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**The International
Technical Standards
and their Legal Effects
in the Light
of the TBT Agreement**

Mario De Rosa

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The International Technical Standards and their Legal Effects in the Light of the TBT Agreement

Mario De Rosa

Abstract

In recent times, international technical standards have come to the fore as one of the most pervasive expressions of globalization and of international private governance. Because of their deep impact on international trade, the WTO Agreement on Technical Barriers to Trade has tried to regulate the way standards are utilized, demanding that Member States adopt international technical standards in their regulations in order to avoid hidden regulatory protectionism. However, the TBT Agreement does not specify which standards must be used and to what extent technical regulations should conform to standards. The recent case law of the Appellate Body seems to cast light on these problems, dictating parameters that should guide these choices especially in contexts characterized by numerous competing standards regulating the same field. In the light of this jurisprudence, the manner through which international technical standards become part of the administrative laws of the United States and the European Union and the differences that exist between the American and the European systems of standardization are of great significance with regard to the negotiation of the Transatlantic Trade and Investment Partnership.

Keywords: international technical standards, TBT, WTO, Tuna Dolphin II, private governance.

INTRODUCTION

Standardization, and the great deal 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 importance for the understanding of global governance and its tight liaison with constitutional democracies.⁶ Because of the magnitude of the phenomenon, our legal analysis will focus on a specific kind of technical standards, known as “international technical 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 fact, the recent case law of the WTO seems to have reshaped the reach of these instruments in a way that is worth analyzing.

In the first part of this paper, 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 part, we will

* The system of citations adopted for this paper is the American Bluebook 19th Edition for Law Review, with minor differences. EBooks in Kindle format will be cited according to their static location number.

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 impact 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 Nov. 6, 2015).

³ Technical standards are only a very limited part of the normalization 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, 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 within 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].

address different methods of production of technical standards, and formulate our hypothesis with regard to the international standards developers that satisfy the parameters dictated by the jurisprudence of the Appellate Body. This part will focus primarily on the ISO/IEC system, the model of standardization followed globally and allegedly favored by the WTO, and the American ANSI system. In the third part, we will briefly 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 if the new parameters of the TBT should govern their discipline.

Before tackling our discussion, however, it is worth making some preliminary considerations that will prove beneficial to our survey, especially given the numerous social sciences that deal with standardization. First, technical standards are normative instruments that defy a clear-cut definition, finding their place both in the realm of the law and in 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 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 or global level often without a precise hierarchy, can (and often do) profoundly influence the principles and dynamics of national

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.*, Thorsten Hüller & Matthias Leonhard Maier, *Fixing the Code? Global Food-Safety Governance Under Review*, in *CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION* 281-285 (Oxford and Portland Hart, 2005); HARM SCHEPEL, *THE CONSTITUTION OF PRIVATE GOVERNANCE: PRODUCT STANDARDS IN THE REGULATION OF INTEGRATING MARKETS* 26 (Oxford and Portland Hart, 2005) (summarizing some well-known theories regarding the possibility to institutionalize the dialogic framework involving science and politics). *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*, 137-180, 138-139 (2006) (affirming that continuous technological development is seriously limiting the spaces dedicated 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 area, politics is often forced to leave important and 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* 327-332 (Oxford and Portland Hart, 2005).

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 (Nov. 6, 2015, 9:18 PM), <http://www.iilj.org/publications/2009-7Stewart-RattonSanchez.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* 937-939 (2005) (underlining the problems related to the denomination of “global administrative law” as opposed to other formulas, such as “international administrative law”).

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 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

INTERNATIONAL TECHNICAL STANDARDS IN THE WTO

Defining International Technical Standards in the “TBT”

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 numerous fields,¹⁷ has started to demand an increasing amount of rules, codes, norms which have the major task of

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 (Nov. 6, 2015, 9:25 PM), <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* 657-661 (2004); Sabino Cassese, *Il diritto amministrativo globale: una introduzione*, *Rivista di diritto pubblico trimestrale*, 338 (2005) (pointing out the tendency of global administrative law to rise “from the neighborhood” as opposed to traditional administrative law).

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 65-67 (Oxford and Portland Hart, 2005) (highlighting WTO’s ability to intrude in the way social, environmental and tax policies are regulated all over the world).

¹³ For an economic and quantitative analysis of this relationship, see generally *World Trade Report 2005 Exploring the links between trade, standards and the WTO*, World Trade Organization, 35-48 (2005) http://www.wto.org/english/news_e/pres05_e/pr411_e.htm (last visited Nov. 10, 2015).

¹⁴ See generally ANDREW T. GUZMAN & JOOST H.B. PAUWELYN, *INTERNATIONAL TRADE LAW 2ND EDITION*, chapter 19 new edition (Wolters Kluwer 2012) (forthcoming).

¹⁵ For an introduction to this topic, 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 March 2013*, EC.EUROPA.EU, http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf (last visited Nov. 05, 2015) (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 regarding the partnership, it is possible to consult the Transatlantic Trade & Investment Partnership Agenda and the most recent reports, available at http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153935.pdf (last visited Nov. 7, 2015).

¹⁶ See PREDIERI, *supra* note 1 (underlining the trend of market economies to be colossal producers and consumers of technical norms).

¹⁷ It should be reminded that this work focuses 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 addressed by the “General Agreement on Trade in Services” [hereinafter GATS].

ensuring the safety, reliability and good quality of the products or services destined to enter the market.¹⁸ These rules are commonly called “standards”.¹⁹

Standards have been defined in various 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 If the use of technical standards in so relevant proportions is a phenomenon that is relatively new to the legal community, the reasons for the reliance on international standards date back to the Industrial Revolution and the first attempts to start mass production by manufacturers. In that context, it soon became clear that in order to grant the interchangeability of production inputs – one of the pillars of the functioning of whichever industry²¹ – certain common rules had to be established and followed.²² To be relied upon, standards should be clearly stated and agreed upon by the industrial community, otherwise their efficacy would be somehow reduced if not completely destroyed. Since that time, this dialectic process – so-called “standardization” – has developed its own 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 normative context, alone or only slightly in conjunction with public powers.²⁴ Several authors refer to this tendency as “Governing without Government”,²⁵ expression that condenses the tangible crisis of the government observed through the lenses of traditional legal categories – accelerated by the ongoing globalization²⁶ – with the innate need of societies, at

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 Nov. 7, 2015). See SCHEPEL, *supra* note 9, at 5 (casting doubts on the concept of the “Invisible hand”, which should govern markets according to some economists). See also generally NATALINO IRTI, *L'ORDINE GIURIDICO DEL MERCATO* (GLF editori Laterza, 2009).

¹⁹ Some standards are 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 Nov. 7, 2015).

²⁰ See TBT Annex 1 “Terms and their Definitions for the Purpose of this Agreement”, art. 2.

²¹ The automotive and the information technology industries constitute a telling example.

²² For a brief overview of the historical roots of standardization, see, e.g., *Le regole del gioco*, UNI, http://www.uni.com/images/stories/uni/verbi/conoscere/pdf/le_regole_del_gioco_ed2013_rev1.pdf (last visited Nov. 7, 2015).

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 (last visited Nov. 7, 2015).

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 theorized by Hans Kelsen is no longer a reliable model in order to understand the current normative structure of globalized societies).

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

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).

different levels, to be governed and to govern themselves.²⁷ Hence, traditional government is abandoned in favor of a more fluid and flexible activity that is known as “governance”,²⁸ where administrative decisions are taken at multiple levels, are characterized by cooperation,²⁹ are neither necessarily binding nor conveyed through standardized sources of law.³⁰

When it comes to our analysis, an element of complexity is the inner international character that distinguishes certain technical standards from others. This because, if aspiring at huge levels of recognition among market players is a permanent component of any standard, standards themselves can have ranges and targets that can be considerably different, being them local, national or international.³¹ The formula adopted by the TBT is “International Standards” and this element certainly warrants some considerations.³² In fact, 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 crafting technical regulations, in case they wish to benefit of the rebuttable presumption set forth in article 2.5 of the TBT, on the other hand it might induce the legal practitioner to consider the standards discussed here as a product of the international legal system.³³ This second assumption is – at least in part – mistaken, considered that international standards constitute the final product of standard bodies that are often private bodies and associations charged with public functions rather than real public bodies, no matter if nationally or internationally based.³⁴ While the use of the periphrasis “global standards” is becoming very

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 (examining the disintegration of the National State as an element of globalization).

²⁸ 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 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).

²⁹ 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 discursive and interdependent structure of normalization adopted by the so-called “New Approach” in the European Union).

³⁰ See Moscarini, *supra* note 24, at 1895-1901.

³¹ 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*].

³² See TBT Preamble.

³³ TBT Annex 3 “Code of Good Practice for the Preparation, Adoption and Application of Standards”, lett. B.

³⁴ 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 whereas entirely private standards abound).

popular among legal scholars,³⁵ 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.³⁶ Alternatively and less radically, international standards could be renamed “private international standards”, in order to stress their consensual-contractual nature.³⁷ This denomination has the advantage of sharpening the difference between the standards involved in the TBT and “private national standards”: difference that will come in handy throughout the analysis of the case law of the Appellate Body of the WTO.

Standards, Technical Regulations and the Dilemma of “Consensus”

Since the beginning of the Kennedy Round, it became clear that the entire process of lowering tariffs and quotas would become useless in the event states were allowed to implement internal forms of barriers to trade, making use of the regulatory powers they retained.³⁸ According to trade scholars, regulatory protection is the worst kind of protectionism, because it increases the so-called “deadweight” at the benefit of none. Neither the importing nor the exporting states can take advantage of a regulatory framework that is willfully discriminatory and protectionist, instead of what happens with regard to tariffs and, more arguably, quotas, where some forms of economic benefit exist for the regulating entity.³⁹

Based on these assumptions, the TBT Agreement deals with regulatory protectionism at great length, and acknowledges both the role played by standards in the harmonizing process and the difficulties that less developed countries might encounter while complying with international standards.⁴⁰ The TBT however distinguishes between standards and technical regulations. Indeed, the relevance of international standards comes to the fore especially when standards are taken into

³⁵ 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 ICH’s guidelines have reached the status of global standards) (last visited Nov. 7, 2015).

³⁶ It should be stressed that some authors have attributed the expression “supra” to legal regimes such as 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 that is detached from the legal systems of the National States. This school has also pointed out that global administrations like the United Nations often lack such separate and independent institutional structures, with consequences for their role as international administrations. See, e.g., CHITI EDOARDO & BERNARDO GIORGIO MATTARELLA, *GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW* 17-19 (Springer, 2011).

³⁷ See Schepel, *The Empire’s Drains*, *supra* note 34.

³⁸ See Cirielli, *supra* note 28, at 417-423.

³⁹ 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 Kluwer Law and Business, 2nd ed. 2012)).

⁴⁰ See also TBT art. 12 (establishing a different regime for developing country members). See also Martina Ghelarducci, *Suggerzioni 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).

account as the foundation for the drafting of technical regulations.⁴¹ This relationship is explained in article 2.4 of the TBT, allegedly the most litigated provision of the overall agreement.⁴² Before addressing that relationship, it should be noted that article 2.4 raises 4 main questions: what is meant by the expression “make use of international standards as a basis for” the drafting of technical regulations; which regulations are addressed by the provision as far as the time frame is concerned; which standards should be considered in the crafting of technical regulations; which standardizing bodies qualify. A number of these questions found an answer in the well-known *Sardines* decision, whereas the last problem was only addressed in recent times and deserves an analysis of its own because – as we maintain – could have serious consequences on the way standardizing bodies function and international standards are chosen.

With regard to the first question that we have mentioned above, namely how to interpret the need for adopting international standards in the drafting process of a regulation, the Appellate Body in *Sardines* has embraced the so-called “substantive approach”: technical regulations have to adopt the benchmark furnished by the available standards that regulate the interested field.⁴³ Consequently, article 2.4 has been defined an “aspirational obligation”, which requires administrative bodies to incorporate the content of international standards when they produce technical regulations.⁴⁴ This approach has been preferred to a rather procedural one, which would have only obliged Member States to consider standards in the production of technical regulations, allowing states to deviate from them. Overall, the decision has failed to explain what degree of correspondence should exist between standards and technical regulation.⁴⁵ The fact that the Appellate Body has affirmed, in dicta, the necessity that a “very strong and substantial relationship” between the regulation and the international standard at stake exists, has proven inefficient to ease

⁴¹ 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).

⁴² See TBT art. 2.4. (“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.”).

⁴³ See Appellate Body Report, *European Communities–Trade Description of Sardines*, WT/DS231/AB/R (adopted Oct. 23, 2002) [hereinafter AB Report *EC-Sardines*]. The case was brought by the Republic of Peru against the European Communities. Peru alleged that the EEC 2136/89 regulation, adopted by the Council of the EC, constituted a violation of article 2.4. That regulation used to set forth certain requirements in order to market sardines in the EC, allegedly favoring certain species of sardines that are more easily fished in the waters that are included within (or are adjacent to) the European Communities (sardine *pilchardus Walbaum*), and excluding other species that are less common in the same areas (sardine *sagax*).

⁴⁴ See Cirielli, *supra* note 28, at 431.

⁴⁵ See 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); Cirielli, *supra* note 28, at 422-432.

this interpretative dilemma.⁴⁶ On the other hand, the choice made by the Appellate Body to favor a substantive approach has solved the second of the aforementioned questions. Despite harsh criticism, the view of the Appellate Body is that 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.⁴⁷

As said, the WTO does not produce standards. It lacks the familiarity (and, perhaps, the economic resources) to deal with such a complex process. Nevertheless, it does not renounce to address the problem of harmonization, which is of crucial importance to the liberalization of international trade. In order to do so, it mostly relies on the expertise of other global bodies and administrations, more akin with the dynamics of standardization.⁴⁸ The process of harmonization leads us to determine now the main differences between standards and regulations. The TBT Agreement has adopted a double-sided mechanism in order to address 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 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.⁴⁹ This complex structure raises the following questions: how should the word “normally” be interpreted? Furthermore, when should regulators comply with the definitions furnished by international standards developers? Article 1.2 provides a partial solution to this conceptual problem. It mainly clarifies that the WTO holds the right to dictate its own definitions regarding standardization. These definitions are addressed in Annex 1 (“Terms and their definitions for the purpose of this Agreement”), which states that the terminology employed in the Agreement shall conform to the one adopted in the ISO/IEC Guide 2: 1991.⁵⁰ Nevertheless, the Annex warns that a certain number of definitions are set forth in the Annex itself.⁵¹

⁴⁶ 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”).

⁴⁷ *Id.* at 389.

⁴⁸ See Stewart & Ratton Sanchez Badin, *supra* note 11, at 20-23.

⁴⁹ TBT art. 1.1; 1.2.

⁵⁰ The ISO/IEC Guide 2: 2004 is the most updated version of the ISO/IEC Guide 2: 1991, “General Terms and Their Definitions Concerning Standardization and Related Activities”.

⁵¹ Among them, we find separate definitions for technical regulations, standards, conformity assessment procedures, international bodies or systems, regional bodies or systems, central local and non-government bodies. 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 has dealt with these discrepancies in *EC - Sardines* and in the recent decision *US - Tuna II*. In *Tuna II*, among the complaints brought by Mexico against the United States there was that concerning the failure to make use, as a basis for the U.S. regulation regarding 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 agreed with Mexico on the matter, it sustained, however, that Mexico had failed to demonstrate that the AIDCP standard was an effective yardstick in order to fulfill the purposes of the U.S. regulation. Instead, the Appellate Body has denied the AIDCP parameters the nature of international standard in the first place.⁵²

We should now underline that in order to interpret annex 1.2 the Appellate Body has looked into its explanatory note,⁵³ and found that the note clarifies an important point: in the language of the TBT, technical regulations are mandatory while standards are voluntary. Hence, the WTO does not recognize mandatory standards. Referring to the ISO/IEC Guide, the Appellate Body has defined international standards as “standards that are adopted by an international standardizing/standards organization and made available to the public”. Then, the Appellate Body has 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. This approach can be questioned in many respects. Most importantly, it does not furnish a substantive definition of international standard, but focuses on the institution, the author of the standard. To this extent, we may affirm that the nature of international standard lies now in the structure of the standards developers, whether they satisfy the requirements set forth in the TBT Agreement.

At this point, we should address the problems related to the interpretation of the word “consensus” in the explanatory note, which the Appellate Body has not directly consider in *Tuna II* even though 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 EC that international standards had to be based on “consensus” in order to constitute an obligatory basis for the drafting of technical

⁵² For a summary of the case, see generally GUZMAN & PAUWELYN, *supra* note 14, chapter 19 new edition (forthcoming).

⁵³ “The terms as defined in ISO/IEC Guide 2 refer to 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 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.”

regulations.⁵⁴ The approach of the Appellate Body was grounded on the last phrase of the explanatory note, which includes “standards not adopted by consensus” in the reach of the TBT Agreement.⁵⁵ In spite of the correctness of this textual analysis, several scholars have criticized this interpretation.⁵⁶ Concretely, this approach can force states to use standards, to which they had previously objected, as a basis for their regulations.⁵⁷ The Appellate Body in *Tuna II* has not dealt with consensus, because both Mexico and the U.S. had accepted the AIDCP. Nonetheless and interestingly, the Panel in the same case has blatantly disagreed with *Sardines*, insisting that the TBT requires that standards be based on “consensus”.⁵⁸

Meeting the Requirement of “Openness” after *Tuna Dolphin II*

If for long time the composition and features of standard producers had not raised questions, the reason lies in *Sardines*. In that case, 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 need to be part of the regulatory process and, in the presence of a broad range of standards addressing the same subject, which standards must be chosen.⁵⁹ The SPS Agreement, on the other hand, makes this choice. While not excluding the possibility that other standards can play a role in the harmonizing 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 Plant Protection Convention”.⁶⁰

⁵⁴ For a summary of the EC’s positions in the case, see Ingo Venzke, *Technical Regulations and International Standards: the EC-Trade Description of Sardines Case*, in GLOBAL ADMINISTRATIVE LAW: THE CASEBOOK, 10962 (Irpa 2012), at 10084.

⁵⁵ See Explanatory note at TBT Annex 1.2.

⁵⁶ See Howse, *supra* note 45, at 387 (sustaining that the complaints that were brought by the EC – that the WTO was turning international standardizing bodies into “world legislators” – were potentially correct, because *Sardines* has basically legitimized a “broad automatic lawmaking mechanism”, where states are substantially deprived of their right to regulate).

⁵⁷ See, e.g., Venzke, *supra* note 54, at 10084.

⁵⁸ 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).

⁵⁹ 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 that are allegedly more familiar with the field).

⁶⁰ 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

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 has compared the definitions of the Annex with the ones set forth in the ISO/IEC Guide 2, coming to the following conclusions.⁶¹ At the outset, the Annex 1.2 mandates that a standard is approved by a “body”. The ISO/IEC Guide 2 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”.⁶² The ISO/IEC Guide 2 determines also further characteristics of the body enabled to produce international standards: the body must be either a “standardizing body” or a “standards body”. While the first category pertains to a body that has “recognized activities in standardization”, the second category relates to standardizing bodies recognized at national, regional or international level, whose main function is the preparation, approval or adoption of standards that are made available to the public.⁶³ The comparison between the two sources has led the Appellate Body to affirm that the ISO/IEC Guide 2 is not in conflict with the TBT Agreement, but specifies the notion of “body” set forth by the Annex: a body has to be “recognized” with respect to its activities in “standardization”.⁶⁴

In the following part of the analysis, the Appellate Body has broken the definition of international standardizing body “in small pieces”. First, it has focused on the concept of standardization, defined in the ISO/IEC Guide 2 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”. Then, it has addressed the concept of “recognition”, sustaining that it requires that body’s activities in standardization be “recognized”. As it did in previous decisions,⁶⁵ the Appellate Body has undertaken a literal interpretation, coming to the conclusion that the word “recognition” encompasses a factual and a legal/normative

recommendations with respect to all aspects of sanitary and phytosanitary measures.”). The SPS Agreement has been the core of numerous disputes involving the European Union, providing a telling example of the pervasiveness of global administrative law. *See, e.g.,* Dario Bevilacqua, *Procedural and substantial limits for national administrations: the EC-Biotech Case*, in GLOBAL ADMINISTRATIVE LAW: THE CASEBOOK, 17957 (Irpa 2012), at 18042.

⁶¹ 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).

⁶² AB Report *U.S.-Tuna II* ¶ 355.

⁶³ AB Report *U.S.-Tuna II* ¶ 357-358. In this work we will consider standardizing and standards bodies together.

⁶⁴ *Id.*

⁶⁵ An analysis of the hermeneutic tools in the hands of panels has been undertaken in the Appellate Body Report, *EC—Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 175-176, WT/DS269/AB/R (*adopted* Sept. 27, 2005) (objecting that dictionaries, while providing a “useful starting point” for the analysis of the “ordinary meaning” of treaty terms, are not necessarily dispositive).

character.⁶⁶ Turning to the composition of the standard developer, the Appellate Body has identified the requirement of “openness” as the characterizing and crucial one. In particular, the membership in an international standardizing body must be “open to the relevant bodies of at least all Members”, where “open” is a synonym of “accessible or available without hindrance, not limited to a few”. Hence, according to the Appellate Body, 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.⁶⁷

It is noteworthy that the Appellate Body has referred to the Decision of the TBT Committee,⁶⁸ on which both Mexico and the U.S. 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.⁶⁹ The Appellate Body has examined the 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”. While the Appellate Body has not clarified the first of these two additional requirements, it has explained that the “non-discrimination basis” prevents standardizing bodies, whose constituting provisions disadvantage *de jure* or *de facto* the bodies of some Members, from being considered “international” standardizing bodies for the purposes of the TBT Agreement.⁷⁰ Furthermore, the TBT Committee Decision furnishes also a determination of the “recognized activities in standardization” in which an international standardizing body can claim to be engaged. The Appellate Body has sustained that “recognition” in the WTO occurs when there is evidence that standardizing bodies are complying with the principles and procedures established in the TBT Committee Decision.⁷¹ 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”.⁷² In the end, the Appellate Body has agreed with the U.S. that

⁶⁶ AB Report *U.S.-Tuna II* ¶ 360.

⁶⁷ *Id* at 364.

⁶⁸ Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2 and 5, and Annex 3 and 4 of the Agreement, G/TBT/9, 13 November 2000, ¶ 20.

⁶⁹ 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.”).

⁷⁰ AB Report *U.S.-Tuna II* ¶ 375.

⁷¹ *Id* at 376. In our opinion, this part of the decision sets forth a circular reasoning. The Appellate Body is explaining the conclusions (the international character of the standardizing bodies according to the TBT Decision) through the premises (the respect of the requirements set forth in the decision itself). Nonetheless, the Appellate Body also 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 that make a serious effort to observe international standardization.

⁷² *Id*.

international standardizing bodies must not privilege any particular interest in the process of developing international standards. Therefore, the AIDCP, whose main interest at the time was to regulate certain fishing activities, could not qualify as an international standardizing body for the purposes of the Agreement.⁷³ Moreover, the Appellate Body has 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 before the panel.⁷⁴

This decision presents several points of interest. First, it gives the WTO enormous discretion to declare whether a standard is “international” or not, being able to “double check” the authority, production and outcome of a standard claimed as international.⁷⁵ Second, it allows all standardizing bodies, even the least renowned ones, to see their standards recognized if the procedures they adopt for implementing their standards comply with the requirements expressed in the aforementioned TBT Committee Decision.⁷⁶ On the other hand, standardizing bodies that 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, could be deprived from acquiring the “indirect normative power” which article 2.4 of the TBT Agreement can grant to standards developers.

METHODS OF PRODUCTION OF INTERNATIONAL STANDARDS

Regulatory Competition and the Preference for ISO/IEC Standards in the WTO

In defining international standards, the TBT has chosen to rely in part on the definitions provided by the ISO/IEC framework as sketched in the ISO/IEC Guide 2: 1991, endorsing, to some extent, the foundations on which two separate institutions, the International Organization for Standardization and the International Electrotechnical Commission, have built their own standardization regimes. Moreover, the TBT leaves open the door to possible coexistence of a number of different standards, with different origin and nature, all geared to regulating the same field.⁷⁷ This form of rivalry among standards and standards bodies is known as “regulatory

⁷³ *Id* at 384-386.

⁷⁴ *Id* at 398. Notice that the AIDCP, for instance, could issue an invitation only if its members had so decided by consensus. Therefore, this invitation was not comparable to a mere “formality”.

⁷⁵ See GUZMAN & PAUWELYN, *supra* note 14, chapter 19 new edition, at 28 (forthcoming).

⁷⁶ AB Report *U.S.-Tuna II* ¶ 392.

⁷⁷ 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)). Even though the TBT Agreement does not specifically deal with them, perhaps the most telling example is furnished by environmental standards. In this field, there are certain ISO standards – particularly the so-called ISO 14001: 2004, related to environmental management – which have an exact parallel in the context of the ASTM Standardization. Some examples may be the standard created in 2013 named D5743 – 97 (2013), which establishes the “Practice for Sampling Single or Multilayered Liquids, With or Without Solids, in Drums or Similar Containers”, or that named E688 – 94 (2011), dictating certain “Standard Test Methods” for waste glass as a raw material for glass manufacturing. 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 allegedly follow the dynamics of technological development more closely than how ISO Committees may effectively

competition” and is now worth examining. Actually, some authors have argued that the choice of a standard, at least as it appears in the words of the TBT Committee Decision, is not completely open-ended. Because standards “should respond to the needs of the market, and should avoid adverse effects on fair competition or stifling innovation and technological development”,⁷⁸ the institutions called upon to draft regulations should be somehow constrained to privilege those standards that are allegedly more market-friendly.⁷⁹

The European Union and the United States, the two economies that are most involved in the production and consumption of international standards, have taken very different positions with regard to the existence of a plethora of international standards potentially concerning homogenous sets of interests and fields.⁸⁰ The EU has consistently argued in favor of a monopoly of the ISO and IEC frameworks,⁸¹ preference that has both a conceptual and an economic basis. As far as the ideological order of reasons is concerned, the EU has embraced what has been defined as a “political concept of consensus”. Practically, as it did in *Sardines* and in several others occasion,⁸² the EU has showed to approve the functioning of the ISO framework, considering national representation in standardizing bodies one of the most effective instruments for the achievement of global consensus in standardization.⁸³ Turning to the more empirical – economic reason, it cannot be underestimated that the EU Institutions have ploughed considerable economic resources in their participation into the ISO/IEC system.⁸⁴ They govern it, outnumbering the competitors from all over the world (the American Standardizing Bodies as well). Their method of producing standards and their standards are inspired by the ISO/IEC model, 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.⁸⁵ On the other hand, the United States has normally allowed (if not encouraged) the coexistence of a number of standards addressing the same field. It has done so on the assumption that letting the market choose the most appropriate set of standards could foster

do. Differences in the choice of standards adopted can have tangible impact. 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 U.S., the ISO system, adopted in many EU Countries, and the JIS, adopted in Japan and resembling the ISO system, with the addition of three keys.

⁷⁸ 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.

⁷⁹ Howse, *supra* note 45, at 393.

⁸⁰ Perhaps, Harm Schepel has conducted the most comprehensive studies on this conflict. For an overview, see, e.g., Schepel, *The Empire's Drains*, *supra* note 34, at 406-408. For a more detailed analysis, see SCHEPEL, *supra* note 9, at 185-193.

⁸¹ SCHEPEL, *supra* note 9, at 185-193.

⁸² See generally the recent EU Regulation No. 1025/2012 Oct. 25 2012; Communication COM (2013) 561 final of 31 July 2013, on the annual Union work program for European standardisation.

⁸³ Schepel, *The Empire's Drains*, *supra* note 34, at 406.

⁸⁴ SCHEPEL, *supra* note 9, at 190-193.

⁸⁵ *Id.*

efficiency, competition and virtuous results.⁸⁶ It is perhaps for this reason that the U.S. and the American Standards Bodies have lobbied against the mingling between the WTO and the ISO/IEC regimes, publicly expressing their dissatisfaction.⁸⁷

Setting Standards within the ISO/IEC System

The International Organization for Standardization (ISO), differently from other private associations dealing with standardization, is a well-structured system, whose resources are not negligible,⁸⁸ and which has set up a considerable number of *fora* for the production of standards.⁸⁹ Located in Geneva, the ISO stemmed from the merger of two organizations: the International Federation of the National Standardizing Associations, created in New York in 1926 and administered in Switzerland; and the United Nations Standards Coordinating Committee, created in 1944, and administered in London.⁹⁰ The mingling of public and private standards developers as members of the ISO has persuaded some scholars to define ISO a hybrid public-private body.⁹¹

Our analysis should start with the management of the ISO, which takes place through several branches. The national members – coming from the technical committees of their states – form the General Assembly, which is responsible for the appointment of the Council.⁹² The Council, then, cooperates with the President, the Vice-President and the Secretary-General of the ISO to govern the activity of the Institution, whose crucial moment is the appointment of the Technical Management Board.⁹³ The Technical Management Board (TMB) is the brain of the process: it is responsible for the establishment of technical committees, for the choice of the chairs,

⁸⁶ Schepel, *The Empire's Drains*, *supra* note 34, at 406. See also SAMUEL KRISLOV, HOW NATIONS CHOOSE PRODUCT STANDARDS AND STANDARDS CHANGE NATIONS 104 (University of Pittsburg Press, 1997).

⁸⁷ *Id.* (quoting the General Position Paper of ASME International on Standards and Technical Barriers to Trade (1997)).

⁸⁸ Standardizing bodies' dimension has been debated. 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).

⁸⁹ See generally *ISO in Figures*, ISO, http://www.iso.org/iso/iso_in_figures-2013.pdf (last visited Nov. 7, 2015) (stressing that, in 2013, ISO 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 that are employed all over the world.).

⁹⁰ See Eicher, *supra* note 23, at 15.

⁹¹ 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). An exhaustive description of the ISO Organization is encompassed in the ISO/IEC Directives, which are published in two parts: the functioning and the management of the institution are addressed in Part 1 of the Directives; the rules governing the drafting of international standards are outlined in Part 2. Both Directives are available at http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_iec_directives_and_iso_supplement.htm. They can be downloaded in the *Consolidated ISO Support*, which encompasses several annexes regarding the relationship of the ISO with other institutions and some procedural rules applicable only to the ISO.

⁹² For an overview of the process, see SCHEPEL, *supra* note 9, at 183. See 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).

⁹³ *Id.*

for the allocation of the secretariats of the committees (and, sometimes, of the subcommittees), and for the distribution of the tasks, prioritizing certain research when needed.⁹⁴ Moreover, it oversees compliance with the Directive and, together with the CEO, monitors the progress within the committees.⁹⁵ The TMBs of both the ISO and the IEC, whose activity can be conducted together and whose procedures have largely been unified to boost cooperation and to provide coherent tools 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.⁹⁶ It should be noted that the advisory group can hardly ever proceed on its own towards the production of technical documents, activity that remains in the absolute province of the technical committees, but it may start proposals for the harmonization of relevant publications.⁹⁷ The CEO in the ISO/IEC system operates as the “communicator of the institution”, arranging 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 analogous work has been conducted in the same area.⁹⁸ The Directive discourages technical committees from adopting their own procedural rules and, to that extent, requires technical committees, in case of possible divergence, to seek authorization from the CEO.⁹⁹ As already said, technical committees are appointed by the TMB, and they may change their nature and their field of research when the work for which they were created has been completed.¹⁰⁰

Overall, the ISO system provides considerable openness with regard to the entities capable of starting the standardization process.¹⁰¹ 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 started 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 managing a certification system operating under the auspices of the organization; another international organization with national body membership.¹⁰² When the CEO receives a proposal, it may underline that the proposal lacks one or more constituting elements or fundamental technical information, but it is barred from expressing any evaluation at this point. To that extent, the CEO can remand the proposal to its author with the purpose of completing it, although the author can specifically request that the

⁹⁴ ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.1.

⁹⁵ *Id.*

⁹⁶ *Id.* at art. 1.2.

⁹⁷ *Id.* at art. 1.2.3.

⁹⁸ *Id.* at art. 1.4.; 1.5.5.

⁹⁹ This procedural rigidity is at the odds with the flexibility that characterizes the ANSI system.

¹⁰⁰ To do so, they need to have specific permission from the TMB. *See Id.* at art. 1.5.2.

¹⁰¹ *See SCHEPEL, supra* note 9, at 183.

¹⁰² ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.5.3.

proposal be voted in its original form.¹⁰³ The CEO then 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 an existing one.¹⁰⁴ If after three months at least 2/3 of the national bodies have expressed their intention to set up a new committee, and at least 5 of those bodies have expressed their will to actively participate in the activity of the new subject, the committee is created, and is immediately required to define its name and its scope, subject to modification by the TMB.¹⁰⁵ It is significant that national bodies can be involved in the activity of the 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 the rights and the obligations that are typical of the national bodies involved in the activity of the committees, but they maintain the right to vote on enquiry and final drafts of international standards.¹⁰⁶

The framework of the technical committees is complex: each committee functions thanks to the activity of a secretariat, a chair and a vice-chair. In the election of each of them, the TMB has 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).¹⁰⁷ Before initiating any project, the technical committee defines a strategic business plan, where it outlines possible areas of development in its field, the areas that should be revised and the areas that may predictably need the commencement of standardization in the upcoming years.¹⁰⁸ It should be noted that in their activities the technical committees are accompanied by a plethora of other committees responsible for different parts of the standardization process.¹⁰⁹ The technical committees themselves can create 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.¹¹⁰ With the expression “liaison”, the Directive refers to a close connection with another committee that technical committees should create in order to carry out their tasks in a more efficient way. Some of these liaisons are

¹⁰³ 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. *See Id.* at art. 1.5.4; 1.5.5.

¹⁰⁴ *Id.* at 1.5.6; 1.5.7.

¹⁰⁵ *See id.* at 1.5.8; 1.5.9; 1.5.10; 1.5.11; 1.6. 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 committees themselves – often with the involvement of their secretariat –, with little intervention from the CEO.

¹⁰⁶ *Id.* at art. 1.7.1.

¹⁰⁷ *See id.* at art. 1.8; 1.8.3; 1.9.

¹⁰⁸ *See id.* at art. 2.1.2.

¹⁰⁹ For instance, the TMB can appoint project committees, whose focus is normally limited to a well-defined number of tasks, mainly related to individual standards, and whose status can successively evolve into a technical committee. *See id.* at art. 1.10.

¹¹⁰ *See generally id.* at art. 1.11; 1.12; 1.13; 1.14.

mandatory, especially with those committees responsible for basic activities of standardization, such as the normalization of the terminology adopted in the process.¹¹¹

We should now stress that each standard in the ISO/IEC system faces several steps before becoming a finished product. The protocol described in the Directives is composed of seven different stages and the process itself can take quite a long time, depending on the complexity of the technical debate.¹¹² The phases are the Preliminary, the Proposal, the Preparatory, the Committee, the Enquiry, the Approval, and the Publication stage.¹¹³ The Preliminary Stage is not mandatory, because standardization can stem from a proposal issued by one of the subjects we have already listed. Any technical committee (as well as any subcommittee) may include preliminary items that are characterized by a certain level of incompleteness into the work program. This prevents them from being analyzed at a further stage or from being assigned a target date indicating the time in which the project is plausible to be completed.¹¹⁴ On the other hand, the Proposal stage is ever-present. The approval of a proposal depends on two factors: the positive vote expressed by the simple majority of the members of the committee, who decide to take charge of the proposal itself, and the commitment to actively participate in the development of the project from the earliest stage, which should be expressed by a calculated number of P-Members.¹¹⁵ Once a proposal has been accepted, the technical committee is 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 by the office of the CEO.¹¹⁶ Sometimes the technical committee may publish the working draft as a Publicly Available Specification (PAS) to meet certain market needs. At this stage, project leaders, who normally call and chair committee meetings, often guide the works.¹¹⁷ The Committee stage, which can be avoided in accordance with Annex SS, is the first moment in which the standard receives feedback from national bodies, which are given from 2 to 4 months in order to examine the CD and to make their remarks.¹¹⁸ Once the comments have been collected, after no longer than 4 weeks, the secretariat consults with the chair of the committee and, if necessary, with the project leader, in order to decide one of three possible options: to proceed to a

¹¹¹ *See id.* at art. 1.15.

¹¹² The length of the process of the ISO/IEC standards has been the object of harsh criticism, in particular by the American standards bodies. The average time is 2, 3 or 4 years, depending on whether the accelerated, the default or the enlarged standards development track is undertaken. *See id.* at art. 2.1.6.1.

¹¹³ ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 2.1.3.

¹¹⁴ *See id.* at art. 2.2.

¹¹⁵ *Id.* at art. 2.3.

¹¹⁶ *Id.* at art. 2.4.8.

¹¹⁷ *Id.* at art. 2.4.5.

¹¹⁸ *Id.* at art. 2.5.1.

discussion on the draft and the comments at the meeting of the committee; to circulate a revised draft; to register the committee draft for the enquiry stage.¹¹⁹

Only when all the P-Members have reached the “consensus” defined in the ISO/IEC Guide: 2004, can the transition to the enquiry stage take place.¹²⁰ During the enquiry stage, the draft is circulated to all national bodies by the office of the CEO for a period of three months. They express their vote, which can be either positive (followed, sometimes, by comments) or negative (always followed by the reasons). Participants can also opt for an abstention.¹²¹ An enquiry draft is approved only if two thirds of the votes of the members composing the committee are favorable, and no more than a quarter of the total number of votes is negative.¹²²

The approval stage resembles the enquiry stage, with the difference that the vote takes place in a shorter time (2 months).¹²³ 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 cancelation.¹²⁴ If the procedure is successful, a report circulates, indicating the outcome achieved by the project.¹²⁵ This is the last step before the publication of the standard, which usually takes place within one month, after the correction of mistakes and errors indicated by the secretariat of the committee is operated by the office of the CEO.¹²⁶ The publication of the standard is the tangible proof that a standard has been agreed upon and come into existence. Despite the “binding nature” the WTO has conferred to ISO standards, initially their character is voluntary, proper of sources of soft law.¹²⁷ Conclusively, it is worth mentioning that the ISO framework grants several forms of appeal against the decisions of the TMB, the Council, the technical committees and the subcommittees.¹²⁸ This is an approach in favor of broadening the rights of the participants and is consistent with the practice of the most developed standardizing bodies.

As the ISO, the International Electrotechnical Commission (IEC) is a non-governmental organization located in Geneva, whose activity does not take place for profit.¹²⁹ Founded in 1906,

¹¹⁹ *Id.* at art. 2.5.3.

¹²⁰ *Id.* at art. 2.5.3. (“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 involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.”)

¹²¹ *Id.* at art. 2.6.1, 2.6.2.

¹²² *Id.* at art. 2.6.3.

¹²³ Compare art. 2.6.3 with art. 2.7.3 (delineating a similar procedure).

¹²⁴ *Id.* at art. 2.7.7.

¹²⁵ *Id.* at art. 2.7.8.

¹²⁶ *Id.* at art. 2.8.1.

¹²⁷ See also Shamir-Borer, *supra* note 92, at 5647 (pairing international standards with recommendations to ISO members).

¹²⁸ ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 5.

¹²⁹ See generally *Who we are*, IEC, <http://www.iec.ch/about/profile/?ref=menu> (last visited Nov. 7, 2015).

IEC's activity is directed to the specific area of the electrotechnical interests, bringing together parties from different areas of the world, ranging from companies to industry associations, educational institutions as well as regulatory and governmental bodies.¹³⁰ The IEC shares several elements with ISO, up to the point that the two systems of standardization are identified as a unified structure.¹³¹ Standardization is overseen by the Standardization Management Board (SMB), whose role is similar to the one performed by the TMB within ISO.¹³² At the bottom of the pyramid, there are the technical committees, the technical advisory committees and several strategic groups.¹³³ Committees and subcommittees' activity is conducted in a way that resembles ISO's standardizing procedures. Between the two organizations, there is a close relationship, which was formalized in 1976.¹³⁴ Its terms are addressed in Annex B to the Directive – First Part, labeled “ISO/IEC procedures for liaison and work allocation”. Possible conflicts between the organizations are solved in compliance with the principle that standardization in the electric and electronic engineering field is within the competence of IEC, whereas standardization in any other field is devolved to ISO. 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. In a “subsidiarity” flavor, the Annex requires the institutions to deal with conflicts at the bottom of their hierarchy, and to refer an issue at a higher level only when the lower level has proven unable to solve the impasse.¹³⁵

Coordination within 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 lasting effects on the future works of the organizations; through decisions on the allocation of work made by the TMB or the SMB or, when needed, by the ISO/IEC Joint Technical Advisory Board (JTAB),¹³⁶ whose function is to foster joint programming and to supervise its realization.¹³⁷ When a proposal for the establishment of a joint technical committee has been made,

¹³⁰ See generally *Global reach*, IEC, <http://www.iec.ch/about/globalreach/?ref=menu> (last visited Nov. 7, 2015).

¹³¹ IEC's management resembles that of the ISO. On top, there is the Council, endowed with para-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 and the Executive Committee, the last one furnished with a central office. For the detailed organogram, see IEC, *supra* note 129.

¹³² It should be noted that, besides the SMB, the IEC counts two other different management structures, namely the Market Strategy Board and the Conformity Assessment Board, in charge of the market strategy and the conformity assessment spheres.

¹³³ The IEC relies on “system work”, collecting opinions from stakeholders worldwide, especially in the newest areas of technology.

¹³⁴ See ISO Council resolutions 49/1976 and 50/1976; IEC Administrative Circular No. 13/1977.

¹³⁵ See Annex B, art. B.2. Possible clashes in the allocation of the works may stem from the activities of a preexisting technical committee, or from the establishment of a new committee.

¹³⁶ *Id.*

¹³⁷ ISO/IEC Directives, Part 1 Consolidated ISO Supplement, 2014, art. 1.3.

unless unanimous vote in its 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.¹³⁸ 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.¹³⁹

The American System of Standardization and Its International Reach

When we address the American Standardization System, the one that has more often contested the monopoly of the ISO in the TBT Agreement, we should immediately take note of a crucial difference, which characterizes that system today: “decentralization”.¹⁴⁰ In our understanding, decentralization means that the numerous associations, institutions and bodies, whose main role is the production of standards, lack a leading center, and are overall autonomous. The institution that 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). Founded in 1918 as a non-for-profit organization, ANSI proclaims itself as that institution whose mission is “to enhance both the 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.”¹⁴¹

Under the Memorandum of Understanding (MOU) signed by ANSI and the National Institute of Standards and Technology (NIST) in 2000,¹⁴² ANSI is asked to oversee standardization and to ensure that principles such as openness, balance of interests, due process and consensus are observed.¹⁴³ Differently from ISO, ANSI’s structure resembles that of a common American corporation rather than a public body.¹⁴⁴ An example is provided by the fact that it is governed

¹³⁸ See Annex B, art. B.3.

¹³⁹ See Annex B, art. B.4.2.1.

¹⁴⁰ Some authors sustain that defining the American model a “system of standardization” is misleading. See KRISLOV, *supra* note 86. 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).

¹⁴¹ 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 Nov. 7, 2015).

¹⁴² Memorandum of Understanding between ANSI and NIST, *available at* http://publicaa.ansi.org/sites/apdl/Documents/About%20ANSI/Memoranda%20of%20Understanding/ansinit_mou.pdf (last visited Nov. 7, 2015).

¹⁴³ See Memorandum of Understanding between ANSI and NIST, 1998, art 3.3.

¹⁴⁴ For 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 Nov. 7, 2015). See also SCHEPEL, *supra* note 9, at 146-147.

through bylaws.¹⁴⁵ What characterizes ANSI is the presence of the so-called Membership Fora; they are four, namely the Company Member, Consumers Interest, Governmental Member, and Organizational Member. ANSI's board of directors is composed of several members.¹⁴⁶ Some of them are appointed by the Board Nominating Committee, while others are members *ex officio* and often play the role of chairperson in one of ANSI's Committees.¹⁴⁷

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.¹⁴⁸ 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's rigidity, even though certain forms of approval of the procedural models adopted are present also within ANSI.¹⁴⁹

ANSI has issued special guidelines, which 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 that reflect the principle of "consensus".¹⁵⁰ Considered the core of the "consensus" required in standardization, due process is understood as the possibility to actively influence the standardizing process.¹⁵¹ The significant attention on the search for consensus is evidenced by the presence of an appeal system, through which those who have objected to a standard and have not succeeded may still appeal to see the issue redressed. In addition, they have the right to be informed about the appeal procedure.¹⁵² With regard to the appeals, 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.¹⁵³

¹⁴⁵ ANSI's bylaws were revised last time in 2004. *See generally* ANSI By-laws, 2009 Edition, *available at* http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=874 (last visited Nov. 7, 2015).

¹⁴⁶ *See* ANSI Bylaws, approved 2009, art. 3.02.

¹⁴⁷ *Id.*

¹⁴⁸ *See* SCHEPEL, *supra* note 9, at 147.

¹⁴⁹ *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 ANSI Procedures, Annex A).

¹⁵⁰ *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 (last visited Nov. 7, 2015).

¹⁵¹ *See* ANSI Essential Requirements 2013, art. 1.0. ("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.").

¹⁵² *Id.* at art. 2.6.

¹⁵³ *See* SCHEPEL, *supra* note 9, at 149.

LEGAL EFFECTS OF INTERNATIONAL STANDARDS IN NATIONAL LEGAL SYSTEMS

Recognition of International Technical Standards in the U.S.

In the previous sections, we have addressed some of the differences that exist between the European and the American standardizing system. We should now underline that while EU standardizing bodies are granted a certain protection by the public sector and are often subsidized, centralized and coordinated towards the realization of determined economic and regulatory goals,¹⁵⁴ American standardizing bodies are more akin to corporations rather than public administrations, and are often governed by private law sources.¹⁵⁵ Our discussion is rendered more complex by the international nature of the standards we are analyzing. For instance, ISO standards 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.¹⁵⁶ Other national (or regional) standards developers frequently adopt them as a model for the production of their own standards.¹⁵⁷ Consequently, the use of standards can vary as well. A common trend started in the U.S. and now spreading in the EU, especially with regard to the environmental sector,¹⁵⁸ 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.¹⁵⁹ For example, 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

¹⁵⁴ See Mattli & Büthe, *supra* note 91. 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) (pairing the effect ISO/IEC standards have in the world trade arena with the effects CEN standards have in the European context).

¹⁵⁵ See SCHEPEL, *supra* note 9, at 146-147.

¹⁵⁶ See Donald A. Carr & William L. Thomas, *Devising A Compliance Strategy Under the Iso 14000 International Environmental Management Standards*, 15 Pace Env'tl. L. Rev. 85, 87 (1997) ("Companies achieving certification under such regimes may expect enhanced relations with employees, the public, and government.").

¹⁵⁷ 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 work transfer from the CEN to the ISO is the preferred route for the standardization process) (last visited Nov. 7, 2015).

¹⁵⁸ The environmental sector constitutes one of the most developed fields when it comes to technical standardization. See generally Nicola Greco, *Crisi del diritto, produzione normativa e democrazia degli interessi. Esemplicità della normazione tecnica in campo ambientale*, Studi parlamentari e di politica costituzionale 9, 9-30 (1998); Iannuzzi, *supra* note 9, at 137-180.

¹⁵⁹ 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 the companies subject to administrative control, environmental certification issued by an accredited certifying entity in accordance with international and EU standards and periodic inspections carried out by certification bodies replace administrative controls or additional administrative verification, including for the purpose of renewing or updating authorizations); see also Carr & Thomas, *supra* note 156, at 110 (pointing out that the EPA was evaluating conditional incentives for promoting forms of environmental self-policing and self-disclosure mechanisms).

facility / organization of their choice, with the purpose of completing it and using it by the end of an agreed period.¹⁶⁰

The administration of standardization in the U.S. has gone through a long and conflicted path, where the legislation on the matter is bony, and guidelines and memoranda abound.¹⁶¹ Inspired by the “negotiated rulemaking”, approach that was popular in the late 1970s, which required “consensus” (defined as unanimity) for the adoption of any regulation,¹⁶² the National Technology Transfer and Advancement Act of 1995 has constituted the crucial step in the recognition of standards as a relevant tool in the work of American public agencies.¹⁶³ Besides leading towards the use of consensus-based standards by administrative agencies, it is well-known for its role in the transfer of technology from the government to society, an aspect that is often related to standardization.¹⁶⁴ In particular, the act has the merit of having modernized the role of the NIST,¹⁶⁵ making it the coordinator and supervisor of the use of consensual standards by Federal agencies.¹⁶⁶ Hence, in conjunction with ANSI, the NIST is today the main responsible for U.S. standards policies.¹⁶⁷ The NIST is a non-regulatory agency operating under the aegis of the U.S. Department of Commerce. Founded in 1901, the NIST is not only involved in standardization, but pursues several other tasks, which should promote the industrial competitiveness of the U.S., from the promotion and assistance of small manufacturers to the involvement in scientific research.¹⁶⁸ Moreover, the NIST is responsible for the Technology Innovation Program, successor of the Advancement Technology Program, which provided cost-shared grants between 2007 and 2011.¹⁶⁹

Equally involved in the promotion of consensual standards is the Office of Management and Budget (OMB), which is an executive office of the President located in Washington DC, whose main task is to assist the President in the preparation of the Federal budget and supervise federal agencies’ compliance with the political and administrative guidelines set forth by the Executive.¹⁷⁰ In 1998, the OMB modified its circular encouraging the use of voluntary standards by federal

¹⁶⁰ 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 Nov. 7, 2015).

¹⁶¹ See SCHEPEL, *supra* note 9, at 87.

¹⁶² See *Id.* at 83.

¹⁶³ *Id.* at 88.

¹⁶⁴ 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).

¹⁶⁵ See 15 USC 3701 § 8 (1996).

¹⁶⁶ See 15 USC 3701 § 12 (1996).

¹⁶⁷ *Id.* See also SCHEPEL, *supra* note 9, at 88.

¹⁶⁸ See *NIST General Information*, NIST, http://www.nist.gov/public_affairs/general_information.cfm (last visited Nov. 7, 2015) (explaining that research takes place by employing NIST laboratories).

¹⁶⁹ See *Technology Innovation Program*, NIST, <http://www.nist.gov/tip/> (last visited Nov. 7, 2015).

¹⁷⁰ For more information on the OMB, see *Office of Management and Budget: Open Government*, WHITEHOUSE, <http://www.whitehouse.gov/omb/open> (last visited Nov. 7, 2015).

agencies (Circular A-119, in place since 1982 but scarcely efficient),¹⁷¹ rendering the use of “voluntary consensus standards” (VCS) mandatory for all federal agencies undertaking regulatory work.¹⁷² Hence, federal agencies are discouraged from adopting their own standards (also known as “government-unique standards” or “GUS”) and are asked to take into account those standards that stem from the market, unless doing so may turn out technically or legally impossible.¹⁷³ Because of this new approach, federal agencies, once deeply engaged in the work of technical committees, are now rarely involved in the process of standardization.¹⁷⁴

The Memorandum for the heads of Executive Departments and Agencies M-12-08 (“Principles for Federal Engagement in Standards Activities to Address National Priorities”), describes the ambivalent technique adopted by the Federal Government when it deals with standardization.¹⁷⁵ On one hand, the governmental action is limited and relies on the private sector, regarding openness, transparency, and multi-stakeholders engagement the engine of standardizing policies. On the other hand, where a relevant national priority is identified, the active engagement of the Government is seen as a positive tool to hasten the development and implementation of those standards needed in order to support scientific progress in sensitive areas.¹⁷⁶ 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. In areas where interoperability constitutes a crucial need – considered the risk of premature obsolescence –, the Government is making technology investments in order to obtain improvements and productivity gains.¹⁷⁷

Coherently with the OMB Circular A-119, the Memorandum warns that, in the event governmental involvement is retained necessary because a national priority has been identified, it is important for the Federal Government to define the breadth of its intervention, to engage private stakeholders at the earliest possible stage in the process of identifying technology, regulatory, and/or procurement objectives, and to make use of techniques of communication that favor

¹⁷¹ See SCHEPEL, *supra* note 9, at 87-88 (pointing out the inefficiency of the 1982 circular for lack of compulsoriness).

¹⁷² The use of VCS is obligatory under the condition that does not trigger a violation of legal obligations, or it is impractical. 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.

¹⁷³ See SCHEPEL, *supra* note 9, at 88.

¹⁷⁴ 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 Nov. 7, 2015).

¹⁷⁵ The Memorandum was 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). See Memorandum for the heads of Executive Departments and Agencies M-12-08, *supra* note 174.

¹⁷⁶ *Id.*

¹⁷⁷ See *id.* at 2-3 (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, and providing the example of the health care and the environmental sectors, in which the Federal Government has ploughed considerable resources, buying equipment such as electronic health record systems or smart grid technologies).

transparency and openness.¹⁷⁸ Moreover, agencies are asked to specify the reasons for their willingness to be more involved in the standardization process, explaining why the existing standards are deficient with respect to some vital public purposes. The Memorandum also mandates the “intra and inter-agency coordination of engagement in standards development activities” and the use of existing procedures whenever this is possible.¹⁷⁹ Finally, the Memorandum requires that agencies be consistent with regard to their involvement in standardization. Agencies should honor their commitment both in terms of invested resources (within the limits of their budget) and with regard to the use of the standards produced through collaborative procedures. Furthermore, agencies should be mindful of the effect standards bear on U.S. competitiveness, and are encouraged to seek the guidance of the USTR with regard to the impact of standardization on trade.¹⁸⁰

The current structure of the OMB Circular A-119 is now under debate.¹⁸¹ Recent executive orders have inspired the possibility of a revision, stressing the importance of encouraging the use of private standards by federal agencies, and taking into consideration the growing phenomenon of international standardization and the obligations arising from international agreements such as the TBT and the SPS.¹⁸² The comments have stressed the importance of favoring voluntary consensus standards over other types of voluntary standards not based on consensus. This is particularly relevant when we consider the influence of international standards like the ISO standards on American standardization, and we pay attention to the differences existing with respect to the definition of “consensus” within the ISO and the ANSI systems. Comments have also called for 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.¹⁸³ Pursuant to Recommendation 78-4 of the Administrative Conference of the U.S., which has further encouraged the use of voluntary

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* at 4 (describing the required dialectic procedure as a two-way communication with private sector interests, and limiting the creation of new procedures to cases of insolvable conflict).

¹⁸⁰ *Id.*

¹⁸¹ An analysis of the proposals for a modification and modernization of the Circular is *available at* <http://www.whitehouse.gov/sites/default/files/omb/inforeg/revisions-to-a-119-for-public-comments.pdf> revision (last visited Nov. 7, 2015).

¹⁸² *Id.* These proposals stem 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.

¹⁸³ Especially, comments have stressed the need for a more rigorous analysis about the correspondence of standards to the needs of agencies.

consensus standards,¹⁸⁴ agencies have to examine both substantive and procedural criteria while deciding to rely on a determined standard.¹⁸⁵ The screening of voluntary standards likely to be adopted takes place on a case by case basis.¹⁸⁶ 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”.¹⁸⁷ In other words, agencies are allowed to comply with their obligation to publish their rules in the Code of Federal Regulations (CFR) by simply referring to standards that have been published or are attached to sources available elsewhere.¹⁸⁸ While this element has favored the use of VCS by agencies, it has loosened the supervision on the adequacy of the standards to be incorporated, heightening the risk that non up-to-date regulations are issued.¹⁸⁹

The comments also take into consideration the obligations stemming from the international trade law arena. To that extent, it is worth mentioning that Recommendation 78-4 used to exclude international standards from its reach, providing no guidance with regard to their discipline.¹⁹⁰ In order to enhance federal agencies’ awareness of the international obligations related to standardization, the proposed revision of the OMB Circular not only directs agencies to consult with the USTR,¹⁹¹ but also with the State Department with regard to international obligations other than trade obligations.¹⁹² The revision should also encourage a more structured coordination among the Interagency Committee on Standards Policy, the Regulatory Working Group, the Trade Policy Staff Committee and its subcommittees, for a more coherent analysis of trade obligations.¹⁹³ The overall effectiveness of Circular A-119 is periodically analyzed by the NIST Report on the Implementation of OMB Circular and the PL 104-13, a document prepared by the NIST and

¹⁸⁴ 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 Nov. 7, 2015).

¹⁸⁵ See Whitehouse, *supra* note 181. The substantive analysis is mainly related to the technical document itself, the way it is drafted and its requisites; the procedural analysis, on the other hand, focuses on the way the standard came into existence, with a particular stress on compliance with the principle of consensus as a leading criterion.

¹⁸⁶ 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.”).

¹⁸⁷ A detailed analysis is available at <http://www.acus.gov/research-projects/incorporation-reference> (last visited Nov. 7, 2015).

¹⁸⁸ *Id.*

¹⁸⁹ See Whitehouse, *supra* note 181. The aforementioned comments to the circular have stressed this problem as well as the other – equally serious – of the lack of consistency of some federal agencies: sometimes, regulated entities have been asked to abide by different versions of the same standard, with an increase in the compliance costs of standardization for the ultimate market players.

¹⁹⁰ See Recommendation 78-4 Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation (Dec. 14-15, 1978) letter (b).

¹⁹¹ The USTR has statutory authority with regard to the trade law policies involving the United States. See 19 U.S.C. § 2171.

¹⁹² See Whitehouse, *supra* note 181.

¹⁹³ *Id.*

presented to the OMB by the U.S. Department of Commerce in compliance with the reporting obligations that are encompassed in the OMB Circular A-119 and the National Technology Transfer and Advancement Act.¹⁹⁴ The most recent reports have underlined a positive trend in the use of VCS, considered that only a limited number of agencies have chosen to develop their own standards.¹⁹⁵ Unsurprisingly, the most conservative administration is the Department of Defense, which, nonetheless, has developed a remarkable “VCS-friendly” policy, substituting an enormous number of GUS with voluntary standards.¹⁹⁶

Due to the recent 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,¹⁹⁷ it is our understanding that the incorporation of international standards in the U.S. 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 machine, making the problem of the different interpretation of “consensus” of minor importance.

An interpretative problem is constituted by the relationship that exists among standards admitted in the WTO, in the ISO and in the American system, given their different nature. As we have seen, the ISO contemplates both standards that are voluntary and that are not voluntary.¹⁹⁸ The WTO only refers to standards that are voluntary, but does not require “consensus” as a constitutive principle in order to determine which standards are to be preferred while implementing a new technical regulation. Instead, the American system favors the use of voluntary standards, which ought to be based on “consensus”.¹⁹⁹ To that extent, the language of the Circular A-119 resembles the parameters that we have encountered when we have examined ANSI’s focus on “consensus” as one of its inspiring criteria in the certification of American standards developers.²⁰⁰ These parameters include many of the elements that in *Tuna II* the Appellate Body has retained necessary

¹⁹⁴ See generally NIST Fifteenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment (June, 2012) available at https://standards.gov/ntaa/resources/ntaa_ar_2011.pdf (last visited Nov. 7, 2015).

¹⁹⁵ *Id.* (underlining that only around 50 GUS are currently preferred to VCS).

¹⁹⁶ *Id.*

¹⁹⁷ 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 Nov. 7, 2015).

¹⁹⁸ TBT Annex 1.

¹⁹⁹ 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.

²⁰⁰ 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.”).

for a standard body to qualify as “international” for the purposes of the TBT Agreement.²⁰¹ These discrepancies might have constituted an obstacle in the event a widely accepted standard did not comply with the preconditions imposed by ANSI with regard to “consensus”. Nonetheless, even so, both the current version of the Circular and its proposed modification encourage agencies to adopt international standards in procurement and regulatory applications, in order to promote trade and observe international trade obligations.²⁰²

Recognition of International Technical Standards in the EU

While the European Court of Justice has mainly handled standardization in connection with competition law cases,²⁰³ standardization has mostly interested European rulers because of its role in fostering the creation of a single market.²⁰⁴ To that extent, it is possible to perceive some analogies between the function standardization bears in the EU and in the WTO.²⁰⁵ While standards and technical regulations do not squarely fall under the coverage of article 34 of the TFEU, decisions like *Van Gend en Loos* and *Cassis de Dijon* seem to have influenced the choices of EU rulers when it comes to standardizing policies.²⁰⁶ Interestingly, some authors point out that, because “normative and decisional supranationalism” were impractical,²⁰⁷ the privatization of governance constituted the only viable path for the administration of standardization.²⁰⁸ This goal was realized

²⁰¹ 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; (iv) 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.

²⁰² 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.

²⁰³ This is a preliminary difference between the European and the American system of standardization, where not only the Congress but also the Supreme Court has intervened to strike down the abuses committed by standards developers, principally with regard to antitrust law. Compare Joined Cases 96 to 102, 104, 105m 108 and 110/82, *Iaz and others v. Comm’n E.C.R.* 3369 (1983) with *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).

²⁰⁴ For an introduction to the relevance of the single market in the political dynamics of the EU, 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 in fostering the freedoms of movement).

²⁰⁵ 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 system of the European Union with the WTO and noticing several points of commonality).

²⁰⁶ See also SCHEPEL, *supra* note 9, at 46-50; Chiti, *supra* note 29, 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 Sabino Cassese, *L’arena pubblica nuovi paradigmi per lo Stato*, *Rivista di diritto pubblico trimestrale* 601, 637-640 (2001).

²⁰⁷ See SCHEPEL, *supra* note 9, at 49.

²⁰⁸ *Id.*

through two legal mechanisms: the Directive 83/189/EEC, also known as “Information Directive”, supplemented and improved by the Directive 98/34/EC; the so called “New Approach”.²⁰⁹

The Information Directive obliges all national institutions willing to engage in standards programs to inform the Commission and the European standards bodies – on an annual basis – about the standards projects they initiated.²¹⁰ However, the duties to inform are slightly different depending on the nature of the document taken into account. When Member States are willing to adopt a technical regulation, they must furnish the Commission with the draft of the document, except in the event the regulation constitutes only a “transposition” of an international or EU standard – in which case, such communication is not necessary.²¹¹ On the other hand, when national standards bodies wish to produce a new standard, they – and not the Member States – have to inform the Commission and the EU standards bodies, and the Commission can call for the creation of a new EU standard (sometimes called “active harmonization”).²¹² The directive seems to grant a safe harbor for regulations and standards based on international and EU standards.²¹³ Moreover, the directive has also enhanced the opportunities for Member States to participate in the process,²¹⁴ and has taken into account the possibility that continuous objections may stall the production of regulations.²¹⁵ Furthermore, the directive should be praised for having clarified the distinction between technical specifications, standards and regulations.²¹⁶

Adopted in 1985, and unsuccessfully supplemented by a Green Paper in 1990, the “New Approach”, so defined in order to stress the substantially different model embraced by the European Union at the end of the 1980s, brought about a major success in the administration of standardization.²¹⁷ What has been *ex post* defined “Traditional Approach” was characterized by

²⁰⁹ *Id.* at 63.

²¹⁰ *See* Directive 83/189/EC art. 2.

²¹¹ *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.”).

²¹² *Id.* at art. 2.1.

²¹³ *See, e.g.*, Directive 83/189/EC art. 8.1.

²¹⁴ *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 29, at 4007.

²¹⁵ *See* Directive 83/189/EC art. 9.2. (explaining that objections may trigger a standstill period that can be doubled in the event the Commission plans to adopt a directive addressing the same subject).

²¹⁶ *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 that exist among the definitions examined here). *See also* Ghelarducci, *supra* note 40, at 41-44 (praising the Information Directive for the clarity it has brought with regard to the distinction between technical standards and technical regulations).

²¹⁷ *See* SCHEPEL, *supra* note 9, at 63-70 (pointing out the failure of the Green Paper).

a number of very detailed normative instruments laying down the requirements by which products and services had to abide in order to be marketable in the EC. Given the long times required to implement the directives, the old approach had high costs, it proved time consuming and was characterized by the risk that the normative instruments lacked the expected modernity.²¹⁸ To the contrary, the New Approach is characterized by a high degree of elasticity and relies on delegation in order to reach its goals.²¹⁹ While the EU legislator is in charge of setting forth the “essential safety requirements” products shall respect,²²⁰ the EU standardizing bodies are independent in determining technical product specifications, whose nature remains voluntary.²²¹

Once products comply with EU standards, they benefit of a “presumption of satisfaction of the essential safety requirements” and are no longer subject to national administrative controls.²²² Nonetheless, under the New Approach, manufacturers keep their right to ignore the standards issued by the EU standards bodies.²²³ However, if they choose to do so, they are still forced to comply with the “essential safety requirements” by means of inspections and procedural controls, which can take different forms depending on the national authorities in charge, and can render production considerably onerous.²²⁴ It is perhaps for these economic reasons that the New Approach has proven so successful. On one hand, EU standards become a rather cheap way for manufacturers to penetrate EU markets. On the other hand, the Commission delegates to other bodies – in this case, to private standards developers – the administrative function of normalization, in a way that resembles the methodology undertaken in the regulation of EU competition.²²⁵ Therefore, while the Commission has sometimes performed a propulsive role, it mainly performs a function of surveillance of standardization, watching over those controversies that arise from the production and adoption of standards.²²⁶

²¹⁸ See *id.* (highlighting the clash between politics and technique that often provoked the directives to be out of date before even becoming binding legal texts).

²¹⁹ See *id.* at 64; Chiti, *supra* note 29, at 4015-4017; Greco, *supra* note 158, 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 creation of a single market).

²²⁰ See generally Council Resolution on a new approach to technical harmonization and standards (May 7, 1985) (85/C OJ C 136/01).

²²¹ 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”).

²²² See *id.*; See also SCHEPEL, *supra* note 9, at 63.

²²³ See Chiti, *supra* note 29, at 4017.

²²⁴ *Id.* See also Bianco & Chiri, *supra* note 219, 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).

²²⁵ 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).

²²⁶ See Chiti, *supra* note 29, at 4009.

In the EU, standardization is in the hands of three bodies: the CEN, the CENELEC and the ETSI. The first two are non-profit technical organizations founded under Belgian law and established in Brussels.²²⁷ Instead, ETSI, which was created in 1982, was established in France, and has a specific focus on the normalization involving the information and communication technology.²²⁸ What characterizes EU standardizing bodies and especially CEN and CENELEC is the similarity with the ISO and the IEC.²²⁹ However, the two systems are characterized by a very different level of dependence on public powers. On one hand, the ISO/IEC system is politically independent.²³⁰ On the other hand, CEN and CENELEC take part in the EU standardization system, and can be considered private bodies entrusted with *public munera*.²³¹ This lack of independence comes to the fore also when we deal with the agreements existing between the ISO/IEC system, CEN and CENELEC,²³² and, in the light of the case law of the Appellate Body we have explored, it may lead us to exclude the “international character” of the standards produced by CEN and CENELEC.

We should now address the effects of international standardization in the EU, in the light of the interaction 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.²³³ Under the “Vienna Agreement” and the twin “Dresden Agreement”, ISO and CEN as well as IEC and CENELEC have integrated their activity, setting up mechanisms for the exchange of information and for the coherent representation of national standards bodies,²³⁴ enhancing the speed and the reliability of their procedures.²³⁵ 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, sets forth the basic principles of the cooperation between the two standardizing organizations. The agreement is based on the assumption that international standards (produced coherently with the WTO Code of Conduct) are to be given

²²⁷ *Id.*; See also *Who we are*, CEN, <https://www.cen.eu/about/Pages/default.aspx> (last visited Nov. 7, 2015). *Who we are*, CENELEC, <http://www.cenelec.eu/aboutcenelec/whoweare/index.html> (last visited Nov. 7, 2015).

²²⁸ See *Our Global Role*, ETSI, <http://www.etsi.org/about/our-global-role> (last visited Nov. 7, 2015).

²²⁹ Both CEN and CENELEC 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. For a survey of their structure, see Chiti, *supra* note 29, at 4010.

²³⁰ See generally Eicher, *supra* note 23.

²³¹ See, e.g., Directive 83/189/EC art. 3.

²³² See Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Basic Principles, art. 3 (1991) (expressing ISO’s consideration for the role CEN plays within the environment of the EEA and the European normalization system).

²³³ ETSI has also started a partnership with IEC and ISO, with the goal of reducing duplications in the technical works. See *International Partnerships*, ETSI, <http://www.etsi.org/about/our-global-role> (last visited Nov. 7, 2015).

²³⁴ See SCHEPEL, *supra* note 9, at 192.

²³⁵ See Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Rationales and Objectives, art. 2 (1991).

priority. Nonetheless, the Agreement recognizes the needs of the EU standardizing community and the right of EU standards bodies to develop standards that differ from those framed in the international arena. Even with regard to the time frame, CEN has the possibility to administer its own schedule and prioritize its activities coherently with the needs of the EU market.²³⁶

The functioning of the Agreement recognizes two different procedural models. In the first model, the ISO leads the technical work; in the second model, it is CEN to lead the work. In both cases, the body that starts the standardization process is responsible for the transfer of the documents to the other body for simultaneous approval.²³⁷ Technical co-operation between the two bodies is realized in a plethora of ways, of which the exchange of information is only one component.²³⁸ The most relevant cooperation tool for our purposes is the adoption of existing international standards as EU standards. In other words, the essential safety requirements we discussed may be satisfied by regulations and standards that have adopted either EU standards or international standards (provided that the reliance on international standards does not produce hindrances).²³⁹

Published in 1996, the Dresden Agreement supplemented the “Lugano Agreement” involving IEC and CENELEC in the same years in which the Vienna Agreement was signed.²⁴⁰ However, the integration between IEC and CENELEC seems to go beyond the achievements of the Vienna Agreement. For instance, in the event CENELEC identifies the need to start new projects not yet undertaken by the IEC, it has to ascertain whether the IEC is capable or willing to undertake those projects on its own.²⁴¹ Moreover, technical work starts in parallel at the IEC and CENELEC,²⁴² and procedures for parallel voting are well established and highly encouraged.²⁴³ For these reasons, CENELEC standards are characterized by a very high resemblance to IEC standards.²⁴⁴

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ See Agreement on Technical Cooperation between ISO and CEN (Vienna Agreement), Modes of cooperation, art. 4 (1991) (pointing out that the exchange of information can take place in different ways and often involves the CEN Management Centre and the ISO Central Secretariat. Information is provided together with work programs, catalogues and even draft standards).

²³⁹ See Chiti, *supra* note 29, at 4018 (underlining the possibility for the European Member States to prohibit the marketability of products retained dangerous for people, animals, and plants).

²⁴⁰ See generally Agreement on Common planning of new work and parallel voting between IEC and CENELEC (Dresden Agreement) (1996), available at ftp://ftp.cencenelec.eu/CENELEC/Guides/CLC/13_CENELECGuide13.pdf (last visited Nov. 7, 2015).

²⁴¹ *Id.* at art. 2.1.

²⁴² *Id.* at art. 2.3.1.

²⁴³ See *id.* at art. 2.3.1.

²⁴⁴ See SCHEPEL, *supra* note 9, at 190-193.

CONCLUSION

International technical standards are an expression of market economies,²⁴⁵ though the range of interests to which they relate is not merely economic.²⁴⁶ 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.²⁴⁷ In other words, the WTO, rather than harmonizing national technical regulations – what it could not do –, delegates this task to international standards developers.²⁴⁸ However, in so doing, the WTO suffers to some extent of a lack of legitimacy,²⁴⁹ given that the subjects of the standardizing process exist by virtue of private law, and often have the juridical form of private institutions.²⁵⁰

Probably because of the crisis that has invested the WTO in recent times,²⁵¹ the tendency of the Appellate Body to conduct a broader search in principles of global administrative law (such as openness and transparency) is noteworthy, as those principles may be considered the connecting tissue of the administrative legal cultures all over the world and play an important legitimizing role.²⁵² To that extent, if the new case law is still vague on the merits of “consensus” as a requirement for the creation of standards,²⁵³ 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 that are crafted by “recognized bodies”, whose membership is open at all time, on a “non-discriminatory basis”. While this trend towards more constitutionally tolerable solutions

²⁴⁵ See also Shamir-Borer, *supra* note 92, at 5721 (noting that standardization is often initiated upon request of the relevant industry).

²⁴⁶ See 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 Nov. 7, 2015) (underlining the possibility for states to protect themselves from the ascertainable risk of harm to specific state interests); Bianco & Chiri, *supra* note 219, at 81-90. See also Cassese, *Gamberetti, tartarughe e procedure*, *supra* note 11, at 663 (stressing that the permeability of trade is responsible for an extended influence of the TBT on several other connected interests).

²⁴⁷ See Howse, *supra* note 45, 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 they are embodied in national regulations, a large portion of the standards we currently adopt find their origin in the global process of standardization).

²⁴⁸ For further details on the functioning of delegation, see Shaffer & Trachtman, *supra* note 91.

²⁴⁹ See Nanz, *supra* note 12, at 62-63 (highlighting the different audience governance “beyond the state” has if compared to traditional governmental activity, where the exercise of the government itself is constantly monitored by those who are governed). This is a common issue when we deal with global administrations. See, e.g., Dagrón, *supra* note 35, at 18-19.

²⁵⁰ See Schepel, *The Empire’s Drains*, *supra* note 34 (talking about a “slow motion coup d’etat”).

²⁵¹ The protest of Seattle may be considered the starting point of this movement against the WTO and other global administrations. 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).

²⁵² See generally AB Report *U.S.-Tuna II* ¶¶ 355-370 (referring to the need for openness as a constituting character of standards developers). See Sabino Cassese, *La funzione costituzionale dei giudici non statali. Dallo spazio giuridico globale all'ordine giuridico globale*, *Rivista di diritto pubblico trimestrale* 609, 622-625 (2007).

²⁵³ 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*).

should be praised (standards agreed upon in broader *fora* may easily be accepted by a larger number of states), there is now the risk that only a small number of international standards may pass what is an exacting test.²⁵⁴

Standards produced at the international level, at the EU level or within the ANSI system, possess different levels of recognition in national jurisdictions. If ISO and IEC standards do not present particular problems, as they are favored within the TBT system and are international by definition, and the standards produced by CEN and CENELEC – though not international – are generally molded on the basis of ISO and IEC standards and accepted in a number of jurisdictions, we should briefly discuss the recognition of ANSI’s standards. It seems hard to understand how standards that qualify as “American” should simultaneously be recognized as “international standards”. Especially the requirement of “openness to the relevant bodies of all Member States”, which the Appellate Body has stressed in its recent jurisprudence, may be troublesome when we look into the functioning of some American standards developers, which tend to consider “openness” as a component of “procedural consensus”²⁵⁵ and could decide to exclude those bodies that are not part of the American regional standardization system from their standardizing activities. Nonetheless, certain American standards have reached such a level of internationality and acceptance by market players that their adoption by a national regulating body would probably avoid a conflict with the provisions of the TBT Agreement. For instance, several standards produced by ASTM International are of an undoubtedly international reach,²⁵⁶ are based on “consensus” and offer guarantee that the procedure through which they were created was “open” to members from all over the world.²⁵⁷ Likewise, ASME standards, which are well known for their reliability in specific engineering contexts, could aspire to international recognition under the TBT despite their traceable American root.²⁵⁸

In conclusion, while some American standards might qualify as international standards as the global industrial community commonly uses them, it seems that, also given the role European

²⁵⁴ See Gregory Shaffer, *supra* note 61, 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.”).

²⁵⁵ See ANSI Essential Requirements 2013, art. 2.1.

²⁵⁶ Nowadays, ASTM counts contributions coming from around 150 different countries. See *About ASTM International*, ASTM, <http://www.astm.org/ABOUT/overview.html> (last visited Nov. 7, 2015).

²⁵⁷ The use of “consensus – based” procedures is highly regarded in the mission of ASTM, and guarantees close relationship between the ASTM model and the ANSI system of certification. *Mission Statement*, ASTM, <http://www.astm.org/ABOUT/mission-statement.html> (last visited Nov. 7, 2015).

²⁵⁸ Especially the ASME Boiler and Pressure Vessel Code – adopted by all 50 States and numerous municipalities and territories in the United States, often without significant modifications – is employed in 100 countries around the world and has been translated in several languages. See *Who we are*, ASME, https://www.asme.org/shop/standards?cm_re=About%20ASME-_-GlobalHeader-_-Standards (last visited Nov. 7, 2015).

standardizing bodies play in the establishment of the EU single market, the European system is still not completely open to international standards originating in contexts that differ from the ISO/IEC – CEN/CENELEC regime, such as those produced within the ANSI system. Indeed, within the European Union, because regulations that adopt international or EU standards have a preferential treatment, the possibility to classify an American standard as an “international standard” is of great momentum, and can make the difference for the market player that has employed an American standard as the yardstick for its production. In the perspective of creating an American and European free trade zone, parties negotiating the TTIP should not overlook the importance of these differences, which are the byproduct of legal cultures that are still poles apart from each other.

BIBLIOGRAPHY

- Auby, J. "Is legal globalization regulated? Memling and the business of baking camels." *Universiteit Utrecht*. 12 2008. <http://www.utrechtlawreview.org/index.php/ulr/article/view/URN%3ANBN%3ANL%3AUI%3A10-1-101098/79> (accessed 11 07, 2015).
- Bevilacqua, D. "Procedural and substantial limits for national administrations: the EC-Biotech Case." In *Global Administrative Law: The Casebook*. By Cassese, S., B. Carotti, L. Casini, E. Cavalieri, and E. MacDonald. 3rd. Kindle edition. IRPA, 2012.
- Bianco, M., and S. Chiri. "Le barriere tecniche al commercio internazionale." In *Competere in Europa: mercato unico e capacità competitiva dell'industria italiana*, by S. Rossi and T. Padoa-Schioppa, 81-114. Bologna: Il Mulino, 1993.
- Biondini, P. "Evoluzione, consistenza e prospettive di "norme" e "regole" tecniche nell'ordinamento europeo." *Studi parlamentari e di politica costituzionale*, 2006: 77-135.
- Carr, D. A., and W. L. Thomas. "Devising A Compliance Strategy Under the Iso 14000 International Environmental Management Standards." *Pace Environmental Law Review* 15 (1997): 85-231.
- Cassese, S. "Diritto amministrativo europeo e diritto amministrativo nazionale: signoria o integrazione?" *Rivista italiana di diritto pubblico comunitario*, 2004: 1135-1142.
- Cassese, S. "Gamberetti, tartarughe e procedure. Standards globali per i diritti amministrativi nazionali." *Rivista di diritto pubblico trimestrale*, 2004: 657-678.
- Cassese, S. "Global Standards for National Democracies?" *Rivista di diritto pubblico trimestrale*, 2011: 701-724.
- Cassese, S. "Il diritto amministrativo globale: una introduzione." *Rivista di diritto pubblico trimestrale*, 2005: 331-357.
- Cassese, S. "La costituzione economica europea." *Rivista italiana di diritto pubblico comunitario*, 2001: 907-921.
- Cassese, S. *La crisi dello Stato*. Bari: GLF editori Laterza, 2002.
- Cassese, S. "La funzione costituzionale dei giudici non statali. Dallo spazio giuridico globale all'ordine giuridico globale." *Rivista di diritto pubblico trimestrale*, 2007: 609-626.
- Cassese, S. "L'arena pubblica nuovi paradigmi per lo Stato." *Rivista di diritto pubblico trimestrale*, 2001: 601-650.
- Cassese, S. "Lo spazio giuridico globale." *Rivista di diritto pubblico trimestrale*, 2002: 323-339.
- Cassese, S. *Oltre lo Stato*. Bari: GLF editori Laterza, 2007.
- Cerulli Irelli, V. "Verso la contrazione dell'area del pubblico." In *Dallo Stato monoclasse alla globalizzazione*, edited by S. Cassese and G. Guarino, 25-48. Milano: Giuffrè, 2000.
- Chalmers, D. "Administrative Globalisation and Curbing the Excesses of the State." In *Constitutionalism, Multilevel Trade Governance and Social Regulation.*, by C. Joerges and E. Petersmann, 351-380. Oxford ; Portland (Or.): Hart, 2006.
- Chiti, E. "La Normalizzazione." In *Trattato di diritto amministrativo*, by S. Cassese and et al., edited by S. Cassese, 4003-4048. Milano: Giuffrè, 2003.
- Chiti, E. and B. G. Mattarella. *Global administrative law and EU administrative law*, Berlin-Heidelberg: Springer, 2011.
- Cirielli, P. "L'armonizzazione tecnica nello spazio giuridico globale." *Rivista di diritto pubblico trimestrale*, 2008: 415-447.
- Clarich, M. *Manuale di diritto amministrativo*. Bologna: Il Mulino, 2013.
- Dagron, S. "Global harmonization through public-private partnership: the case of pharmaceuticals, IRPA GAL Working Paper 2012/1." *IRPA website*. 12 31, 2011. <http://www.irpa.eu/irpa-working-papers/> (accessed 11 07, 2015).
- Daniele, L. *Diritto del mercato unico europeo. Cittadinanza, libertà di circolazione, aiuti di Stato*. 2nd. Milano: Giuffrè, 2012.
- Della Cananea, G., and A. Sandulli. *Global standards for public authorities*. Napoli: Editoriale Scientifica, 2013.
- Eicher, L. D. et al. *Friendship among Equals, recollections from ISO's first fifty years*, Geneva: ISO Central Secretariat, 1997.
- Fisher, E. "Beyond the Science/Democracy Dichotomy: The World Trade Organisation Sanitary and Phytosanitary Agreement and Administrative Constitutionalism." In *Constitutionalism, Multilevel Trade Governance and Social Regulation*, by C. Joerges et E. Petersmann, 327-349. Oxford ; Portland (Or.): Hart, 2006.
- Ghelarducci, M. "Suggerzioni e contributi dell'ordinamento internazionale alla nascita ed alla elaborazione della categoria delle "norme tecniche"." *Studi parlamentari e di politica costituzionale*, 2006: 39-75.

- Gibson, C. S. "Globalization and the Technology Standards Game: Balancing Concerns of Protectionism and Intellectual Property in International Standards." *Berkeley Technology Law Journal*, 2007: 1403-1484.
- Gillham, P. F. "Complexity & Irony in Policing and Protesting: The World Trade Organization in Seattle." *Social Justice* 27 (2000): 212-236.
- Greco, N. "Crisi del diritto, produzione normativa e democrazia degli interessi. Esemplicità della normazione tecnica in campo ambientale." *Studi parlamentari e di politica costituzionale*, 1998: 9-30.
- Guzman, A. T., et J. H.B. Pauwelyn. *International Trade Law*. 2nd. New York: Wolters Kluwer Law & Business, 2012.
- Howse, R. "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*, by C. Jorges and E. Petersmann, 383-396. Oxford; Portland (Or): Hart, 2006.
- Hüller, T., et M. L. Maier. "Fixing the Code? Global Food-Safety Governance Under Review." In *Constitutionalism, Multilevel Trade Governance and Social Regulation*, by C. Joerges et E. Petersmann, 267-299. Oxford ; Portland (Or.): Hart, 2006.
- Iannuzzi, A. "Caratterizzazioni della normazione tecnica nell'ordinamento italiano. Il campo di analisi e di verifica della materia ambientale." *Studi parlamentari e di politica costituzionale*, 2006: 137-180.
- Irti, N. *L'ordine giuridico del mercato*. 5th. Milano: GLF editori Laterza, 2009.
- Joerges, C. "Constitutionalism in Postnational Constellations: Contrasting Social Regulation in the EU and in the WTO." In *Constitutionalism, Multilevel Trade Governance and Social Regulation*, by C. Joerges and E. Petersmann, 491-527. Oxford; Portland (Or.): Hart, 2006.
- Joseph, F. "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 March 2013, EC.EUROPA.EU, <http://trade.ec.europa.eu/doclib/docs/2013/march.> *Europa.eu.* 03 2013. http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf (accessed 11 07, 2015).
- Kerrigan, K. E., e C. J. Brasco. "The Technology Transfer Revolution: Legislative History and Future Proposals." *Public Contract Law Journal* 31 (2002): 277-291.
- Kingsbury, B. "The concept of "Law" in Global Administrative Law, IILJ Working Paper 2009/1." *IILJ website*. 02 27, 2009. <http://www.iilj.org/publications/2009-1Kingsbury.asp> (accessed 11 07, 2015).
- Kogan, L.A. "EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy." *The National Foreign Trade Council, Inc.* 08 2003. http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_eu_reg_final_e.pdf (accessed 11 07, 2015).
- Krislov, S. "How Nations choose Product Standards and Standards change Nations." Pittsburg: University of Pittsburg Press, 1997.
- Mattarella, B. G. "Umberto Borsi e il diritto amministrativo internazionale." *Rivista italiana di diritto pubblico comunitario*, 2005: 933-947.
- Mattli, W., and T. Büthe. "Global Private Governance: Lesson from a National Model of Setting Standards in Accounting." *Law and Contemporary Problems*, 2005: 225-262.
- Mattli, W., and T. Büthe. "Setting International Standards: Technological Rationality or Primacy of Power?, 56 1, 25 (2003)." *World Politics*, 2003: 1-42.
- Moscarini, A. "Le fonti dei privati." *Giurisprudenza Costituzionale*, 2010: 1895.
- Nanz, Patrizia. "Democratic Legitimacy and Constitutionalisation of Transnational Trade Governance: A View from Political Theory." In *Constitutionalism, Multilevel Trade Governance and Social Regulation*, by C. Joerges and E. Petersmann, 59-82. Oxford; Portland (Or.): Hart, 2006.
- Napolitano, G. "L'ora del diritto transatlantico: un'adeguata normativa per consolidare la partnership economica." *Il Sole 24 Ore*, 04 02, 2013: 1.
- Predieri, A. "Norme tecniche come fattore di erosione e di trasferimento di sovranità." In *Studi in onore di Feliciano Benvenuti*, by Benvenuti F., 1413-1454. Modena: Mucchi, 1996.
- Schepel, H. *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets (International Studies in the Theory of Private Law)*. Oxford and Portland: Hart, 2005.
- Schepel, H. "The Empire's Drains: Sources of Legal Recognition of Private Standardisation Under the TBT Agreement." In *Constitutionalism, Multilevel Trade Governance and Social Regulation*, by C. Jorges and E. Petersmann, 397-412. Oxford; Portland (Or.): Hart, 2006.
- Shaffer, G. "The WTO Tuna-Dolphin II Case: United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products." *American Journal of International Law*, no. 1 (2013): 1-10.

- Shaffer, G., and J. Trachtman. "Interpretation and Institutional Choice at the WTO." *Virginia Journal of International Law*, 2011: 103-153.
- Shamir-Borer, E. "Legitimacy without Authority in Global Standardization Governance: The Case of the International Organization for Standardization." In *Global Administrative Law: The Casebook*. By Cassese, S., B. Carotti, L. Casini, E. Cavalieri, and E. MacDonald. 3rd. Kindle edition. IRPA, 2012.
- Shapiro, M. "'Deliberative, Independent Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?" *Law and Contemporary Problems* 68 (2005): 341-356.
- Sørensen, K. E. *Liberalising trade in the EU and the WTO*. Cambridge: Cambridge University Press, 2012.
- Stewart, R. B., and M. Ratton Sanchez Badin. "The World Trade Organization and Global Administrative Law, IILJ Working Paper 2009/7." *IILJ website*. 10 14, 2009. <http://www.iilj.org/publications/2009-7Stewart-RattonSanchez.asp> (accessed 11 07, 2015).
- Venzke, I. "Technical Regulations and International Standards: the EC-Trade Description of Sardines Case." In *Global Administrative Law: The Casebook*. By Cassese, S., B. Carotti, L. Casini, E. Cavalieri, and E. MacDonald. 3rd. Kindle edition. IRPA, 2012.

ELECTRONIC RESOURCES

- ANSI. *About ANSI overview*. http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1 (accessed 11 07, 2015).
- . *ANSI Organization*. http://www.ansi.org/about_ansi/organization_chart/chart.aspx?menuid=1 (accessed 11 07, 2015).
- . *Memorandum of Understanding ANSI NIST*. http://publicaa.ansi.org/sites/apdl/Documents/About%20ANSI/Memoranda%20of%20Understanding/ansinist_mou.pdf (accessed 11 07, 2015).
- . *Publicaa ANSI*. <http://publicaa.ansi.org/default.aspx> (accessed 11 07, 2015).
- ASME. *Boiler and Pressure Vessel Code 2013 Edition*. <https://www.asme.org/shop/standards/new-releases/boiler-pressure-vessel-code-2013> (accessed 11 07, 2015).
- ASTM. *About ASTM International*. <http://www.astm.org/ABOUT/overview.html> (accessed 11 07, 2015).
- . *Mission Statement*. <http://www.astm.org/ABOUT/mission-statement.html> (accessed 11 07, 2015).
- . *Waste Management Standards*. <http://www.astm.org/Standards/waste-management-standards.html> (accessed 11 07, 2015).
- CEN. *Agreement on Technical Cooperation between ISO and CEN*. <http://www.cencenelec.eu/intcoop/StandardizationOrg/Pages/default.aspx> (accessed 11 07, 2015).
- . *The history of CEN*. <http://www.cen.eu/cen/products/en/pages/default.aspx> (accessed 11 07, 2015).
- CENELEC. *Agreement on Common planning of new work and parallel voting between IEC and CENELEC*. ftp://ftp.cencenelec.eu/CENELEC/Guides/CLC/13_CENELECGuide13.pdf (accessed 11 07, 2015).
- . "Who we are." *CENELEC Website*. Who we are, CENELEC.EU <http://www.cenelec.eu/aboutcenelec/whoweare/index.html> (accessed 11 07, 2015).
- Codex Alimentarius. *About Codex*. <http://www.codexalimentarius.org/about-codex/en/> (accessed 11 07, 2015).
- EC. *Trade EC EUROPA*. <http://ec.europa.eu/trade/> (accessed 11 07, 2015).
- EPA. *Implementing ISO 14001 Environmental Management System at the Municipal Level*. <http://water.epa.gov/polwaste/wastewater/Implementing-ISO-14001-Environmental-Management-Systems-at-the-Municipal-Level.cfm> (accessed 11 07, 2015).
- ETSI. *International Partnerships*. <http://www.etsi.org/about/our-global-role> (accessed 11 07, 2015).
- IEC. *About the IEC*. <http://www.iec.ch/> (accessed 11 07, 2015).
- . *Global reach*. <http://www.iec.ch/about/globalreach/?ref=menu> (accessed 11 07, 2015).
- . *Who we are*. <http://www.iec.ch/about/profile/?ref=menu> (accessed 11 07, 2015).
- ISO. *Benefits of International Standards*. <http://www.iso.org/iso/home/standards/benefitsofstandards.htm> (accessed 11 07, 2015).
- . "Directives and Policies." *ISO Website*. 04 30, 2014. http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_iec_directives_and_iso_supplement.htm (accessed 11 07, 2015).

- . *ISO 14000 Environmental management.* <http://www.iso.org/iso/home/standards/management-standards/iso14000.htm> (accessed 11 07, 2015).
- . *ISO in Figures.* 06 2014. http://www.iso.org/iso/iso_in_figures-2013.pdf (accessed 11 07, 2015).
- . "ISO/IEC Guide 2:2004." *ISO Website.* http://www.iso.org/iso/catalogue_detail?csnumber=39976 (accessed 11 07, 2015).
- NIST. "NIST Fifteenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment." *NIST Website.* 06 2012. NIST Fifteenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment (accessed 11 07, 2015).
- . *NIST General Information.* http://www.nist.gov/public_affairs/general_information.cfm (accessed 06 15, 2014).
- . *Technology Innovation Program.* <http://www.nist/tip/> (accessed 11 07, 2015).
- UNI. *Le regole del gioco.* http://www.uni.com/images/stories/uni/verbi/conoscere/pdf/le_regole_del_gioco_ed2013_rev1.pdf (accessed 11 07, 2015).
- White House. *Office of Management and Budget: Open Government.* <http://www.whitehouse.gov/omb/open> (accessed 11 07, 2015).
- . "Proposed revision to Circular A-119." *White House OMB Website.* 02 11, 2014. <http://www.whitehouse.gov/sites/default/files/omb/inforeg/revisions-to-a-119-for-public-comments.pdf> (accessed 11 07, 2015).
- WHO. *FCTC.* 06 2014. <http://www.who.int/fctc/en/> (accessed 11 07, 2015).
- WTO. "World Trade Report 2005 Exploring the links between trade, standards and the WTO." *WTO.* 2005. http://www.wto.org/english/news_e/pres05_e/pr411_e.htm (accessed 11 07, 2015).