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Regulatory Coherence and Standardization Mechanisms in the Trans-Pacific Partnership

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ABSTRACT

This article posits a new taxonomy and framework for assessing regulatory coherence in the new generation of mega-regional, cross-cutting free trade agreements. Using the Trans-Pacific Partnership as the primary example, this article situates the rise of regulatory coherence within the current trade landscape, provides clear definitions of regulatory coherence, and argues that the real engine of regulatory coherence lies in the work of international standard setting organizations. This work has been little examined in the current literature. The article provides a detailed examination of the mechanics by which the Trans-Pacific Partnership promotes regulatory standardization and concludes with some normative implications and calls for future research.

CONTENTS

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I. Introduction

A dramatic shift has occurred in the field of international trade law. Governments and trade negotiators have been hard at work in crafting a new generation of broad spectrum economic treaties, often working either in secret or with minimum input from the public, interested non-governmental organizations (NGOs) and civil society.[1] Both the European Union (EU)-United States (U.S.) Transatlantic Trade and Investment Partnership[2] (TTIP) and the multi-lateral Trans-Pacific Partnership[3] (TPP) among the United States and eleven Pacific Rim countries are both examples of the new generation of trade treaties. These 21st Century trade treaties[4] not only reduce tariffs (to zero under the TPP) and non-tariff barriers, including behind-the-border technical barriers to trade, but also encompass ambitious cross-cutting issues like regulatory coherence, intellectual property, and global supply chain management plus non-trade issues like transparency and anti-corruption. Due to their ambitious scope, these trade agreements have been dubbed Mega-Regional Free Trade Agreements.[5] Not only do the TTIP and TPP have expansive scope going well beyond the coverage of traditional trade treaties, but they have been the subject of widespread criticism, particularly regarding the cloak of secrecy over the negotiations process. The TPP in particular has received much criticism, and its passage in the United States Congress[6] may

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1 *See, e.g.,* Marija Bartl & Elaine Fahey, *A Post National Marketplace: Negotiating the Transatlantic Trade and Investment Partnership (TTIP)*, in Transatlantic Community of Law: Legal Perspectives on the Relationship between the EU and US legal Orders 210 (Elaine Fahey & Deirdre Curtin eds., 2015); Marika Armanovica & Roberto Bendini, European Parliament: Directorate-General for External Policies, *Civil Society's Concerns about Transatlantic Trade and Investment Partnership* (Oct. 14 2014), *available at* http://www.europarl.europa.eu/RegDataletudes/IDAN/2014/536404/EXPOIDA(2014)536404EN.pdf; *Trans-Pacific Partnership (TPP): More Job Offshoring, Lower Wages and Unsafe Food Imports*, Public Citizen, *available at* http://www.citizen.org/TPP (last visited May 11, 2016).

2 Transatlantic Trade and Investment Partnership, currently being negotiated by the United States and European Union, no definitive or complete text available. However, some of the European Commission's negotiation texts are *available at* http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230 (last visited May 10, 2016).

3 Trans-Pacific Partnership, signed on Oct. 5, 2015 by Brunei, Chile, New Zealand, Singapore, Australia, Canada, Japan, Malaysia, Mexico, Peru, United States, and Vietnam. Not yet entered into force. Full text of treaty *available at* http://tpp.mfat.govt.nz/text (last visited May 10, 2016) and https://ustr.gov/sites/default/files/TPP-Final-Text-Regulatory-Coherence.pdf (last visited May 13, 2016).

4 Claude Barfield, *The Trans-Pacific Partnership: A Model for Twenty-First-Century Trade Agreements?*, International Economic Outlook, Washington D.C.: American Enterprise Institute for Public Policy Research, 2011, *available at* https://www.aei.org/publication/the-trans-pacific-partnership (last visited May 11, 2016).

5 Reeve T. Bull, Neysun A. Mahboubi, Richard B. Stewart & Jonathan B. Wiener, *New Approaches to International Regulatory Cooperation: The Challenge of TTIP, TPP, and Mega-Regional Trade Agreements*, 78(4) Law & Contemp. Probs. 1, 2 (2015).

6 Prominent democrats like Hilary Clinton, Bernie Sanders and Elizabeth Warren oppose the TPP. *See* Jason Easley, *Hilary Clinton Sides with Elizabeth Warren and Bernie Sanders against Obama Trade Agenda*, PoliticusUSA (Jun. 15, 2015), *available at*

be in jeopardy due, in part, to the lack of transparency in the process as well as the open opposition of President Donald Trump who recently withdrew the U.S. signature from the TPP.[7] During the seven years of negotiations, no drafts or texts of the TPP were made available openly to the public, although some chapters were leaked early. So secretive was the process that WikiLeaks leaked confidential drafts, such as the environmental chapter.[8] Even after the TPP was signed on October 5, 2015,[9] no complete draft of the agreement was made public until November 5, 2015. While the lack of transparency in the negotiations has received a lot of attention in the popular press and academia, there is another aspect that has received little attention, but is of equal, and perhaps greater lasting concern: the challenges posed by the hardening of "soft law" standardization and harmonization provisions throughout the TPP.

This article tackles the problem of such hardening in three distinct ways. First, as a way to broadly define the current trade landscape, I argue that the rise of regulatory harmonization rules enforced by stronger global administrative law mechanisms enables the new generation of trade treaties to be "shape-shifters," switching between benchmark (or effort/aspirational) and resolution (or benchmark/enforceable) within the same treaty regime. This phenomenon is important because it undermines our traditional understandings of hard law versus soft law, and also blurs the distinction between public law and private law. Second, I define regulatory coherence and trace its development in recent American bilateral free trade agreements, showing that it has found its most ambitious expression in the new mega-regional agreements. Third, I use the TPP as a case-study to show that reliance on international standard setting organizations is now common-place, and moreover, a powerful mechanism for regulatory harmonization. Even if the TPP does not enter into force, its structure and content will shape future trade deals so that the mechanisms studied in this article still merit attention. Lastly, I explore some normative implications of these trends, highlighting important questions for future research.

This article proceeds in five parts. Section II situates the article in the current debate on the proper role of multilateral efforts in international trade law, defines some key terms, and traces the history of U.S. bilateral free trade agreements' approach to regulatory coherence. Section III discusses the growing power of international standard setting organizations and demonstrates how they can impact the nature of trade norms in the new generation of trade treaties. Section IV provides a detailed analysis of the different mechanisms embedded in the TPP with respect to regulatory coherence, harmonization, and standardization. Section V highlights implications and identifies areas for future research. Section VI concludes.

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http://www.politicususa.com/2015/06/15/hillary-clinton-sides-elizabeth-warren-bernie-sanders-obama-trade-agenda.html.

7 Jana Kasperkevic, *TPP or not TPP? What's the Trans-Pacific Partnership and Should We Support It??* The Guardian, Oct. 5, 2015, *available at* http://www.theguardian.com/business/2015/oct/05/tpp-or-not-tpp-whats-the-trans-pacific-partnership-and-should-we-support-it.

8 *Secret Trans-Pacific Partnership Agreement (TPP) - Environmental Chapter* (Press Release), WikiLeaks, Jan. 14, 2014.

9 The TPP is still subject to legal review and domestic ratification processes.

II. A New Generation of Trade Treaties

A. Critiques of Multi-lateral Legal Regimes

Traditional treaty-making has come under assault in recent years, both in the popular press and in the academic literature. In the international environmental law arena, disappointment with the lack of results from international climate conferences in Durban, South Africa[10] (the successor to Kyoto)[11] has led the New York Times to opine that such conferences are futile and ineffective.[12] Trade treaties have also come under attack, with frustrations running high in particular during the long years of the stalemate in the World Trade Organization's Doha round of negotiations.[13]

In the academic literature, critiques of the multilateral trading regime have come in numerous forms. For purposes of this article, it suffices to summarize the main critiques. The critiques fall broadly into three categories: pragmatic, privatization, and liberal theory. Pragmatist critiques tend to fault multilateral treaty negotiations are too cumbersome, long, and inefficient. For example, Professors Sungjoon Cho and Claire R. Kelly have argued that extensive lobbying slows treaty negotiations,[14] negotiators are loath to curtail their flexibility by making meaningful commitments,[15] and treaties are often concluded with numerous reservations and exceptions that hamstring their effectiveness.[16] A second set of scholars, like Professors Kenneth Abbott and Duncan Snidal, exemplifies the privatization critique of traditional treaty regimes. Abbott and Snidal criticize the "persistent regulatory inadequacies" of treaty-centric "Old Governance" and favor voluntary, private networks as more effective and more likely to fill regulatory gaps.[17]

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10 *See* Geoffrey Lean, *Climate Change Conference: Durban Deal Gives the World a Chance*, Telegraph, Dec. 12, 2011, *available at* http://www.telegraph.co.uk/earth/environment/climatechange/8950144/Climate-change-conference-Durban-deal-gives-the-world-a-chance.html (discussing a "third consecutive all-night session" and noting that the conference ended thirty-six hours late). *See also* United Nations Framework Convention on Climate Change, Durban Climate Change Conference - Nov./Dec. 2011, *available at* http://unfccc.int/meetings/durban_nov_2011/meeting/6245.php (celebrating progress at Durban as a "breakthrough on the international community's response to climate change").

11 *See* United Nations Framework Convention on Climate Change, Kyoto Protocol (2012), *available at* http://unfccc.int/kyoto_protocol/items/2830.php.

12 *See* Editorial, *Beyond Durban*, N.Y. Times, Dec. 17, 2011 at A24 [hereinafter Editorial, N.Y. Times] (opining that large multilateral conferences are not the place to search for solutions to climate change).

13 *See* Phoenix X.F. Cai, *Between Intensive Care and the Crematorium: Using the Standard of Review to Restore Balance to the WTO*, 15 Tulane J. Int'l & Comp. L. 465 (2007).

14 Sungjoon Cho & Claire R. Kelly, *Promises and Perils of New Global Governance: A Case of the G20*, 12 Chi. J. Int'l L. 491, 497 (2012) (collecting literature on multilateral treaty failures and identifying why treaties are ineffective at coordinating global financial regulations and advocating for regulatory networks supervised by the G20).

15 *See id.* at 498.

16 *See id.* at 497.

17 *See* Kenneth W. Abbott & Duncan Snidal, *Strengthening International Regulation Through Transnational New Governance: Overcoming the Orchestration Deficit*, 42 Vand. J. Transnat'l L. 501, 510 (2009) (describing and advocating a transnationally linked and voluntarily promulgated system of regulatory norms); *see also* Robert V. Percival, *Global*

Yet other scholars, like Professor Anne-Marie Slaughter, advance the argument, central to liberal theory, that one of the "most important and effective" means of global governance is not top-down international treaty law but "direct regulation of private actors ... with deliberate transnational or global intent."[18] Each of the pragmatic, privatization, and liberal theory critiques is powerful on its own and together, they have opened the door for a new generation of treaties to emerge. Whether these broad, 21st century trade agreements succeed in tackling persistent technical barriers to trade depends largely on how well they fulfill the promise of regulatory coherence. As commentator Thomas Bollyky has explained, technical barriers are particularly problematic in a globalized economy because "[u]nclear, excessive, or duplicative regulatory requirements can impede new global production. In unbundled global supply chains, intermediate services and parts crisscross borders multiple times. As the number of countries and transactions multiply, so do the costs of inefficient and divergent regulations."[19] The next section defines what is meant by regulatory coherence and traces its evolution in modern U.S. bilateral free trade agreements to its current form in the TPP.

B. Regulatory Coherence as a core concept in 21st Century Trade Treaties

The concept of regulatory coherence, while much bandied about, is difficult to define. Regulatory coherence is often used very generically, encompassing a huge continuum of activities, ranging from, on the one hand, uncoordinated regulatory activities with some information sharing (or transparency) mechanisms to fully uniform regulatory homogeneity, fully harmonized regulations (or a single global administrative law), on the other hand. Others take the approach that regulatory coherence is primarily concerned with the procedural aspects of good regulatory practices. The TPP's regulatory coherence chapter takes this approach:

> Regulatory coherence refers to the use of good regulatory practices in the process of planning, designing, issuing, implementing, and reviewing regulatory measures in order to facilitate achievement of domestic policy objectives, and in efforts across governments to enhance regulatory cooperation in order to further those objectives and promote international trade and investment, economic growth and employment.[20]

Law and the Environment, 86 Wash. L. Rev. 579, 582, 633-34 (2011) (recommending a focus on "global law," which encompasses various governmental and nongovernmental methods of enhancing the transparency of multinational corporate acts).

18 *See* Anne-Marie Slaughter, *A Liberal Theory of International Law*, 94 Am. Soc'y Int'l L. Proc. 240, 245-46 (2000) (applauding the rise of transnational regulatory networks and "private regimes" arising from corporate codes of conduct" as a more democratic form of global governance); *see also* Jose E. Alvarez, *Interliberal Law: Comment*, 94 Am. Soc'y Int'l L. Proc. 249, 251 (2000) (characterizing as a central assumption of liberal theory the proposal "that the future of effective international regulation lies not with traditional treaties ... but with transnational networks of government regulators").

19 Thomas J. Bollyky, *Better Regulation for Freer Trade, Council on Foreign Relations*, Jun. 2012, Policy Innovation Memorandum 22, *available at* http://www.cfr.org/trade/better-regulation-freer-trade/p28508.

20 *See* TPP, *supra* note 3, art. 25.2.

The TPP approach reflects the growing consensus among leading bodies in the regulatory reform movement, such as the Asia-Pacific Economic Cooperation Committee (APEC), to which all TPP member states are party, and the Organisation for Economic Co-operation and Development (OECD) to focus on good regulatory practices. Both APEC and OECD have spear-headed efforts to define good regulatory practices.[21] The OECD's approach is illustrative:

> Good regulation should: (i) serve clearly identified policy goals, and be effective in achieving those goals; (ii) have a sound legal and empirical basis; (iii) produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental and social effects into account; (iv) minimise costs and market distortions; (v) promote innovation through market incentives and goal-based approaches; (vi) be clear, simple, and practical for users; (vii) be consistent with other regulations and policies; and (viii) be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels.[22]

A key component of the OECD's good regulatory practices metrics is the Regulatory Impact Assessment, defined as a "process of systematically identifying and assessing the expected effects of regulatory proposals, using a consistent analytical method."[23] The OECD advocates cost/benefit and similar analyses for proposed regulations and emphasizes the need for evidence-based decision-making, particularly in the fields of public safety, public health, and environmental protection.[24] These principles have been part of the U.S. regulatory toolbox for some time, and the TPP extends their reach to other member states.[25]

This article uses the term "regulatory coherence" to refer broadly to all the procedural mechanisms related to good regulatory practices, following the approach of the TPP and the OECD. Thus, regulatory coherence sweeps in all components of good regulatory practices as well as the use of regulatory impact assessments as a specific tool of good regulatory practice.

However, it is also necessary to define regulatory cooperation, regulatory harmonization, and regulatory standardization, all terms that are either not defined or ill-defined in the existing literature, or confused with regulatory coherence. I use *regulatory cooperation* to refer to exercises in transparency, such as notification requirements, public hearings, publication of proposed regulations in plain language and/or a website, information exchanges with other regulators, notifying other governments of proposed regulations, timely notice of changes to regulations,

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21 *See, e.g.,* OECD, APEC-OECD Integrated Checklist on Regulatory Reform (OECD Publishing, 2008), *available at* https://www.oecd.org/regreform/34989455.pdf.

22 OECD, OECD Guiding Principles for Regulatory Quality and Performance 3 (OECD Publishing, 2005), *available at* http://www.oecd.org/fr/reformereg/34976533.pdf.

23 OECD, Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA) (OECD Publishing, 2008), *available at* https://www.oecd.org/gov/regulatory-policy/44789472.pdf.

24 Council of the OECD, Recommendation of the Council on Regulatory Policy and Governance 4 (OECD Publishing, 2012), *available at* http://www.oecd.org/governance/regulatory-policy/49990817.pdf.

25 *See, e.g.,* Improving Regulation and Regulatory Review, Executive Order 13563, 76 Fed. Reg. 3821 (Jan. 18, 2011).

and such like measures.[26] *Regulatory harmonization*, on the other hand, entail much deeper forms of integration. It does not mean that all jurisdictions must adopt the same or substantially similar regulations, which would not be appropriate. However, as used in this article, regulatory harmonization refers to all the different mechanisms that can be used to reduce *substantive* differences or divergences across regulatory jurisdictions. Regulatory harmonization efforts can take many forms, including recognition of another country's regulations as equivalent, mutual recognition of tests and certifications (called conformity assessments), adoption and recognition of international standards, adoption of joint regulations through a single integrated regulatory body, or adoption of a global administrative law. Currently, there are few examples of a joint regulator[27] and the prospects for a global regulatory law are probably quite distant.[28] However, recognition of another country regulations, mutual recognition of conformity testing and certifications, and recognition of international standards are ubiquitous examples of harmonization. The TPP contains numerous examples of all of these methods.[29]

Lastly, I use *regulatory standardization* to refer to the process of adopting or recognizing of international codes of standards, including private codes of conduct, regardless of the mechanism used to do so. Thus, for example, if the United States adopts an international standard as part of a domestic regulation or if the United States is required to recognize an international standard that has been adopted by the World Trade Organization's Committee on Technical Barriers to Trade, both would be examples of standardization. Thus, for purposes of this article, standardization is a possible pathway to harmonization, which deals with substantive norms, while regulatory coherence deals with procedural safeguards ensuring good regulatory practices. For ease of reference, the following table summarizes the key terms as used in this article:

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[26] I use "regulatory cooperation" as equivalent to transparency measures, and therefore as fairly shallow integration, in order to highlight the fact that cooperation is not the same as regulator harmonization. In this regard, I differ from many commentators who seem to use the terms cooperation and harmonization as loosely synonymous. *See, e.g.*, Bernard M. Hoekman & Petros C. Mavroidis, *Regulatory Spillovers and the Trading System: From Coherence to Cooperation*, 2-3, E15 Initiative, ICTSD and World Economic Forum, Apr. 2015, *available at* http://e15initiative.org/wp-content/uploads/2015/04/E15-Regulatory-OP-Hoekman-and-Mavroidis-FINAL.pdf (defining regulatory cooperation as measures that may reduce regulatory differences between jurisdictions and distinguishing between shallow and deep cooperation measures.) In Hoekman and Mavroidis's framework, what I call cooperation would be their shallow cooperation and what they call deep cooperation would be what I call harmonization.

[27] The leading example is the joint Food Standards Australia and New Zealand (FSANZ) created in 1995, *see generally,* http://www.foodstandards.gov.au/Pages/default.aspx (last visited May 12, 2016).

[28] *But see generally,* Benedict Kingsbury, Nico Kirsh & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 Law & Contemp. Probs. 15 (2005) (assessing the normative case for and against promotion of a unified field of global administrative law).

[29] *See infra* section IV.

Term	Brief Definition	Focus
Regulatory **Coherence**	Good regulatory practices	Procedural
Regulatory **Cooperation**	Transparency and outreach	Procedural
Regulatory **Harmonization**	Reduction of divergences	Substantive
Regulatory **Standardization**	A means to reduce divergences through adoption of international codes or standards	Substantive

C. U.S. Regulatory Coherence Efforts and the Emergence of Regulatory Coherence as a Policy Goal

1. U.S. Bilateral Free Trade Agreements

Recent U.S. bilateral free trade agreements (other than U.S.-Korea) have largely taken a two-pronged approach to regulatory coherence: (1) a World Trade Organization (WTO) driven strategy based on incorporation of WTO disciplines, including any interpretations and recommendations of the WTO Committee on Technical Barriers to Trade and (2) a focus on regulatory cooperation and transparency, including a coordination chapter or committee to oversee such cooperation. This two-pronged approach, without the addition of any substantive harmonization efforts, characterizes the U.S. bilateral free trade agreements with Australia (2005), Bahrain (2006), Chile (2004), Columbia (2012), Morocco (2006), and Peru (2009). All of these bilateral agreements contain a chapter on technical barriers on trade that are substantially similar to each other, if not identical. With respect to regulatory coherence efforts, they tend to use soft, hortatory language such as "the parties shall intensity their joint work"[30] or "the parties shall give positive consideration to accepting as equivalent technical regulations."[31]

These agreements do contain detailed provisions aimed at one key aspect of regulatory harmonization - the broad range of mechanisms for recognition of conformity assessments, which facilitates international trade by ensuring that exporters need to have their products tested and certified for conformity with regulations only once. The language from the U.S.-Peru Free Trade Agreement is typical and illustrative:

> Article 7.4: Conformity Assessment
>
> 1. The Parties recognize that a broad range of mechanisms exists to facilitate the acceptance in a Party's territory of the results of conformity assessment procedures conducted in another Party's territory. For example:

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[30] *See, e.g.,* U.S.-Columbia Free Trade Agreement, entered into force May 15, 2012, art. 7.3, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text (last visited May 13, 2016).

[31] *See, e.g.,* U.S.-Australia Free Trade Agreement, entered into force Jan. 1, 2005, art. 8.5.1, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text (last visited May 13, 2016).

> (a) the importing Party may rely on a supplier's declaration of conformity;
> (b) a conformity assessment body located in the territory of a Party may enter into a voluntary arrangement with a conformity assessment body located in the territory of another Party to accept the results of each other's assessment procedures;
> (c) a Party may agree with another Party to accept the results of conformity assessment procedures that bodies located in the other Party's territory conduct with respect to specific technical regulations;
> (d) a Party may adopt accreditation procedures for qualifying conformity assessment bodies located in the territory of another Party;
> (e) a Party may designate conformity assessment bodies located in the territory of another Party; and
> (f) a Party may recognize the results of conformity assessment procedures conducted in the territory of another Party.
>
> The Parties shall intensify their exchange of information on these and other similar mechanisms.[32]

The treaty continues by requiring each party, upon request, to explain the reasons for not recognizing conformity assessments[33] or for refusing to negotiate on mutual recognition agreements[34] and to give the other party's assessments bodies national treatment (no less favorable or non-discriminatory treatment).[35]

The recent generation of free trade agreements also contain similar approaches to standardization. All of them contain the identical provision that:

> In determining whether an international standard, guide, or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement exists, each Party shall apply the principles set out in Decisions and Recommendations adopted by the Committee since 1 January 1995, G/TBT/1/Rev.8, 23 May 2002, Section IX (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), issued by the WTO Committee on Technical Barriers to Trade.[36]

However, the U.S.-Australia Free Trade Agreement goes one step further by requiring that "[e]ach Party shall use relevant international standards to the extent provided in Article 2.4 of the Technical Barriers to Trade (TBT) Agreement, as a basis for its technical regulations."[37] It also requires the U.S. and Australia to

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[32] U.S.-Peru Free Trade Agreement, entered into force Feb. 1, 2009, art. 7.4.1, *available at* https://ustr.gov/sites/default/files/uploads/agreements/fta/peru/asset_upload_file555_9514.pdf (last visited May 13, 2016).

[33] *Id.* art. 7.4.2.

[34] *Id.* art. 7.4.4.

[35] *Id.* art. 7.4.3.

[36] *See, e.g.,* U.S.-Morocco Free Trade Agreement, entered into force Jan. 1, 2006, art. 7.3, *available at* https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file803_3833.pdf (last visited May 13, 2016).

[37] *See* U.S.-Australia Free Trade Agreement, *supra* note 31, art. 8.4.1.

"consult and exchange views"[38] on regulations under discussion in international or regional standard setting organizations.

The Korea-U.S. Free Trade Agreement adds on a few more layers of regulatory coherence obligations. It lays the foundation for the approach adopted in the mega-regionals like the TTIP and the TPP. The Korea-U.S. Free Trade Agreement contains all the characteristics described above (without the two additional provisions on international standards in the U.S.-Australia Free Trade Agreement) and adds on a few worth noting. First, it introduces more specific requirements related to transparency, in both its section on technical barriers to trade and a separate Chapter 21 on Transparency.[39] For example, there are provisions calling for regulations to be published in advance,[40] with an allowance of at least 60 days for comment from the other party,[41] an opportunity for public comment,[42] and notification of any technical standards that comply with international standards.[43] More significantly, the Korea-U.S. Free Trade Agreement introduces for the first time a separate annex on automotive standards and technical regulations.[44] This sectoral, industry-specific approach, with binding substantive annexes on technical standards, would be expanded on and used heavily in the TPP. Appearing on stage for the first time, it requires Korea and the U.S. to "cooperate bilaterally, including in the World Forum for Harmonization of Vehicle Regulations of the United Nations Economic Commission for Europe (WP.29) to harmonize standards for motor vehicle environmental performance and safety."[45] It also adds a substantive requirement that "technical regulations related to motor vehicles shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking into account of the risks non-fulfillment would create."[46] In addition, the treaty establishes an Automotive Working Group to monitor compliance, and vests it with the power to conduct post-implementation review of the Automotive Annex.[47] Lastly, the Korea-U.S. Free Trade Agreement explicitly defines good regulatory practice, adopting verbatim the OECD definition.[48]

The approach of recent U.S. free trade agreements to regulatory coherence may be summarized into two phases. The first phase builds on existing WTO commitments, especially based on the TBT agreement, but adds a number of transparency and cooperation mechanisms. The second phase, seen first in the U.S.-Australia Free Trade Agreement, but reaching a more mature expression in Korea-U.S., increasingly focuses on regulatory good practice, particularly on pushing adoption and recognition of international standards. The Korea-U.S. agreement goes even further by explicitly adopting harmonization of international

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38 *Id.* art. 8.4.3.

39 U.S.-Korea Free Trade Agreement, entered into force Mar. 15, 2012, ch. 21, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text (last visited May 13, 2016).

40 *Id.* art. 7.6.3.

41 *Id.* art. 7.6.3.

42 *Id.*

43 *Id.* art. 7.6.6.

44 *Id.* art. 9.7.

45 *Id.* art. 9.7.1.

46 *Id.,* art. 9.7.2.

47 *Id.* Annex 9-B, arts. 2, 3, 4, and 5.

48 *Id.* art. 9.10, *see also, supra* note 22.

standards in automotive emissions and safety as a goal. In the Korea-U.S. Free Trade Agreement, we witness a combination of 1) establishment of new substantive standards, 2) use of industry specific annexes and 3) post implementation review mechanisms as an enforcement tool.

2. Regulatory Cooperation Councils

In addition to free trade agreements, the U.S. has pursued regulatory coherence through bilateral efforts with Canada and Mexico, its NAFTA partners, although seemingly not under the direct aegis of NAFTA. The U.S.-Mexico and U.S.-Canada Regulatory Cooperation Councils are both examples of bilateral cooperation efforts among domestic regulators to facilitate regulatory cooperation. The U.S.-Canada Regulatory Cooperation Council was established in February 2011, and launched a joint action plan in December 2011 adopting 29 initiatives to foster new approaches to regulatory cooperation. In 2014, it released another joint action plan detailing lessons learned from the 29 laboratories of inter-agency cooperation.[49] The U.S.-Canada Regulatory Cooperation Council's future work will focus on 1) department level regulatory partnerships, 2) department to department commitments and work plans, and 3) cross-cutting issues in bilateral regulatory cooperation. The efforts of the council seem to be well-received.[50] The U.S.-Mexico High-level Regulatory Cooperation Council is similar to the U.S.-Canada one. It was established in 2010 and released a work plan in February 2012 outlining activities in seven sectors: food, transportation, nanotechnology, e-health, oil and gas, and conformity assessment.[51] The parties filed a progress report on their work in August 2013[52] and future efforts seem to be focused on getting stakeholder input. While these bilateral cooperative efforts are undoubtedly important for opening and continuing dialogue and information exchange among domestic regulatory actors in each country, it is difficult at this point to assess how much has been accomplished.

3. Executive Order 13609

Yet another example of recent U.S. efforts to domestically encourage regulatory cooperation with trading partners is President Obama's Executive Order 13609, ordering executive-branch agencies to avoid unnecessary divergences between U.S. regulations and those of major trading partners.[53] The order's goal is to increase regulatory efficiency and simplification in the international arena, calling on agencies and to reduce redundant and unnecessary regulations and

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49 *See generally,* http://www.trade.gov/rcc/documents/RCC_Joint_Forward_Plan.pdf (last visited May 13, 2016).

50 Cheryl Bolen, *If U.S.-Canada Cooperation is a Good Idea, Why Aren't More Federal Agencies Doing It?*, Bloomberg BNA Daily Rep. for Executives (Oct. 17, 2014), *available at* http://www.bna.com/uscanada-cooperation-good-n17179897089 (last visited May 13, 2016).

51 United States-Mexico High-Level Regulatory Cooperation Council Work Plan, *available at* https://www.whitehouse.gov/sites/default/files/omb/oira/irc/united-states-mexico-high-level-regulatory-cooperation-council-work-plan.pdf (last visited May 13, 2016).

52 *See generally,* http://trade.gov/hlrcc (last visited May 13, 2016).

53 Exec. Order No. 13609, 77 Fed. Reg. 26,413 §3 (May 1, 2012).

develop strategies and practices across the federal bureaucracy designed to enhance international regulatory cooperation. Executive Order 13609 is laudable and important as a means of signaling, at the highest level, the importance of regulatory cooperation. It communicates clearly to federal regulators that they would "receive credit for economic savings achieved through eliminating unnecessary regulatory divergences,"[54] thereby creating a clear incentive for them to invest efforts in regulatory cooperation efforts. Nonetheless, Executive Order 13609 falls short in two significant ways. It lacks any enforcement mechanisms.[55] Second, it does not define clearly which regulations are likely to have "a significant international impact."[56] There are a number of possible approaches to take, such as, among others, all rules dealing with major trading partners, rules involving the largest amounts of foreign direct investment, rules involving goods or services contributing significantly to U.S. imports or exports, or all rules that the United States notifies to the WTO's Technical Barriers to Trade Committee. Using the latter approach, one commentator estimates that of the over 3500 rules the United States issues every year, approximately an average of 20% likely has a significant impact on international trade and investment.[57] Nonetheless, each regulatory agency must undertake its own subjective qualitative assessment to determine which of its rules are subject to Executive Order 13609,[58] and this can lead to uneven implementation.

4. Concerns with the Regulatory Coherence Measures of Mega-Regional Free Trade Agreements

Regulatory coherence has also taken center stage in both the TTIP and TPP negotiations. The specific approach of the TPP will be discussed in greater detail below in Section IV. Here, I will briefly sketch out some of the most salient concerns swirling in the academic literature around the rise of mega-regionals and their incorporation of regulatory coherence provisions. Many scholars worry that the horizontal, cross-cutting regulatory chapters will undermine democratic input and regulatory autonomy.[59] A related worry is the fear that comprehensive mega-regional free trade agreements will lead to governance problems such that they should include strong constitutional, participatory, and deliberative democratic

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54 *See* Bull, Mahboubi, Stewart and Wiener, *supra* note 5 at 21.

55 *See supra* note 53.

56 Daniel Perez, *Identifying Regulations Affecting International Trade and Investment: Better Classification Could Improve Regulatory Cooperation* 102, in US-EU Regulatory Cooperation: Lessons & Opportunities, Apr. 2016 Draft Report of the Regulatory Studies Center, The George Washington University, *available at* https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/US-EU_report_GWRSC.pdf (last visited May 13, 2016).

57 *Id.* at 102-07.

58 *Id.* at 102.

59 *See,* e.g., Alberto Alemanno, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences*, 18 J. Int'l Econ. L. 625 (2015); Jane Kelsey, *Preliminary Analysis of the Draft TPP Chapter on Domestic Coherence*, Citizens Trade Campaign, *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific_RegCoherence-Memo.pdf (last visited May 11, 2016).

protections.[60] Other scholars focus on institutional design issues in promoting regulatory convergence and cooperation. [61] Still others worry about conflicts between mega-regional trade agreements and the WTO, focusing particularly on the risk of regulatory gains not being extended to countries outside the mega-regional agreements.[62] A related strand considers the strong role international organizations have traditionally played in the field of regulatory cooperation and how such organizations will contribute under new trade agreements.[63] Still others highlight the benefits of laboratories of regulatory experimentation and urge caution in striving for uniformity of regulations.[64] Some commentators, less optimistically, raise the specter of "race to the bottom" regulations and the hardening of less than adequate rules into norms.[65] On the other hand, others welcome the attention drawn to regulatory processes for providing opportunities for institutional and procedural improvement in these processes.[66] This is by no means a comprehensive list of the concerns around regulatory coherence, but it provides a useful bird's eye view of the field and of the intensity of interest it has fostered. It is also worth noting that the current literature does not raise any concerns specific to the use of international standards as a method of regulatory harmonization.[67]

III. Trends Worth Watching

Two characteristics of the new generation of treaties bear examination for purposes of this article.[68] Both affect regulatory coherence in ways that have not been

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60 *See, e.g.,* Ernst-Ulrich Petersmann, *Transformative Transatlantic Free Trade Agreements without the Rights and Remedies of Citizens?* 18 J. Int'l Econ. L. 579 (2015).

61 *See, e.g.,* Debra P. Steger, *The Importance of Institutions for Regulatory Cooperation in Comprehensive Economic and Trade Agreements: The Canada- EU CETA*, 39 Legal Issues of Econ. Integration 1 (2011).

62 *See, e.g.,* Robert Howse, *Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?*, 78 Law & Contemp. Probs. 137 (2015).

63 *See, e.g.,* Jeffrey L. Dunoff, *Mapping A Hidden World of International Regulatory Cooperation,* 78 Law & Contemp. Probs. 267 (2015).

64 Jonathan B. Wiener and Alberto Alemanno, *The Future of International Regulatory Cooperation: TTIP as a Learning Process Towards a Global Policy Laboratory*, 78 Law & Contemp. Probs. 103 (2015).

65 *See, e.g.,* Filippo Fontanelli, *ISO and Codex Standards and International Trade Law: What Gets Said is Not What's Heard*, 60 Int'l & Comp. L. Q. 895 (2011) (arguing that standards are being used inappropriately as a ceiling rather an as a floor for regulation).

66 *See, e.g.,* Dan Ciuriak & Harsha Vardhana Singh, *Mega-Regionals and the Regulation of Trade: Implications for Industrial Policy*, 6-9, *available at* http://ssrn.com/abstract=2460501 (last visited May 13, 2016).

67 In fact, most commentators seem to view standardization positively. *See, e.g.,* James Bacchus, Clough Center Lecture, *A Common Gauge: Harmonization and International Law*, 37 B. C. Int'l & Comp. L. Rev. 1 (2014), K. William Watson & Sallie James, *Regulatory Protectionism: A Hidden Threat to Free Trade*, 723 Cato Inst. Pol'y Analysis 1, 3 (2013) (arguing that agencies should consider whether proposed rules are more trade restrictive than necessary to meet regulatory goals).

68 It is beyond the scope of this article to fully explore all the normative, theoretical, and practical implications, so I focus only on the two that are most salient for purposes of my argument.

closely studied in the literature to date. The first is increasing participation by non-governmental entities, including multinational corporations, NGOS, industry groups and representatives, and other private entities in treaty negotiations. This first trend is a direct response to both the privatization and liberal theory (democratic deficit) critiques. The second trend centers around the influence and power of international standard setting organizations, like the International Organization of Standardization, who now wield the power to shape the nature of treaty obligations.

A. Private Entity Participation in International Organizations and International Treaty Negotiations

Private entities began to obtain rights to participate in international organizations that were previously open only to state participation starting in the late 1990s. For example, the WTO dramatically changed its procedure after its Appellate Body ruled that WTO member could select "whomever they wished to represent them, from the government or outside."[69] Not only did this confirm the use of private firm representation for WTO dispute settlement cases, the WTO then began to accept submissions and amicus curiae briefs from non-state actors.[70] Soon environmental groups asked to submit amicus briefs for pending cases, and once the WTO agreed, industry groups and industry advocates for multinational corporations quickly jumped on the band-wagon.[71] The European Court of Human Rights has also granted access to non-state entities.[72] By 2001, approximately two hundred of the non-state actors with consultative status with the UN are business or industry associations.[73] In international treaty negotiations, corporations or their industry-related associations are also starting to exert greater direct influence. They are not only lobbying their national governments to ensure favorable outcomes in treaty conventions,[74] but they are actively shaping the discourse. It is not uncommon now for corporate representatives to be present in the negotiating room.[75] The U.S. solicited input from diverse stakeholder groups throughout the TPP negotiation

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69 *See* Philippe Sands, *Turtles and Torturers: The Transformation of International Law*, 33 N.Y.U. J. Int'l L. & Pol. 527, 544-47 (2001).

70 *Id.* at 544-45.

71 *Id.* at 545-46.

72 *Id.* at 546-47.

73 Stephen Tully, Corporations and International Lawmaking 7 (2007).

74 *See, e.g.*, John H. Cushman Jr., *Intense Lobbying Against Global Warming Treaty*, N.Y. Times, Dec. 7, 1997 at 28 (describing lobbying by "powerful business interests" against the climate change accord), *see also* Kasperkevic, *supra* note 7 (detailing the donations corporate members of the US Business Coalition for TPP made to U.S. Senate Campaigns during Senate debate on fast track approval authority for the TPP).

75 *See* Sands, *supra* note 69 at 547 ("[I]t is quite normal nowadays ... for the negotiating room to be half filled with representatives of industry and NGOs, for governments to find themselves sitting alongside British Petroleum and Friends of the Earth."); *see also* Tully, *supra* note 73 at 175-76 (describing participation by non-state actors at treaty conventions and noting that at one convention "the U.S. delegation met with national industries four times over two weeks and hosted a bilateral event with the host government together with local firms").

process, holding direct stakeholder engagement events and lectures,[76] as well as receiving written reports from numerous industry-specific advisory committees.[77] While NGOs also lobby and participate in treaty conventions, they are generally positively perceived as providing a powerful voice for the powerless and thereby enhancing the democratic process of openness and full participation.[78] However, the public is more suspicious of the motives[79] of corporate actors who in practice "create or shape the content, interpretation, efficacy, or enforcement of legal regimes."[80] Corporate actors influence treaty negotiations through efforts such as "lobby governments, frame issues in economic terms, submit proposals, distribute position papers, organize side events and raise issues for deliberation."[81] The influence of corporate actors in this context is problematic in several respects. Corporate actors are not accountable to the public in the same way state actors should be.[82] This leads to concerns that trade treaties benefit largely multinational corporations at the expense of the public at large. The inequality critique has animated the anti-globalization social movement for decades,[83] and still continues to provoke popular protests against trade treaties.[84] Some commentators also criticize

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76 *Direct Stakeholder Engagement,* Off. of the U.S. Trade Rep., *available at* https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/direct-stakholder-engagement (last visited May 12, 2016).

77 *Advisory Committee Reports on the Trans-Pacific Partnership,* Off. of the U.S. Trade Rep., *available at* https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/advisory-group-reports-TPP (last visited May 12, 2016).

78 Sigfrido Burgos Caceres, *NGOs, IGOs, and International Law: Gaining Credibility and Legitimacy Through Lobbying and Results*, 13 Geo. J. Int'l Aff. 79, 81 (2012) (demonstrating that well-organized political lobbying by NGOs can result in state-NGO alliances, such as the Landmines Convention and the International Criminal Court); Sophie Smyth, *NGO's and Legitimacy in International Development,* 61 U. Kan. L. Rev. 377, 382 (2012-2013) (arguing that NGO's contributions to international institutions turns not on legitimacy but on perceptions of effectiveness).

79 For critiques that shifting regulatory decision-making to transnational bodies enables well-organized economic interests to exert power and influence in "laundering" their preferred policies, *see, e.g.,* Barry Steinhardt, *Problem of Policy Laundering*, American Civil Liberties Union (Aug. 13, 2004), *available at* http://26konferencja.giodo.gov.pl/data/resources/SteinhardtB_paper.pdf; *see also* Eyal Benvenisti & George W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 Stan. L. Rev. 595, 629 (2007).

80 Dan Danielsen, *How Corporations Govern: Taking Corporate Power Seriously in Transnational Regulation and Governance*, 46 Harv. Int'l L.J. 411 at 412 (2005) (examining significant private business roles in global governance); *see also* Sean D. Murphy, *Taking Multinational Corporate Codes of Conduct to the Next Level*, 43 Colum. J. Transnat'l L. 389, 392-95 (2005) (noting that "in an ideal world" governments might - on the prompting of civil society groups - issue more stringent regulations to control the behavior of multinational corporations, but in the real world civil society groups often do not press for more stringent regulations; moreover, some governments are "unwilling or unable" effectively to constrain multinational corporations through regulation).

81 *See* Tully, *supra* note 73 at 165.

82 Kishanthi Parella, *Outsourcing Corporate Accountability*, 89 Wash. L. Rev. 747, 749 (2014).

83 *The New Trade War*, Economist (Dec. 2, 1999).

84 *See, e.g.*, Thousands Protests TPPA around the Country, Yahoo News New Zealand, Aug. 16, 2015, Zach Carter, *Bernie Sanders' Brutal Letter on Obama's Trade Pact Fore-*

the TPP on the basis that it inappropriately addresses subject matters not related to trade.[85] Moreover, corporate actors have a strong incentive to persuade treaty negotiators to enshrine pre-existing norms in private regulatory networks that they have already espoused. I will address specific examples of this phenomenon in the context of the TPP in Section IV below. For now, it suffices to observe that, often, the norms in these private, largely voluntary regulatory networks are administered by international standard setting organizations, thereby creating a self-enforcing, hermetically sealed system in which corporate actors play a decisive role.

B. The Increasing Power of International Standard Setting Organizations

Private governance takes many forms. Professors Abbott and Snidal refer to the broad network of mechanisms - many of which are voluntary - in which corporate actors directly inform and create industry association standards, corporate social responsibility best practices, and transparency initiatives collectively as "Transnational New Governance."[86] The transnational new governance model is responsible for establishing norms for business conduct in a wide range of activities, from fair trade certification[87] to labor standards in the apparel industry[88] to investment banking norms for international project finance transactions.[89] These norms, which often start out as non-binding and voluntary in nature, can morph or harden into binding and enforceable norms over time. For example, fair trade certification regimes are voluntary in principle, but in practice they may accrue a compulsory market effect if they become widely accepted by both the industry concerned and by consumers. Fair trade coffee so dominates the brewed coffee market that the certification is virtually compulsory.[90] Interestingly, in the transnational new governance model, both governments and civil society assist in

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shadows 2016 Democratic Clash, The Huffington Post, Jan. 5, 2015; *see also* Paola Casale, *Everyone but the U.S. is Protesting the TPP, Why?*, Economy in Crisis, *available at* http://economyincrisis.org/content/everyone-but-the-u-s-is-protesting-the-tpp-why (last visited May 10, 2016).

85 Kelsey, *see supra* note 59.

86 *See* Abbott & Snidal, *supra* note 17 at 508-10.

87 *See* Abbott & Snidal, *supra* note 17 at 518, (discussing the Fairtrade Labeling Organization, an umbrella for national fair trade programs, as a collaborative effort between NGOs and firms); *see also* Margaret Levi & April Linton, *Fair Trade: A Cup at a Time?*, 31 Pol. & Soc'y 407, 414 (2003) ("Interlocking [government] relationships and interests with agribusiness make it unlikely that governments in coffee-producing countries will voluntarily regulate the coffee industry in ways that benefit small growers and workers").

88 *See* Alexis M. Herman, Sec'y of Labor, Remarks at the Marymount University Academic Search for Sweatshop Solutions (May 30, 1997), *available at* http://www.dol.gov/oasam/programs/history/herman/speeches/sp970603.htm (explaining that the U.S. Department of Labor convened a broad range of apparel industry stakeholders as the Apparel Industry Partnership, thereby setting the initial framework for regulatory standard setting in the apparel sector).

89 *See* Andrew Hardenbrook, *The Equator Principles: The Private Financial Sector's Attempt at Environmental Responsibility*, 40 Vand. J. Transnat'l L. 197, 200-01 (2007).

90 *See* Levi & Linton, *supra* note 87 at 419 (noting that "at least five European governments … subsidize NGO efforts to promote Fair Trade coffee").

this process of norm hardening. States do so by facilitating information sharing among industry groups, assisting with standard setting, threatening to regulate, or granting or withholding legal licenses.[91] NGOs contribute by publicizing private industry standards through compelling public relations campaigns, engaging in transnational litigation, boycotts, social media initiatives, and other means to enlist public support for and enforcement of better industry practices.[92]

Yet another aspect of the transnational new governance model is the role played by private standard setting organizations like the International Organization for Standardization or ISO.[93] ISO claims on its website to be "an independent, non-governmental membership organization and the world's largest developer of voluntary International Standards."[94] It consists of 162 members and is operated by a Central Secretariat based in Geneva.[95] ISO is not a public organization; its members must pay a fee to join.[96] ISO members are not delegates of national governments, but may be government officials or operate under a government mandate.[97] Other members hail from the private sector, and often represent national partnerships of industry groups and associations.[98] Since its founding in 1947, ISO has established

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91 *See* David Scheffer & Caroline Kaeb, *The Five Levels of CSR Compliance: The Resiliency of Corporate Liability under the Alien Tort Statute and the Case for a Counterattack Strategy in Compliance Theory*, 29 Berkeley J. Int'l L. 334, 334-35 (2011) (explaining the factors that motivate private industry to undertake corporate responsibility ventures); *see also* Neil Gunningham, *Corporate Environmental Responsibility: Law and the Limits of Voluntarism*, *in* The New Corporate Accountability: Corporate Social Responsibility and the Law 476-500 (Doreen McBarnet et al. eds., 2007) (introducing the concept of varied "licenses to operate" that inspire and motivate corporate social responsibility ventures).

92 *See, e.g.,* Joanne Scott, *From Brussels with Love: The Transatlantic Travels of European Law and the Chemistry of Regulatory Attraction*, 57 Am. J. Comp. L. 897, 920-28, 940 (2009) (showing how NGOs took a role in the transnational spread of the REACH regulations by publicizing industry use of dangerous chemicals); Sarah Dadush, *Profiting in (Red): The Need for Transparency in Cause-Related Marketing*, N.Y.U. J. Int'l L. & Pol. (2010) (arguing that many caused-based marketing organizations lack transparency); *see also* Gunningham, *supra* note 91 at 488-89 (explaining how industry CSR ventures are responsive to public reputation factors); David B. Hunter, *The Implications of Climate Change Litigation: Litigation for International Environmental Law-Making*, in Adjudicating Climate Change: State, National, and International Approaches 357, 357-74 (William C.G. Burns & Hari M. Osofsky eds., 2009) (proposing that transnational litigation is a meaningful strategy to prompt public awareness and private accountability for climate change even if the litigation is ultimately unsuccessful); Scheffer & Kaeb, *supra* note 91, at 335 (noting that reputational pressures contribute to development of CSR regimes).

93 The International Organization for Standardization (ISO) was formed in 1946 in order to "facilitate the international coordination and unification of industrial standards." Discover ISO: ISO's Origins, ISO, http://www.iso.org/iso/about/discover-iso_isos-origins.htm.

94 *About,* International Organization for Standardization, http://www.iso.org/iso/home/about.htm (last visited May 10, 2016).

95 *Id.*

96 *About Governance,* International Organization for Standardization, *supra* note 94.

97 *Membership Manual,* International Organization for Standardization, *supra* note 94.

98 *Id.*

over 20,500 standards, covering virtually every industry.[99] ISO does not establish standards for the electronic engineering and telecommunications industries, but collaborates with the two other international standards development agencies that work in these fields.[100] In recent years, ISO has expanded its scope and adopted standards relating to environmental protection and climate change (the ISO 14000 series[101]) and social responsibility and sustainable development (the ISO 26000 series[102]) launched in 2010. ISO's primary mission is the adoption of voluntary standards, leaving domestic implementation or incorporation of these standards to member countries. In practice, ISO standards are implemented directly by firms, who purchase ISO standards and engage in some form of certification (self or third-party) in order to signal quality to their customers.[103] As a result, ISO standards have achieved widespread market penetration, thanks in large part to its diffuse certification system, which relies heavily on self-certifications.[104] When a free trade treaty contains provisions on mutual recognition of conformity assessments (as the TPP does) and define them to include ISO certifications (as the TPP effectively does also), then the treaty contributes exponentially to ISO's market penetration.

Firms and consumers rely on ISO standards to send signals about quality. However, ISO explicitly sees its mandate as extending beyond improving quality through the adoption of uniform industrial standards: ISO's second mission is to facilitate international trade. In this sphere, ISO's importance to international trade took an exponential leap in 1995 after the WTO incorporated ISO standards into the regulatory framework of the TBT Agreement.[105] Similarly, the standards promulgated by the Codex Alimentarius Commission were incorporated into the Sanitary and Phyto-Sanitary Agreement (SPS).[106] WTO endorsement and adoption gave these private, voluntary standards the force of law, and the subject has

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99 *About,* International Organization for Standardization, *supra* note 94.

100 *About Governance,* International Organization for Standardization, *supra* note 94.

101 *Management Standards*, International Organization for Standardization, *supra* note 94; *see also,* J. Clapp, *The Privatization of Global Environmental Governance: ISO 14000 and the Developing World*, 4 Global Governance 295 (1998).

102 *Store,* International Organization for Standardization, *supra* note 94; *see also*, Diller, *infra* note 110 for a detailed account of the history and adoption of the ISO 26000 series.

103 ISO standards are not available to the public, but may only be purchased by interested firms and parties for a fee. The author conducted a quick review of approximately 150 standards across eight different industrial sectors and found that the fees for each standard range from 16 to 198 Swiss Francs, with most falling into the 38 to 88 Swiss Francs range. *See* International Organization for Standardization, *supra* note 94.

104 *See* D. A. Wirth, *The International Organization for Standardization: Private Voluntary Standards as Swords and Shields*, 36 B.C. Envir. Affairs L. Rev. 79, 85 (2009) (showing that certification for the ISO 14000 Environmental series are predominantly self-certifications despite the fact that the standards are written to be auditable and certifiable).

105 Agreement on Technical Barriers to Trade, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, opened for signature Apr. 15, 1994, entered into force Jan. 1, 1995, *available at* https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm (last visited May 10, 2016).

106 Sanitary and Phyto-Sanitary Agreement, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, opened for signature Apr. 15, 1994, entered into force Jan. 1, 1995, *available at* https://www.wto.org/english/tratop_e/sps_e/sps_e.htm (last visited May 10, 2016).

received a lot of scholarly attention.[107] Some scholars applaud the usefulness of these standards in assisting the WTO's efforts to combat regulatory protectionism[108] and other forms of disguised restrictions on trade. For example, James Bacchus, a former member of the WTO Appellate Body, believes that the WTO should lean in more and actively assist to develop, promulgate and enforce the standards in the TBT and SPS Agreements, arguing that the resulting global "common gauge" or standardization would "lower costs and increase efficiency, productivity, quality, reliability, and diversity of products."[109] Others worry about the lack of transparency in the development of such standards and seek to encourage more deliberate coordination between existing international governance structures and private standardization regimes.[110]

It is, however, abundantly clear that international standards are both here to stay and will continue to lie in the "very center of the trade debate."[111] Both the United States and the European Union have publically emphasized that the TTIP will yield great economic benefits resulting from mutual recognition and harmonization of standards.[112] Similarly, the TPP has explicitly incorporated the WTO's TBT Agreement as well as its adoption of standards set by organizations

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107 *See, e.g.,* Henrik Horn and Joseph H.H. Weiler, *European Communities - Trade Description of Sardines: Textualism and Its Discontent in* The American Law Institute Report 2002, 251, 260 (H. Horn & Petros C. Mavroidis eds., 2005); M. Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation and the Codex Alimentarius*, 81 N.Y. U. L. Rev. 766, 786-789 (2006); Y. Bonzon, *Institutionalizing Public Participation in WTO Decision Making: Some Conceptual Hurdles and Avenues,* 11 J. Int'l Econ. L. 751, 775ff (2008); J. Scott, *International Trade and Environmental Governance: Relating Rules (and Standards) in the EU and the WTO*, 15 Eur. J. Int'l L. 307, 310 (2004); 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, 391 (C. Joerges & Ernst U. Petersmanm eds., 2006). *C.f. see* Filippo Fontanelli, *ISO and Codex Standards and International Trade Law: What Gets Said Is Not What's Heard*, 60 Int'l & Comp. L.Q. 895 (2011) (questioning the hardening of ISO and Codex standards and arguing that the standards serve different purposes once incorporated into the WTO structure).

108 Alan O. Sykes, *Regulatory Protectionism and the Law of International Trade*, 66 U. Chi. L. Rev. 1, 1 (1999) (defining regulatory protectionism as intentional non-tariff barriers created by domestic regulations).

109 *See* Bacchus, *supra* note 67 at 1, 10-11 (2014).

110 *See, e.g.,* Janelle M. Diller, *Private Standardization in Public International Lawmaking*, 33 Mich. J. Int'l L. 481 (2011-2012) (examining the development of ISO Standard 26000 on Social Responsibility and proposing a set of best practices for improved coordination, openness and transparency).

111 *See* Bacchus, *supra note 109*, at 10 ("For standards are no longer at the periphery of the trade debate; with the continuing evolution of a fully global economy connected by the endless intricacies of global value chains, and with the concurrent rise of "regulatory protectionism," standards are now at the very center of the trade debate").

112 Michael Froman, Ambassador, U.S. Trade Rep., Remarks at the No Labels Business Leaders Forum (Sept. 17, 2014), https://ustr.gov/about-us/policy-offices/press-office/speeches/2014/September/Remarks-by-Ambassador-Froman-at-No-Labels-Business-Leaders-Forum; Karel De Gucht, E.U. Trade Commissioner, The Transatlantic Trade and Investment Partnership: Where Do We Stand on the Hottest Topics in the Current Debate? (Jan. 22, 2014), http://trade.ec.europa.eu/doclib/docs/2014/january/tradoc_152075.pdf.

like ISO and its partners in the telecommunications and electronic equipment industries.[113] The new generation of trade treaties all emphasize reducing regional divergences in standards through regulatory mutual recognition, information-sharing, and harmonization. While the economic effects anticipated through these efforts at regulatory coherence are likely to be significant, and indeed worthwhile, they may also have some unintended consequences.

C. Trade Treaties as Shape-Shifters

International agreements exhibit great heterogeneity. Some are binding, others are expressly non-binding. Some are robustly enforced and monitored with complex dispute settlement mechanisms. Others completely lack sanctions or compliance structures. Some require deep policy changes in terms of domestic implementation. Others merely set forth frameworks for creating new agreements. Still others do little more than enshrine the status quo. Despite the great variety of international treaties, it is possible to characterize the great majority of international treaties by considering four characteristics. I use the following four axis taxonomy based on a highly simplified, but still extremely useful, system derived from the work of Professor Kal Raustiala, who provides a much more detailed and nuanced conceptual framework for analyzing the architecture of treaties based on both form and substance characteristics.[114] However, this much simplified taxonomy allows us to see very clearly the core traits of the new generation of trade treaties, and to isolate the effects of international standards on these core traits.

Let's consider a simple four quadrant framework divided along (1) the vertical axis of Benchmark/Deep or Effort/Shallow treaties with either deep, substantive standards or shallow ones and (2) the horizontal axis of Resolution/Contract or Persuasion/Pledge treaties with either legally binding form containing enforceable contract-like provisions on one extreme and non-legally binding pledges designed to nudge or influence behavior (persuade states or private firms to change their behavior) and the other extreme. Treaties fall into four quadrants and plotting a treaty along the continuum offered by the two axis allows one to accommodate a great variety of treaties. This taxonomy also borrows from Melissa Durkee's work analyzing the characteristics of persuasion treaties in the international environmental law arena, and from her work I derive the resolution/persuasion dichotomy.[115] The system may be graphically depicted as follows:

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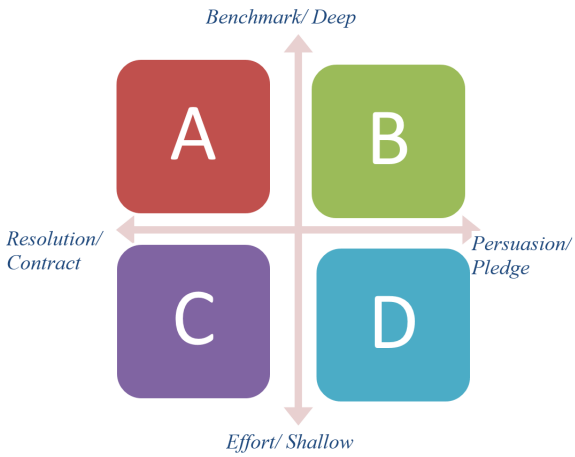
[113] *See* TPP, *supra* note 3, chapter 8 (Technical Barriers to Trade), arts. 8.1, 8.4, 8.8, and 8.9.

[114] Kal Raustiala, *Form and Substance in International Agreements*, 99 Am. J. Int'l L. 581 (2005).

[115] Melissa Durkee, *Persuasion Treaties*, 99 Va. L. Rev. 63 (2013).



Treaties may be plotted along the spaces provided by the four lettered quadrants provided by the two axis. To take a few examples, the WTO TBT and SPS Agreements would likely fall somewhere in Quadrant A, as they consist of binding substantive norms backed by a formal dispute settlement system. The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is likely to fall in Quadrant C because it consists of a mix of shallow substantive pledges (functioning as floors for protection of intellectual property rights) but with the backing of a dispute settlement system. On the other side, the Montreal Protocol is an example of a Quadrant B agreement as it calls for states to eliminate ozone depleting substances at a specific rate, although without robust enforcement. The United Nations Framework Convention on Climate Change with its shallow commitments would fit into Quadrant D. Some treaties may, of course, be hybrids, and would have to be plotted in multiple quadrants to best reflect the nature of different substantive provisions.

Classification of treaties, extremely useful in itself, is however, not the primary focus of this article. What interests me is the possibility that treaties may change character, or shift their shape, with time. With the overlay of international standardization efforts, a treaty that starts out in Quadrant B, may move over into Quadrant A due to the introduction and adoption of new international standards. This type of exogenous transformation, originating in activities outside the framework of the treaty, and in private organizations, has fascinating implications. A closer examination of the TBT and Regulatory Coherence chapters illustrates some of the complexities and raises new questions for further research. These issues are explored in greater detail in the next section.

IV. The Trans-Pacific Partnership and Harmonization of Standards

A. Regulatory Coherence

The Trans-Pacific Partnership provides an excellent case study to see the how international standards are transforming the very nature of international trade law. This account will focus on aspects of the TPP related to the interplay between the

Chapters on Regulatory Coherence (Chapter 25) and Technical Barriers to Trade (Chapter 8).

The preamble of the TPP articulates the general purpose of the treaty:

> [… to] establish a comprehensive regional agreement that promotes economic integration to liberalise trade and investment, bring economic growth and social benefits, create new opportunities for workers and businesses, contribute to raising living standards, benefit consumers, reduce poverty and promote sustainable growth;[116]

In addition, the parties to the TPP affirm, among other goals, that the treaty builds upon existing WTO rights and obligations,[117] and is aimed at establishing "a predictable legal and commercial framework for trade and investment through mutually advantageous rules."[118] In addition, the preamble refers to the goal of promoting "transparency, good governance and rule of law, and eliminate bribery and corruption in trade and investment."[119] While the language used here is typical of multi-lateral free trade treaties of similar scope, the TPP goes further than its predecessors in the prevalence of measures and obligations designed to enforce regulatory standardization and harmonization. For the first time in the history of American free trade agreements, the TPP devotes an entire separate chapter (Chapter 25) to regulatory coherence,[120] which super-imposes a thick layer of additional procedural and substantive obligations on TPP parties on top of the norms laid out in the subject-specific chapters of the treaty. The novelty of the approach is highlighted in the U.S. Trade Representative's new dedicated website to the TPP,[121] which sets out the full text of the signed treaty along with plain-language explanation advocating the TPP. The paragraph describing the new features of the Regulatory Coherence Chapter reads:

> TPP is the first U.S. Free Trade Agreement (FTA) to include a chapter on regulatory coherence, reflecting a growing appreciation of the relevance of this issue to international trade and investment. As in the United States, we expect these commitments to promote "good regulatory practice" principles in the regulatory development process, including coordination among regulators, opportunities for stakeholder input, and fact-based regulatory decisions that will serve to eliminate the prospect of overlapping and inconsistent regulatory requirements or regulations being developed unfairly and without

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116 TPP, *supra* note 3, Preamble.

117 *Id.* Preamble, 3rd paragraph.

118 *Id.* Preamble, 7th paragraph.

119 *Id.* Preamble, page 2.

120 *Id.,* ch. 25, Regulatory Coherence, art. 25.2: (General Provisions) defines regulatory coherence as follows: "regulatory coherence refers to the use of good regulatory practices in the process of planning, designing, issuing, implementing and reviewing regulatory measures in order to facilitate achievement of domestic policy objectives, and in efforts across governments to enhance regulatory cooperation in order to further those objectives and promote international trade and investment, economic growth and employment."

121 *See Trans-Pacific Partnership*, Office of the United States Trade Representative, *https*://ustr.gov/tpp/ (last visited May 14, 2016).

> a sound basis, including so as to benefit a particular stakeholder. Nothing in the chapter will affect the U.S. or other TPP Parties' right to regulate in the public interest, nor will anything in it require changes to U.S. regulations or U.S. regulatory procedures."[122]

As a piece of advocacy writing, it is not surprising that the description strikes a balance between exhorting the new feature of a separate Regulatory Coherence Chapter while at the same time emphasizing U.S. regulatory autonomy and "no effect" on U.S. regulations or regulatory procedures. However, the "no effects" claim is not warranted. In fact, the Regulatory Coherence chapter does introduce robust new obligations, many of which are framed as procedural safeguards that will, over time, change U.S. regulatory procedures and possibly substantive regulations as well.

While the TPP is voluminous, running to thousands of pages, the Regulatory Coherence Chapter is a slim nine pages, with only eleven sub-sections. It is an easy read, and at first glance, seems disarmingly non-ambitious in scope. It has only five key elements. First, it establishes domestic coordination and review processes to ensure no duplication and conflict among regulations.[123] Second, it urges TPP parties to implement good regulatory practices, including reliance on regulatory impact assessments based on an examination of the need for the regulation, examination of feasible alternatives, cost and benefit analysis, and up to date scientific, technical, economic or other relevant information.[124] Third, it sets up a Committee on Regulatory Coherence composed of TPP government officials, tasked with overseeing the implementation of the chapter. The Committee must met within one year of the date of the entry into force of the TPP[125] and at least once every five years.[126] In structure and scope, the committee is virtually identical to similar committees established under the U.S.-Korea, U.S.-Peru, U.S.-Chile and U.S.-Columbia Free Trade Agreements. Fourth, the Regulatory Coherence Chapter contains numerous cooperation mechanisms for the treaty parties to coordinate regulatory activities, including information sharing, training programs, and information exchanges among regulators.[127] Fifth and last, the chapter is exempt from the dispute settlement mechanism of the TPP established by Chapter 28, which creates a two-step consultation/good offices plus a definitive panel report by three trade experts reminiscent of the first two stages of WTO dispute settlement procedures.[128]

The Regulatory Coherence Chapter also contains many new initiatives aimed at transparency and public participation. For example, Article 25:2 (2) (d) requires parties to "take into account input from interested persons in the development of regulatory measures." The term "interested persons" is not defined, and thus may be broadly

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122 *Available at Regulatory Coherence*, Office of the United States Trade Representative, https://medium.com/the-trans-pacific-partnership/regulatory-coherence-6672076-f307a#.r09lu8ima (last visited May 11, 2016).

123 *See* TPP, *supra* note 3, art. 25.4.

124 *Id*. art. 25.5.

125 *Id*. art. 25.5 (6).

126 *Id*. art. 25.5 (7).

127 *Id*. art. 25.7.

128 *Id*. art. 25.11.

interpreted to include individuals, firms, corporate actors, NGOS, consumer advocacy groups, private standard-setting agencies, industry groups and even lobbying groups, regardless of geographic location. It is unprecedented for an economic treaty to mandate that governments take into consideration the submissions and views of such a diverse group of interested parties. It is also interesting to compare the language of Article 25:8 (Engagement with Interested Persons) with the language of Article 25:2. Article 25.8 requires the Committee on Regulatory Coherence (established by Article 25:6)[129] to "establish appropriate mechanisms to provide continuing opportunities for *interested persons of the Parties* to provide input on matters relevant to enhancing regulatory coherence."[130] Thus, the Committee on Regulatory Coherence, composed of government officials of the treaty parties, is required to heed input from "interested persons of the Parties" (presumably government and regulatory officials) while domestic governments need to take into account the views of all "interested persons" without regard to official status or national origin.

The TPP's regulatory coherence chapter also introduces a complex network of rules related to coordination, review processes, cooperation, and implementation of core good regulatory practices. These measures include, *inter alia*, improved interagency coordination (including the establishing of a central regulatory coordination agency by each member)[131] to minimize regulatory redundancies;[132] the establishment of regulatory impact assessment procedures in conformity with existing relevant scientific, technical or economic information;[133] information exchanges,[134] and coordination and agenda-setting by the Committee on Regulatory Coherence, which has the mandate to conduct reviews every five years to update recommendations on good regulatory practices.[135]

Numerous provisions in the TPP are aimed at increasing transparency by making available to the public information about regulatory measures, changes to such measures, and review and comment procedures. For example, Article 25:4 of the Regulatory Coherence Chapter exhorts each "Party should generally produce documents that include descriptions of those processes or mechanisms and that can be made available to the public."[136] The Chapter on Technical Barriers on Trade similarly contains numerous transparency measures, including the electronic publication, preferably either on the WTO website or another website, all proposals for new technical regulations, amendments or assessment procedures.[137]

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129 *Id.* art. 25:6 (Committee on Regulatory Coherence).

130 *Id.* art. 25:8 (Engagement with Interested Persons) (emphasis added).

131 *Id.* art. 25:4 (Coordination and Review Processes or Mechanisms), sec. 1.

132 *Id.* art. 25:4 (Coordination and Review Processes or Mechanisms), sec. 2(b).

133 *Id.* art. 25:5 (Implementation of Core Good Regulatory Practices).

134 *Id.* art. 25:5 (Cooperation), sec. 1(a).

135 *Id.* art. 25:6 (Committee on Regulatory Coherence), sec. 7.

136 *Id.* art. 25:4, sec. 2.

137 *Id.* ch. 8.7 (Transparency), 4*ter*, requires that "Each Party shall publish, preferably by electronic means, in a single official journal or website all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies, that a Party is required to notify or publish under the TBT Agreement or this Chapter, and that may have a significant effect on trade."

Thus, one can fairly summarize that the new Regulatory Coherence Chapter of the TPP focuses on regulatory practice and procedure, and not on substantive harmonization of regulations. Given the great diversity among TPP members on culture, legal traditions, and level of economic development, it is not surprising that negotiators failed to push for substantive harmonization. Indeed, many commentators anticipated the procedural approach.[138] However, one cannot dismiss the TPP as weak on pushing the substantive regulatory harmonization agenda.[139] Indeed, a very different picture emerges when one reads the Regulatory Coherence Chapter in conjunction with the TBT chapter and carefully consider how each informs and shapes the other. While some commentators have argued that the TPP's Regulatory Coherence lacks teeth due to the lack of dispute settlement enforcement or for the failure to impose sector-specific disciplines on regulatory barriers,[140] I argue that these critiques miss the point. The TPP's Regulatory Coherence Chapter is significant because it creates a systemic governance framework to ensure and deliver continuing improvements to the quality of regulations. It does so not by adopting any ground-breading substantive new rules on specific regulatory subjects, but by weaving a thick web of procedures that can used to deliver ongoing regulatory improvements. These procedures, when coupled with the mechanisms enforcing standardization of regulations, can and will advance regulatory harmonization. The next section illustrates how the substantive goal of regulatory harmonization may be pursued through a clear pathway laid out by the TBT obligations.

B. Standardization in the TBT Chapter of the TPP

By examining the substantive provisions of the TPP's chapter on technical barriers to trade, it will become clear that international standardization, harmonization, and regulatory coherence measures are key tools utilized in the TPP to promote predictability, stability, transparency, good governance and the rule of law. In particular, international standards play a prominent role, and are indeed the engine behind the TPP's regulatory coherence agenda. As a preliminary matter, the TPP's Chapter 8 on Technical Barriers to Trade incorporates by reference most of the

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138 *See generally*, Bollyky, *supra* note 19; Rodrigo Polanco, *The Trans-Pacific Partnership Agreement and Regulatory Coherence*, *in* Trade Liberalisation and International Co-operation: A legal Analysis of the Trans-pacific partnership, 254-6 (Tania Voon ed., Edward Elgar, 2013).

139 *Cf.* Elizabeth Sheargold & Andrew D. Mitchell, *The TPP and Good Regulatory Practices: An Opportunity for Regulatory Coherence to Promote Regulatory Autonomy?*, World Trade Review (2016) (forthcoming), *available at* http://ssrn.com/abstract=2728771 (last visited May 9, 2016) (arguing that the regulatory coherence chapter of the TPP does not break any substantive new ground, but is significant for its affirmation of good regulatory practices).

140 *See generally, e.g.,* Ines Willemyns, *Regulatory Cooperation in the WTO and at the Regional Level: What Is Being Achieved by CETA and TPP?* (Apr. 1, 2016). *Available at* SSRN: http://ssrn.com/abstract=2768058 (last visited May 12, 2016) (arguing that neither the TPP nor CETA succeeds in enacting adequate disciplines on regulatory barriers to trade in services).

substantive provisions of the WTO TBT Agreement.[141] The aim of the TBT Chapter is to "to facilitate trade, including by eliminating unnecessary technical barriers to trade, enhancing transparency, and promoting greater regulatory cooperation and good regulatory practice."[142] The TBT Chapter contains 11 sections of substantive and procedure rules, plus the addition of seven annexes covering specific rules related to wine and distilled spirits,[143] information technology products,[144] pharmaceuticals,[145] cosmetics,[146] medical devices,[147] proprietary formulas for pre-packaged food and food additives,[148] and organic products.[149]

The TBT Chapter relies heavily on international standards. In Article 8.5(1), the parties "acknowledge the important role that international standards, guides and recommendations can play in supporting greater regulatory alignment, good regulatory practice and reducing unnecessary barriers to trade."[150] On the question of what constitutes an international standard, the TPP parties agree to conform to the decisions of the WTO Committee on Technical Barriers to Trade.[151] The TBT Chapter echoes many of the coordination, cooperation, information sharing, and transparency measures set forth in the Regulatory Coherence Chapter. However, some divergences are noteworthy.

The TBT Chapter introduces specific rules for the mutual recognition of conformity assessment bodies of other treaty parties. Conformity assessments are tests and certifications of substantive compliance with a regulation by an entity, governmental or private. TPP parties are required to give national treatment (non-discriminatory recognition) to each party's conformity assessment body. This facilitates trade by ensuring that a firm's products need only be tested and certified once before accessing other TPP markets. Article 8:6 requires that each party "shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party."[152] TPP members are also required to apply the same or equivalent procedures for accreditation or licensing purposes to conformity assessment bodies located in the territory of other parties.[153] Strikingly, Article 8:6, Section 9 seems tailored to ensure that organizations like ISO are treated on an equal footing with national conformity assessment bodies. It is worth citing Section 9 in full:

> Further to Article 9.2 of the TBT Agreement, a Party *shall not refuse to accept*, or take actions which have the effect of, directly or indirectly,

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141 TPP, *supra* note 3, ch. 8 (Technical Barriers to Trade), art. 8.4 (Incorporation of Certain Provisions of the TBT Agreement).
142 *Id.* art. 8.2 (Objective).
143 *Id.* annex 8-A.
144 *Id.* annex 8-B.
145 *Id.* annex 8-C.
146 *Id.* annex 8-D.
147 *Id.* annex 8-E.
148 *Id.* annex 8-F.
149 *Id.* annex 8-G.
150 *Id.* art. 8.5 (International Standards, Guides and Recommendations), sec. 1.
151 *Id.* art. 8.5 (International Standards, Guides and Recommendations), sec. 2.
152 *Id,* art. 8.6 (Conformity Assessment), sec. 1.
153 *Id.*

> requiring or encouraging the refusal of acceptance by other Parties or persons of conformity assessment results from a conformity assessment body because the accreditation body that accredited the conformity assessment body:
> (a) operates in the territory of a Party where there is more than one accreditation body;
> (b) *is a non-governmental body*;
> (c) is domiciled in the territory of a Party that does not maintain a procedure for recognising accreditation bodies;
> (d) *does not operate an office in the Party's territory*; or
> (e) is a for-profit entity.[154]

Taken as a whole, the language of Section 9 could not describe ISO more perfectly: ISO is a not for profit, non-governmental body operating mainly in Geneva, with no presence in any of the TPP countries. However, the conformity assessments of private organizations like ISO shall be accorded the same treatment and deference as the accreditation bodies of treaty members.

The transparency mechanisms of the TBT Chapter also extend beyond the means contemplated in the Regulatory Coherence Chapter. It provides access to representatives of other treaty parties to "participate in the development of technical regulations, standards and conformity assessment procedures by its central government bodies"[155] by providing interested parties a reasonable opportunity to comment on proposed measures and by taking such comments into account prior to adoption of the regulation.[156] Parties are also encouraged to consider the use of electronic tools and public outreach or consultations in the development of technical regulations.[157] Moreover, Parties are enjoined to encourage non-governmental bodies in its territory to comply with the participation measures discussed here.[158]

Under the guise of transparency, the TBT Chapter establishes avenues for private organizations to receive unprecedented recognition, in the form of equal treatment with national accreditation or conformity assessment bodies, as well as new ways for non-governmental bodies to participate in the regulatory work of national bodies. Ironically, such measures may in practice undermine transparency goals. For example, under the TPP, member governments are required to publish, use notice and comment procedures, and justify any changes to certification or conformity assessment processes.[159] However, no provision requires a private non-governmental organization like ISO to follow the same procedures. In fact, the substantive contents of ISO standards are not available for public or scholarly viewing, but may only be purchased.[160] While each standard is not expensive on its own, with over twenty-thousand standards, it would be prohibitively costly to comprehensively examine applicable standards in any one industry. Nonetheless,

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154 *Id.* art. 8.5 (International Standards, Guides and Recommendations), sec. 9 (internal footnotes omitted and emphasis added).
155 *Id.* art. 8.7 (Transparency), sec. 1.
156 *Id.* art. 8.7 (Transparency), Footnote 4 to sec. 1.
157 *Id.* art. 8.7 (Transparency), sec. 2.
158 *Id.* art. 8.7 (Transparency), sec. 3.
159 *Id.* art. 8.5 (International Standards, Guides and Recommendations), secs. 1, 3, 11; *see also* art. 8.7 (Transparency), Footnote 4 to sec. 1.
160 *See supra* note 103.

despite the lack of transparency and public availability, ISO's certifications or conformity assessments would receive mutual recognition under Section 9 of Article 8.5 of TBT Chapter, even though they may be adopted without the same procedure safeguards that bind member states. Thus, one may characterize this aspect of the TBT Chapter as strikingly lop-sided - being far less restrictive of international standard setting organizations than of member states.

The subject matter specific annexes of the TBT Chapter also contain similarly problematic provisions aimed at standardization. The approach adopted in the regulation of pharmaceuticals and cosmetics are typical of the overall tone and methodology taken in the annexes. The Annex on Pharmaceuticals requires parties to "seek to collaborate through relevant international initiatives, such as those aimed at harmonization"[161] and to "consider relevant scientific or technical guidance documents developed through international collaborative efforts with respect to pharmaceutical products when developing or implementing regulations for marketing authorisations of pharmaceuticals products."[162] Most significantly, the Pharmaceuticals Annex sets the format and content of applications for marketing authorizations of new drugs, requiring the use of principles found in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Common Technical Document.[163] Vietnam negotiated for an extended period, to January 1, 2019, to comply with this provision. The Annex on Cosmetics contains similar provisions on harmonization initiatives,[164] requiring reliance on relevant scientific or technical guidance documents developed by international collaborative efforts,[165] and mandating a risk-based approach to regulating cosmetics.[166] Lastly, the Cosmetics Annex makes mandatory the use of relevant international standards when a member adopts good manufacturing guidelines, allowing a deviation only when the standards "would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued."[167]

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161 TPP, *supra* note 3, annex 8-C (Pharmaceuticals), sec. 5.

162 *Id.* annex 8-C (Pharmaceuticals), sec. 6.

163 *Id.* annex 8-C (Pharmaceuticals), sec. 11. "With respect to applications for marketing authorisation for pharmaceutical products, each Party shall accept for review safety, efficacy, and manufacturing quality information submitted by a person seeking marketing authorisation in a format that is consistent with the principles found in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Common Technical Document (CTD), including any amendments thereto, recognising that the CTD does not necessarily address all aspects relevant to a Party's determination to approve marketing authorisation for a particular product."

164 *Id.* annex 8-D (Cosmetics), sec. 5.

165 *Id.* annex 8-D (Cosmetics), sec. 6.

166 *Id.* annex 8-D (Cosmetics), sec. 7.

167 *Id.* annex 8-D (Cosmetics), sec. 13. "Where a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetic products, or the relevant parts of them, as a basis for its guidelines except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued."

C. Harmonization Mechanisms in Practice in the TPP: Fifty Ways to Adopt a Standard

Let's consider the effect of these myriad harmonization and standardization measures in terms of mapping onto the four treaty quadrants laid out above in Section III.C. Movement between the quadrants may occur purely as a function of standard-setting by private standardization organizations. I identify six new distinct methods in the TPP by which standards could harden into norms/regulations or alter the content of norms/regulations. These are by no means the only means, but merit examination because they are explicitly codified in the TPP as substantive obligations. For purposes of simplification only, I illustrate each of the methods in terms of the resulting movement leftward along the horizontal access from shallow to deep (from Quadrant D to A, and B to A), but the analytical framework is applicable for movements in other directions (from C to B, or A to D, for example) as well. In other words, the following examples highlight how international standards become deep, binding norms. The simplified mono-directional nature of the illustrations serves two purposes. First, it makes the analysis easier to follow. Second, it highlights why we should scrutinize the work of international standard setting bodies more closely because the power they wield under the TPP is considerable as a result of these six methods for their standards to transform into deep, binding norms.

There are six possible mechanisms for international standardization bodies (ISBs) to affect the nature of substantive norms under the TPP. The first four of the methods are endogenous to the TPP and last two are hybrids, originating in exogenous events at the WTO, but subsequently incorporated into the TPP. The mechanisms are: (1) direct domestic adoption, enforced by mutual recognition, of the certification procedures and decisions of ISBs,[168] (2) the participation of ISBs in notice and comment regulatory rule making procedures,[169] (3) the participation of ISBs in international cooperative efforts aimed at harmonization and mutual recognition,[170] (4) implementation by the TBT Committee of the TPP of new standards with respect to either the annexes of the TBT Chapter or the overall TBT Chapter,[171] (5) formal adoption of standards set by ISBs by the WTO TBT Committee, which are incorporated into the TPP,[172] and (6) any recognition of the legal or binding status of ISB standards through either the WTO dispute settlement process or the TPP dispute settlement process under Article 28 related to the Technical Barriers to Trade Chapter, although not the Regulatory Coherence Chapter.[173]

Let us consider a specific example related to the use of water as an ingredient in cosmetic products. This falls within the ambit of good manufacturing practices, and there is an applicable ISO standard: ISO 22716: 2007, Cosmetics - Guidelines on Good Manufacturing Practices.[174] The United States Food and Drug Administration

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168 *See, e.g.,* TPP, *supra* note 3, art. 8.6 of ch. 8 (Technical Barriers to Trade).
169 *See, e.g.,* TPP, *supra* note 3, art. 25:2 of ch. 25 (Regulatory Coherence).
170 *See, e.g.,* TPP, *supra* note 3, art. 8.9 of ch. 8 (Technical Barriers to Trade).
171 *See, e.g.,* TPP, *supra* note 3, arts. 8.11 & 8.12 of ch. 8 (Technical Barriers to Trade).
172 *See, e.g.,* TPP, *supra* note 3, art. 8.5 of ch. 8 (Technical Barriers to Trade).
173 *Id. supra* note 3, ch. 28, Dispute Settlement.
174 *Catalogue,* International Organization for Standardization, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=36437 (last visited May 13, 2016).

(FDA), in its June 2013 guidance for industry on cosmetic good manufacturing practices, has explicitly considered and decided to incorporate, modify or exclude specific aspects of ISO 22716 into its non-binding industry guidance.[175] The FDA does not explicitly state which aspects of ISO 22716 were excluded or modified, nor does it explain its reasons, stating only that its determinations are "based on [our] experience."[176] The FDA guidelines calls for industry to determine if the water used as a cosmetic ingredient is used as-is (directly from the tap) or has been treated through deionization, distillation, or reverse osmosis.[177] They also call for procedures to test water for quality, water treatment effects, and risks of contamination.[178] Now, here are the ways that ISO 22716 may harden into a regulatory norm as a result of the TPP's TBT Chapter's Cosmetics Annex, which requires that:

> Where a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetics products, or the relevant parts of the, as a basis for its guidelines except where such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.[179]

First, either the FDA's guidelines or ISO 22716 could be extended mutual recognition by other TPP parties as the binding regulations on good manufacturing practices. Ironically, the fact that the FDA fails to explain where and why it deviated from ISO 22716 in its guidelines would be a contravention of U.S. TPP obligations under the Cosmetics Annex,[180] and the FDA guidelines would have to be amended if or when the TPP enters into force. Second, ISO itself could, pursuant to Article 2 of the Regulatory Coherence Chapter of the TPP, participate in notice and comment procedures at the FDA, should it either decide to amend its guidelines or issue a binding rule related to cosmetics manufacturing. Presumably, nothing would preclude ISO from advocating that its ISO 22716 should be adopted in full by the FDA. A third possibility is that ISO could participate in international cooperative efforts, such as the work of the U.S.-Canada Regulatory Cooperation Council to push for adoption of its standards as the means for regulatory harmonization. If this occurs, even at the bilateral or regional level, the TPP's regulatory coherence mechanisms would then kick in to "amp up" or "super-charge" such efforts into the mega-regional level. Fourth and fifth, the TPP Committee on Technical Barriers to Trade, established by Article 8.11 of the TPP, or the WTO's TBT Committee, respectively, could adopt ISO 22716 as a part of its regular review and monitoring work on international standards. Lastly, it is also possible that a TPP party could force adoption ISO 22716 in a case arising under either WTO dispute settlement processes or TPP dispute settlement related to the Technical Barrier to Trade Chapter.

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175 U.S. Food and Drug Administration, Guidance for Industry, Cosmetic Good Manufacturing Practices 3 (Feb. 12, 1997, revised Apr. 24. 2008 and Jun. 2013), http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM358287.pdf (last visited May 13, 2016).

176 *Id. at 3.*

177 *Id. at 8.*

178 *Id.*

179 TPP, *supra* note 3, Ch. 8, annex 8D (Cosmetics), art. 13.

180 *Id.*

The most striking aspect of the foregoing analysis is the diversity and proliferation of methods by which a privately developed standard, ISO 22716, could enter the pantheon of hard law through regulatory coherence mechanisms embedded in the TPP. In the relatively closed universe of public international law, it is extraordinary to have so many avenues for a private code to be adopted and implemented as a mandatory regulatory norm. It brings to mind the lyrics of the Simon & Garfunkel song "Fifty Ways to Leave Your Lover."[181] This article highlights only the six most obvious methods to adopt an international standard. There are probably forty-six others.

V. Some Closing Thoughts on Implications

This section explores, in brief, the normative implications of the harmonization and standardization mechanisms considered above with respect to both the new generation of international trade treaties in general and the TPP in particular. This is only the first of a series of articles examining standardization as a powerful engine of regulatory harmonization.

A. Governance Concerns and Institutional Design

Of the numerous methods established by the TPP to advance regulatory coherence and harmonization, the use of international standards is the most potent and fundamental. The TPP creates a thick network of procedural and substantive obligations that have the effect of hardening standards into norms. The result is a new regulatory governance framework in which standards play a leading role. The recognition that standardization is the primary mechanism for regulatory harmonization is the first step in focusing future studies on the global governance, transparency, and democratic implications of standardization. How can we make the work of international standardization bodies more open and transparent? How can we incentive our domestic regulatory institutions to meaningful participate in the development of such standards? Which aspects of the institutional work and architecture of TPP committees need to be carefully structured to interact meaningfully with standardization bodies? What roles should international organizations play?[182] Full participation by corporations, civil society, and public-private collaboration in the work of international standardization organizations will contribute to greater chance of TPP treaty success.

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[181] Simon & Garfunkel, *50 Ways to Leave Your Lover*, Lyrics, *available at* http://www.azlyrics.com/lyrics/paulsimon/50waystoleaveyourlover.html (last visited May 13, 2016).

[182] *See, e.g.,* Tim Buthe, *The Globalization of Health and Safety Standards: Delegation of the Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organization*, 71 Law & Contemp. Probs. 219 (2008) (using principal-agent theory to conceptualize international delegation as a form of institutionalized co-operation).

B. Sovereignty and Regulatory Autonomy

A number of scholars have studied the relationship between regulatory coherence,[183] harmonization,[184] and regulatory autonomy. However, the central question, "do regulatory coherence and harmonization measures lead to better regulations?" remains fundamentally unanswered. The answer should be an empirical one. Do international standards result in good rules that are (1) locally responsive the needs and risk tolerances of different populations and (2) not disguised protectionism?

C. Legal Transplantation and Regulatory Convergence Concerns

A possibility for accelerated legal transplantation and convergence emerges as a direct result of the standardization mechanisms studied in this article. Private codes of conduct and standards will achieve wide market penetration more quickly as a result of the approaches adopted in the TPP. Is such regulatory convergence a good thing? Are there implementation lessons we can learn from a comparative law analysis?

D. Public-Private Blurring

The increasing use of industrial self-policing through standardization and harmonization mechanisms encourages the incorporation of diverse soft-law approaches to trade policy toolbox. While the increasingly blurred lines between private, public, and hybrid regulations has been well studied[185], and is a core aspect of the privatization critique, little attention has been paid to the role of international standardization bodies. One particularly under-studied area is the role self-certifications play in conformity assessments for a wide variety of goods and services.[186] Detailed empirical studies on the role international standards play in self-certifications would be particularly beneficial.

E. Cross-Cultural Communication and Capacity-Building Challenges

The TPP members represent a wide spectrum of diversity with respect to culture, business practices, legal traditions, regulatory structures, economic development, involvement in international organizations, and integration into complex global supply chains. Each of these divergences presents unique cross-cultural communication challenges. Effective technical assistance, capacity building,

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183 *See generally,* Alberto Alemanno, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences*, 18 J. Int'l Econ. L. 625 (2015); Sheargold & Mitchell, *supra* note 139.

184 *See* Bacchus, *supra* note 67.

185 *See* Abbot & Snidal, *supra* note 17.

186 Very little literature exists in this field. *See, e.g.,* Mahesh Chandra, *ISO Standards from Quality to Environment to Corporate Social Responsibility and Their Implications for Global Companies*, 10 J. Int'l Bus. & L. 107 (2011); *see also,* Diller, *supra* note 110.

and training are important aspects of successful implementation of regulatory coherence and cooperation efforts. Success in these areas must reflect a sensitive approach to cross-cultural communication.[187] Of course, understanding these issues is also critical in legal education, as we must train the next generation of scholars, practitioners, civil society leaders, lawyers, and government officials to employ these new regulatory tools in a balanced and thoughtful way. Here too, cultural competency and managing cultural communication conflicts must be a critical part of the curriculum.

V. Conclusion

The Trans-Pacific Partnership has attracted a lot of controversy. It has rightfully come under criticism for the secrecy of negotiations and a number of substantive critiques, like reducing access to affordable generic medicines.[188] However, the TPP has successfully dodged much deserved criticism for the power it has arrogated to harmonization and standardization organizations, especially under its Chapters on Technical Barriers to Trade and Regulatory Coherence. This arrogation or delegation of regulatory power presents new-found challenges to transparency, and makes standardization the least-studied of the methods for regulatory harmonization. Alarm bells should ring. At a minimum, these trends merit closer scholarly attention. I hope this article is the first of many to raise the alarm and lead to deep exploration of the normative, policy, economic, educational, and empirical implications of the issue.

[187] The author has forthcoming articles on the cross-communication challenges posed by regulatory coherence and on the need to thoughtfully design regulatory cooperation measures to maximize the quality of regulations while minimizing externalities and inefficiencies.

[188] Médecins Sans Frontières, *Briefing Note: Access Campaign, Trading Away Health: The Trans-Pacific Partnership Agreement (TPP)*, *available at* http://www.doctorswithoutborders.org/sites/usa/files/Access_Briefing_TPP_ENG_2013.pdf (last visited May 9, 2016).