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Four Challenges for TTIP Regulatory Cooperation

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SYMPOSIUM

FOUR CHALLENGES FOR TTIP REGULATORY COOPERATION

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INTRODUCTION

While public debate over trade policy focuses on the Trans-Pacific Partnership (TPP) trade agreement, another mammoth trade agreement is moving forward, more quietly, between two of the three largest economies in the world: The United States (US) and the European Union (EU). The Transatlantic Trade and Investment Partnership (TTIP) aims to create the largest free trade zone in the world, encompassing two huge economies that together comprise nearly half of the world's gross domestic product.[1]

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[*] Professor of Law, University of Connecticut School of Law. While the views expressed herein are those presented at the American Association of Law Schools panel in Jan. 2015, TTIP is a work in progress and this article accordingly draws on sources that post-date that conference.

[1] *See* SHAYERAH ILIAS AKHTAR & VIVIAN C. JONES, CONG. RESEARCH SERV., R43158, PROPOSED TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (T-TIP): IN BRIEF 3 (2014) [hereinafter *CRS TTIP Report*].

The two sides hope that TTIP will generate more than 200 billion dollars per year in benefits for producers and consumers on both sides of the Atlantic.[2] But the gains being sought in this agreement are not the traditional sort, involving reductions in classic tariffs, quotas, and other forms of protection. Rather, according to a recent study commissioned by the EU, up to eighty percent of the economic gains forecast for TTIP are expected to flow from transatlantic regulatory cooperation reducing production costs and non-tariff barriers to trade.[3]

How can regulatory cooperation produce such savings? To take just one example: US and EU automobile industry representatives claim that divergent safety regulations between the two blocs require one hundred unique parts, forty-two million dollars in additional development costs, duplicative testing of thirty-three vehicle systems, and 133 extra people in the manufacturing process.[4] According to a joint submission by the US and EU automobile industries, these incompatible—but substantively equivalent—sets of regulations are essentially imposing an *ad valorem* tariff of twenty-six percent on producers and consumers.[5] The industry estimates that eliminating all actual tariffs plus just one-quarter of these regulatory, non-tariff trade barriers would increase EU auto-related exports to the US by 149 percent, and increase US auto-related exports to the EU by 347 percent.[6] Other industries such as specialty toys, apparel, and footwear reported similar regulatory deadweight losses.[7] TTIP negotiators are examining regulatory trade barriers in nine different sectors. In each sector, they are seeking ways to achieve cost (and price) savings for producers and consumers through at least three distinct modes of regulatory cooperation. These include:

(1) Harmonizing new regulations so that producers can design and manufacture to a single standard;
(2) Recognizing each other's separate standards as mutually equivalent (where they are, indeed, equivalent) so that meeting either standard will allow market access; and

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[2] JOSEPH FRANCOIS, CTR. FOR ECON. POLICY RESEARCH, REDUCING TRANSATLANTIC BARRIERS TO TRADE AND INVESTMENTS, at vii (2013).

[3] EUROPEAN COMMISSION, TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: THE ECONOMIC ANALYSIS EXPLAINED 6 (2013), http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf.

[4] *See CRS TTIP Report*, *supra* note 1, at 8.

[5] *U.S.–E.U. Automotive Regulatory Convergence*, AMERICAN AUTOMOTIVE POLICY COUNCIL & EUROPEAN AUTOMOBILE MANUFACTURERS' ASSOCIATION (Apr. 10–11, 2013), at 8, https://www.uschamber.com/sites/default/files/legacy/grc/AAPC-ACEA%20Joint%20Presentation%20at%20Regulatory%20Cooperation%20Forum%20April%2011,%202013%20FINAL%20PDF.pdf.

[6] *Id.* at 9.

[7] *See CRS TTIP Report*, *supra* note 1, at 8. *See also* Samuel Benka, *Regulatory Convergence in the TTIP: Facilitating Trade and Cooperation in the Transatlantic Region*, AMERICA'S TRADE POLICY (June 10, 2014), http://americastradepolicy.com/regulatory-convergence-in-the-ttip-facilitating-trade-and-cooperation-in-the-transatlantic-region/#.VaJoRrWyiAc.

(3) Eliminating duplicative testing, inspection, and conformity assessment procedures that impose pointless costs on regulators and regulated entities alike.[8]

While the goal is to eliminate unnecessary and costly trade barriers, negotiators also recognize that such barriers have developed over decades. Regulators on each side are loath to abandon long-standing custom and practices. Industries on both sides have invested billions in designing products to satisfy two incompatible regulatory specifications. TTIP talks will not fully eliminate these widespread and entrenched inconsistencies, even in the nine sectors currently under active discussion, much less in the many additional sectors that have generated requests for future regulatory rationalization.

Recognizing this fact, TTIP delegates have adopted a three-pronged approach to promoting transatlantic trade in the regulatory realm:

(1) The nine simultaneous sectoral negotiations mentioned above;
(2) Parallel discussions seeking commitments from each side to adopt specified best practices for their domestic regulatory process (under the heading of "regulatory coherence"); and
(3) Negotiations aimed at establishing a set of institutions and processes to guide continued efforts at regulatory cooperation after TTIP is ratified (under the heading of "regulatory cooperation").[9]

The ultimate goal is to unlock billions of dollars in savings while preserving—and perhaps enhancing—health, safety, environmental, and financial protections. Of course, this is a long-term goal, and achieving it will require a long-term effort. Meanwhile, the short timeline for TTIP negotiations (negotiators hope to conclude talks by the end of 2016) means that the third initiative identified above—crafting a "horizontal chapter" that sets forth a workable process for promoting regulatory cooperation in the long run—is in many ways the most important.

This article thus addresses the major challenges facing negotiators of the regulatory cooperation (horizontal) chapter of TTIP, and it offers recommendations on how negotiators might address each challenge.

I. FOUR CHALLENGES FOR TTIP REGULATORY COOPERATION

The principal challenges facing TTIP negotiators in the field of international regulatory cooperation (IRC) can be grouped into four broad categories. This section will provide a concise overview of these challenges, which the next section will address in detail.

- Industry is dissatisfied that years of transatlantic regulatory dialogue have not led more often to regulatory cooperation. Industry wants assurances that

[8] *See generally E.U. Negotiating Texts, Chapter-by-Chapter: Part 2: Regulatory Cooperation*, EUR. COMM'N (May 4, 2015), http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230#regulatory-cooperation.

[9] *See Textual Proposal on Regulatory Cooperation in TTIP*, EUR. UNION, n. 7 (May 4, 2015), http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf.

TTIP will bring real regulatory cooperation across a broad spectrum of economic activity.[10]

- Public interest groups on both sides are concerned that the "regulatory cooperation" process will be captured by industry and trade ministries, and used to put downward pressure on regulatory protections.[11]
- Public interest groups and regulators alike are worried that adding new requirements for international consultation and "trade impact analysis" will further burden and ossify the regulatory process.[12]
- The secrecy of the talks, particularly on the US side, has bred public suspicion of negotiators and complicated their task of reaching an informed consensus on both the substance and the process of cooperation.[13]

A. The Challenge of Making Cooperation Happen (This Time)

History is seldom written on a clean slate. As Chase and Pelkmans have documented, IRC dialogue between the US and EU has been ongoing for over twenty years.[14] While these efforts have yielded significant progress in a few areas, including a 2009 agreement on commercial aircraft airworthiness certifications and a 2012 agreement on mutual recognition of US and EU approaches to "organic" labeling, regulatory cooperation efforts have fallen short of industry expectations in many others.[15] A joint US-EU solicitation of comments that took place in 2012, in the run-up to TTIP, yielded upwards of eighty (often quite specific) industry requests for additional IRC efforts spanning a wide range of sectors.[16] Industry groups on both sides of the Atlantic quite understandably want to see new institutions and processes that will ensure that the past is not repeated, and that transatlantic regulatory rationalization moves forward with purpose and effect.

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[10] *See, e.g.*, PETER CHASE & JACQUES PELKMANS, CTR. FOR EUROPEAN POLICY STUDIES & CTR. FOR TRANSATLANTIC RELATIONS, THIS TIME IT'S DIFFERENT: TURBO-CHARGING REGULATORY COOPERATION IN TTIP (2015).

[11] *See, e.g.*, *Regulation—None of Our Business?*, CORPORATE EUROPE OBSERVATORY (Dec. 26, 2013), http://corporateeurope.org/trade/2013/12/regulation-none-our-business [hereinafter *CEO Report*].

[12] *See, e.g.*, HEALTH AND ENVIRONMENT ALLIANCE, STATEMENT BY CIVIL SOCIETY ORGANISATIONS ON REGULATORY COOPERATION IN TTIP (2015), http://env-health.org/IMG/pdf/statement_regulatory_cooperation_feb_2015_1.pdf.

[13] For a particularly articulate statement of this concern, see Thomas B. Edsall, Opinion, *Free Trade Disagreement*, N.Y. TIMES (Feb. 2, 2014), http://www.nytimes.com/2014/02/05/opinion/edsall-free-trade-disagreement.html?_r=0 (addressing secrecy in the more controversial Trans-Pacific Partnership, but raising concerns that apply equally to TTIP).

[14] CHASE & PELKMANS, *supra* note 10, Annex 1.

[15] *Id.*

[16] CHASE & PELKMANS, *supra* note 10, at 6–8, Annex 1. The solicitation may be found at http:/transatlanticrelations.org/content/ctr-articles. For the industry comments see, on the US side, http://www.regulations.gov/#!documentDetail;D=USTR-2012-0028-0001, and on the EU side, http://trade.ec.europa.eu/consultations/index.cfm?consul_id=160 (click on "Full versions of the contributions").

B. The Challenge of Finding the Right Balance Between Autonomy and Coordination

Europe and the United States are by no means identical in their risk preferences or regulatory risk management policies. Indeed, a leading comparative study of EU and US risk preferences and regulatory regimes revealed a checkerboard pattern of risk tolerance, in which the EU is more protective in some areas, the US in others.[17]

However, the two sides also recognize that they are both democracies committed to the rule of law and to rational regulation, and they do follow similar principles and procedures in the drafting and implementation of regulation, even if those procedures do not always lead to precisely the same result.[18] Moreover, both sides are generally committed to a high level of protection of health, safety, the environment, and economic security. A key premise of TTIP, therefore, is that both sides should be able to collaborate fruitfully to eliminate at least some costly and duplicative conformity assessments (in cases where US and EU substantive protections diverge), and hopefully to make their substantive requirements more similar over time. This would reduce costs for producers and consumers without lowering regulatory standards.[19]

Civil society groups are not convinced, however. Even in areas where the two sides maintain regulations of roughly equal stringency, civil society groups and large swaths of the public (particularly in Europe) have expressed deep concerns that "regulatory cooperation" may become, in practice, a source of downward pressure on health, safety, and environmental protections.[20] Those critics see TTIP regulatory

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[17] Jonathan B. Wiener & Michael D. Rogers, *Comparing Precaution in the United States and Europe*, 5 J. RISK RESEARCH 317, 322 (2002) ("Europe appears to be more precautionary than the US about such risks as GMOs, hormones in beef, toxic substances, phthalates, climate change, guns, and antitrust/competition policy. The US appears to be more precautionary than Europe about such risks as new drug approval, the ban on CFCs in aerosol spray cans and the ban on supersonic transport to protect the stratospheric ozone layer, nuclear energy, lead in gasoline, particulate air pollution, highway safety, teenage drinking, cigarette smoking, mad cow disease in blood donations, potentially violent youths, 'right to know' information disclosure requirements, and missile defences.")

[18] *See, e.g.*, UNITED STATES–EUROPEAN COMMISSION, HIGH-LEVEL REGULATORY COOPERATION FORUM: COMMON UNDERSTANDING ON REGULATORY PRINCIPLES AND BEST PRACTICES (2011), http://trade.ec.europa.eu/doclib/docs/2011/july/tradoc_148030.pdf.

[19] Cecilia Malmström, *TTIP: What Consumers Have to Gain*, EUR. COMM'N (Jan. 26, 2016), http://trade.ec.europa.eu/doclib/docs/2016/january/tradoc_154173.pdf ("In our conversations with the US we recently heard an example of this with the US Food and Drug Administration. Today they spend just under half of their resources for international cooperation on the EU. But the products they are most concerned about in terms of dangers to US public health like poor quality medicine or medical devices come from other countries. If they were able to trust the EU's own enforcement mechanisms they could redirect resources to where it matters, making the US public safer. The same would apply to many other products and certainly applies to our own resources here in Europe.").

[20] For example, 110 public health and environmental organizations in the EU and US object to the inclusion of the chemicals sector in TTIP, raising the fear that "[s]tronger, more precautionary and protective measures for carcinogens, hormone (endocrine) disruptors, and nanomaterials by the E.U. are all targeted by USTR and the chemical industry as trade barriers." Nadia Prupis, *Leaked TTIP Documents Reveal Powerful Chemical Industry Wins*, COMMON DREAMS (Oct. 1, 2014), http://www.commondreams.org/news/2014/10/01/leaked-ttip-documents-reveal-powerful-chemical-industry-wins. Food safety groups are also concerned. Food and farm issues being negotiated under TTIP include: genetically engineered crops, animal drugs and hormones, animal welfare, livestock antibiotics, chemically washed poultry, and nanotechnology. Debbie Barker, international program director at the US-based Center for Food Safety, worries: "Many people don't know that these secret negotiations

cooperation as a sort of Trojan horse for business interests to apply corporate and trade pressure on regulators, both during the TTIP talks and afterwards when public attention has died down. The goal of such pressure, civil society groups fear, would be to harmonize US and EU standards around the lowest common denominator. This might be done either directly or (more likely) by recognizing each other's different standards as mutually equivalent and therefore interchangeable, thereby achieving the same effect as downward harmonization in cases where levels of protection are declared equivalent but actually diverge.[21]

The central challenge for TTIP, then, is to establish procedures that will streamline regulatory compliance and promote the elimination of needless regulatory barriers to trade, while providing solid assurance that such procedures and mechanisms will not lead to weakened protections for health, safety, the environment or financial security.

C. The Resource Challenge

US agencies already face a formidable array of analytic requirements that attach to all significant new regulations, as well as growing requirements for the retrospective review of existing regulations.[22] Critics are concerned that these onerous and unfunded mandates—combined with increasingly searching and skeptical review by the Office of Management and Budget (OMB)—have already ossified agency regulation at the expense of timely intervention to protect health, safety, or the environment.[23] Rather than ease this burden, TTIP negotiators are pondering proposals that would add to agencies' analytical requirements. These proposed new requirements include additional transatlantic consultations as well as "trade impact" or "regulatory compatibility" assessments that have not been required as a regular matter to date. The question arises, where will the resources for all of this extra effort come from?

D. The Transparency Challenge

Objections to the excessive secrecy on the US side compound concerns about the substance and process of TTIP regulatory cooperation. A comparison of the European Commission and United States Trade Representative (USTR) web pages relevant to TTIP tells a tale of vastly dissimilar approaches.[24] On the EU website, negotiating

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may undermine efforts on both sides of the Atlantic to protect our food, our health, and our environment." *Center for Food Safety Report Warns TTIP Could Undermine Critical Food Safety and Environmental Regulations*, CTR. FOR FOOD SAFETY (May 14, 2014), http://www.centerforfoodsafety.org/press-releases/3153/center-for-food-safety-report-warns-ttip-could-undermine-critical-food-safety-and-environmental-regulations. *See also* HEALTH AND ENVIRONMENT ALLIANCE, *supra* note 12.

[21] For a representative statement of the civil society position on the TTIP Regulatory Coherence chapter, see *CEO Report*, *supra* note 11.

[22] *See, e.g.*, Exec. Order No. 12,866, 58 Fed. Reg. 190 (Oct. 4, 1993).

[23] *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" The Rulemaking Process*, 41 DUKE L.J. 1385 (1992); CURTIS W. COPELAND, CONG. RESEARCH SERV., RL32397, FEDERAL RULEMAKING: THE ROLE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS (2009).

[24] *Compare In Focus: Transatlantic Trade and Investment Partnership*, EUR. COMM'N, http://ec.europa.eu/trade/policy/in-focus/ttip/index_en.htm, *with Transatlantic Trade and Investment Partnership (T-TIP)*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/ttip, *and Non-Tariff Barriers and Regulatory Issues*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE,

positions and texts are put forward for each round of TTIP talks, along with explanations, fact sheets, and position papers. These support the EU position on the horizontal chapter as well as on each of the nine sectoral discussions underway in the IRC portion of the talks.[25] The USTR website mentions virtually nothing relevant to TTIP regulatory cooperation. This contrast is not an artifact of different webmasters; rather, it is rooted in policy. The EU has made the decision to share its negotiating texts with the public, but the USTR and OMB's Office of Information and Regulatory Affairs (OIRA) have elected to share their position and negotiating texts only with "cleared advisors" who are themselves sworn to secrecy as a condition of their access.[26] Moreover, the cleared committees set up to advise USTR and OIRA in these talks tend to be industry-dominated.[27] The result, critics claim, is skewed transparency on the US side that privileges industry views and breeds resentment and suspicion among public interest groups.[28] Ultimately, listening sessions for public interest groups offer only a semblance of meaningful public participation in decision-making.

Two main consequences, both negative, flow from this state of affairs. First, excluding experts and knowledgeable stakeholders means that the US government may not get the best advice on complex technical issues, or may receive it in a piecemeal and inefficient format. Second, a policy of official secrecy means that

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https://ustr.gov/trade-agreements/free-trade-agreements/transatlantic-trade-and-investment-partnership-t-tip/t-tip-2. Note that all written comments on the IRC process submitted by members of the public are archived online at http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=USTR-2012-0028. Notably absent, however, is any (online) window into the thought process of US government regulators or negotiators themselves.

[25] The nine sectors covered in the TTIP IRC talks for which one finds fact sheets and position papers on the EU website (but not the US website) are: chemicals, cosmetics, engineering, medical devices, pesticides, information technology, textiles, and vehicles. *See E.U. Negotiating Texts*, *supra* note 8 (at "Specific Industries").

[26] Interestingly, the EU began TTIP talks with the same posture on transparency as USTR, saying "we don't share negotiating texts with the public." The EU, however, moved away from that position as the talks progressed. The US did not. *See* Steve Suppan, *The Struggle for Transparency in the U.S.-E.U. Trade Deal*, THINK FORWARD BLOG (Nov. 5, 2013), http://www.iatp.org/blog/201311/the-struggle-for-transparency-in-the-us-eu-trade-deal.

[27] For example, on the US side, much of USTR's advice from industry comes either from informal one-on-one contacts or from Industry Trade Advisory Committees (ITACS), listed on the USTR website at http://ita.doc.gov/itac/committees/index.asp. *See* Edsall, *supra* note 13. Inspection of the membership of these committees reveals that they are not evenly balanced among interest groups and, in fact, most have no public interest representation at all. According to a recent USTR Federal Register notice soliciting nominations for ITAC membership: "Historically, the Secretary [of Commerce] and the USTR have appointed a representative of the public health or health care community to each of ITACs 3 [Chemicals, Pharmaceuticals, Health/Science Produces and Services] and 15 [Intellectual Property Rights], and an environmental representative to each of ITACs 3 and 7 [Forest Products]. The Secretary and the USTR will continue to consider nominations for representatives of such viewpoints to those ITACs." Request for Nominations for the Industry Trade Advisory Committees (ITACS); Amendment, 79 Fed. Reg. 51,552, 51,554 (Aug. 29, 2014).

[28] *See, e.g.*, Andrew Ranallo, *Leaked Document Reveals U.S.-E.U. Trade Agreement Threatens Public Safety*, INSTITUTE FOR AGRICULTURE AND TRADE POLICY (July 24, 2014), http://www.iatp.org/documents/leaked-document-reveals-us-eu-trade-agreement-threatens-public-health-food-safety. The only truly public consultative process to be found in the US takes the form of USTR and OIRA "listening sessions" with the public, who voice their aspirations for, and concerns about, TTIP. But, the government does not respond in these sessions, which starkly limits their usefulness. *See* James Love, *USTR "Listening Session" for Public Interest Groups on TTIP Trade Negotiations*, JAMES LOVE'S BLOG (May 2, 2013, 9:59 A.M.), http://keionline.org/node/1714.

public interest groups, outside scholars, and advisors must guess—based on hearsay—what the US government negotiating positions are. As a result, many of these actors have come to regard the whole process with suspicion.[29] An opportunity to garner widespread support for TTIP is lost.[30]

II. ANALYSIS AND RECOMMENDATIONS

The analysis in the preceding section identified four main challenges facing the TTIP agreement in the area of regulatory coherence and cooperation. This section offers a few ideas and recommendations on how to address each challenge.

A. A Mechanism for Ensuring Action

The first question is the one most urgently advanced by industry. After two decades of dialogue with meager results, how does TTIP reassure industry that future efforts at regulatory rationalization will move forward rapidly and with purpose?

As the EU proposal for the horizontal chapter currently contemplates, the two sides may need to create a central oversight body—a Regulatory Cooperation Body (RCB)—to manage the cooperative process, giving it energy and direction.[31] The RCB should include the OIRA on the US side, along with the Commission's Secretary General on the EU side. Just as clearly, it should include representatives of the regulatory agencies whose cooperation is desired. The RCB obviously should not strip regulators of their traditional legal prerogatives to regulate, de-regulate, or recognize another regulation as equivalent to their own. But it could provide a mechanism for identifying regulations or guidance documents with substantial transatlantic impact which merit discussion in the RCB forum. Further, the RCB should be empowered to set the agenda for transatlantic regulatory cooperation and establish reasonable timetables for decision. That mandate should come with the understanding that the regulators on each side reserve the right to make the final decision on the most appropriate means to protect the public interest.

Once the RCB is created, what is the procedure to be followed for reviewing agency actions? There are two broad options. The first would permit private actors on each side to petition their own government, which then would decide whether to espouse the cause and bring the matter to the RCB. Under the second option, private actors could petition the RCB directly to request a hearing (which may be a paper hearing). Either approach would work, and this author has no preference between them. Indeed, they are not mutually exclusive.

The next question involves the scope of the RCB's jurisdiction. What types of requests for action may the RCB consider? Should its jurisdiction only extend to

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[29] For good examples of this dynamic, see the sources collected in *supra* note 20.

[30] While the opacity of the US position has been offset in some measure by the relative clarity of the EU position—hearing one side of a conversation yields some understanding of it—even this partial transparency cannot be sustained much longer. Once talks reach the point where negotiating texts are merged into a single bracketed draft, the parties will need to decide whether that draft is all public or all private. At that point, if the USTR position prevails, the talks will enter a black hole that will only heighten suspicion of the agreement among civil society groups on both sides of the Atlantic.

[31] *See Textual Proposal on Regulatory Cooperation in TTIP*, *supra* note 9.

requests by industry for adjustments to new or existing regulations to reduce trade impacts? Or, should civil society groups and regulatory bodies be empowered to propose collaboration among regulators in, say, the testing of chemicals or pesticides? Clearly, broadening the scope of RCB jurisdiction to encompass both trade-enhancing and regulation-enhancing goals would reassure the public that the goal of the RCB, and of TTIP, is not just to promote trade but also to make regulators more effective in carrying out their protective mission.

B. Promoting Sound Decisions While Preserving Autonomy to Disagree

Once the parties have created an RCB with the power to prioritize and energize (but not control) regulatory cooperation initiatives, the next question is how to ensure that the RCB process is conducive to sound decision-making. Different interests approach this question from different perspectives. For industry, sound decisions would exploit all opportunities for cost-effective regulatory rationalization. For civil society groups, sound decisions would ensure that the RCB does not become a source of downward pressure on health, safety, environmental, and consumer financial protections.

Given these competing priorities and goals, it seems clear that a broad and balanced array of stakeholders must be involved in shaping regulatory cooperation decisions. Health, safety, environmental, or financial (HSEF) regulation is intrinsically complex and requires analyzing large amounts of data, most of which is in the possession of stakeholders (usually industry). But a process that includes only industry and regulators is a process ripe for regulatory capture. Whether seeking a common approach to new regulation or mutual recognition of different existing requirements, excluding whole categories of stakeholders from the decision-making process is not an attractive option.

In general, there are three broad procedural approaches for involving stakeholders in rulemaking having transatlantic significance:

(1) Each bloc makes a unilateral draft decision and then proposes it for public comment, allowing the other regulator to comment on the proposal at the same time as the general public;

(2) Regulators on both sides confer with each other privately in the pre-proposal phase, and seek agreement on a common (or convergent) proposal prior to issuing either separate or joint proposals. The regulators then issue their proposal(s) and take comment, jointly or separately, from their respective publics before reaching a final decision, possibly after further transatlantic regulator dialogue; or

(3) Regulators on each side confer with each other and with stakeholders—either jointly or separately—prior to issuing their proposal or proposals. The regulators then publish a notice, and take comments on the proposed rule prior to final action.

The mechanism adopted in the TTIP talks will likely involve, at least implicitly, some choice among these options. The best option, in this author's judgment is the third option, because it allows for structured and meaningful stakeholder consultations

early in the process, before the agency commits major resources to developing an approach that later public consultations may reveal as fundamentally flawed. It is also the option that is most easily integrated into the existing consultative procedures of both sides.

What happens if, after all this deliberation, the two sides simply cannot agree on a single regulatory approach, and do not recognize the other side's regulation as equivalent? Here, the correct answer has already been embraced by TTIP negotiators on both sides: once the required consultations end, each side will remain free to cooperate (or not) on that particular issue, and the decision either way will not result in dispute settlement or sanctions. In other words, the process is mandatory, but the outcome is voluntary.

Given this position, it may seem odd that civil society groups continue to worry that the TTIP process will create downward pressure on regulatory protections. One reason for their concern may be the new requirements for "trade impact assessment" (TIA) or "regulatory compatibility assessment" (RCA) that have been proposed for the horizontal chapter of the TTIP Agreement.[32] The point of "trade impact assessment" is to require agencies to assess, before they regulate, not only the costs and benefits of any proposed regulation, but also its probable trade impact across the Atlantic.[33] For civil society groups, this proposed requirement raises the specter of "paralysis by analysis" addressed in the next section. It also spawns fears that TIA will create new pressure points which trade ministries (or regulatory overseers like OIRA) can use to "persuade" their own regulators to soften for the benefit of transatlantic trading partners. These concerns are not alleviated by the fact that each side formally reserves its sovereign right to autonomous decisions. The issue is not sovereignty, but the internal balance of power among agencies or ministries within the sovereign.

This may be the most difficult issue to address, conceptually, in the IRC portion of TTIP. Neither the request for TIA or RCA, nor the concerns outlined above, are unreasonable. Both sides have a point. However, two considerations may be worth bearing in mind as these options are weighed.

The first begins with the observation that both regulatory compatibility analysis (RCA) and trade impact analysis (TIA) have been proposed, but they are somewhat different concepts. The former is better defined and less threatening to civil society and public interest values than the latter.

TIA connotes a highly quantitative exercise that focuses narrowly on the expected impact of a proposed regulation on international trade. A mandate to quantify trade impacts in addition to other costs and benefits would raise troubling questions of how trade impacts should be defined in the context of a regulation that is facially non-discriminatory, how regulators should obtain such information on possible trade

[32] CHASE & PELKMANS, *supra* note 10, at 17–18.

[33] UNITED STATES-EUROPEAN HIGH LEVEL WORKING GROUP ON JOBS AND GROWTH, FINAL REPORT 4 (2013), http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf.

impacts *ex ante*, and whether trade-based pressures will be used to ratchet down regulatory effectiveness.[34]

RCA, by contrast, is a broader concept that allows for a common-sense, qualitative assessment of both trade impacts and regulatory needs. In this process, regulators might examine improvements that could streamline or strengthen regulation while exploring ways to avoid needless regulatory inconsistency.

Significantly, two notable experts on regulatory cooperation—Peter Chase, Vice-President for Europe at the US Chamber of Commerce, and Jacques Pelkmans, Senior Fellow at the Center for European Policy Studies—have endorsed RCA as their preferred mode of analysis within the TTIP framework.[35] They have also outlined in broad strokes their view of how RCA might be implemented. Their vision would ask the initiating regulatory body (Regulator A) to investigate, in the earliest stages of regulatory development, whether its transatlantic counterpart (Regulator B) already has a regulation in place to address the same problem. If so, Regulator A would be required to the determine whether its proposed approach is "compatible with" Regulator B's. If not, Regulator B would be required to "evaluate the costs and benefits of adopting a non-compatible approach."[36] This assessment would be made available for public comment.

The Chase and Pelkmans proposal, though interesting, raises questions that the authors do not answer about how "regulatory compatibility" would be defined. Much more work is needed to flesh out the concept before it is possible to determine its precise contours and utility. However RCA is defined, it seems clear that any transatlantic dialogue aimed at enhancing regulatory collaboration (including RCA-focused dialogue) should include: (1) early consultation between sovereigns and (2) early consultations among sovereigns and stakeholders on both sides. The need for consultation at some stage is obvious: competent regulation and regulatory impact assessment require data, and data often resides with stakeholders or with a sovereign

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[34] For an introduction to the conceptual and analytical intricacies of "trade impact assessment," see *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts of International Trade and Investment*, OFFICE OF MANAGEMENT AND BUDGET AND THE SECRETARIAT GENERAL OF THE EUROPEAN COMMISSION (2008), https://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/sg-omb_final.pdf. This Report reveals the conceptual difficulty of defining "trade impact." Annex B2 of this Report examines several case studies involving US cost-benefit analyses of draft regulations that would affect foreign producers. But it fails to identify a single case in which a US agency successfully measured a "trade impact" as distinct from a simple cost of regulation applied to a foreign producer. *Id.* at 17–25. The report calls for additional guidance on defining trade impacts, without providing such guidance. *Id.* at 26. The Obama Administration's recent guidelines on this point likewise call on US agencies to identify, and consult with the Office of the US Trade Representative (USTR) and the Office of Information and Regulatory Affairs (OIRA) on draft regulations that are reasonably expected to have significant "trade impacts", but without offering any useful guidance on how a "trade impact" will be measured. *See Guidelines on Executive Order 13609*, REGULATORY WORKING GROUP 14 (2015), https://www.whitehouse.gov/sites/default/files/omb/inforeg/eo_13609/eo13609-working-group-guidelines.pdf. Is "trade impact" simply a cost of compliance experienced by a foreign producer? If so, US agencies already consider such costs. Or is "trade impact" an actual impact on volume and value of trade, in which case basic questions arise as to how such impacts are to be forecast *ex ante*. Clearly, it will be difficult to justify requiring a detailed analysis of a concept which itself remains poorly defined.

[35] CHASE & PELKMANS, *supra* note 10, at 17–18.

[36] *Id.*

counterparty. As seen above, early consultation is beneficial because it ensures that input is received when it is most likely to be useful: before the the agency has committed major resources to developing a "proposal" which it may be quite reluctant to change. Moreover, because it is much easier and cheaper to alter ideas than proposals, conferring at the idea stage would allow consideration of more ideas and alternatives than if public consultations were deferred until proposals were drafted, thereby improving the odds of the the "right" approach being selected for proposal. For both these reasons, this author suggests that the initial impact assessments/public consultations should be held early in the process, at the "idea" stage of regulation. More specifically, they should come after the identification of alternatives for regulatory response, but well before the issuance of a notice of proposed rulemaking. And they should consist of back-of-the-envelope assessments based on input from stakeholders received in a structured consultation process, rather than elaborate, monetized assessments in the style of OIRA-mandated cost-benefit analyses.

C. The Challenge of Finding Resources

However transatlantic regulatory cooperation is structured and implemented, one thing is certain: it will require resources. This fact itself poses a third, and formidable, challenge to most US regulatory agencies. Ours, it seems, is an age of both super-abundance and scarcity. Huge resources flow to sports stadiums and casinos, while agencies charged with protecting the public interest are perennially starved of both human and financial resources.

Common sense teaches that in government, as in life, you get what you pay for. Resource-starved agencies are not going to deliver the smart, consumer-protecting-yet-trade-promoting regulations that citizens, stakeholders, and negotiators want. Adding to agencies' fiscal burdens by requiring transatlantic consultations and additional analysis, on top of the massively under-funded analysis already required of them, will only make scarcity more acute. Moreover, given the erratic politics of the US budget and appropriations process, relying on annual appropriations to solve this resource problem is not an arrangement that inspires confidence.

Faced with this conflict between means and ends, TTIP negotiators should think creatively. Perhaps they could build into TTIP implementing legislation a dedicated funding mechanism modeled on the US Superfund or EPA permitting schemes. This mechanism would both finance and institutionalize the transatlantic cooperation and public consultation that an effective TTIP agreement will require.

How large would such a fund need to be? I do not have a precise dollar figure to offer, but given the enormous stakes involved—a regulation must cost at least 100 million dollars per year even to be considered economically significant—surely the marginal cost of smarter regulation will be trivial in relation to its net benefits. Simple common sense suggests investing a few dollars or euros in a process that will save many more. Indeed, industry stakeholders have privately indicated (to this author) that say they might support such an arrangement if it were proposed, even though it involves a fee.

Though the proposal may seem Utopian at first glance, in fact it is neither novel nor unworkable. On the contrary, the idea has clear precedent on both sides of the

Atlantic and would be quite easy to implement.[37] It seems Utopian in the current political environment only because the current Congressional leadership is so ideologically opposed to the very idea of regulation. It is thus unlikely to establish a funding source dedicated to supporting heightened regulatory analysis, even for the purpose of reducing unnecessary obstacles to trade.

Such an attitude is unfortunate, and ultimately self-defeating. Conservative critics of regulation should reflect upon the fact that inept regulation is always cheaper to put in place than smart regulation. For example, the simple edict "thou shalt not pollute" does not require much regulatory analysis, but no rational regulator or stakeholder would replace the nuanced laws and regulations that now exist with such a simple but draconian rule. Smart regulation seeks the most cost-effective strategy for maximizing benefit in relation to the burden on jobs and growth. It can save millions or even billions of dollars over the medium to longer term, but it inevitably drains agency resources in the short-term. Investing in smart regulation—and in a broad-based consultative process to achieve it—is a wise choice even for, especially for, conservative policymakers. In short, funding smart transnational regulatory cooperation with a dedicated user fee would not cost industry much, and would pay for itself many times over in the enhanced protection of citizens, while promoting jobs and growth.

D. The Transparency Challenge

As seen in Section I.D. above, the EU and the US have followed different approaches to transparency in TTIP negotiations. The EU has chosen the path of openness while the US, to date, has followed the path of secrecy. The US approach presents a singular anomaly. On one hand, it professes devotion to increasing the transparency of regulation on both sides. Yet it insists on working towards this through a negotiating process that is almost entirely secret, except to a handful of cleared advisors who are themselves bound to secrecy. This secrecy offers the public no opportunity for informed comment on the US proposals in specific fields.

What motivates this strange US position? It is at odds with the fundamental commitment to openness that President Obama announced at the outset of his administration.[38] Moreover, the administration has offered no explanation of its aversion to transparency in the TTIP proceedings. Based on my experience as a former Assistant General Counsel at the USTR, I suspect the reasoning may track the following syllogism: trade negotiations, like most foreign policy dialogues, require confidentiality. TTIP regulatory cooperation talks are trade negotiations. Ergo, TTIP regulatory cooperation talks should be confidential.

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[37] *See, e.g.*, Prescription Drug User Fee Act § 103, 21 U.S.C. § 379(h) (2013) (empowering the US Food and Drug Administration to levy a fee to cover agency costs of reviewing human drug applications); *see also Funding*, EUR. MEDICINES AGENCY, http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&mid=WC0b01ac0580029336 (last visited Mar. 10, 2016) (noting that the European Medicines Agency receives 277 million euros in fees and charges levied for regulatory services, charged to the European pharmaceutical industry).

[38] *See* Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 21, 2009).

If this is the reasoning, it harbors a modicum of truth. Traditional trade negotiations seek tit-for-tat agreements to reduce tariffs or import quotas. When governments agree to trade US tariff concessions on cotton shirts for Chinese tariff reductions on semiconductors, they do not necessarily want the cotton industry in the room. They also do not want to circulate publicly a piece of paper that proposes such a trade-off. Governments prefer to cut traditional trade deals in private, then roll out the package publicly at the end of the day. Their hope is that the winners will outshout the losers in deliberations preceding the ensuing up-or-down vote on trade agreements to which Trade Promotion Authority applies.[39]

If this is the reasoning, it is certainly understandable in the context of traditional trade negotiations. However, the USTR errs in assuming that every aspect of every trade negotiation must be governed by the same rules of procedure. In fact, talks on regulatory cooperation are a quite different species of diplomacy than traditional trade negotiations. Regulatory cooperation talks are not tit-for-tat negotiations aimed at picking winners and losers in the hope that wins will outweigh losses—and winners outshout losers—at the end of the day. They are problem-solving exercises aimed at finding win-win outcomes based on highly technical data that is most often in the hands of private parties. Regulatory cooperation talks do involve foreign governments, but they also involve, centrally, the domestic regulatory processes of both parties. Those domestic regulatory processes are, and ought to remain, transparent. If secrecy is the norm in foreign policy, then openness is the norm in domestic policy. The goal of TTIP, ironically, is to make those domestic processes even more open.

So why not simply re-conceptualize the TTIP IRC negotiating process? Instead of regarding IRC talks as an extension of foreign policy with a built-in presumption of secrecy, view them an extension of domestic policy where publishing and seeking comment on proposals is the norm. The EU has already shown that this can be done, and how to do it. All that remains is for the US to follow suit. The result will be a better agreement, with broader support from the public.

CONCLUSION

This Article has examined four challenges confronting TTIP negotiators as they attempt to build a framework of regulatory cooperation that surpasses anything yet attempted in a trade agreement. After reviewing these challenges, we considered recommendations on how to meet each challenge. The task will not be easy but the prize at the end of the day could be significant: huge savings for industry and consumers, achieved within a cooperative regulatory framework that preserves and enhances health, safety, environmental, and financial protections on both sides.

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[39] *See Trade Promotion Authority*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/trade-topics/trade-promotion-authority (last visited Mar. 16, 2016).