practice for the Preparation, Adoption and Application of Standards".

On the other hand, article 4.2 establishes that those standardizing bodies which have accepted and complied with the provisions of the Code are entitled to be acknowledged for this achievement.[91]

I.4: THE RELATIONSHIP EXISTING BETWEEN INTERNATIONAL STANDARDS AND TECHNICAL REGULATIONS: THE READING OF THE APPELLATE BODY IN *SARDINES*

Once we have completed the analysis of the most relevant provisions of the TBT, we should focus on Article 2.4, one of the most controversial provisions in international trade law, which continues to pose several questions to scholars and results crucial to our analysis, referring to the relationship existing between international standards and technical regulations and the way standards abandon their soft law nature to become binding norms.[92] The provision reads as follows:

"Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

This drafting raises four questions: what is meant by the expression "make use of international standards *as a basis for*" the drafting of technical regulations; which technical

[91] TBT art. 4.

[92] *See generally* Stewart & Ratton Sanchez Badin, *supra* note 11, at 19-25.

regulations, in terms of time framework, are addressed by the provision; which standards should be taken into account in the crafting of technical regulations; which standardizing bodies qualify.[93]

The first two questions will be answered in this paragraph; we will address the remaining questions while dealing with the last two paragraphs of this chapter.

As soon as the TBT Agreement was drafted, a bunch of different approaches became popular with regard to the first problem.

The first approach is procedural: once the legislator or the competent administrative body has taken into account the international standard existing at the time, the regulation itself can deviate from it. Hence, the standard constitutes only the starting point of the overall procedure.[94]

The second of these approaches is rather substantive: standards acquire a more considerable relevance, because technical regulations have necessarily to deal with the benchmark furnished within the standards themselves.[95] According to this view, article 2.4 has been defined as an "aspirational obligation", which calls upon the administrative bodies of the Member States to incorporate the content of the international standards while creating their technical regulations.[96]

A third approach, suggested by a minority of the doctrine, considers the requirement of article 2.4 satisfied once a "reasonableness test" has been conducted, in order to assess if the relation between the standards and the technical regulation exists. It takes into account

[93] *See* Venzke, *supra* note 71, at 10040.

[94] *See*, *e.g.,* Howse, *supra* note 48, at 384.

[95] *Id.*

[96] *Id*. *See* Cirielli, *supra* note 36, at 431.

both procedural and substantive elements and provides panels with a more flexible interpretative tool for the evaluation of the respect of article 2.4.[97]

The Appellate Body in *Sardines*,[98] the leading case on the matter, has embraced the substantive approach, without solving the main drawback intertwined with it: what degree of correspondence should exist between international standards and technical regulations?[99]

The case was brought by the Republic of Peru against the European Communities. Peru alleged that the regulation EEC 2136/89, adopted by the Council of the European Communities, constituted a violation of (among the others) article 2.4. That regulation used to set forth certain requirements in order to market sardines in the European Community, allegedly favoring certain species of sardines more easily fished in the waters adjacent to the European Community (*sardine pilchardus Walbaum*) and excluding other species less common in the same areas (*sardine sagax*).[100]

For the purposes of our analysis, the part of the Appellate Body Report which interests us is the one related to the possibility of "Code Stan 94" to be used as a basis for the EC regulation.[101] "Code Stan 94" is a standard adopted by the *Codex Alimentarius Commission* of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO), which sets the requirement to abide by in order to market certain food products as sardines and sardine-type products.[102]

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[97] Howse, *supra* note 48, at 385.

[98] *See* Appellate Body Report, *European Communities–Trade Description of Sardines*, WT/DS231/AB/R (*adopted* Oct. 23, 2002) [hereinafter AB Report *EC-Sardines*].

[99] *See* Howse, *supra* note 48, at 384 - 386; Cirielli, *supra* note 36, at 422-432.

[100] *See* AB Report *EC-Sardines* ¶ 2-8.

[101] *See* AB Report *EC-Sardines* ¶ 234-258.

[102] *See About Codex*, CODEX ALIMENTARIUS, http://www.codexalimentarius.org/about-codex/en/ (last visited June 15, 2014).

The Code clearly encompassed the *sardina sagax* in the order of those species which qualify for the marketing under the label of sardine and sardine-type products while the European Communities excluded that species from the ones which could have been marketed accordingly to regulation EEC 2136/89.

In order to justify its divergent position, the EC argued that article 2.4 is satisfied any time "a rational relationship" between the standard and the technical regulation on the substantive aspects of the standard in question exists.[103]

This approach reminds us of the procedural one already discussed above. The Appellate Body did not embrace it, opting for a substantive approach. However, in dicta, the Appellate Body made its position more complex, affirming the necessity that a "very strong and substantial relationship" between the regulation and the substance of the international standard in question existed.[104]

Needless to say, the reading of the Appellate body leaves us without a benchmark. A "very strong and substantial relationship" does not differ in broadness from the "rational relationship" put forth by the European Communities.[105]

This uncertainty becomes more harmful when we address the problem of the "consensus" required in order for an international standard to acquire its privileged status under the TBT Agreement. This problem is strictly related to "what a standard is" and will be addressed in the following section.

The choice made by the Appellate Body to favor a substantive approach has on the other hand solved the second of the questions introduced above. Even if the point has been

[103] *See* AB Report *EC-Sardines* ¶ 241.

[104] *See* AB Report *EC-Sardines* ¶ 245 ("There must be a very strong and very close relationship between two things in order to be able to say that one is "the basis for" the other").

[105] Howse, *supra* note 48, at 386.

highly criticized by scholars, in the view of the Appellate Body standards that are not yet in place when a determined regulation is issued become relevant for the purposes of article 2.4 at a later stage. This means that a State can be found in breach of the obligations set forth in the TBT Agreement if a new standard comes out and the Member State fails to promptly revise its regulations.[106]

I.5: THE DEFINITION OF INTERNATIONAL STANDARD AND THE PROBLEM OF "CONSENSUS" IN THE TBT AND THE ISO/IEC

The WTO does not produce international standards. It lacks the familiarity (and, perhaps, the economic resources) to deal with such a complex process. Nevertheless, as described above, it does not renounce to address the problem of harmonization, so crucial to the liberalization of international trade.[107] In order to do so, it mostly relies on the expertise of other global bodies and administrations, more akin with the dynamics of international standardization but still uncomfortable with the rules germinated in the Global Administrative Law.[108]

At this point it should be asked: What is a standard? What is, on the other hand, a technical regulation?

The TBT Agreement has adopted a double-sided mechanism in order to establish the definitions related to the standardizing process. On one hand article 1.1 recognizes that, normally, the terms for standardization and procedures for assessment of conformity have to keep the meaning attributed to them "by the definitions elaborated in the United Nations

[106] *Id.* at 389.

[107] Recollect the analysis conducted in paragraph I.2.

[108] *See* Stewart & Ratton Sanchez Badin, *supra* note 11, at 20-23.

system and by international standardizing bodies, taking into account their context and in the light of the object and purpose of this Agreement". On the other hand, article 1.2 requires that the meaning of the terms [of the standardizing process] established in Annex 1 applies.[109]

This complex structure raises the following questions: how should the word "normally" be interpreted? When are the terms for the standardization process required to comply with the definitions furnished by the international standards developers? And, finally, when can they be interpreted under different canons of interpretation? Article 1.2 constitutes only a partial solution to this conceptual problem. It clarifies that the WTO, while not directly posing international standards, holds the right to dictate its own definitions regarding standardization. These definitions are addressed in Annex 1.

Annex 1, labeled "Terms and their definitions for the purpose of this Agreement", states that the terminology employed in the Agreement shall conform to the one exposed in the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities.[110] Nevertheless, after this preamble, the Annex warns that a certain number of definitions are set forth directly in the Annex. Among them we find separate definitions for technical regulations, standards, conformity assessment procedures, international bodies or systems, regional bodies or systems, central government bodies, local government bodies and non-government bodies.[111]

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[109] TBT art. 1.1; 1.2.

[110] The ISO/IEC Guide 2: 1991 can be purchased at http://www.iso.org/iso/catalogue_detail?csnumber=39976. A new version of the guide, ISO/IEC Guide 2: 2004, is now available.

[111] *See* TBT Annex 1.

The definitions provided in the ISO/IEC Guide 2 do not always match the ones provided for in the TBT Agreement. The Appellate Body dealt with these discrepancies in *EC - Sardines* and, in more details, in the recent decision *US - Tuna II*, which will also be the focus of the last paragraph of this chapter.[112]

In *Tuna II*, among the several complaints brought by Mexico against the United States there was one concerning the failure to make use, as a basis for the US regulation concerning the labeling of tuna products as "dolphin-safe", of the requirements provided in the context of the Agreement on the International Dolphin Conservation program (hereinafter "AIDCP"). While the panel had agreed with Mexico on the matter, it sustained, however, that Mexico had failed to demonstrate that the AIDCP standard was an effective and appropriate yardstick in order to fulfill the purposes of the U.S. regulation. The Appellate Body denied the nature of international standards to the AIDCP requirements in the first place.[113]

The Appellate Body, after paraphrasing Annex 1.2,[114] looked thoroughly into the explanatory note at the article which for the reader's convenience is reported below:

"The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement

[112] AB Report *U.S.-Tuna II.*

[113] For a concise summary of the case, *see generally* GUZMAN & PAUWELYN, *supra* note 14, chapter 19 new edition (forthcoming).

[114] "Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method."

standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus."

The explanatory note clarifies one first major distinction: technical regulations are mandatory while standards are voluntary in the language of the TBT. The WTO does not recognize standards which are mandatory in nature.

In *Tuna II* the Appellate Body undertook the analysis which was missing in *Sardines.* After clarifying that in the event of a conflict between the provisions of the Guide and the TBT, the definitions set forth in the TBT prevail, the Appellate Body looked at the provisions of the TBT through the lenses of the ISO/IEC Guide 2.[115]

Referring to the Guide, the Appellate Body defined the international standards as "standards that are adopted by an international standardizing/standards organization and made available to the public".[116] Then, the Appellate Body asserted that it is mainly the character of the standardizing body – whether it is international or not – which makes possible for a standard to be considered "international" for the purposes of the TBT Agreement.[117]

This approach, different from the one adopted in *Sardines,* can be questioned in many respects. It does not furnish a substantive definition of international standards but focuses on the institution, the author of the standard. To this extent, we may affirm that the very nature of the international standards lies now in the analysis of the standards developers: whether

[115] AB Report *U.S.-Tuna II* ¶ 353-354.

[116] *Id*.

[117] *Id*.

they satisfy the requirements set forth in the TBT Agreement and the reading provided by the Appellate Body. We will deal with these requirements in the last paragraph.

At this point, it is worth spending some words on the interpretation of the word "consensus" in the explanatory note reported above, which the Appellate Body did not directly address in *Tuna II* even if it had turned out controversial at the panel stage.

In *Sardines* both the Panel and the Appellate Body rejected the argument put forward by the European Communities that international standards, in order to constitute an obligatory basis for the drafting of technical regulations, had to be based on "consensus".[118] This approach was grounded on the last phrase of the explanatory note, which comprehends "standards not adopted by consensus" in the reach of the TBT Agreement.[119]

In spite of the correctness of the textual analysis undertaken by the Appellate Body, several scholars have highly criticized this decision. Howse, for instance, has warned that the EC complaints that the WTO was turning international standardizing bodies into "world legislators" was not wrong in its premises, because *Sardines* had basically legitimized a "broad automatic lawmaking mechanism" where States are substantially deprived of their right to regulate.[120] This meant, also, that States could have been forced to use standards – which they had previously objected to in the standardizing process – as a basis for their technical regulations.[121]

The Appellate Body in *Tuna II* has not dealt with consensus, because both Mexico and the United States had accepted the AIDCP system. Nonetheless, interestingly, the Panel

[118] For a clear summary of the positions made by the EC in the case, *see* Venzke, *supra* note 71, at 10084.

[119] *See* Explanatory note at TBT Annex 1.2.

[120] *See* Howse, *supra* note 48, at 387.

[121] *See, e.g.*, Venzke, *supra* note 71, at 10084.

in the same case blatantly disagreed with the Appellate Body of *Sardines*, affirming that the TBT requires standards to be based on "consensus".[122]

This divergence can be explained from a political perspective: the Doha Round and the protests after Seattle had perhaps weakened the legitimacy of the WTO and made necessary a step backwards in the direction of horizontal harmonization.[123] Nonetheless, the silence of the Appellate Body on the matter does not allow us to assess what the role of "consensus" will be in the future of the TBT Agreement.

I.6: INTERNATIONAL STANDARDIZING BODIES: MEETING THE REQUIREMENT OF "OPENNESS" AFTER THE RULING IN *TUNA II*

As already stressed in the previous paragraph, the features of international standardizing bodies have become crucial in order to determine the nature of the international standards themselves, dividing those which can become the basis for national technical regulations from those which cannot have this influence.

It seems surprising that the composition and the nature of the standards developers has become relevant only at this stage of the history of the TBT. However, an explanation could be found in *Sardines.* In that decision the question was whether Code Stan 94 should have been used as a standard for the EC Regulation regarding the labeling of sardines.[124] The discussion of the Appellate Body focused mainly on the standard and less on the characteristics of the standardizing body.

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[122] *See* Panel Report *United States-Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 7670-7679, WT/DS381/R, (*adopted* 15 September 2011).

[123] *See* GUZMAN & PAUWELYN, *supra* note 14, at 121-124.

[124] Recollect the analysis undertaken in paragraph I.4.

In that decision, none doubted that the Codex Alimentarius Commission was to be considered an international standardizing body, being it strictly connected with the FAO and the WHO, both organizations linked with the United Nations and endowed with a solid system of national representation.

It should be reminded here that the TBT Agreement lacks a system of direct appointment of the international standardizing bodies whose standards are to be granted the special status of substantially "binding norms" according to article 2.4. This makes harder for the legal practitioner to define which standards will be necessary to take into account in the regulatory process and, in the presence of a broad range of standards addressing the same issue, which standard to choose.[125]

The SPS Agreement, on the other hand, makes this choice. While not excluding the possibility that other standards can play a role in the harmonization process, it gives its preference to three main institutions with their related appendices: "the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention".[126]

[125] *See* Stewart & Ratton Sanchez Badin, *supra* note 11, at 21 (making the example of software standards, where ISO Standards compete with standards provided by several other organizations allegedly more familiar with the field).

[126] *See, e.g.*, Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1.2., 1869 U.N.T.S. 401 [hereinafter SPS], art. 4 ("Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.").

Asked by the United States to evaluate if the entity approving the AIDCP standards could satisfy the requirements established in the TBT Agreement and the related Annex 1, the Appellate Body compared literally the definitions of the Annex with the ones set forth in Guide 2, coming to the conclusions which will be presented below.[127]

At the outset, the Annex 1.2 mandates that a standard is approved by a "body". The ISO/IEC Guide 2: 1991 does not disagree on this point, affirming that international standards have to be approved by an "organization". The Guide furnishes definitions for both these terms: while a body is a "legal or administrative entity that has specific tasks and composition", an organization is a "body that is based on the membership of other bodies or individuals and has an established constitution and its own administration".[128]

The ISO/IEC Guide 2 provides also some further characteristics of the body enabled to produce international standards: it must be either a "standardizing body" or a "standards body". While the first category pertains to a body which has "recognized activities in standardization", the second category is related to standardizing bodies recognized at national, regional or international level, whose principal function, by virtue of their statutes, is the preparation, approval or adoption of standards that are made available to the public.[129]

The outcome of the comparison between the two sources at stake has led the Appellate Body to affirm that the ISO/IEC Guide 2: 1991 is not in conflict with the TBT

[127] For a complete analysis of the case, *see generally* Gregory Shaffer, *The WTO Tuna-Dolphin II Case: United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, Am. J. of Int'l. L., Issue 1 (2013).

[128] AB Report *U.S.-Tuna II* ¶ 355.

[129] AB Report *U.S.-Tuna II* ¶ 357-358. In this work we will consider both typologies together.

Agreement and only further specifies the notion of "body" existing in the Annex: it has to be "recognized" with respect to its activities in "standardization".[130]

In the following part of the analysis the Appellate Body went on "breaking in small pieces" the definition of international standardizing body. It focused before on the concept of standardization. The ISO/IEC Guide 2: 1991 defines it as the "activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context".[131]

The judicial organ of the WTO then focused on the concept of "recognition": it required that the body's activities in standardization are "recognized". The Appellate Body, as it did in previous decisions,[132] undertook a literal interpretation, coming to the conclusion that the word "recognition" encompasses a factual and a legal/normative character, both relevant in order to establish which bodies may satisfy the requirements indicated in the TBT Agreement.[133]

Turning to the composition of the standard developer, the Appellate Body identified the requirement of "openness" as the characterizing and crucial one. Membership in an international standardizing body must be "open to the relevant bodies of at least all Members", where "open" is, in the view of the Appellate Body, a synonym of "accessible or available without hindrance, not limited to a few". Hence, according to the Appellate Body,

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[130] *Id.*

[131] The definition of "standard" is also examined in paragraph I.1.

[132] An analysis of the optimal hermeneutic tools to be employed has been undertaken by the Appellate Body in the Appellate Body Report, *EC–Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 175-176, WT/DS269/AB/R (*adopted* Spt. 27, 2005) (objecting that dictionaries, while providing a "useful starting point" for the analysis of "ordinary meaning" of treaty terms, are not necessarily dispositive).

[133] AB Report *U.S.-Tuna II* ¶ 360.

only those standards developers whose membership is generally open and not restricted to some relevant bodies may be considered international bodies capable of producing international standards.[134]

It is also noteworthy the reference the Appellate Body made to the Decision of the TBT Committee[135] on which both Mexico and the United States had relied and which, to that extent, could be considered a "subsequent agreement" within the meaning of article 31 (3)(a) of the Vienna Convention on The Law of the Treaties.[136] The Appellate Body examined the further interpretative elements provided in the Decision, particularly articles 6 and 7, and concluded that in order to qualify for the purposes of the TBT Agreement, an international standardizing bodies must not only be open "at every stage of standards development" but also "on a non-discriminatory basis".

The Appellate Body has not clarified the first of these two additional requirements, but has explained that the "non-discrimination basis" prevents standardizing bodies, whose constituting provisions disadvantage the relevant bodies of some Members *de jure* or *de facto*, from being considered "international" standardizing bodies for the purposes of the TBT Agreement.[137]

The TBT Committee Decision furnishes also a determination of the "recognized activities in standardization" in which an international standardizing body can claim to be

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[134] *Id* at 364.

[135] Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement, G/TBT/9, 13 November 2000, ¶ 20 and Annex 4.

[136] United Nations Convention on the Law of the Treaties, May 23, 1969, 1155 U.N.T.S. 331, art. 3(a) ("There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.").

[137] AB Report *U.S.-Tuna II* ¶ 375.

engaged. The Appellate Body sustained that "recognition" in the WTO by the Member States occurs precisely when there is evidence that the standardizing body is complying with the principles and procedures established in the TBT Committee Decision.[138] In our opinion, this part of the decision looks like a circular reasoning.[139]

The Appellate Body then provides us with a useful example: a body which spreads information about its standardization activities – coherently with the transparency procedures established by the TBT Committee Decision – will be likely considered "international" by all the WTO Member States which make a serious effort to respect international standardization. Hence, as the Appellate Body has specified, compliance with the principles and procedures decided by the WTO Member States is a signal that the body has "recognized activities in standardization".[140]

The Appellate Body agreed with the United States that international standardizing bodies must not privilege any particular interest in the process of developing international standards. Hence, the AIDCP, whose main interest was (and is) to regulate fishing activities, did not qualify as an international standardizing bodies for the purposes of the Agreement.[141]

Also, the Appellate Body stressed that to be "open", an international standardizing body can require an invitation, but this requirement has to be purely formal and automatic, what Mexico had failed to show. AIDCP, for instance, could issue an invitation only if its

[138] *Id* at 376

[139] Apparently, the Appellate Body is explaining the conclusions (the international character of the standardizing bodies according to the TBT Decision) with the premises (the respect of the requirements expressed in the decision itself).

[140] *Id.*

[141] *Id* at 384-386.

members had so decided by consensus. Therefore, this invitation was not comparable to a "formality".[142]

This decision presents several points of interest. It gives the WTO an enormous discretion to ultimately declare if a standard is "international" or not, being so able to "double check" the authority, process and outcome of a standard claimed as international.[143]

It allows all standardizing bodies, even the least renowned, to see their standards recognized if the procedures they adopt for implementing their standards comply with the requirements expressed in the TBT Committee Decision mentioned above.[144]

On the other hand, international standardizing bodies which limit the participation of Member States, *de jure* or *de facto*, no matter how widespread and popular their standards may be in the global industrial community, are deprived from acquiring the "indirect normative power" which article 2.4 of the TBT Agreement can grant to standards developers.

As a conclusive remark, we should briefly consider the "interest" requirement. Several international standardizing bodies pursue a clear and determined interest.[145] Can this be a limiting factor for standards to become relevant in the international arena?

Our task is now to examine some of the major international standardizing bodies and their related standards, in order to understand if they may satisfy the requirements provided by the Appellate Body in *Tuna II*.

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[142] *Id* at 398.

[143] *See* GUZMAN & PAUWELYN, *supra* note 14, chapter 19 new edition at 28 (forthcoming).

[144] AB Report *U.S.-Tuna II* ¶ 392.

[145] We have already referred to the "AWWA" above in paragraph I.1.

CHAPTER II:

DIFFERENT MODELS AND PRODUCTION MECHANISMS OF THE INTERNATIONAL TECHNICAL STANDARDS

II.1: REGULATORY COMPETITION AND THE APPARENT PREFERENCE ACCORDED TO ISO AND IEC STANDARDS IN THE TBT AGREEMENT

As already underlined in the first chapter while addressing the role the international standardization covers in the world trade arena, the TBT Agreement, in defining international standards, has chosen to rely in part on the definitions provided by the ISO/IEC framework as sketched in the ISO/IEC Guide 2: 1991.[146] Put it differently, the WTO has endorsed – to a certain extent – the foundations on which two separate institutions, the International Organization for Standardization and the International Electrotechnical Commission,[147] have built their own standardization regimes.

Before analyzing in more depth how international standards are concretely produced, we ought to examine to what extent the TBT Agreement has only made use of the conceptual framework which governs these two private institutions or if ISO and IEC standards have been granted a privileged status.

This inquiry acquires specific interest here if we consider the possibility (or, in certain fields, even probability) that a number of international standards, with different origin and perhaps nature, regulate the same field.[148] Even though the TBT Agreement does not deal specifically with them,[149] perhaps the most telling example is furnished by the environmental

[146] *See* ISO/IEC Guide 2: 1991, *available at* http://www.iso.org/iso/catalogue_detail?csnumber=39976.

[147] For more information related to the IEC, *see About the IEC*, IEC, http://www.iec.ch/ (last visited June 15, 2014).

[148] *See* Stewart & Ratton Sanchez Badin, *supra* note 11, at 21 (quoting Joost H.B. Pauwelyn, Non-Traditional Patterns of Global Regulation: Is the WTO "Missing the Boat?" (Sep. 24-25, 2004) (conference paper available at http://scholarship.law.duke.edu/faculty_scholarship/1311)).

[149] *See* Cirielli, *supra* note 36, at 425.

context.[150] In this field there are certain ISO Standards – particularly, the so called ISO 14001: 2004,[151] related to environmental management – which have an exact parallel in the context of the ASTM Standardization.[152] Some examples may be the standard created in 2013 named D5743 - 97(2013), which sets the Practice for Sampling Single or Multilayered Liquids, With or Without Solids, in Drums or Similar Containers or the one named E688 - 94(2011), dictating certain Standard Test Methods for Waste Glass as a Raw Material for Glass Manufacturing.[153]

Other examples of similar conflicts exist in the growing area of software development. Here ISO standards struggle with a huge set of standards issued by several hybrid bodies which, perhaps, follow the dynamics of technological development more closely than how ISO Committees may effectively do.[154]

Differences in the choice of standards adopted can have a tangible effect. A common example is the different size and positioning of computer keyboards, where at least three systems compete: the American ANSI – IBM standard, mostly used in the United States, the ISO system, adopted in many European Countries, and the JIS, adopted in Japan and resembling the ISO system, with the addition of three keys.[155]

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[150] *See* Howse, *supra* note 48.

[151] *See ISO 14000 - Environmental management*, ISO, http://www.iso.org/iso/home/standards/management-standards/iso14000.htm (last visited 15 June, 2014).

[152] *See generally Waste Management Standards*, ASTM, http://www.astm.org/Standards/waste-management-standards.html (last visited 15 June, 2014).

[153] *Id.*

[154] *See* Stewart & Ratton Sanchez Badin, *supra* note 11, at 20.

[155] Further information on this technical example are *available at* http://deskthority.net/wiki/ANSI_vs_ISO (last visited May 23, 2014).

This form of rivalry among standards and standards bodies is better known as "regulatory competition", a phenomenon already addressed at the outset of the present work whose features is now worth examining.

First of all, regulatory competition finds its roots in the aforementioned lack in the TBT Agreement, in contrast with the SPS Agreement, of any list of standardizing bodies endowed with the task of setting up standards qualified under article 2.4. In the absence of this choice, it could be wondered whether a regulating body – no matter if governmental, local or nongovernmental – would be completely free of choosing any international standard available when creating a new technical regulation (provided, of course, the respect of the principles dictated in the TBT Agreement and the "Decision on Principles for International Standardization" analyzed in the first chapter).

Some authors have argued that the choice, at least as it appears in the words of the aforementioned TBT Committee Decision, is not open-ended. Particularly, because standards "should respond to the needs of the market, should avoid adverse effects on fair competition or stifling innovation and technological development",[156] the institutions called upon to draft the regulations should be somehow constrained to privilege those standards that are allegedly more market-friendly.[157]

The European Union and the United States, the two economies more involved in the production and consumption of international standards, have taken very different positions

[156] *See* Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement, G/TBT/9, 13 November 2000, ¶ 10.

[157] Howse, *supra* note 48, at 393.

with regard to the existence of a plethora of international standards potentially concerning homogenous sets of interests and fields.[158]

The European Union has consistently argued in favor of a monopoly of the ISO and IEC frameworks.[159] The reasons for this preference are both conceptual and economic.

As far as the ideological order of reasons is concerned, the European Union has embraced what has been defined as a political concept of "consensus". We have already encountered the problem of consensus in the first chapter, explaining how the Appellate Body in *Sardines* had tried to downsize its relevance.[160] The European Union, in that context as well as in several others,[161] has showed to approve the functioning of the ISO framework, considering national representation in the standardizing bodies one of the most effective instruments for the achievement of global consensus in standardization.[162]

Turning to the more empirical – economic reason, it cannot be underestimated that European Standardizing Bodies and Institutions have ploughed a considerable amount of economic resources in their participation into the ISO/IEC system.[163] They govern it, blatantly outnumbering the other competitors from all over the world (the American Standardizing Bodies as well).[164] Their method of production of standards and their standards

[158] Perhaps the most comprehensive studies on this conflict have been conducted by Harm Schepel. For a broad overview, *see, e.g.*, Schepel, *The Empire's Drains*, *supra* note 40, at 406-408. For a more detailed analysis, *see* SCHEPEL, *supra* note 9, at 185-193.

[159] SCHEPEL, *supra* note 9, at 185-193.

[160] A deeper analysis of this approach has been conducted in paragraph I.4.

[161] *See generally* the recent Regulation (EU) No 1025/2012 Oct. 25 2012; Communication COM (2013) 561 final of 31 July 2013 on the annual Union work program for European standardisation.

[162] Schepel, *The Empire's Drains*, *supra* note 40, at 406.

[163] SCHEPEL, *supra* note 9, at 190-193.

[164] *Id*.

themselves are considerably inspired to the ISO/IEC models, with CEN (European Committee for Standardization) standards resembling the ISO standards in 40% of the cases and CENELEC (European Committee for Electrotechnical Standardization) standards resembling IEC standards in 70% of the cases.[165]

The United States, on the other hand, has normally allowed (if not encouraged) the coexistence of a number of different standards addressing the same field. This on the assumption that letting the market choose the most appropriate set of standards to be employed in the production dynamics – as it happens for any kind of product – produces more efficient outcomes not only in micro but also macroeconomic terms.[166]

In other words, this approach towards "consensus" is more procedural, where no national representation counts as much as the capability of the procedural framework to guarantee the fair and equal representation of all – economic and non-economic – interests.[167]

It is perhaps for this reason that the United States – and the American Standards Bodies specifically – have always lobbied against any form of mingling between the WTO Institutions and the ISO/IEC regimes, sometimes publicly expressing their dissatisfaction.[168]

Conclusively, to answer the very question opening this chapter and before analyzing in more details the methods of production of the international standards in the different

[165] *Id*.

[166] Schepel, *The Empire's Drains*, *supra* note 40, at 406. *See also* SAMUEL KRISLOV, HOW NATIONS CHOOSE PRODUCT STANDARDS AND STANDARDS CHANGE NATIONS 104 *(*University of Pittsburg Press, 1997).

[167] SCHEPEL, *supra* note 9, at 186-187.

[168] *Id.* (quoting the General Position Paper of ASME International on Standards and Technical Barriers to Trade (1997)).

context of the ISO, the IEC and other relevant standards developers, we should take a closer look at the TBT Agreement and, in more details, the TBT Commission Decision several times mentioned above.

If the TBT Agreement is silent on this regard, there is at least one passage in paragraph 12 of the TBT Decision that, besides encouraging the cooperation among international standardizing bodies, seems to privilege the existence of a single forum in order to deal with international standardization in a way that "avoids the development of conflicting international standards".[169] This because, if standardizing bodies should strive to avoid duplication, they should consequently recognize the product of the standardization process undertaken by other international bodies.

Such a plain recognition could take place, as we believe, only emphasizing the concept of "relevant international bodies", a periphrasis which remains obscure in many regards and is not supplemented by any instrument which could help us to understand how to compute the degree of relevance.

If such a forum should be individuated, we are persuaded that the one meant in the TBT Agreement is the International Organization for Standardization – which we will now examine – whose structure (from its very name) claims the highest degree of internationality and whose relevance is not under scrutiny, considered that the TBT itself has made use of its founding pillars in order to build its structure.

[169] Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement, G/TBT/9, 13 November 2000, ¶ 12 ("In order to avoid the development of conflicting international standards, it is important that international standardization bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential.").

II.2: THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION AND THE ISO STANDARDS

The International Organization for Standardization, differently from what can be said of several other private associations dealing with standardization,[170] is a compact and well-structured system, whose resources are not negligible and whose outcomes are considerable both in terms of the *fora* set up for the production of new standards and in terms of the number of standards produced.[171]

Located in Geneva, the ISO stemmed from the merger of two different organizations: the ISA (International Federation of the National Standardizing Associations), created in New York in 1926 and administered from Switzerland; and the UNSCC (United Nations Standards Coordinating Committee), created in 1944, and administered in London.[172]

In 2013, the ISO has brought together 164 national standardizing bodies, overviewed the work of 100000 experts divided in 3483 different technical committees, producing over 1100 standards which, together with the previous works – partly reviewed, modified and amended – count 19977 international technical standards, employed all over the world.[173] The mingling of national public and private standards developers as members of the ISO has

[170] For an interesting development of this argument, *see* Am. Soc. of Mech. Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 556, 585-587 (1982) (Powell, J., dissenting) (retaining treble damages inappropriate against standardizing bodies given their limited budget).

[171] *See generally ISO in Figures*, ISO, http://www.iso.org/iso/iso_in_figures-2013.pdf (last visited June 15, 2014).

[172] *See* Eicher, *supra* note 23, at 15.

[173] *See generally ISO in Figures*, ISO, http://www.iso.org/iso/iso_in_figures-2013.pdf (last visited June 15, 2014).

persuaded some scholars to define the ISO as an hybrid public-private body rather than a private association.[174]

An exhaustive description of the ISO Organization is encompassed in the ISO/IEC Directives which are published in two parts.[175] A description of the functioning and the management, as well as the way in which its technical works is conducted, is encompassed in Part 1 of the Directives. The rules which govern the structure and drafting of the international standards are outlined in Part 2.

The management of the ISO takes place through several branches which go from the general to the particular. The national members – coming from the respective technical committees of their National States – form the General Assembly, which is then responsible for the appointment of the Council.[176] The Council, then, cooperates with the President, the Vice-President and the Secretary-General of the ISO to govern the Institution's activity, whose crucial moment is the appointment of the Technical Management Board.[177]

The Technical Management Board (TMB) is the real brain of the works that are conducted: it is responsible for the establishment of the technical committees, for the choice of the relative chairs, for the allocation of the secretariats of the committees and, sometimes,

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[174] *See generally* Walter Mattli & Tim Büthe, *Setting International Standards: Technological Rationality or Primacy of Power?*, 56 World Politics 1, 25 (2003). *See also* Gregory Shaffer & Joel Trachtman, *Interpretation and Institutional Choice at the WTO*, Virginia J. of Int'l L., 112-114 (2011).

[175] Both Directives are *available at* http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_iec_directives_and_iso_supplement.htm , free of charge and in several formats. They can also be downloaded in the *Consolidated ISO Support*, which encompasses also several annexes regarding the relationship of the ISO with other institutions and some procedural rules applicable only to the ISO.

[176] For an overview of the process, *see* SCHEPEL, *supra* note 9, at 183. S*ee also* Eran Shamir-Borer, *Legitimacy without Authority in Global Standardization Governance: The Case of the International Organization for Standardization (ISO)*, in GLOBAL ADMINISTRATIVE LAW: THE CASEBOOK, 10040 (Irpa 2012).

[177] *Id.*

of the subcommittees; it is also responsible for the distribution of the works, prioritizing certain research when necessary or demanding determined studies on new technologies in other cases.[178] It also overviews the respect of the Directive and, together with the CEO (whose role will be analyzed later) monitors the progress of the technical work.[179]

The TMB of either the ISO and the IEC, whose activity can be conducted together and whose procedures have been largely unified in the years to boost cooperation and to provide a more coherent tool for the resolution of technical problems worldwide, may appoint, jointly or separately, an advisory technical group whose role is to assist the TMB of the relative institutions.[180]

It should be noted that the advisory group can hardly ever proceed on its own towards the production of the technical documents, activity which remains in the absolute province of the technical committees, but it may start certain proposals for the harmonization of the relevant publications.[181]

Before addressing the activity of the technical committees some words should be said with regard to the CEO of the Institution. The CEO in the ISO/IEC system is considered the "communicator of the institution", arranging all the contacts that take place among the technical committees, the Council board and the TMB and referring the proposals for the adoption of new standards to the responsible committees when there is the suspect that

[178] ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.1.

[179] *Id.*

[180] *Id.* at art. 1.2.

[181] *Id.* at *art.* 1.2.3.

analogous works have been conducted in the same field.[182] It is also responsible, as we have already pointed out, for the maintenance of the rules encompassed in the Directive.[183]

It should be mentioned here that the Directive itself discourages the technical committees from adopting their own procedural rules and, to that extent, requires the technical committees, in case of possible divergence, to seek the authorization of the CEO.[184] Needless to say, this procedural rigidity is at the odds with the flexibility that characterizes the ANSI system, which we will analyze later in this chapter.

As we have seen, the TMB is responsible for the appointment and dissolution of the technical committees.[185] The technical committees can also change their nature and their field of research when the work they were formed for has been completed, depending, in any case, on the will of the TMB.[186]

The ISO system provides considerable openness with regard to the entities capable of starting the standardization process.[187] In fact, a proposal for work in a new field of technical activity which seems to demand the establishment of a new technical committee can be made by either a national body, a technical committee or relative subcommittee, a project committee, a policy level committee, the TMB itself, the CEO, anybody responsible for

[182] *Id.* at art. 1.4; 1.5.5.

[183] *Id.* at art.1.4.

[184] *Id.*

[185] *Id.* at art. 1.5.1.

[186] *Id.* at art. 1.5.2.

[187] *See* SCHEPEL, *supra* note 9, at 183.

managing a certification system operating under the auspices of the organization and, conclusively, another international organization with national body membership.[188]

The CEO receiving the proposal may consider it lacking one or more constituting elements or fundamental technical information (but it is barred, at this point, from expressing any value judgment). To that extent, the CEO can remand the proposal to its author with the purpose of completing it, although the author can require that the proposal is voted as in its original form. Under the 2014 edition of the directive, in the event the proposer does not make the required changes, the TMB can even decide to block the proposal until the changes take place.[189]

The CEO makes the proposal circulate among the national bodies, asking if the proposal itself should be analyzed by a new technical committee or should be assigned to the works of an existing one.[190] If after three months at least 2/3 of the national bodies have expressed their intention to set up a new technical committee and at least 5 of those bodies have expressed their will to actively participate in the works of the new technical committee, the committee is created and is immediately required to define its name and its scope – namely the precise limits of its work –, both subject to modification by the TMB.[191]

An analogous procedure takes place when the technical committees decide to set up a subcommittee, with the difference that the crucial decisions are taken by the technical

[188] ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.5.3.

[189] *Id*. at art. 1.5.4; 1.5.5.

[190] *Id*. at 1.5.6; 1.5.7.

[191] *Id*. at 1.5.8; 1.5.9; 1.5.10; 1.5.11.

committees themselves – often with the involvement of their secretariat –, with little intervention of the CEO.[192]

National bodies can be involved in the works of the technical committees in at least three manners: as P-Members (participating), as O-Members (observers), as none of the first two options. In this last case, they lack substantially the rights and the obligations typical of the national bodies involved in the activity of the technical committees, but they still maintain their right to vote on the enquiry drafts and final drafts of international standards.[193]

The framework of the technical committees is pretty developed: each committee's activity takes place through the works of a secretariat, a chair and a vice-chair. In the election of each of them the TMB has a considerable influence: it is entitled to the appointment of the secretariat and the approval of the chair and vice-chair (who are normally nominated by the secretary of the Technical Committee).[194]

Before initiating any work, the technical committee defines a strategic business plan where it defines the possible areas of development of its field, the areas which should be revised and the areas which may need the commencement of standardization in the predictable upcoming years.[195]

The technical committees are accompanied in their works by a plethora of other committees responsible for different parts of the standardization process. For instance, the TMB can appoint project committees, whose focus is normally limited to a well-defined

[192] *Id*. at art. 1.6.

[193] *Id*. at art. 1.7.1.

[194] *See id.* at art. 1.8; 1.8.3; 1.9.

[195] *See id.* at art. 2.1.2.

number of tasks mainly related to individual standards, and whose status can successively evolve into a technical committee.[196]

The technical committees themselves can create other minor entities, such as the editing committees, or distribute the work in a cooperative manner – what they are normally encouraged to do –, establishing advisory groups, ad hoc committees, working groups and liaisons.[197]

With the expression "liaison', the Directive basically refers to a strong connection with another committee which the technical committees should create in order to conduct their work in a more efficient way, exchanging documents and referring proposals to each other. Some of these liaisons are almost mandatory, especially with certain committees responsible for basic activities of standardization, like the ones involved in the standardization of the terminology adopted in the standardization process itself.[198]

Each standard in the ISO/IEC system encounters several steps before becoming a finished product. Normally, the protocol described in the Directives is composed of 7 different stages and can take quite a long time[199] depending on how complex the technical

[196] *See id.* at art. 1.10.

[197] *See generally id.* at art. 1.11; 1.12; 1.13; 1.14.

[198] *See id.* at art. 1.15.

[199] The average times are 2, 3, 4 years, respectively when the accelerated, the default and the enlarged standards development tracks are undertaken. *See id.* at art. 2.1.6.1.

debate develops[200]: the Preliminary, Proposal, Preparatory, Committee, Enquiry, Approval, Publication stage.[201]

The Preliminary Stage is not mandatory, because the standardization process can stem directly from a proposal issued by one of the subjects listed above. Any technical committee (as well as any subcommittee) may include into the work program preliminary items characterized by a certain level of incompleteness. This prevents them from being analyzed at a further stage or from being assigned a target date indicating the time in which the work is plausible to be completed.[202]

The first real omnipresent stage is the Proposal stage. As we have seen, a proposal may be rejected in the first place and remanded to its author, who has nonetheless the right to see its proposal voted in the original draft presented. The approval of a proposal presented to a technical committee depends on two factors[203]: the positive vote expressed by the simple majority of the members of the committee to take charge of the proposal itself; the commitment to actively participate in the development of the project, from the preparatory stage, which should be expressed by a calculated number of P-Members.[204]

Once a proposal has been accepted, the technical committee is then responsible for the preparation of a working draft (WD), which will subsequently circulate among the Member States as committee draft (CD), a standard in its premature form, already registered

[200] It should be remembered that the length of the process of the ISO/IEC Standards has been one of the reasons of the strong critics moved by the American standards bodies in the TBT arena, as it has been sketched in paragraph II.1.

[201] ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 2.1.3.

[202] *See id.* at art. 2.2.

[203] *Id.* at art. 2.3.

[204] *Id.*

by the office of the CEO.[205] Sometimes the technical committee may publish the working draft as a Publicly Available Specification (PAS) to meet certain market needs.[206] The works of the committee at this stage are often guided by the so called project leader, who normally convenes and chairs the meetings of the relative committee.[207]

The Committee stage, which can be avoided in accordance with Annex SS, is the first moment in which the standard receives feedback from the national bodies, which are given from 2 to 4 months in order to examine the CD and to express comments.[208] No more than 4 weeks after, the secretariat of the committee, once the comments have been collected, consults with the chair of the committee and – if necessary – with the project leader in order to decide one of three possible outcomes: a discussion of the draft and the comments to be conducted at the meeting of the committee; the circulation of a revised draft; the registration of the committee draft for the enquiry stage.[209]

The transition to the enquiry stage takes place only when all the P-Members have reached, on the matter discussed, the "consensus" defined in the several times mentioned ISO/IEC Guide: 2004, namely[210]:

"*General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that*

[205] *Id.* at art. 2.4.8.

[206] *Id.*

[207] *Id.* at art. 2.4.5.

[208] *Id.* at art. 2.5.1.

[209] *Id.* at art. 2.5.3.

[210] *Id.* at art. 2.5.3.

involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments."

During the enquiry stage, the draft is circulated by the office of the CEO for a period of three months to all the national bodies. They express their vote either positive (followed, sometimes, by comments) or negative (always followed by the reasons of such a position), even though all participants may also opt for an abstention.[211] An enquiry draft is approved only if two thirds of the votes of the committee are favorable and not more than a quarter of the total number of votes is negative.[212]

The approval stage resembles the enquiry stage, with the only difference that the vote takes place in a shorter time (2 months).[213] It is only at this point that the draft may finally become an ISO (or IEC) standard.

When a standard has been voted against, the committee can pursue three different paths: it can resubmit a modified draft as a committee, enquiry or final draft; it can publish a technical specification instead or it can abandon the project through means of cancelation.[214]

If the procedure has been successfully completed, a report circulates indicating the favorable vote obtained by the project.[215] This is the last step before the publication of the

[211] *Id.* at art. 2.6.1, 2.6.2.

[212] *Id.* at art. 2.6.3.

[213] *Compare* art. 2.6.3 *and* art. 2.7.3 (delineating a similar procedure).

[214] *Id.* at art. 2.7.7.

[215] *Id.* at art. 2.7.8.

standard, normally within one month, after the correction by the office of the CEO of eventual mistakes or errors indicated by the secretariat of the committee.[216]

The publication of the international standard is the tangible proof that a standard has been agreed upon and has come into existence. Despite the "binding nature" that the WTO has conferred to ISO standards per se, their original character is essentially voluntary, proper of other forms of soft law.[217]

Conclusively, it should be reminded that the ISO framework grants several forms of appeal against the decisions of the TMB, the Council, the technical committees and the subcommittees[218]: an approach clearly in favor of broadening the rights of the participants in the standardization process and consistent with the practice of the most developed standardizing bodies.[219]

II.3: THE INTERNATIONAL ELECTROTECHNICAL COMMISSION AND THE IEC STANDARDS

As the ISO, the International Electrotechnical Commission (IEC) is a non-governmental organization whose activity does not take place for profit and is located in Geneva.[220]

Founded at the very beginning of the last century, in 1906, the IEC focus is, differently from the ISO, directed to the highly specific area of the electrotechnical interests,

[216] *Id.* at art. 2.8.1.

[217] S*ee also* Shamir-Borer, *supra* note 176, at 5647 (pairing international standards with recommendations to ISO members).

[218] ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art.5.

[219] Further in the discussion we will deal with some of them, such the ANSI system.

[220] *See* generally *Who we are*, IEC, http://www.iec.ch/about/profile/?ref=menu (last visited June 15, 2014).

bringing together parties from different areas of the world, ranging from companies to industry associations, educational institutions as well as regulatory and governmental bodies.[221]

The IEC shares several elements in common with the ISO, up to the point that the two systems of standardization are often identified as a comprehensible and unified structure.[222]

The IEC management resembles the one of the ISO. On top of the overall framework seats the Council, endowed with legislative functions and composed of the Presidents of all IEC Full Member National Committees, the current IEC Officers and all Past Presidents, the Council Board members. Its operative organs are the Council Board (CB) and the Executive Committee, this last one furnished with a central office.[223]

The standardization process is overseen by the Standardization Management Board (SMB), whose role is similar to the one performed by the TMB in the ISO framework.[224]

At the bottom of the pyramid there are the technical committees – responsible of the standardization process itself –, the technical advisory committees and several strategic groups.[225]

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[221] *See* generally *Global reach*, IEC, http://www.iec.ch/about/globalreach/?ref=menu (last visited June 15, 2014).

[222] We have mentioned several times the references made in the TBT agreement to the ISO/IEC standardization system.

[223] For the detailed organigramme, *see* IEC, *supra* note 220.

[224] It should be noted that, besides the SMB, the IEC counts two other different management structures, the Market Strategy Board (MSB) and the Conformity Assessment Board (CAB), respectively in charge of the market strategy and the conformity assessment spheres.

[225] The IEC relies profoundly on "system work", collecting, especially in the newer fields of technology, interests and opinions from a large number of stakeholders worldwide.

The work of the committees and the subcommittees is conducted in a way almost equivalent to the one we have already analyzed in depth in the previous paragraph. This strong relationship between the two organizations has matured over a long period of time and has been formalized in 1976.[226] It has been codified in great details in Annex B to the several times mentioned Directive – First Part, with the title of "ISO/IEC procedures for liaison and work allocation".[227]

The possible conflicts which may arise in the distribution of the works between the two organizations are solved on the basis of the principle that the standardization in the electric and electronic engineering field is exclusively referred to the IEC, while the standardization in any other field is devolved to the ISO.[228] When defining the relevant area proves arduous because of the possible mingling of aspects involving both organizations, the distribution takes place by means of mutual agreement.[229]

Possible clashes in the allocation of the works may stem from the activities of a preexisting technical committee or when a new committee is established. In a "subsidiarity" flavor the Annex requires possible conflicts to be dealt with at the bottom of the hierarchy, and to be referred at a higher level only when the lower level has proven unable to solve the impasse.[230]

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[226] *See* ISO Council resolutions 49/1976 and 50/1976; IEC Administrative Circular No. 13/1977.

[227] Annex B to the ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014 is encompassed in the *Consolidated ISO Support* already, *available at* http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_iec_directives_and_iso_supplement.htm.

[228] *See* Annex B, art. B.2.

[229] *Id.*

[230] *Id.*

Coordination within the IEC takes place in different ways: by means of formal liaisons between ISO and IEC committees (inter-committee cooperation); through organizational consultations, normally involving experts and representatives of the CEOs in cases where technical coordination may produce a lasting effect on the future works of the organizations; through decisions on the allocation of work by the TMB or the SMB or, when necessary, by the ISO/IEC Joint Technical Advisory Board (JTAB),[231] whose function is to foster the joint programming and to supervise its possible realization.[232]

When a proposal for the establishment of a joint technical committee has been made, unless an unanimous vote in favor has been expressed, a meeting of experts in the field is convened with the representatives of the Chief Executive Offices. These experts meet in order to evaluate the best allocation of the work, which can take place through the establishment of a technical committee or in a different way.[233]

The Annex has considered the risk of possible overlaps between the works of the organizations and for this reason it has encouraged both systems to entrust the work of each other.[234]

The modes of cooperation of such entrusted committees are substantially five, namely: the Informative Relation (concerned principally with the exchange of information); the Contributive Relation (where one of the organizations leads the work while the other makes written contributions); the Subcontracting Relation (where one of the organizations

[231] *Id.*

[232] ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.3.

[233] *See* Annex B, art. B.3.

[234] *See* Annex B, art. B.4.2.1.

conducts the work in full but refers a specific part to the second organization, due to the level of specialization of the committee operating in that context); the Collaborative Relation (where one organization is in charge of the activities but the work sessions and meetings receive delegates with observer status from the other institution); the Integrated Liaison (where both the Joint Working Groups and Joint Technical Committees ensure integrated meetings for the realization of standards characterized by an equal degree of participation).[235]

It is hard to grasp substantial differences in the way the IEC manages the standardization process. Except with regard to the time required for determined operations (for instance, the publication of a standard has to be completed within one months in the ISO, within 1,5 months in the IEC; an appeal to any decision issued in the process of standardization can be presented by a national body within 3 months in the ISO system, only two months in the IEC)[236] the two standardizing bodies have reached such a level of integration that, nowadays. it would be hard to think of them as totally separate entities.

II.4: THE AMERICAN SYSTEM OF STANDARDIZATION AND ITS INTERNATIONAL REACH

May standards characterized by a solid link with a determined State be branded as "international" and, to that extent, fall under the definition of "international standards" encountered in Annex 1.2 of the TBT Agreement?[237] And, considered the new relevance attributed to the institutions responsible of standardization by the *Tuna II* decision, may

[235] *See* Annex B, art. B.4.2.2.

[236] *See* ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 2.8; 5.

[237] For further details, recollect the analysis undertaken in paragraph I.5, dealing with the relationship between the definition of international standards in the WTO/TBT Agreement and in the ISO/IEC system.

standard bodies "national in nature" be considered as effective producers of international standards?[238]

This and the next paragraph will try to give an answer to these questions by briefly analyzing the structure and the standardization machine of some of the most well-known standards developers around the globe.

When tackling the analysis of the American Standardization System, the one which has more harshly contested the monopoly of the ISO in the TBT Agreement,[239] we should immediately take note of a crucial difference which characterizes the way that system displays itself today: "decentralization".[240]

In our understanding, decentralization means that the numerous associations, institutions and bodies whose main role is the production of standards do not refer to a leadership center: they simply do not need one.

The institution which has been charged with the role of accrediting standard developers and acknowledging their standards as valid "American National Standards" is the American National Standards Institute (ANSI).[241] Founded in 1918 as a non-for-profit organization, ANSI proclaims itself as that institution whose mission is "*To enhance both the*

[238] For further details, recollect the analysis undertaken in paragraph I.6, discussing the recent jurisprudence of the Appellate Body interpreting the TBT Agreement.

[239] Recollect the analysis conducted at the beginning of this chapter.

[240] Some authors even object that defining the American way a proper "system of standardization" is misleading. *See* KRISLOV, *supra* note 166. *See also* SCHEPEL, *supra* note 9, at 145; Christopher S. Gibson, *Globalization and the Technology Standards Game: Balancing Concerns of Protectionism and Intellectual Property in International Standards*, 22 Berkeley Tech. L.J. 1403, 1413 (2007).

[241] For some details on ANSI (on the institution as well as for purchasing standards), *see About Ansi overview*, ANSI, http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1 (last visited June 15, 2014).

global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity."[242]

Under the Memorandum of Understanding (MOU) signed by the ANSI and the National Institute of Standards and Technology (NIST) in 2000,[243] ANSI is asked to oversee the activity of standardization and to ensure that certain basic principles (such openness, balance of interests, due process and consensus) are respected.[244]

The structure of ANSI, differently from the one of the ISO analyzed above, resembles more the framework of a common American corporation than the one of a public body.[245] An example is the fact that its structure is governed by bylaws, revised last time in 2004.[246] The most peculiar element is the presence of the so called Membership Fora; they are four, namely the Company Member, Consumers Interest, Governmental Member, Organizational Member (all but the Consumer's forum representing a determined membership of ANSI).[247]

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[242] *Id.*

[243] Memorandum of Understanding between ANSI and NIST, *available at* http://publicaa.ansi.org/sites/apdl/Documents/About%20ANSI/Memoranda%20of%20Understanding/ansinist_mou.pdf .

[244] *See* Memorandum of Understanding between ANSI and NIST, 1998, art 3.3.

[245] For some further details on the structure of ANSI, *see Ansi organization*, ANSI http://www.ansi.org/about_ansi/organization_chart/chart.aspx?menuid=1 (last visited June 15, 2014). *See also* SCHEPEL, *supra* note 9, at 146-147.

[246] *See generally* ANSI By-laws, 2009 Edition, *available at* http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=874 .

[247] *See* ANSI, *supra* note 241.

The Board of Directors of ANSI is composed by several members.[248] Some of them are appointed by the Board Nominating Committee while others are members *ex officio*, often covering the role of chairman in one of the Committees of ANSI.[249]

As for the ISO, also ANSI's activity is dominated by technical committees. However, their role is partially different because their major task is to "resolve turf battles among organizations", leaving the technical aspects of standardization to the organizations themselves.[250]

The level of discretion enjoyed by the technical committees in the ANSI system is considerable, especially with regard to the drafting of their own rules and procedures. This is an important difference with the ISO/IEC framework, even though certain forms of approval of the procedural models adopted are required also by ANSI.[251]

ANSI has issued special guidelines that should lead the activity of the standards developers willing to be accredited. The guidelines focus on the principles of due process, lack of dominance (intended as the lack of a dominating interest which may overcome other interests in terms of representation and opportunities), openness and harmonization, with the purpose of developing standards according to the principle of "consensus".[252]

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[248] *See* ANSI Bylaws, approved 2009, art. 3.02.

[249] *Id.*

[250] *See* SCHEPEL, *supra* note 9, at 147.

[251] *Compare, e.g.*, art. 1.1 ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014 *with* art. 6.16.5.1 ANSI Bylaws (2009). *See also* SCHEPEL, *supra* note 9, at 147 (analyzing the ANSI Procedures, Annex A).

[252] *See* ANSI Essential Requirements 2013, *available at* http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2013_ANSI_Essential_Requirements.pdf .

Due process, considered the core of the "consensus" required in standardization, is understood as follows:

"Any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal."[253]

The significant attention on the search for consensus is articulated in the presence of an appeal system through which those who object to a determined standard and have been voted against may still appeal in order to see the issue redressed. To that extent, they have also the right to be informed about the appeal procedure.[254] With regard to the appeals available, it is remarkable that the ANSI system grants two different forms of appeal: one at the standard developer level and one at the ANSI level.[255]

It seems hard to understand how standards that qualify as American standards should, at the same time, be recognized as "international standards". Especially the requirement of "openness to the relevant bodies of all Member States"[256] may be problematic when looking into the functioning of the most part of American Standards developers, which tend to consider "openness" as a component of "procedural consensus",[257] sometimes limiting the bodies ultimately admitted to the procedure itself.

[253] *See* ANSI Essential Requirements 2013, art. 1.0.

[254] *Id.* at art. 2.6.

[255] *See* SCHEPEL, *supra* note 9, at 149.

[256] For further details, recollect the analysis undertaken in paragraph I.6., discussing the recent jurisprudence of the Appellate Body interpreting the TBT Agreement.

[257] *See* ANSI Essential Requirements 2013, art. 2.1.

Undoubtedly, certain American Standards have reached such a level of internationality and general acceptance by the market that their adoption by a determined regulating body – even as a substitute for competing ISO or IEC standards – would probably avoid a conflict with the provisions of the TBT Agreement.

A clear example is provided by the standards produced by ASTM International, once called American Society for Testing and Materials (ASTM), whose procedures are based on consensus and whose admission is open to members from all over the world (today counting contributions coming from around 150 different countries).[258] The use of "consensus – based" procedures is highly regarded in the mission statements of ASTM and guarantees that strong relationship between the ASTM model and the ANSI system of certification already addressed above.[259]

Probably harder to reconcile with the principles of the TBT Agreement because of their more traceable American root, ASME standards are also well known all over the world.[260] Especially the ASME Boiler and Pressure Vessel Code, adopted by all 50 States and numerous municipalities and territories of the United States – sometimes without significant modifications or only minor changes – is employed in 100 countries around the world and has been translated in several languages.[261]

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[258] *See About ASTM International*, ASTM, http://www.astm.org/ABOUT/overview.html (last visited April 18, 2014).

[259] *Mission Statement*, ASTM, http://www.astm.org/ABOUT/mission-statement.html (last visited April 18, 2014).

[260] *See Who we are*, ASME, https://www.asme.org/shop/standards?cm_re=About%20ASME-_-GlobalHeader-_-Standards (last visited April 18, 2014).

[261] For further details, *see* ASME, *supra* note 19.

Conclusively, the American experience with regard to standardization has definitively an international reach that should be taken in due account when evaluating the possibility that standards produced in that context may be considered "international standards". However, as we will examine in the last chapter, the United States and the European Union have taken different position with regard to the recognition of American standards in their standardization regimes.

II.5: Other Relevant International Standards: The Existing Conflict with The ISO/IEC and the TBT Regime

It is certainly impossible to consider the activity of all the standards developers around the world and the way they are affected by the Global Administrative Law Principles analyzed so far.

As we have seen, the language of the treaty may be open to distortions and misunderstandings. In this section we will provide two examples of these possible interpretative dilemmas.

The first case is related to the WLAN Authentication and Privacy Infrastructure (WAPI) security standard for wireless devices, a standard developed by the Chinese governmental standard-setting bodies that should have been incorporated in the devices imported or sold into China in pursuance of a decree of the Chinese standard body itself.[262]

[262] *See generally* Gibson, *supra* note 240, at 1404-1406. *See also* Zia K. Cromer, *China's Wapi Policy: Security Measure or Trade Protectionism?*, Duke L. & Tech. Rev, at 18 (2005) (analyzing the concern of the wireless industry once the decree was emanated).

Because the standard adopted all over the world for comparable devices is substantially different, this coercive approach would have significantly impaired the capabilities of companies to export to China, unless they had purchased the standard and implemented it in their production.[263]

The development of the new encryption standard was motivated by the intention of the Chinese institutions to increase the level of data protection that the notorious standard 802.11 Wireless Fidelity (Wi-Fi) was unable to provide.[264] Unsuccessfully, China sought to obtain recognition of the WAPI standard at the ISO level.[265]

In addition to the public policy issue whose relation with the phenomenon of standardization is still largely unexplored, this conflict presents the interesting quarrel of the lucrative nature of international standards and their relationship with Intellectual Property protection.[266]

Particularly interesting to our purposes is the nature of the international standardizing bodies in China, which are struggling to see themselves recognized as international standards developers in compliance with the requirements of the TBT Agreement.

The Chinese Government has invested relevant economic resources in the development of an efficient standardizing framework. The SAC (Standardization Administration of China), endowed with vice-ministerial status under authorization from

[263] *See also* Cromer, *supra* note 262.

[264] *Id.*

[265] *Id.*

[266] An overview of these themes is presented in the conclusion.

China's State Council, is managed by the AQSIQ (Administration for Quality Supervision, Inspection and Quarantine), working closely with the Chinese Ministry of Information Industry (MII).[267]

Also the SAC functions through the work of several specialized committees. It looks after the harmonization of standards adopted in China, the coordination of different standardizing bodies and the proper functioning of the overall standardization machine. Moreover, SAC represents Chinese interests in the ISO/IEC system.[268]

Nevertheless, the similarities of the Chinese standardization framework with the more developed European and American systems do not solve the still relevant deficiencies in transparency and openness, which constitute the core of the recognition of standardizing bodies under the TBT Agreement.

As some authors have pointed out, foreign stakeholders are still asked to face a number of encumbrances in order to affect the standardization process in China, being often limited to a role of mere observer. Especially in the most highly sophisticated areas of the technological development, foreign stakeholders are frequently barred from participating in the drafting of standards altogether.[269]

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[267] *See* Standardization Administration of China, CHINACSRMAP, http://www.chinacsrmap.org/Org_Show_EN.asp?ID=533 (last visited April 18, 2014).

[268] *Id.; see* Christopher Gibson, *supra* note 240, at 1413-1416.

[269] *See* Gibson, *supra* note 240, at 1416 -1417.

Hence, the opaqueness of the procedures and the strong guidance of public powers in the standardization process constitute a hindrance to a further recognition of Chinese standards as international standards under the conditions of the TBT Agreement.[270]

The second example of interpretative disagreement under the TBT Agreement is related to the new legislation mandating the plain packaging of cigarettes implemented by the Australian Government in 2012, which is producing friction with regard to the use of the standards available on the matter.[271] That legislation forbids any form of branding, logos or symbols on tobacco packaging, and it requires that packets be olive green in color, with health warnings clearly visible on the packets.[272]

The conflict is taking place with regard to the use made by the Australian Government of the standards established by the World Health Organization "Framework Convention on Tobacco Control".[273]

It is crucial to balance the obligation to use an international standard – in this case, a standard created in the undeniably open context of the World Health Organization – with the possibility for a State to pursue its policies and preserve its sovereign ability to regulate.

Interestingly, the TBT has envisaged this conflict in article 2.4, providing that National States are required to make use of available standards

[270] *Id.*

[271] *See generally Tobacco Plain Packaging Act 2011* No. 148 (2011).

[272] *See* GUZMAN & PAUWELYN, *supra* note 14, chapter 19 new edition at 31-33 (forthcoming).

[273] The Convention on Tobacco Control, *available at* http://www.who.int/fctc/en/.

"except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."[274]

However, as the Australian situation is showing, the balancing test encompassed in article 2.4 results particularly delicate. Especially when several standards are available, it is evidently hard for national bodies to decide which model should be given precedence.

[274] TBT art. 2.4. For a deep analysis of the publicly relevant motives which can justify exceptions to art. 2.4, *see also* Lawrence A. Kogan, *EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three- Dimensional Trade Strategy*, The National Foreign Trade Council, Inc. (August 2003), 10-11, available at http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_eu_reg_final_e.pdf (last visited 30 May, 2013).

CHAPTER III:

LEGAL EFFECTS OF THE INTERNATIONAL TECHNICAL STANDARDS IN THE U.S. AND THE EU

III.1: RECOGNITION OF THE INTERNATIONAL TECHNICAL STANDARDS IN THE U.S.

As it will become clearer in this final chapter and as we have already had an opportunity to appreciate in the previous one with regard to the Chinese WAPI standard, the way standardization is regulated reflects governmental policies which are strictly interrelated to the constant demand for harmonized standards expressed by the global industrial community.[275]

When dealing with the way international standardization is administered in the United States and the European Union, several differences can be perceived at a glance; this seems comprehensible if we consider the different nature of standards developers in the two jurisdictions.

On one hand, European standardizing bodies – relying on their privileged connection with the ISO/IEC systems[276] and having emulated that model – are granted a certain protection by the public. They have often been subsidized, centralized and coordinated by the European and National institutions, towards the realization of determined economic and regulatory goals.[277]

[275] *See* SCHEPEL, *supra* note 9, at 2.

[276] A complete analysis of this phenomenon will take place in paragraph III.2.

[277] *See* Mattli & Büthe, *supra* note 174. *See also* Chalmers, *supra* note 32 (pairing the effect ISO/IEC standards have in the world trade arena with the effects CEN standards have in the European context).

American standardizing bodies, as we have already seen in the last chapter talking about the ANSI system, look more like American corporations than like public administrations, [278] being often governed by private law sources and instruments.[279]

Our discussion is rendered more complex by the international nature of the standards we are analyzing in this chapter. ISO standards, for instance, do not only provide the basis for the drafting of administrative regulations by the administrative agencies or the benchmark to which market players are encouraged to direct their efforts;[280] they are frequently adopted by other national (or regional) standards developers as a model for the production of their own standards.[281]

A common trend started in the United States and now spreading also in the European Union, especially with regard to the environmental sector,[282] is the progressive substitution of administrative inspections with compliance systems based on the use of standards agreed upon at the international or the regional level.[283]

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[278] For some further details on the structure of ANSI, *see* ANSI, *supra* note 145. *See also* SCHEPEL, *supra* note 9, at 146-147.

[279] *See* ANSI Bylaws, approved 2009.

[280] *See* Donald A. Carr & William L. Thomas, *Devising A Compliance Strategy Under the Iso 14000 International Environmental Management Standards*, 15 Pace Envtl. L. Rev. 85, 87 (1997) ("Companies achieving certification under such regimes may expect enhanced relations with employees, the public, and government.").

[281] *See generally* Agreement on Technical Cooperation between ISO and CEN ("Vienna Agreement"), Basic Principles, (1991) art. 3, *available at* http://www.cencenelec.eu/intcoop/StandardizationOrg/Pages/default.aspx (pointing out that the transfer of work from the CEN to the ISO is the preferred route for the standardization process, even though it is not the only one).

[282] The environmental sector represents one of the most developed when it comes to technical standardization. *See generally* Nicola Greco, *Crisi del diritto, produzione normativa e democrazia degli interessi. Esemplarità della normazione tecnica in campo ambientale*, Studi parlamentari e di politica costituzionale 9, 9-30 (1998); Iannuzzi, *supra* note 9, at 137-180.

[283] *See* art. 30 of D. L. n. 112 of 25 June 2008, containing 'Urgent provisions for economic development, simplification, competitiveness, the stabilization of public finance and tax equalization' (stating that 'for

For instance, the Office of Wastewater Management and the Office of Compliance of the Environmental Protection Agency (EPA) have initiated a pilot program by means of which certain administrations, comprehending six municipalities as well as a State organization and one country, are developing an ISO 14001 EMS facility / organization of their choice with the purpose of having it in place at the end of the period set by the program.[284]

The administration of standardization in the United States has gone through a long and conflicted path.[285] Interestingly, the legislation on the matter is pretty bony while guidelines and memoranda abound.[286]

Inspired by the so called "negotiated rulemaking", approach popular in the late 1970s that required "consensus" (defined as unanimity) for the adoption of any regulation,[287] the National Technology Transfer and Advancement Act has constituted the crucial step in the recognition of standards as a relevant tool in the work of American public agencies.[288]

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companies subject to environmental certification or issued by an accredited certifying entity in accordance with international and European standards, periodic inspections carried out by certification bodies replace administrative controls or additional administrative verification, including for the purpose of renewal or updating of authorizations for activity); *see also* Carr & Thomas, *supra* note 280, at 110 (pointing out, already at that time, that the EPA was evaluating conditional incentives for promoting forms of environmental self-policing and self-disclosure mechanisms).

[284] For further details on the project, *see Implementing ISO 14001 Environmental Management System at the Municipal Level*, EPA, http://water.epa.gov/polwaste/wastewater/Implementing-ISO-14001-Environmental-Management-Systems-at-the-Municipal-Level.cfm (last visited May 13, 2014).

[285] *See* SCHEPEL, *supra* note 9, at 87.

[286] This point will be clarified making reference to several non-binding documents. We have already encountered an example before in our analysis in paragraph II.4 with the Memorandum of Understanding (MOU) signed by ANSI and the National Institute of Standards and Technology (NIST) in 2000.

[287] *See* SCHEPEL, *supra* note 9, at 83.

[288] *Id.* at 88.

The Act was passed in 1995. Besides leading a successful movement towards the use of consensus-based standards by administrative agencies, it is also well-known for its role in the transfer of technology from the government to society, a topic often related to standardization. [289]

The Act has the merit of having modernized the role of the National Institute of Standards and Technology (NIST),[290] endowing it with the task of coordinator and supervisor of the use of consensual standards by Federal agencies.[291] Hence, the NIST is today the responsible of the standards policies in the United States.[292] Certainly, it is fair to underline that it is not the only one, if we recollect the considerable part undertaken by the ANSI in the certification of American Standards.[293]

As for its legal statute, the NIST is a non-regulatory agency operating under the aegis of the U.S. Department of Commerce.[294] Founded in 1901, the NIST is not only involved in standardization, but it pursues several other tasks which should promote the industrial competitiveness of the United States, from the direct promotion and assistance of small manufacturers to the direct involvement in scientific research through the use of the NIST

[289] *See* National Technology Transfer and Advancement Act of 1995, 15 U.S.C. 3701 § 3, PL 104–113, March 7, 1996, 110 Stat 775. *See also* Jack E. Kerrigan & Christopher J. Brasco, *The Technology Transfer Revolution: Legislative History and Future Proposals*, 31 Pub. Cont. L.J. 277, 286 (2002).

[290] *See* 15 USC 3701 § 8, (1996).

[291] *See* 15 USC 3701 § 12 (1996).

[292] *Id. See also* SCHEPEL, *supra* note 9, at 88.

[293] Recollect the role of the Memorandum of Understanding (MOU) signed by ANSI and NIST in 2000, in paragraph II.4.

[294] *See NIST General Information*, NIST, http://www.nist.gov/public_affairs/general_information.cfm (last visited May 13, 2014).

laboratories.[295] Moreover, the NIST is also responsible for the Technology Innovation Program (TIP), successor of the Advancement Technology Program, which has provided cost-shared grants between 2007 and 2011.[296]

Equally involved in the promotion of consensual standards is the Office of Management and Budget (OMB), executive office of the President located in Washington DC, responsible of the assistance of the President in the preparation of the Federal budget and supervisor of the work of the agencies with regard to the respect of the political and administrative guidelines of the Executive.[297]

In 1998 the OMB modified its circular encouraging the use of voluntary standards by federal agencies (Circular A-119) in place since 1982 but scarcely efficient,[298] rendering the use of "voluntary consensus standards" (VCS) mandatory for all federal agencies in their regulatory work; this under the condition that making use of VCS does not trigger a violation of legal obligations and it is not impractical.[299]

To put it differently, federal agencies are discouraged from adopting their own standards (also known as "government-unique standards" or "GUS") and are asked to take in

[295] *Id.*

[296] *See Technology Innovation Program*, NIST, http://www.nist.gov/tip/ (last visited May 13, 2014).

[297] *For more information on the OMB, see Office of Management and Budget: Open Government*, WHITEHOUSE, http://www.whitehouse.gov/omb/open (last visited May 13, 2014).

[298] *See* SCHEPEL, *supra* note 9, at 87-88 (pointing out the inefficiency of the 1982 circular for lack of compulsoriness).

[299] *See* § 6 OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Oct 2 1998.

due consideration those standards which stem from the consensual dynamics of the market, unless doing so may result technically or legally impossible.[300]

This new approach has experienced a limited involvement in the standardization process by the federal agencies, once deeply involved in the work of the technical committees by means of their agents.[301]

The Memorandum for the heads of Executive Departments and Agencies M-12-08, on the "Principles for Federal Engagement in Standards Activities to Address National Priorities", released on January 2012 by the OMB together with the Office of Science and Technology Policy (OSTP) and the Office of the United States Trade Representative (USTR), efficiently describes the ambivalent technique adopted by the federal government in dealing with standardization. [302]

On one hand, the governmental action is rather delimited and relies deeply on the private sector, regarding openness, transparency, and multi-stakeholders engagement as the engine of the standards strategy.[303] On the other hand, where a relevant national priority is identified, the active engagement of the Federal Government is seen as a positive tool to hasten the development and implementation of the standards needed in order to support the

[300] *See* SCHEPEL, *supra* note 9, at 88.

[301] *See id.* at 89 (analyzing the decrease in agency staff participation as a phenomenon at the odds with the progressive improved reliance of federal agencies on standards produced by the market). *See also* the Memorandum for the heads of Executive Departments and Agencies M-12-08, on the Principles for Federal Engagement in Standards Activities to Address National Priorities (Jan. 17, 2012) *available at* http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08_1.pdf (last visited June 13, 2014).

[302] *See* Memorandum for the heads of Executive Departments and Agencies M-12-08, *supra* note 301.

[303] *Id.*

scientific progress in the more sensitive areas.[304] Thus, the Federal Government has become a catalyzer, capable of interacting with private standards developers both as an active proposer and as a generous contributor.[305]

Two examples of this larger governmental involvement in standardization are provided already in the memorandum itself with regard to the economic efforts the Federal Government has ploughed in the health care technology and the environmental sector.[306]

In these areas, where interoperability represents a crucial need considered the risk of premature obsolescence, the Government is making technology investments such as electronic health record systems and smart grid technologies in order to obtain improvements in the overall outcomes as well as productivity gains.[307]

Coherently with the OMB Circular A-119 encountered above, the Memorandum warns that, in the event the Governmental involvement is retained necessary because a national priority has been identified, it is important for the Federal Government to clearly define the breadth of its intervention, to engage private sector stakeholders at the earliest stage possible in the process of identifying technology, regulatory, and/or procurement objectives, and to make use of broad-based techniques of communication, in the respect of the principles of transparency and openness.[308]

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[304] *Id.*

[305] *See id.* at 3 (describing the role of the Federal Government as constantly changing, ranging from mere user of standards to participant, facilitator, advocate, technical advisor/leader, convener, or source of funding).

[306] *See id.* at 2.

[307] *Id.*

[308] *Id.*

The memorandum is also detailed with regard to the responsibilities of the agencies. For instance, it requires them to clearly specify the reasons for their willingness to be more consistently involved in the standardization process, explaining why the standardization as shaped by private developers is retained deficient with respect to some vital public purposes. It also mandates the "intra and inter-agency coordination of engagement in standards development activities" and the use of the existing processes whenever this is possible, leaving the possibility of creating new procedures to the cases of insolvable conflict.[309]

Finally, the Memorandum requires agencies to be consistent in their involvement in standardization. Agencies should honor their commitment both in terms of resources invested (in the limits of their budget capability) and with regard to the use of the standards produced through the collaborative procedure.[310]

Furthermore, federal agencies should take in consideration the effect of standards on the competitiveness of the United States and, to that extent, they are encouraged to seek the guidance of the USTR with regard to the the impact of standardization on the administration of international trade.[311]

The actual structure of the OMB Circular A-119 is now under debate and some commentators have solicited the possibility of a modernization of the Circular in the light of

[309] *Id.* at 4 (describing the required dialectic procedure as a two-way communication with private sector interests).

[310] *Id.*

[311] *Id.*

the changes that have taken place during these fifteen years.[312] The core tenets that have inspired the possibility of a revision have not only further stressed the importance of encouraging the use of private standards by the federal agencies; they have taken in due consideration the growing phenomenon of international standardization and the obligations arising under the international agreements, like the ones we have analyzed with regard to the TBT and the SPS Agreement.[313]

These proposals stem in part from a series of executive orders which have followed the circular: Executive Order 13563 ("Improving Regulation and Regulatory Review"), which emphasized that the U.S. regulatory system "must protect public health, welfare, safety, and the environment while promoting economic growth, innovation, competitiveness, and job creation"; Executive Order 13609 ("Promoting International Regulatory Cooperation"), which sought to diminish "unnecessary differences in regulation between the United States and its major trading partners through international regulatory cooperation", encouraging the development of Federal strategies to promote internationally good regulatory practices; Executive Order 13610 ("Identifying and Reducing Regulatory Burdens"), which, besides institutionalizing the "retrospective review mechanism set forth in Executive Order 13563", required agencies to reduce the so called "cumulative effects", including the cumulative burdens of regulation.[314]

The comments received by the OMB, originating from a diversified set of stakeholders (academics, private citizens as well as public interest groups and – of course –

[312] A complete analysis of the proposals for a modification of the Circular is *available at* http://www.whitehouse.gov/sites/default/files/omb/inforeg/revisions-to-a-119-for-public-comments.pdf where several issues are treated in order to solicit public comments on the possibility of the revision.

[313] *Id.*

[314] *Id.*

standards developers), have stressed the importance of favoring voluntary consensus standards even over other types of voluntary standards not based on consensus.[315] This is particularly relevant when we analyze the influence of international standards like the ISO standards on American standardization, considered that the definition of "consensus" elaborated by American standards developers does not correspond to the one framed in the ISO/IEC system.[316]

Furthermore, the comments have called upon a redrafting of the circular in order to strengthen the procedural rigor involved in the analysis of the adequacy of technical standards operated by the agencies with regard to the needs with which the agencies are asked to deal.[317]

Pursuant to Recommendation 78-4 of the Administrative Conference of the United States (ACUS), which has further encouraged the use of voluntary consensus standards by the agencies,[318] the agencies will have to examine both substantive and procedural criteria while deciding to rely on a determined standard.[319] The substantive analysis is mainly related to the technical document itself, the way it is drafted and its requisites;[320] the procedural

[315] *Id.*

[316] Recollect the analysis conducted with regard to the ongoing regulatory competition in paragraph II.1.

[317] *Id.*

[318] *See generally* Recommendation 78-4 Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation (Dec. 14-15, 1978), *available at* http://www.acus.gov/research-projects/incorporation-reference (last visited May 23, 2014).

[319] *See* Whitehouse, *supra* note 312.

[320] *Id.*

analysis, on the other hand, focuses on the way the standard came into existence, with a particular stress on the respect of consensus as a leading criterion.[321]

In any event, the screening of the voluntary standard to be adopted and its suitability takes place individually.[322]

From the point of view of the administrative law scholar, it is of interest to underline that the privileged way for the adoption of standards in the American system is the so called "incorporation by reference".[323] In other words, agencies are allowed to comply with their obligation to publish rules in the Code of Federal Regulations (CFR) by simply referring to standards that have been published or are attached to sources available elsewhere.[324]

While this element has clearly favored the use of voluntary consensus standards by federal agencies, it has also made looser the control on the effective adequacy of the standards incorporated, heightening the risk that non up-to-date regulations are issued.[325] The aforementioned comments to the circular have stressed this problem as well as the other – equally serious and strictly related – of the lack of consistency of some federal agencies: sometimes, regulated entities have been asked to abide by different versions of the same

[321] *Id.*

[322] *See* Recommendation 78-4 Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation (Dec. 14-15, 1978) letter (d) ("[t]he appropriateness of particular voluntary consensus standards for use by an agency in the development of mandatory health or safety regulations should be determined on a case-by-case basis. Of course, before adopting any mandatory standard, the agency should identify a need for doing so.").

[323] A detailed analysis of this process is *available at* http://www.acus.gov/research-projects/incorporation-reference (last visited May 23, 2014).

[324] *Id.*

[325] *See* Whitehouse, *supra* note 312.

standard, with an increase in the compliance costs of standardization for the ultimate market players.[326]

As already stated, one of the themes addressed by the comments is the necessity, for the federal agencies, to take in due consideration the obligations stemming from the international trade law arena. To that extent, it is worth mentioning that Recommendation 78-4 did not even consider international standards but for their explicit exclusion from the range of the recommendation itself.[327]

In order to enhance the awareness the federal agencies have of the international obligations related to standardization, the proposed revision of the OMB Circular not only directs agencies to consult with the USTR – which has statutory authority with regard to the trade law policies involving the United States[328] – but also with the State Department with regard to international obligations other than trade obligations.[329] The revision should also encourage a more structured coordination among the Interagency Committee on Standards Policy ("ICSP"), the Regulatory Working Group, the Trade Policy Staff Committee and its subcommittees for a more coherent analysis of trade obligations.[330]

The overall effectiveness of Circular A-119 is periodically analyzed in quantitative terms by the NIST Report on the Implementation of OMB Circular and PL 104-13, a document prepared by the NIST and presented to the OMB by the U.S. Department of

[326] *Id.*

[327] *See* Recommendation 78-4 Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation (Dec. 14-15, 1978) letter (b).

[328] *See* 19 U.S.C. § 2171.

[329] *See* Whitehouse, *supra* note 312.

[330] *Id.*

Commerce in compliance with the reporting obligations encompassed in the OMB Circular A-119 and the National Technology Transfer and Advancement Act already mentioned above.[331] The most recent reports have underlined a positive trend in terms of reliance on VCS, considered that only a limited number of agencies have preferred to develop their own standards and just around 50 GUS are currently preferred to VCS.[332] Unsurprisingly, the most conservative administration is the Department of Defense (DoD), which, nonetheless, has developed a remarkable "VCS-friendly" policy, substituting an enormous number of GUS with voluntary standards.[333]

Even though the report does not deal specifically with the treatment international standards have received in the American standardization system, we can make some conclusive remarks on the topic thanks to the analysis conducted in the previous chapter.

Especially due to the recent increasing involvement of ANSI in the works of the ISO and IEC systems, the American standards developers being represented in 80% of the Technical Committees and leading 20% of them,[334] it is our understanding that the incorporation of international standards in the United States will find less hindrances in the upcoming future. This also because international standards, agreed at the ISO/IEC level with the ANSI participation, may have already gone through the filter of the ANSI dialectic

[331] *See generally* NIST Fifteenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment (Jun, 2012) *available at* https://standards.gov/nttaa/resources/nttaa_ar_2011.pdf .

[332] *Id.*

[333] *Id.*

[334] For further details on the participation of ANSI in the ISO, *see ISO Programs*, ANSI, http://www.ansi.org/standards_activities/iso_programs/overview.aspx?menuid=3 (last visited May 23, 2014).

machine we have summarized above,[335] making the problem of the different interpretation of "consensus" of minor importance.

One clear interpretative problem is constituted by the relationship among standards admitted in the WTO, in the ISO and the American system, given their different nature. As we have seen, the ISO contemplates both standards that are voluntary and that are not voluntary.[336] The WTO only refers to standards that are voluntary, but does not require "consensus" as a constitutive criterion in order to determine which standards are to be preferred while implementing a new technical regulation.[337]

The American favor for the use of voluntary standards finds as a precondition their foundation on "consensus" and, hence, the activity of voluntary consensus standards bodies.[338] The language of the Circular A-119 resembles the parameters encountered when we have examined the ANSI's reference to "consensus" as one of its inspiring criteria in the certification of American standards developers.[339] These parameters include many of the

[335] Recollect the analysis undertaken in II.4.

[336] TBT Annex 1.

[337] Recollect the analysis conducted with regard to the substantial indifference expressed by the Appellate Body with regard to the necessity of basing technical regulations on consensus-based standards in paragraph I.5.

[338] *See, e.g.,* Recommendation 78-4 Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation (Dec. 14-15, 1978) letter (b). *See also* § 3 (f) OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Oct 2 1998.

[339] *See also* § 4 (a) OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Oct 2 1998 ("Voluntary consensus standards bodies are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures.").

elements that the Appellate Body in *Tuna II* has predicated as necessary for a standard body in order to qualify as "international" for the purposes of the TBT Agreement.[340]

These discrepancies might have represented an insurmountable obstacle in the event a determined standard widely accepted by market players resulted not complying with the preconditions imposed by ANSI with regard to consensus. However, both the actual version of the Circular and its proposed modification encourage federal agencies to consider international standards in procurement and regulatory applications in order to promote trade and implement the provisions of international treaty agreements.[341]

III.2: RECOGNITION OF THE INTERNATIONAL TECHNICAL STANDARDS IN THE EU

The European Court of Justice has only sporadically treated the argument of standardization, mainly in connection with competition law cases.[342] Differently, as it will be shown below, standardization in the EU has soon become a crucial topic in terms of governance, requiring consistent efforts towards harmonization from the European rulers.

This is a preliminary difference between the European and the American system of standardization, where not only the Congress but also the Supreme Court have often

[340] *Compare, e.g.*, § 4 (a) OMB Circular A-119 ("A voluntary consensus standards body is defined by the following attributes: (i) Openness; (ii) Balance of interest; (iii) Due process; (vi) An appeals process; (v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.") *with* AB Report *U.S.-Tuna II* ¶ 364.

[341] *See, e.g.,* § 6 (h) OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Oct 2 1998.

[342] *See, e.g.,* Joined Cases 96 to 102, 104, 105m 108 and 110/82, Iaz and others v. Comm'n E.C.R. 3369 (1983).

intervened in order to strike down the abuses committed by the standards developers, principally (but not only) with regard to antitrust law.[343]

Since its very beginning, the phenomenon of standardization in Europe has been intertwined with the need to create a common market that should have been the connecting tissue of the European Union.[344] To that extent, if we recollect the reasons why the Members States of the WTO found necessary to draft the SPS and the TBT Agreements in the first place, it is possible to perceive some analogies between the European Union and the WTO.[345]

From a general point of view, it is worth examining the treatment of standards in the European legal framework. In the opinion of scholars, both standards and technical regulations do not squarely fall under the coverage of article 34 of the TFEU. It has been for this reason that standards have required a handling different from the one adopted for quantitative restrictions, even though classical decisions like *Van Gend en Loos* and *Cassis*

[343] *See, e.g.*, Am. Soc. of Mech. Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 556, 572 (1982); Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 496-497 (1988).

[344] For an introductory analysis of the relevance of the single market in the political dynamics of the European Union, *see generally* LUIGI DANIELE, DIRITTO DEL MERCATO UNICO EUROPEO. CITTADINANZA, LIBERTÀ DI CIRCOLAZIONE, AIUTI DI STATO 1-25 (Giuffrè, 2012); SCHEPEL, *supra* note 9, at 37-39. *See also* Sabino Cassese, *La costituzione economica europea*, Rivista Italiana di diritto pubblico comunitario 907, 907-915 (2001) (stressing the role of technical harmonization to foster the freedoms of movements).

[345] Recollect the analysis related to the origins of the TBT Agreement in paragraph I:2. *See generally* Christian Joerges, *Constitutionalism in Postnational Constellations: Contrasting Social Regulation in the EU and in the WTO*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 491, 491-495 (Oxford and Portland Hart, 2005) (pairing the systems of the European Union with the WTO and noticing several points of commonality).

de Dijon have certainly influenced the choices of EU rulers with regard to the method to elect in the administration of standardization.[346]

Schepel points out that, because "normative and decisional supranationalism" were impractical,[347] the only viable path for the administration of standardization in the European Union was the privatization of governance.[348] This goal has been realized thanks to two legal mechanisms: the Directive 83/189/EEC, also known as "Information Directive", supplemented and improved by Directive 98/34/EC; the so called "New Approach".[349] For the purposes of our analysis, mainly regarding international standards as opposed to national and regional standards, the second of these normative tools is more relevant. Nonetheless, it is worth spending some words on the features of the Information Directive, which has deeply influenced the dialectic process characterizing the European system of standardization.[350]

The Information Directive mandates all national institutions willing to engage in standards programs to inform the Commission and the European standards bodies – on an annual basis – with regard to the standards programs initiated.[351] However, the duties to inform are slightly different with regard to the nature of the document taken into account. When Member States are willing to adopt a technical regulation, the Commission shall be

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[346] *See also* SCHEPEL, *supra* note 9, at 46-50; Chiti, *supra* note 37, at 4007. For a concise analysis of the dialectic dynamics that involve the European and National administrative laws, especially with regard to "mutual recognition", *see generally* Sabino Cassese, *Diritto amministrativo europeo e diritto amministrativo nazionale: signoria o integrazione?*, Rivista italiana di diritto pubblico comunitario 1135, 1135-1140 (2004). With a more specific focus on mutual recognition in pharmaceutical products, *see* Cassese, *L'arena pubblica*, *supra* note 34 at 637-640.

[347] *See* SCHEPEL, *supra* note 9, at 49.

[348] *Id.*

[349] *Id.* at 63.

[350] *Id.* at 51.

[351] *See* Directive 83/189/EC art. 2.

furnished with the draft of the document, except in the event the regulation constitutes the "transposition" of an international or European standard, in which case such communication is not necessary.[352] On the other hand, when the national standards bodies wish to produce a new standard, they – and not the Member States to which they refer – have to inform the Commission and the European standards bodies, with the possibility for the Commission to call upon the creation of a new European standard.[353]

Some commentators have stressed how the role of the Commission, unable to cope with the technical aspects of standardization that are today in the hands of the European standards bodies, [354] has been fundamental in monitoring compliance with standstill obligations.[355] The Commission has also promoted "active harmonization" by requesting the creation of new European standards from CEN and CENELEC.[356]

To our purposes it is worth underlining that the directive seems to grant a safe harbor for technical regulations and standards based on international and European standards.[357] We will have to come back to the reasons of the equal treatment of international and European standards in the following pages.

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[352] *See id.* at art. 8.1 ("Member States shall immediately communicate to the Commission any draft technical regulation, except where such technical regulation merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a brief statement of the grounds which make the enactment of such a technical regulation necessary, where these are not already made clear in the draft.").

[353] *Id.* at art. 2.1. *See also* SCHEPEL, *supra* note 9, at 51 (criticizing this difference as incoherent with the main purpose of granting the freedoms of movement).

[354] *See* SCHEPEL, *supra* note 9, at 59.

[355] *Id.* at art. 61.

[356] *Id.*

[357] *See, e.g.*, Directive 83/189/EC art. 8.1.

The directive has set up a system by means of which the Member States, once promptly notified by the Commission with regard to the existence of a new national technical regulation, are allowed to make comments to it.[358] An eventual further objection to the draft regulation triggers a standstill period that can be doubled in the event the Commission plans to adopt a directive regarding the same subject.[359]

Among the achievements of the Information directive it is also worth mentioning the calibration of the terms that relate to the standardization process,[360] with the distinction among technical specifications, technical standards and technical regulations that has certainly been beneficial to the whole European standardization system.[361]

A major success in the administration of technical standards has been brought by the "New Approach", so defined in order to stress the substantially different model embraced by the European Union at the end of the 1980s. It has been adopted by the Council with a resolution in 1985[362] and it has been unsuccessfully supplemented by a Green Paper in 1990.[363]

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[358] *See* Directive 83/189/EC art. 9.1 ("Without prejudice to paragraph 2, Member States shall postpone the adoption of a draft technical regulation for six months from the date of the notification referred to in Article 8 (1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged must be amended in order to eliminate or reduce any barriers which it might create to the free movement of goods."). *See* SCHEPEL, *supra* note 9, at 51; Chiti, *supra* note 37, at 4007.

[359] *See* Directive 83/189/EC art. 9.2.

[360] *Id.* at art. 1.

[361] *See* Paola Biondini, *Evoluzione, consistenza e prospettive di "norme" e "regole" tecniche nell'ordinamento europeo*, Studi parlamentari e di politica costituzionale 77, 93-97 (2006) (clearly stressing the differences among the definitions). *See* also Ghelarducci, *supra* note 73, at 41-44 (praising the directive for the clarity it has brought about with regard to the distinction between technical standards and technical regulations).

[362] *See* SCHEPEL, *supra* note 9, at 63.

[363] *Id.* at 68-70 (pointing out the failure of such a policy document).

What has been *ex post* defined "Traditional Approach" was characterized by a number of very detailed normative texts (most of the times, directives), laying down the requirements products and services had to abide by in order to be marketable in the EC. That system had predictably high costs, it proved time consuming and it was characterized by the risk that the normative instruments lacked the expected modernity, given the long time required to implement the directives themselves.[364]

The New Approach, on the other hand, is characterized by a high degree of elasticity and relies heavily on delegation in order to reach its goals.[365]

First of all, the European legislator is only in charge of setting forth the "essential safety requirements" products shall respect.[366] Therefore, only the European standards bodies are asked to determine the technical product specifications, whose nature remains voluntary.[367] Once products comply with those standards, they benefit of a "presumption of satisfaction of the essential safety requirements" and are no longer subject to national administrative controls.[368]

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[364] *See id.* (stressing the clash between politics and technique that often provoked the directives to be out of date before even becoming binding legal texts).

[365] *See id.* at 64; Chiti, *supra* note 37, at 4015-4017; Greco, *supra* note 282, at 11. *See also* Magda Bianco & Salvatore Chiri, *Le barriere tecniche al commercio internazionale*, in COMPETERE IN EUROPA: MERCATO UNICO E CAPACITÀ COMPETITIVA DELL'INDUSTRIA ITALIANA 81, 98-100 (Il Mulino Bologna 1993) (sustaining that the New Approach, combined with the European Single Act, has considerably speeded up the procedures for the creation of a single market).

[366] *See generally* Council Resolution on a new approach to technical harmonization and standards (May 7, 1985) (85/C OJ C 136/01).

[367] *See* Annex II to Council Resolution on a new approach to technical harmonization and standards (May 7, 1985) (85/C OJ C 136/01) ("these technical specifications are not mandatory and maintain their status of voluntary standards").

[368] *See id. See also* SCHEPEL, *supra* note 9, at 63.

Under the New Approach, manufacturers keep their right to ignore the standards issued by the European standards bodies.[369] However, if they choose to do so they are forced to comply with the "essential safety requirements" by means of tests, inspections and procedural controls that can take different forms depending on the national authorities in charge and can render the production in several Member States considerably onerous.[370]

It is perhaps for these economic reasons that the New Approach has proven very successful. On one hand European standards become a rather cheap way for manufacturers to penetrate European markets. On the other hand, the Commission, in a manner similar to the one adopted in competition law, delegates to other bodies – in this case, to private standards developers – the administrative function of standardization.[371]

At this point, it is worth spending some words on the actors of the New Approach, with a particular emphasis on the European standards developers. As we have seen, once the Commission has performed its propulsive role, it only performs a function of surveillance of the standardization process, watching over the eventual controversies that may arise among the participants in the production and adoption of standards and the quality of the standards themselves.[372]

The standards bodies that have assumed a relevant role in the European regional standardization are the CEN, the CENELEC and the ETSI. The first two are non-profit

[369] *See* Chiti, *supra* note 37, at 4017.

[370] *Id. See also* Bianco & Chiri, *supra* note 365, at 81-83 (pointing out that not following strategies that abide by the agreed technical standards may make the penetration in the single market very expensive).

[371] *See* SCHEPEL, *supra* note 9, at 67 (stressing how the New Approach has been defined by scholars as a form of "privatization" of Community law).

[372] *See* Chiti, *supra* note 37, at 4009.

technical organizations founded under Belgian law and established in Brussels.[373] ETSI on the other hand, created in 1982 and established in France, has a specific focus on the standardization involving the Information and Communication Technology.[374]

What characterizes the European standardization bodies and especially the CEN and the CENELEC is the similarity with the ISO and the IEC. Both possess a General Assembly that collects the interests of all the national standardizing bodies; both are governed by a president together with an administrative board; both work through the activity of a considerable number of technical committees.[375] However, the two system are characterized by a very different level of independence from public powers.

On one hand, the ISO and the IEC systems are politically independent.[376] On the other hand, CEN and CENELEC are firmly collocated in the European standardization systems:[377] they can be considered private bodies entrusted with *public munera*, public administrative functions. This feature has been taken in due account also in their relationships with ISO and IEC.[378] This lack of independence characterizing CEN and CENELEC can be a persuasive element in order to exclude their "international character" under the requirements set forth in the TBT Agreement.

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[373] *Id. See also Who we are*, CEN, https://www.cen.eu/about/Pages/default.aspx (last visited May 24, 2014). *Who we are*, CENELEC, http://www.cenelec.eu/aboutcenelec/whoweare/index.html (last visited May 24, 2014).

[374] *See Our Global Role*, ETSI, http://www.etsi.org/about/our-global-role (last visited May 25, 2014).

[375] For a complete survey of the composition of the organizations, *see* Chiti, *supra* note 37, at 4010.

[376] *See generally* Eicher, *supra* note 23.

[377] *See, e.g.*, Directive 83/189/EC art. 3.

[378] *See* Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Basic Principles, art. 3 (1991) (expressing respect from the ISO to the role CEN covers within the political environment set both in the EEA and the European Standardization system).

We should now address the effects of international standardization in the European Union. We have dealt with the way standards are received by Member States and how they influence the trade of products in the single market. It should be asked to what extent these considerations are applicable to standards adopted by organizations benefiting from the qualification of "international" as defined in the TBT. To that extent it is worth repeating the great level of interaction and integration existing between the European Standards Developers (CEN and CENELEC) and the ISO/IEC system, a "marriage" that has often worried other standards producers all over the world.[379] Also ETSI has started a partnership with both IEC and ISO, with the goal of reducing duplications in the technical works.[380]

Under the so called "Vienna Agreement" and the twin "Dresden Agreement", ISO and CEN as well as IEC and CENELEC have efficiently structured the respective work, setting up mechanisms for the exchange of information and for the coherent representation of the national standards bodies in both regimes, [381] enhancing the expectations of speed and reliability of the technical work. [382]

Published in 1991 and reedited after one decade, the Vienna Agreement, following the Lisbon Treaty on the exchange of technical information between ISO and CEN, represents a concise document and sets forth the basic principles of their cooperation.[383]

[379] Recollect the criticism expressed by ANSI with regard to the agreements existing between ISO/IEC and CEN/CENELEC in paragraph II.1.

[380] *See International Partnerships*, ETSI, http://www.etsi.org/about/our-global-role (last visited May 25, 2014).

[381] *See* SCHEPEL, *supra* note 9, at 192.

[382] *See* Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Rationales and Objectives, art. 2 (1991).

[383] *Id.*

The agreement is based on the assumption that international standards (produced coherently with the WTO Code of Conduct) are to be given hierarchical priority. Nonetheless, the Agreement recognizes the particular needs of the European standardization community and the right of European standards bodies to develop standards (even substantially) different from the ones framed in the international arena.[384]

Even with regard to the time framework, CEN has the possibility to administer its own schedule and prioritize its work coherently with the needs of the European market.[385]

The functioning of the Agreement recognizes two different procedural models. In the first hypothesis, the ISO leads the technical work; in the second one, the work is led by the CEN. In both cases, the body initiating the standardization process is responsible for the transfer of the documents to the other body for the simultaneous approval.[386]

Technical co-operation between the two standardization bodies is realized in a plethora of different ways and the exchange of information is only the oldest and more elementary one. It can take place in different ways and it often involves the CEN Management Centre and the ISO Central Secretariat through the exchange of work programs, catalogues and even draft standards.[387] Occasionally, ISO and CEN submit relevant and

[384] *Id.*

[385] *Id.*

[386] *Id.*

[387] *See* Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Modes of cooperation, art. 4 (1991).

approved work items within the same scope to procedures encompassing agreements on leadership.[388]

The most relevant tool of cooperation for our purposes is the adoption of existing international standards as European standards.[389] Such possibility may clarify the reasons why the same presumption of satisfaction of the essential safety requirements enjoyed by the regulations and the standards incorporating European standards involves also those regulations and standards that comply with international standards (in this case, provided that the reliance on those standards does not imply hindrances).[390]

The Dresden Agreement, published in 1996, has supplemented the functioning of the "Lugano Agreement" involving IEC and CENELEC in the same years in which the Vienna Agreement was signed.[391]

The level of integration between IEC and CENELEC seems even more structured than the one established in the Vienna Agreement between ISO and CEN. For instance, in the event CENELEC identifies the need to start new works not yet covered by the IEC, it has to ascertain whether the IEC is capable of undertaking those works.[392] Technical work starts in parallel both at the IEC and CENELEC level, regardless of the nature of the action

[388] *Id.*

[389] *Id.*

[390] *See* Chiti, *supra* note 37, at 4018 (underlining the possibility for the European Member States to prohibit the marketability of products retained dangerous for people, animals, plants).

[391] *See generally* Agreement on Common planning of new work and parallel voting between IEC and CENELEC (Dresden Agreement) (1996), reported also in CENELEC Guide n° 13 *available at* ftp://ftp.cencenelec.eu/CENELEC/Guides/CLC/13_CENELECGuide13.pdf (last visited May 23, 2014).

[392] *Id.* at art. 2.1.

undertaken in the standardization.[393] Moreover, procedures for parallel voting are well established and highly encouraged in both systems.[394] It is mainly for these reasons that CENELEC standards are characterized by a very high resemblance to IEC standards.[395]

Conclusively, it may be stated that ISO and IEC standards are easily received by the European system of standardization, either by means of "direct incorporation" (when the National or European Legislator directly refers to the standard in the normative text) or by means of "indirect incorporation" (when the international standard is adopted by the European standard developer in its own standard and then transferred in a normative text).

The condition of standards different from the ones produced at the ISO/IEC level (like the ANSI standards) appears more problematic. Even supposing that some American standards may qualify as international standards, it seems that the European system is still scarcely accessible to international standards originating in contexts different from the ISO/IEC regime because of the strong connection European standards developers have with that model.

[393] *Id.* at art. 2.3.1.

[394] *See id.* at art. 2.3.1.

[395] *See* SCHEPEL, *supra* note 9, at 190-193.

CONCLUSION

International technical standards, as we could often underline in our analysis, are an expression of market economies,[396] though the range of interests to which they relate is not merely economic.[397] Yet, in the institutional framework of the WTO, they have acquired a normative significance, that of being the instrument through which technical harmonization is accomplished on a global scale.[398]

In other words, the WTO, rather than harmonizing national technical regulations – what it could not do –, delegates this task to international standards developers.[399]

[396] S*ee also* Shamir-Borer, *supra* note 176, at 5721 (underlining the fact that the standardization process is in the majority of the cases initiated upon request of the relevant industry).

[397] *See, e.g.*, Kogan, *supra* note 274 (stressing the possibility for States to protect themselves from the ascertainable risk of harm to specific State interests); Bianco & Chiri, *supra* note 365, at 81-90. *See also* Cassese, *Gamberetti, tartarughe e procedure*, *supra* note 11, at 663 (stressing that the permeability of trade is responsible of an extended influence of the TBT on several other connected interests).

[398] Recollect the analysis conducted in the first chapter. *See* Howse, *supra* note 48, at 387 (examining the automatic binding effect of private standards in the TBT). *See* SCHEPEL, *supra* note 9, at 404-405 (underlining that, even when embodied in national regulations, a large portion of the standards we currently adopt find their origin in the global process of standardization).

[399] For further details on the functioning of delegation, *see* Shaffer & Trachtman, *supra* note 174.

Our task herein is to draw some conclusions with respect to the interpretive issues to which technical standardization at the global level gives rise. Mostly, they will refer to the relation between international standardization (and the related regulation of international trade) and constitutional law. It is a relationship that cannot be grasped on the basis of traditional categories of public law,[400] but requires a rethinking of constitutional and administrative law *per se*, more geared to a malleable legal space, structured into several layers which, of necessity, continuously communicate with each other.[401]

As several scholars have pointed out, the WTO suffers, to some extent, from a lack of legitimacy.[402] This becomes clear to the observer with regard to international standardization, where the subjects of the process, existing by virtue of private law and having the juridical form of private institutions, find their (indirect) legitimation in the aforementioned delegation existing in the TBT Agreement.[403]

This rather odd combination of private and public elements, where the technical rules, at the origin, are not conceived as binding norms, proves complex, especially considering the persistent lack of clarity on the features that distinguish a qualified "international body" –

[400] *See* Cassese, *supra* note 37, at 323-325 (sustaining the unsuitability of the traditional ermeneutic tools adopted by administrative law scholars when the global arena constitutes the focus of the analysis).

[401] *See* Auby, *supra* note 5, at 216 (referring to Sabino Cassese's concept of the "conjunctive tissue of globalization"). *See also* Ernst-Ulrich Petersmann, *Multilevel Trade Governance in the WTO Requires Multilevel Constitutionalism*, in CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 5, 5-6 (Oxford and Portland Hart, 2005) (stressing the necessity of a multilevel constitutionalism in order to properly address multilevel trade governance). *But see* Gaetano Silvestri, *Il problema della sovranità nello Stato Pluriclasse*, in DALLO STATO MONOCLASSE ALLA GLOBALIZZAZIONE, 135, 140 (Giuffrè, 2000) (arguing the possibility of applying the traditional concept of subjective sovereignty to the actual phenomena of Global Governance).

[402] *See* Nanz, *supra* note 12, at 62-63 (underlining the different audience governance "beyond the State" has if compared to traditional government activity, where the exercise of the government itself is constantly monitored by the ones who are governed). This problem is not an uncommon one when it comes to global administrations. *See, e.g.*, Dagron, *supra* note 55, at 18-19.

[403] *See* Schepel, *The Empire's Drains*, *supra* note 40 (talking about a "slow motion coup d'etat").

whose standards should be adopted when a new technical regulation is under discussion – from a standard developer which does not meet those very requirements.[404]

Probably because of the crisis that has invested the WTO in the past five years,[405] it is noteworthy the tendency of the recent jurisprudence of the Appellate Body to conduct a broader search in those principles of global administrative law (such openness and transparency) that represent the core tenets of the administrative laws of all countries. These principles may coherently be considered the connecting tissue of the administrative legal culture all over the world and play an important legitimizing role.[406]

To that extent, if the new case law is still vague on the merits of "consensus" as a requirement for the creation of international standards which would then successfully qualify under the TBT Agreement,[407] the decision in *Tuna II* has tried to address the excesses of a blind faith in international standardization, improving the filter mechanism through which international standards are chosen. In their regulatory processes, States are now required to adopt only those standards which are crafted by "recognized bodies", whose membership is open at all time, on a "non-discriminatory basis".[408]

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[404] Recollect the analysis of the case law of the Appellate Body undertaken in paragraph I.6. *See generally* AB Report *U.S.-Tuna II* ¶ 355 – 370.

[405] The starting point of this movement against the WTO and other global administrations may be considered the protest of Seattle. *See generally* Patrick F. Gillham, *Complexity & Irony in Policing and Protesting: The World Trade Organization in Seattle*, in 27 Social Justice 212, 212-236 (2000).

[406] *See generally* AB Report *U.S.-Tuna II* ¶ 355 - 370 (referring broadly to the necessity of openness as a constituting character of standards developers). *See* Cassese, *La funzione costituzionale dei giudici non statali*, *supra* note 64, at 622-625.

[407] *See* Panel Report *United States-Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 7670-7679, WT/DS381/R, (*adopted* 15 September 2011) (objecting to the analysis undertaken by the Appellate Body in *Sardines*).

[408] Recollect the analysis of the most recent decisions of the Appellate Body undertaken in paragraph I.6.

In our opinion, this trend towards more constitutionally tolerable solutions should be praised. Standards agreed upon in broader *fora* may easily be accepted by a larger number of nations. Nonetheless, there is now the risk that only a small number of international standards would successfully pass what is obviously an exacting test.[409]

Another complex problem with regard to the nature of international standards and their legitimacy is in their relationship with intellectual property. International standards are not only often protected by intellectual property law, but are marketable, and their cost can be very high.[410] This should not be of any surprise, as we have seen that standards bear a relevant market value and are the object of continuous competition one against the other. However, when a standard becomes the benchmark to which a specific technical regulation refers, the existence of costs or copyright protection may hinder the access of the regulated subject to the source of the law.[411]

Focusing more specifically on the European Union and the United States, it seems fair to state that the phenomenon of standardization bears a relevant role, even for the different reasons we have addressed in the third chapter. The manner in which international standards are received by the legal systems of the European Union and the United States is considerably different. The United States has a relatively flexible system, through the use of non-binding instruments such as recommendations, memoranda and guidelines, while the

[409] *See* Gregory Shaffer, *supra* note 127, at 8 ("The AB decision to not recognize the AIDCP as an "international standard" could be viewed as a means of promoting transparency and participation in international standard-setting processes. Yet one should question whether its approach will actually promote international environmental standard setting since it is easier to reach agreements with fewer participants.").

[410] For a complete analysis of the issue, *see generally* Gibson, *supra* note 240, at 1403.

[411] *Id.* at 1481 (calling upon the adoption of clearer policies at the WTO level in order to achieve the appropriate balance between international standardization and intellectual property rights).

European Union is considerably more structured, under the lead of the Commission and through the procedural framework of the "New Approach".

Also, the way in which standards developers are perceived in the two jurisdictions runs on different tracks – substantially private market players in the United States, hardly ever influenced by the government;[412] still semi-public entities in the European Union, largely dependent on the public and highly involved in the standardization as overseen by the Commission. We believe that the different structure of the two systems is also responsible for the possibly different treatment that international standards other than the ISO/IEC could receive once they enter the European Union rather than the United States.[413]

In conclusion, it is our opinion that international standards will continue to constitute, perhaps with growing frequency, the principal method for boosting technical harmonization and the progressive elimination of the still numerous barriers to international trade.[414] Nonetheless, nowadays, in spite of the relevant role international standards developers have acquired,[415] their qualification as global administrations is still problematic. This is because, although the recent jurisprudence emerging from the TBT Agreement has envisioned this

[412] Mattli & Büthe, *supra* note 174, at 24 ("American SDOs have a long tradition of keeping government at arm's length, and attempts at governmental interference in the workings of the private standards system are few."). *But see* 19 USCS § 2533 ("It is the sense of the Congress that no State agency and no private person should engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States."); ANSI Procedures for U.S. Participation in the International Standards Activities of ISO, http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/International%20Standardization/2013_ANSI_International_Procedures.pdf ("ANSI's membership in these organizations provides U.S. interests with the opportunity to participate in the work of the ISO and IEC toward the development of international standards.").

[413] Recollect the analysis dedicated to the acquisition of the ANSI standards in the European Union undertaken at the end of paragraph III.2.

[414] *See* Auby, *supra* note 5, at 214 (observing the tendency of globalized law to make use of soft law mechanisms and, among them, deep use of standards).

[415] *See* Kingsbury, Krisch & Stewart, *supra* note 67, at 9 (pointing out that standardization performed by ISO enters in the 5th typology of regulatory function at the global level, the one realized by private bodies).

possibility, international standardizing bodies[416] are neither formally endowed with public power nor vested with any form of direct legitimization.[417]

We must also consider that it is questionable whether the international standardizing community itself is ready or willing to embrace the administrative function of providing international technical standards on a global scale.[418] The WTO clearly lacks the resources or expertise to cope with such administrative functions. Notwithstanding, we believe that, in the long run, the normative power of international technical standards remains significant and will continue to be of interest to the legal community in the near future.

Mario De Rosa

[416] The analysis is clearly different for the CEN and CENELEC which, as we have discussed, cannot be considered international but rather regional standards developers, deeply mingled with the European Commission.

[417] It could be argued that international standardizing bodies benefit of a "twice indirect" form of legitimation, considered that their normative power stems from an agreement constituting the WTO, global administration also only indirectly legitimized. *See generally* Cassese, *La funzione costituzionale dei giudici non statali*, *supra* note 64, at 609-624 (underlining that global administrations are only granted an "indirect legitimation", which generates at the State level).

[418] *See generally* Kingsbury, *supra note 10* ("Some entities are given roles in global regulatory governance which they may not wish or be particularly designed or prepared for."). *But see* Annex SM to the ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014 ("The formation of the WTO and the subsequent adoption of the WTO Technical Barriers to Trade Agreement (WTO/TBT), placed an obligation on ISO to ensure that the International Standards it develops, adopts and publishes are globally relevant.").

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