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What the TTIP Leaks Mean for the On-going Negotiations and Future Agreement?

Editors: *Alberto Alemanno*[*] and *Alexia Herwig*[+]

While the TTIP leaks are not the first (nor will they be the last) leak since the inception of the negotiation in 2013, they revealed for the first time the US negotiating position regarding certain chapters of the TTIP draft agreement. As such, the TTIP leaks provide an unprecedented opportunity not only to analyse the contrasting positions of the EU and US on several issues in the on-going negotiations, but also to test the veracity of the competing narratives devised by opponents and proponents of the agreement. To what extent do their respective storylines find support in the actual texts? What do the TTIP leaks mean for the on-going negotiations and future agreement? At a time in which the ongoing negotiations enter a maker-breaker moment, this symposium of the ***European Journal of Risk Regulation*** provides a timely analysis of most of the documents released and contextualises them within the broader, on-going negotiations. It contains 10 research-based opinion pieces by leading academics and practitioners who have been closely following the negotiations in their respective areas of expertise, such as international regulatory cooperation, pharmaceuticals, food safety, agriculture and geographical indications, financial regulations as well as sustainable development.

[*] Jean Monnet Professor of EU Law and Risk Regulation, HEC Paris; Global Clinical Professor of Law, NYU School of Law.

[+] Assistant Professor, University of Antwerp.

[*] Jean Monnet Professor of EU Law and Risk Regulation, HEC Paris; Global Clinical Professor of
[+] Assistant Professor, University of Antwerp.

What the TTIP Leaks Mean for the On-going Negotiations and Future Agreement?

Time to Overcome TTIP's many Informational Asymmetries

Alberto Alemanno[*]

Abstract

One of the major merits of the TTIP leaks has been to highlight the underlying information asymmetry characterising the on-going TTIP negotiations. By systematically releasing its position papers before each negotiation, the EU actual disclosure policy contributes to a permanent yet overlooked information imbalance between the EU and its trading partner(s). The ensuing asymmetry does not only alter the overall negotiating environment, but also how the media, academics, and, in turn, the public actually perceive it. As a result, only the EU positions have been studied, criticized and closely debated, with the US negotiating positions remaining largely a mystery. After briefly presenting the how's of the TTIP leaks, this opening piece examines the what's and why's behind this unprecedented revelation of negotiating texts. It is against this backdrop that the other contributors to this symposium explore which are the most immediate consequences of the TTIP leaks on the on-going negotiations and future agreement.

I. Introduction

On 1 May 2016, Greenpeace Netherlands released 248 pages of TTIP negotiating texts stemming from previous negotiating rounds[1]. Although it is not the first (and will not be the last) leak since the inception of the negotiation in 2013[2], this is the first to reveal the US negotiating position regarding 13 out of the 24 TTIP chapters.

As such, the TTIP leaks provide an unprecedented opportunity to not only analyse the contrasting positions of the EU and US on several issues in the ongoing negotiations, but also to test the veracity of the competing narratives devised by opponents and proponents of the agreement. To what extent do their respective storylines find support in the actual texts?

[*] Jean Monnet Professor of EU Law and Risk Regulation, HEC Paris; Global Clinical Professor of Law, NYU School of Law.

[1] Contrary to the initial claims, not all leaked texts date from March 2016, and some of them, like the regulatory cooperation chapter, appear as old as mid-2015.

[2] Green Party leaks confidential TTIP document, Euractiv, March 11, 2014, available at http://www.euractiv.com/section/trade-society/news/green-party-leaks-confidential-ttip-paper/

Supporters of TTIP have proposed fact-checking as an antidote against the misinformation around TTIP. Yet, having been predominantly advocated and provided for by the EU Commission rather than by the media, institutional fact-checking failed to counter the massive misinformation characterizing the public and political discourse surrounding the negotiations. Unfortunately, when it comes to public perception, the line between pedagogy and propaganda is fuzzy.

One of the merits of the TTIP leaks is to highlight and - partly overcome - the underlying information asymmetry characterising the negotiations. By systematically releasing its position papers (and, sometimes, its textual proposals) before each negotiation, the EU actual disclosure policy contributes to a permanent yet largely overlooked information asymmetry between the EU and its trading partner(s). As it may be inferred from the TTIP *Tactical State of Play* document leaked by Greenpeace, the existing information imbalance alters not only the overall negotiating environment - by shaping the way trade negotiators interact and draft their texts -, but also how the media, academics, and, in turn, the public perceive it. While the EU disclosure policy might be expected to provide it a comparative advantage over the US[3], paradoxically, the more the EU reveals its negotiation to the public, the less the public appears pleased about the EU Commission's democratic accountability when acting as an international negotiator for the whole EU. In the aftermath of the TTIP leaks, calls by EU leaders to re-examine the mandate granted to the EU Commission to negotiate the agreement are bourgeoning. Likewise the requests by national parliaments to submit TTIP approval to a vote (regardless of its mixed nature) are also multiplying. But there is more.

The patent transatlantic asymmetry surrounding the negotiations generates many other information imbalances within the EU itself: that between the negotiators and the elected representatives (partly addressed by the establishment of the so called reading rooms), that between corporate and civil society interest groups (partly addressed by the TTIP advisory group), and eventually between the 'TTIP circus' and the general public. However, there is also a significant academic imbalance surrounding the TTIP negotiations. If the negotiators themselves have hijacked (and quickly exhausted) the rhetoric of fact-checking, academics have not yet had their chance to contribute to the discussion.

[3] Politico Europe, Playbook, 3 May 2016: "The success of a leak is not only a function of the quality and quantity of information revealed, but is also about its ability to prompt future change." By this standard the impact of yesterday's leak is "embarrassingly modest," says Alemanno. It revealed the U.S.'s insistence on secrecy but fell short of confirming the worst concerns raised by the anti-TTIP camp, Alemanno says. "Contrary to what has been claimed by Greenpeace — and blindly echoed by mainstream media — there's no proof that the EU is ready to give in to U.S. demands. As a result, the leak rather strengthens the EU negotiating position."

Limited access to the negotiating texts has initially produced some 'chilling effect' on academic writing on both sides of the Atlantic. Then, due to the sudden change in the EU policy disclosure, the availability of EU-only position papers has fuelled a growing literature focusing exclusively on the EU position in the negotiations as opposed to the (unknown) stance of the US. As a result, only the EU positions have been studied, criticized and closely debated, with the US negotiating positions remaining largely a mystery.

How can we expect the on-going negotiations to bear fruit when the conditions under which those negotiations have taken place have been so endogenously and exogenously imbalanced?

At a time in which the many transatlantic information asymmetries emerge as one of the major obstacles to the on-going negotiations, this symposium of the EJRR provides a cutting edge analysis of the documents unveiled by Greenpeace in the framework of the TTIP leaks. It contains 10 research-based opinion pieces by leading academics and practitioners who have been closely following the negotiations in their respective areas of expertise.

After briefly presenting the how's of the TTIP leaks, this opening piece examines the what's and why's behind this unprecedented revelation of negotiating texts. It is against this backdrop that the contributors to this symposium explore which are the most immediate consequences of the TTIP leaks on the negotiations and future agreement.

II. The TTIP Leaks: An Appraisal

The documents released by Greenpeace Netherlands consist of 13 consolidated TTIP chapters, plus a tactical note stemming from previous negotiating rounds[4]. These documents, which amount to about half of the draft text as of April 2016, appear to capture the state of the negotiations prior to the 13th round of TTIP negotiations between the EU and the US that took place in New York City on 25-29 April 2016 (just a few days before the publication of the leaked documents). Contrary to how they have been depicted by the media, consolidated documents differ from codified documents insofar as they limit themselves to show EU and US positions *side by side*, without reflecting a compromised text.

Greenpeace did not disclose the origins of the documents. After receiving the documents, Greenpeace Netherlands, together with a German

[4] All the documents are available here: https://www.ttip-leaks.org/.

investigative research partnership (comprised of *Rechercheverbund NDR*[5], *WDR*, and *Süddeutsche Zeitung*) analysed and compared them to existing documents. Moreover, to render it more difficult to trace the source of the leak, the original text has been retyped, and obvious spelling and grammar errors (possibly put there deliberately as markers to identify the origin in case of a leak) were removed[6].

Given the restrictive confidential policy pursued by the US, these leaked documents allowed the public to see for the first time the position of the US in 13 sectoral chapters.

III. Why the TTIP Leaks

The declared rationale pursued by Greenpeace is 'to provide much needed transparency and trigger an informed debate on the treaty'[7]. When measured against these objectives, the leaks seem to have met only the former aim. While the TTIP leaks – by revealing concealed information - indisputably favour transparency, it appears more doubtful that they have prompted a more informed debate. The subsequent polarisation among EU political leaders around TTIP would rather suggest the opposite.

As it emerges from the detailed analysis provided by the contributors to this Symposium, the narrative crafted by Greenpeace's press release, and which the mainstream media has blindly echoed, does not survive basic fact-checking.

The overall impression in the aftermath of the leaks is that Greenpeace devoted more time to preparing and announcing the release of the documents than to studying their contents. In particular, among the published documents there is no 'smoking gun' to substantiate the worst concerns raised by the anti-TTIP contingent.

Not only is there no proof that the EU is ready to give in to US demands when it comes to relaxing the level of consumer protection, food safety, or the environment, but the documents seem rather to highlight the EU Commission's commitment to its treaty obligations (which primes over international treaty

[5] The *Rechercheverbund*, which consists of different German media, has covered, amongst other big stories, the Snowden leaks and the recent Volkswagen emissions scandal.

[6] This explains why Greenpeace Netherlands does not offer access to the original documents. By containing 'markers' in the form of deliberate typos or formatting, they might enable the identification of the documents' origins.

[7] See Press Release by Greenpeace Netherlands, available at http://www.greenpeace.org/international/en/press/releases/2016/Leaked-TTIP-documents-confirm-major-risks-for-climate-environment-and-consumer-safety/.

negotiations) to mainstream environmental and health concerns in all its policies and keeping its policy process open and inclusive. Moreover, the regulatory cooperation chapter – as it has been put forward by the EU Commission in Spring 2016 – clearly conditions its operation on the attainment of an equal (or higher) level of protection.

In these circumstances, it would appear naïve to buy into the pedagogical aim pursued by Greenpeace in disclosing such fanfare. Rather, the aim was to influence public opinion prematurely regarding the negotiation by spinning the language employed in the documents and further strengthening anti-TTIP bias within the EU.

A quick glance at recent events suggests that the strategy delivered the expected yet undeclared outcome: to mount public pressure on some EU political leaders, such as Francois Hollande and Sigmar Gabriel, so as to force them to distance themselves publicly from the agreement. That forced the EU Commission to call for a vote within the European Council to check whether all EU Member States would confirm the original negotiating mandate in TTIP[8].

IV. Contextualizing the TTIP Leaks: The Information Asymmetries

Parties to trade agreements traditionally invoke confidentiality so as to preserve tactical decisions, trust formation, and protect sensitive commercial interests at stake. Yet, the negotiations of a 'new generation' of trade agreements, such as the Anti-counterfeiting Trade Agreement (ACTA),[9] the Comprehensive Economic Trade Agreement (CETA) and the Transatlantic Trade and Investment Partnership (TTIP), by the European Union have prompted civil society increasingly to question their 'behind-the-door' nature.

Given the wide policy scope that these trade agreements cover and their rather intrusive approach to domestic regulatory autonomy, the interests at stake are not only broader than in previous trade agreements but also of constitutional significance, affecting private companies, civil society organisations, individual citizens as well as third-party States. The democratic accountability of their negotiations as well as the outcomes are increasingly questioned today. In particular, as these agreements increasingly target regulations and policies enacted by countries that exercise their sovereign power in an effort to promote regulatory cooperation, there has been mounting demand that their negotiations

[8] See http://www.politico.eu/pro/juncker-to-ask-eu-leaders-to-reconfirm-ttip-mandate-at-june-council/.

[9] ACTA was rejected by the European Parliament in July 2012, and did not enter into force. European Parliament, 'European Parliament Rejects ACTA, Press Release,' July 4, 2012, http://www.europarl.europa.eu/news/en/news-room/20120703IPR48247/European-Parliament-rejects-ACTA.

be conducted with greater transparency than conventional trade negotiations. The rationale pursued by the claim for greater transparency is to guarantee equal access and representation of the many interests affected by the proposed agreements. This should be true not only at the time of their negotiation but also when they will be implemented and enforced[10].

As far as the negotiations are concerned, the TTIP negotiating process remained in large parts confidential until the EU Commission and Council of the EU were pushed to react by an unlikely alliance consisting of 250 NGOs acting jointly[11], the EU Ombudsman,[12] and eventually also by the European Parliament.[13]

Their joint request to the EU Commission included making available to the public the EU negotiating mandate, the EU position papers and related documents tabled for discussions, the draft and final versions of individual chapters, as well as the whole agreement at all steps of its drafting process. The European Ombudsman insisted that a proactive publication of documents by the EU Commission was important to improve the legitimacy of the negotiations in the eyes of the general public.[14] Acknowledging the need for some level of confidentiality in trade negotiations, the Ombudsman underlined that confidentiality in negotiations may be justified only when disclosure would damage the trust between negotiators, inhibit free and effective discussions,

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[10] Alberto Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences", 18(3) *JIEL* 2015, pp. 625–640..

[11] See http://www.foeeurope.org/sites/default/files/foee_ttip-civil-society-transparency-call190514.pdf.

[12] The EU Ombudsman opened a case on the transparency and public participation in relation to the TTIP negotiations on 29 July 2014, and reached a decision on 31 October 2014. For all documents related to the EU Ombudsman's arguments in favour of transparency, see http://www.ombudsman.europa.eu/en/cases/caseopened.faces/en/54631/html.bookmark.
See, in particular, European Ombudsman, 'Letter to the Council of the EU Requesting an Opinion in the European Ombudsman's Own-Initiative Inquiry OI/11/2014/MMN Concerning Transparency and Public Participation in Relation to the Transatlantic Trade and Investment Partnership (TTIP) Negotiations,' July 29, 2014, http://www.ombudsman.europa.eu/cases/correspondence.faces/en/54634/html.bookmark;
European Ombudsman, 'Letter to the European Commission Requesting an Opinion in the European Ombudsman's Own-Initiative Inquiry OI/10/2014/MMN Concerning Transparency and Public Participation in Relation to the Transatlantic Trade and Investment Partnership (TTIP) Negotiations,' July 29, 2014, http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/54633/html.bookmark.

[13] Report containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP), (2014/2228(INI)).
http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2015-0175&language=EN.

[14] European Ombudsman, "Letter to the Council of the EU Requesting an Opinion in the European Ombudsman's Own-Initiative Inquiry OI/11/2014/MMN Concerning Transparency and Public Participation in Relation to the Transatlantic Trade and Investment Partnership (TTIP) Negotiations," July 29, 2014, http://www.ombudsman.europa.eu/cases/correspondence.faces/en/54634/html.bookmark.

and/or reveal strategic elements of the negotiations.[15] Taking into account these recommendations, the Council of the European Union disclosed the negotiating mandate [16] and the Commission unveiled a new strategy to enhance its transparency in TTIP negotiations in November 2014,[17] - which subsequently extended to the negotiations of all trade agreements - with regards to the general public and the Parliament. As a result, the EU Commission now discloses regularly its position papers – generally in advance of the negotiating rounds –, keeps information classified until it has been shared with the other party, systematically reports on negotiating rounds, provides detailed explanation on the different thematic sections, and allows all Members of the European Parliament to consult 'EU Restricted' and 'Limited' negotiating documents.[18] The EU Commission has made public a list of all documents communicated to both the Council and the Parliament since 2013, with links to these documents when available.[19]

When measured against the traditionally confidential approach governing trade negotiations, the EU's sudden change in disclosure policy appears quite revolutionary.

This appears all the more true when compared with its counterpart in the TTIP negotiations, the US administration, and in particular the United States Trade Representative (USTR), which continues to maintain a very confidential approach.[20] In so doing, the US government fails to recognize the specificity of the new generation trade agreements, which – by intruding into the exercise of regulatory autonomy – seem to call for greater transparency and openness than

[15] The EU Ombudsman makes reference to the argumentation of the European Court of Justice in Judgment of the General Court (Second Chamber) of 19 March 2013. Sophie in 't Veld v European Commission. Case T-301/10, ECLI:EU:T:2013:135. See letter by EU Ombudsman to EU Commission in this regard, at http://www.ombudsman.europa.eu/cases/correspondence.faces/en/54634/html.bookmark.

[16] Council of the European Union, Directives for the negotiations on the Transatlantic Trade and Investment Partnership between the European Union and United States of America, http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf.

[17] Communication to the Commission concerning transparency in TTIP negotiations, http://ec.europa.eu/news/2014/docs/c_2014_9052_en.pdf.

[18] *Ibid*.

[19] European Commission, "The Transatlantic Trade and Investment Partnership (TTIP), List of Documents," February 26, 2016, http://trade.ec.europa.eu/doclib/docs/2015/march/tradoc_153263.pdf.

[20] The secrecy of the US approach to trade negotiations has been widely criticised, both in the context of the TTIP and the TPP agreements. The US has indeed argued in favour of confidentiality of trade negotiations because of the sensitive interests at stake. Therefore, it did not publish the negotiated texts or its official position papers, but rather fact sheets on the addressed issues and the corresponding US position. United States Trade Representative, 'T-TIP Negotiating Document Procedures', July 5, 2013, https://ustr.gov/sites/default/files/US%20signed%20conf%20agmt%20letter_0.pdf.

that required by other, conventional trade negotiations.[21] When these different approaches coexist in the same trade negotiation, as is the case in TTIP, this might lead to a significant imbalance between the parties and the ensuing public debate. Moreover, as highlighted by the TTIP leaks, an unequal transparency policy during the negotiations may tarnish the trust in the process and lead to questioning their overall predictability. This appears a paradoxical outcome insofar as the argument for non-disclosure put forward by the US is to build trust between parties.

It is submitted that the information asymmetry characterizing the TTIP negotiations represents an insurmountable obstacle insofar as it signals a different understanding of what can and cannot be shared during the negotiations. The EU Commission has convincingly shown to the US (and its other trading partners) that there exists a conspicuous space in the negotiation of a trade agreement that could be disclosed without automatically risking the untouchable 'space to think and trade' inherent to any trade negotiation. In other words, the EU has shown that not only can trade partners offer a heightened level of openness without compromising the negotiation process, but also that this is necessary within the framework of the new generation trade agreements. Yet, the EU has failed – at least thus far – to persuade the US to embrace such an innovative approach to transparency in the negotiations. Unless this information asymmetry will be addressed by a change in the US disclosure policy there is a risk that it may further prevent mutual trust.

There are further important consequences stemming from the systemic imbalance in the disclosure policy across the Atlantic. This is because an information asymmetry emerges not only at the level of the information disclosed (one party discloses more than the other) but also at the level of the stakeholders consulted (business representatives have a more prominent place in the negotiations). On the absence of ready-made available material, corporate interests tend to gain better access to the information than civil society organisations.

This dual information asymmetry (between trade partners and between their respective government and their constituencies) calls for the need to reconsider the meaning, role, and level of transparency required in their negotiation and adoption[22].

[21] In the case of TPP, the text of the agreement was only disclosed a month after its conclusion. Regarding the negotiating documents, the New Zealand Chapter of Transparency International informed us that the parties to the TPP would be required to maintain information on the negotiations confidential for four years. This is confirmed in a letter released by New Zealand as depositary of the TPP Agreement to other parties for signature: http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/TPP%20letter.pdf.

[22] On the need for a new understanding of confidential trade negotiations, see V. Abazi, in this issue of the Journal.

V. Conclusions

Due to its pioneering bilateral and multilateral efforts to improve transparency in trade, the EU emerges – as it has been demonstrated by this analysis – as one of the most well positioned actors to change the transparency paradigm in trade negotiations. Yet, for this to occur in the framework of TTIP, a move from the US appears needed. Given the patent asymmetry in transparency practices between the EU and its trade partners, it seems as though any additional steps to improve the overall transparency of trade negotiations will depend on some concessions from those partners. As suggested by its bold commitment to the Open Government Partnership,[23] the US officially positions itself in favour of similar transparency ambitions as the EU in many regards.[24] As an agreement between two like-minded countries and powerful trader partners, TTIP is expected to become the golden standard for a new generation of trade agreements. For this to occur, it will be crucial that TTIP also sets a new 'transparency benchmark' aimed at unsettling, and possibly overcoming, existing practice. Should the Transatlantic leadership be capable to identify the outer limits of transparency in trade negotiations, this solution might be plurilateralized and perhaps even be multilateralized to the benefit of a more transparent multilateral trading system. Unless the EU and the US, two like-minded countries and powerful traders, will be able to lay down a joint transparency policy the fate of the TTIP negotiations is already written.

[23] See http://www.opengovpartnership.org/country/united-states.

[24] The Obama administration has announced it would strengthen efforts to improve transparency, particularly in trade negotiations, and engage with the public and stakeholders. See United States Trade Representative, 'Transparency and the Obama Trade Agenda', January 2015, https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2015/january/fact-sheet-transparency-and-obama. Arguably, such ambitious transparency pledges may set the expectations of the general public too high, giving rise to more criticism when those promises are not implemented.

Just the TTIP of the Iceberg? Dynamics and Effects of Information Leaks in EU Politics

Ronny Patz[*]

The TTIP leaks in May 2016 continue a series of major public disclosures of documents revealing the evolution of the transatlantic trade negotiations between the EU and the US. This article studies these leaks in the light of EU leaks as a much wider phenomenon. When the demand of the public to be much better informed is faced with EU secrecy, the likelihood increases that leaks will continue to produce headlines. The particular salience of TTIP as a major topic in today's EU politics makes it a showcase for these dynamics. Different to previous EU leaks, however, the TTIP leaks have not just stirred up a continuous debate about the regulatory substance of the negotiations but they have questioned, more generally, the democratic legitimacy of the governance of international or transnational risk regulation through trade agreements. This raises doubts whether confidentiality can still be a sensible default option for EU trade negotiations, especially those with regulatory effects.

I. Introduction

"[M]any observers agree that the Commission has been 'leaking like a sieve" [25]

Leaks have become a major element of European Union politics. The Transatlantic Trade and Investment Partnership (TTIP) leak in early May 2016[26] is neither the first of its kind nor will it be the last. Transparency by leaks – or "transleakancy" as the series of publications of confidential TTIP negotiation documents has already been coined[27] – is one element of the political game that different interest groups, governmental and non-governmental, play on both sides of the Atlantic. And yet, leaked EU documents have been shared in wider policy-networks all along, independent of whether they have received media attention or not.[28] The difference is that leaks similar to those that we see on TTIP have reached a new level of importance. Here, the mere fact of their

[*] Post-doctoral research fellow working with the Chair in Political Systems and European Integration at LMU Munich, Germany.

[25] Carsten Grønbech-Jensen, "The Scandinavian tradition of open government and the European Union: problems of compatibility?", 5 *Journal of European Public Policy* (1998), pp. 185 *et sqq.,* at p. 191.

[26] Documents published by Greenpeace Netherlands at https://ttip-leaks.org (Last accessed: 19 May 2016).

[27] Christoph Herrmann, "Transleakancy" in Christoph Herrmann, Bruno Simma, Rudolf Streinz (eds.) *Trade policy between law, diplomacy and scholarship. Liber amicorum in memoriam of Horst G. Krenzler* (Cham et al.: Springer 2015), pp. 39 *et sqq.*

[28] Ronny Patz, "Information flows in the context of EU policy-making : affiliation networks and the post-2012 reform of the EU's Common Fisheries Policy", Doctoral Thesis, University of Potsdam (2014), available at: https://publishup.uni-potsdam.de/files/6824/patz_diss.pdf (last accessed: 19 May 2016).

existence makes them newsworthy. The impact of these leaks on public debates is seen as a major risk for negotiators. They are a risk, first, because they reveal negotiation positions and intermediary compromises, which could delay agreement between negotiation partners. Second, the appearance of secrecy in areas of regulatory governance undermines the credibility of the process in the eyes of a wider a public that fears that democratic principles and regulatory standards are not respected. When democratic legitimacy is lost and public outcries become more audible, EU member states and the Commission risk rejection of the compromises and deals they have made behind closed doors once they are presented on the public stage of the European Parliament. The refusal of the European Parliament (EP) to give consent to the Anti-Counterfeiting Trade Agreement (ACTA) in 2012 as a result of the mediatisation of leaks published by Wikileaks and La Quadrature du Net[29] has demonstrated to EU policy-makers that this risk is not only hypothetical, but very real.

I argue below that, while leaks are a common phenomenon in EU politics, the TTIP disclosures are more than just the tip of the iceberg of EU leaks. In light of this observation, I reflect on recent discussions regarding the democratic governance of risk regulation, the transparency of EU decisions-making and the implications of these debates for the ongoing transatlantic negotiations. The TTIP leaks demonstrate, ultimately, that trade negotiations with regulatory effects require a new level of transparency to convince the outside world that all matters of concern are dealt with in the public interest.

II. Leaks in European Union Politics: A Review of a Common Phenomenon in the Light of the TTIP leaks

Brussels has been described as a notoriously 'leaky' environment for quite some time.[30] Leaks happen in EU politics, as elsewhere, where outside demand for inside information is larger than the supply that institutional transparency, or secrecy, rules provide. Defining when to speak of a 'leak' and when it is 'moral' depends on context and perspective.[31] In public debates, leaks are often

[29] Josef Eibauer, "Blessing or curse? The effects of transparency on the European Commission's success at the international ACTA negotiations", Working Papers by the Center for International Political Economy 14(2014), at pp. 14-15; http://www.diss.fu-berlin.de/docs/servlets/MCRFileNodeServlet/FUDOCS_derivate_000000002277/PIPE_Working_Paper_14-12_Eibauer_-_Blessing_or_Curse__Effects_of_Transparency.pdf (last accessed: 19 May 2016).

[30] Grønbech-Jensen 1998, "The Scandinavian tradition of open government", *supra* note 1; Wilhelm Magnusson, "Non-state actors' role in the EU forest policy making – A study of Swedish actors and the Timber Regulation negotiations"; Master Thesis, Swedish University of Agricultural Sciences, Department of Forest Products (2014); available at: http://stud.epsilon.slu.se/6935/1/Magnusson_W_20140625.pdf (last accessed: 19 May 2016), at pp. 36-37.

[31] Cf. Jurgen De Jong, Michiel de Vries, Michiel "Towards unlimited transparency? Morals and facts concerning leaking to the press by public officials in the Netherlands", 27 *Public*

discussed as information disclosures that are considered unauthorised or illegal by those holding the information, or as actions of whistleblowers trying to reveal some sort of actual or perceived wrongdoing. But leaks can be much more profane. They are part of power plays between political interests. In the EU, national or European officials distribute confidential information to allow interest groups with whom they share common goals to have more influence thanks to informational advantages.

The fact that the TTIP leaks have received major media attention demonstrates that there is a large public demand for more detailed insights into such political processes at EU level. In relation to this demand, the TTIP negotiation partners have not shared enough information that the public, and in particular certain interest groups, demand in order to be able to judge whether their concerns are properly addressed throughout the negotiations. And this demand for inside information has only increased with the emergence of the "Wikileaks World".[32] A series of mega-leaks has gained global attention and increased the mediatisation of leaks in recent years. Most notably is the vast amount of documents published by Wikileaks over several years, the NSA-leaks by Edward Snowden, or the recent so-called 'Panama Leaks'. They have raised awareness about what types of information are withheld from the public, not all for legitimate reasons, and they have created a public interest in knowing what only insiders used to know.

The TTIP leaks are exemplary for EU leaks that actually become visible to the wider public through their mediatisation. In academic research, this is the type of leaks most frequently referred to.[33] The scandalisation of leaks, even for minor issues, allows EU stories to be sold more easily to editors and national publics who otherwise find EU politics boring. Leakers, even those who ultimately publish the original source material online, have therefore given preferential treatment to major global news outlets such as the Financial Times to ensure maximum visibility of their leak.[34] Most leaks, however, happen below the public radar. They concern EU matters that are not 'sexy' enough for old and new media, some because they are only affecting limited groups, others because their

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Administration and Development (2007), pp. 215 *et sqq*.; Kathryn Flynn, "Covert Disclosures - Unauthorized leaking, public officials and the public sphere; 7 *Journalism Studies* (2006), pp. 256 *et sqq*., at p. 258.

[32] Christopher Hood, "From FOI World to WikiLeaks World: A New Chapter in the Transparency Story?", 24 *Governance* (2011), pp. 635 *et sqq*.

[33] See for example: William D. Coleman, Stefan Tangermann, "The 1992 CAP Reform, the Uruguay Round and the Commission: Conceptualizing Linked Policy Games", 37 *JMCS: Journal of Common Market Studies* (1999), pp. 385 *et sqq*.; Frank J. Convery, Luke Redmond, "Market and Price Developments in the European Union Emissions Trading Scheme", 1 *Review of Environmental Economics & Policy* (2007), pp. 88 *et sqq*.; Hussein Kassim, Dionyssis G. Dimitrakopoulos, "The European Commission and the future of Europe", 14 *Journal of European Public Policy* (2007), pp. 1249 *et sqq*.,

[34] Farrel Corcoran, Declan Fahy, "Exploring the European elite sphere", 10 *Journalism Studies* (2009), pp. 100 *et sqq.*

importance for the general public is simply not recognised. But even where leaks are not mediatised, they are part of EU politics.

EU leaks have been mentioned in debates ranging from EU lobbying[35] to institutional reform discussions,[36] from inter-institutional relations[37] to Comitology,[38] from discussions on EU secrecy[39] to EU communications.[40] The policy domains in which EU leaks have been observed include agriculture,[41] international trade and copyright[42] or EU constitutional politics.[43] Although leaks are rarely at the centre of research, they have been used, for example, as empirical material for the study of advocacy on the Anti-Counterfeiting Trade Agreement (ACTA).[44] First studies have also started tracing the flow of leaked EU documents in wider EU networks.[45] However, there have been calls that empirical research could make even more use of leaked information.[46]

Anecdotal evidence on EU leaks reveals a number of interesting features. Leaks are observed where there is internal conflict inside institutions.[47] Whether leaks are effective can depend on the right timing and exclusiveness of the information received through leaks.[48] The timing of leaks can range from hours[49] or several

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[35] Adam W. Chalmers, "Interests, Influence and Information: Comparing the Influence of Interest Groups in the European Union", 33 *Journal of European Integration* (2011), pp. 471 *et sqq*.
[36] Hussein and Dimitrakopoulos 2007, "The European Commission and the future of Europe", *supra* note 9.
[37] Guri Rosén, "EU Confidential: The European Parliament's Involvement in EU Security and Defence Policy", 53 *JMCS: Journal of Common Market Studies* (2014), pp. 383 *et sqq.*
[38] Gijs J. Brandsma, "The effect of information on oversight: the European Parliament's response to increasing information on comitology decision-making", 78 *International Review of Administrative Sciences* (2012), pp. 74 *et sqq*.
[39] Deirdre Curtin, "Overseeing Secrets in the EU: A Democratic Perspective", 52 JCMS: Journal of Common Market Studies (2014), pp. 684 *et sqq*.
[40] Christoph C. Meyer, "Political Legitimacy and the Invisibility of Politics: Exploring the European Union's Communication Deficit". 37 *JCMS: Journal of Common Market Studies* (1999), pp. 617 *et sqq*.; Corcoran and Fahy 2009, "Elite Sphere", *supra* note 10.
[41] Alan Greer, Thomas Hind, "Inter-institutional decision-making: The case of the Common Agricultural Policy", 31 Policy and Society (2012), pp. 331 *et sqq.;* Henrike Klavert, Niels Keijzer, "A review of stakeholders' views on CAP reform"; ODI research paper (Maastricht , 2012); available at: http://www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/7888.pdf (last accessed: 19 May 2016).
[42] James Losey, "The Anti-Counterfeiting Trade Agreement and European Union Civil Society: A Case Study on Networked Advocacy" 4 *Journal of Information Policy* (2014), pp. 205 *et sqq*.; Andreas Dür, Gemma Mateo, "Public opinion and interest group influence: how citizen groups derailed the Anti-Counterfeiting Trade Agreement", 21 *Journal of European Public Policy*, pp. 1199 *et sqq.*
[43] Hussein and Dimitrakopoulos 2007, "The European Commission and the future of Europe", *supra* note 9.
[44] Losey 2014, "The Anti-Counterfeiting Trade Agreement", *supra* note 18.
[45] Patz 2014, "Information flows in EU policy-making", *supra* note 4.
[46] Gabriel J. Michael, "Who's Afraid of WikiLeaks? Missed Opportunities in Political Science Research", 32 *Review of Policy Research* (2015), pp.175 *et sqq.*
[47] Karoline H. Flåm, "A Multi-level Analysis of the EU Linking Directive Process. The Controversial Connection between EU and Global Climate Policy", FNI Report 8/2007, Fridtjof Nansen Institute, available at: http://www.fni.no/pdf/FNI-R0807.pdf (last accessed 19 May 2016).
[48] Chalmers 2011, "Interests, Influence and Information", *supra* note 11.

months[50] before official publication of the respective documents. Different to legislative leaks, trade negotiation leaks have been observed long before documents would have eventually been disclosed,[51] suggesting that the dynamics of leaks may differ between different types of political processes.

What makes the TTIP leaks so special is that, compared to other types of EU leaks, they have been used repeatedly to stir up public debate about the differing principles in the regulation of risks between the US and the EU[52] combined with more general discussions about EU decision-making and the democratic nature of transnational negotiations. To understand the new dimensions of these debates, one has to remember that trade policy has become a much more salient political matter since the European Parliament (EP) gained new powers under the Lisbon Treaty. And the salience of TTIP should have been obvious even to the most casual observer of EU politics from the moment it became a major topic in the European Parliament election campaign in 2014.[53] Subsequently, TTIP was made one of the priorities of the new Juncker Commission,[54] and TTIP transparency became an issue in the first Commission Work Programme (CWP) for 2015.[55] Ironically, the draft 2015 CWP was itself leaked[56] and critically discussed days before its official presentation in the European Parliament. TTIP has thus been a frequent object of leaks and a salient topic for the media, for lobbyists and for activists who have been using these leaks to amplify their messages and reach diverse audiences.

In summary, we know that leaks are omnipresent in EU politics. The TTIP leaks constitute, however, a new type of mediatised leaks in a policy field – trade politics – with increasing regulatory importance. Decision-making in these regulatory domains was previous subject to ordinary legislative procedures or implementing legislation and not part of diplomacy-type international negotiations between the EU and third parties. The new regulatory nature of

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[49] Hussein and Dimitrakopoulos 2007, "The European Commission and the future of Europe", *supra* note 9.
[50] Coleman and Tangermann 1999, "The 1992 CAP Reform", *supra* note 9.
[51] Dür and Mateo 2014, "Public opinion and interest group influence", *supra* note 18.
[52] On the different principals in the TTIP negotiations see Lucas Bergkamp and Lawrence Kogan, "Trade, the Precautionary Principle, and Post-Modern Regulatory Process. Regulatory Convergence in the Transatlantic Trade and Investment Partnership", 4 *European Journal of Risk Regulation* (2014), pp. 493 *et sqq*.
[53] Patrick R. Hugg and Sheila M. Wilkinson, "The 2014 European Parliament Elections and the Transatlantic Trade and Investment Partnership: Economics and Politics Collide", 24 *Journal of Transnational Law & Policy* (2014-15), pp. 116 *et sqq.*, at 148-52.
[54] See priority "A balanced EU-US Free Trade Agreement" at https://ec.europa.eu/priorities/balanced-eu-us-free-trade-agreement_en (last accessed: 19 May 2016).
[55] European Commission, "Commission Work Programme 2015. A New Start", Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Council and the Committee of the Regions, COM(2014)910 final, 16.12.2014, at p.8.
[56] For example by Corporate Europe Observatory, see: http://corporateeurope.org/power-lobbies/2014/12/leaked-draft-commission-work-programme-2015 (last accessed: 19 May 2016).

trade deals such as TTIP now raises an important question: What level of transparency is necessary not to undermine public legitimacy and not to risk European Parliament agreement to compromises reached during negotiations?

III. TTIP Leaks and the Democratic Legitimacy of Transnational Governance of Risk Regulation

By 2014, the Commission and member states in the EU Council realised that secrecy of negotiations was undermining the decision-making process in the case of TTIP. As a result, the EU's negotiation mandate and more documents have been published from 2014 onwards.[57] This need for pro-active publication without waiting for the EU courts to force the institutions to provide access to documents shows in how far transparency has become a central norm of EU decision-making. Until the mid-1990s, EU institutions still argued that, because non-public information was anyway accessible to the press and to lobbyists through leaks, there was no need to introduce the formal right to access EU documents.[58] With the adoption of Regulation 1049/2001 on access to EU documents,[59] the legal position of the public changed. However, several exceptions to the right to access EU documents included in the regulation, such as the protection of international relations, were still used to keep documents from international trade negotiations confidential.[60] The argument behind these exceptions is that openness could undermine the effectiveness and efficiency of the decision-making process, for example by closing spaces for open deliberations or by making it harder to find difficult compromises over certain red lines previously established by the respective negotiation partners.

Recent research on transparency in the EU Council suggests, however, that openness does not necessarily undermine effectiveness of negotiations as some argue. Instead, making "records available to the public helps overcome problems of incomplete information and can help decrease the length of negotiation processes."[61] Given the complexity of the TTIP negotiations, it is difficult to judge whether the level of public controversy around the many leaks has actually prolonged the negotiations, or whether the leaks are simply increasing the visibility of challenging negotiations that would anyway take a long time. In the

[57] Vigjilenca Abazi and Maarten Hillebrandt, "The legal limits to confidential negotiations: Recent case law developments in Council transparency: Access Info Europe and In 't Veld", 52 *Common Market Law Review* (2015), pp. 825 *et sqq.*, at p.844.
[58] Grønbech-Jensen 1998, "The Scandinavian tradition of open government", *supra* note 1, at p. 191.
[59] Regulation 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents, O.J. 2001, L 145/43.
[60] Christoph Herrmann, "Transleakancy", *supra* note 3.
[61] Sara Hagemann and Fabio Franchino, "Transparency vs efficiency? A study of negotiations in the Council of the European Union", *European Union Politics* (2016), DOI: 10.1177/1465116515627017, at p. 18.

same way, it can be questioned whether the new level of openness by the European Commission and the member states in the EU Council can accelerate negotiations, especially in light of the continuing focus of the public on leaked documents and the many controversial issues within TTIP.

The question is therefore whether transparency of TTIP and other trade negotiations should simply be seen with regard to the effectiveness and efficiency of the process. Alternatively, one could highlight the particular value of transparency that is already reflected in the substance of the negotiations: One of the aims of TTIP is to strengthen "transparency, stakeholder consultations, and impact assessment" as one of the means "to build bridges between [the EU and US regulatory] systems."[62] By increasing the default level of transparency in the TTIP negotiations, this process of bridge=building can start already during the core negotiation process, not afterwards. Where negotiation mandates and (intermediate) compromises are transparent early on, a wider public can critically assess the impact following from these compromises, and the public debate could inform EU negotiators about potential negative consequences of their decisions. In this sense, transparency could better protect the interests of the general public throughout the negotiations, whereas confidentially may only protect the individual interests of the negotiators without making the negotiations more effective. Pro-active transparency, as opposed to 'transleakancy', would be one of the means to achieve more effective negotiations. When negotiation partners reach compromises on institutional or substantial aspects of the TTIP agreement that can actually stand an open debate, these compromises will become more legitimate. Ultimately, this could make complex trade negotiations more robust against strategic leaks published by those who want to derail negotiations late(r) in the process.

IV. Conclusion: TTIP Leaks as a Phenomenon of their own

> "[T]here is no doubt that the TTIP marks the start of a new approach to transparency in trade negotiations that is very much to be welcomed."[63]

TTIP most visibly represents the expansion of international decision-making into spheres of regulatory governance, spheres in which transparency was already considered the default option at EU-level. Continued secrecy in these emerging regulatory spheres then created room for leaks, and for their subsequent politicisation. The public attention for the repeated leaks shows that fascination for this phenomenon is extensive, even though Pozen claimed that "[o]ur

[62] Alberto Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences", 18 *Journal of International Economic Law* (2015), pp. 625 *et sqq.*, at p. 630.
[63] Marise Cremona, "Guest Editorial: Negotiating the Transatlantic Trade and Investment Partnership (TTIP)", 52 *Common Market Law Review* (2015), pp. 351 *et sqq.*, at p. 361.

comprehension of leaking has not kept pace with our fascination".[64] This article has therefore sought to contribute in some ways to expand on the comprehension of the TTIP leaks in a wider context of different types of EU leaks.

What emerges from this discussion is that the TTIP leaks have already become a phenomenon of their own, catalyzing not just debates about EU transparency but more generally about the transnational governance of the regulation of risk. Despite increased levels of transparency since 2014, the media attention surrounding the latest leaks in May 2016 reflects that the substance and transparency of TTIP negotiations continue to stir up controversy. Due to the wide regulatory scope of TTIP, each chapter contains matters that relate to major political debates across the EU. These debates, from food safety and environmental protection to the production of cultural goods, resonate in several national public spheres, including in major member states like Germany or France. In the face of such public concern about the regulatory impact of TTIP, confidentiality as the perceived default option has proven to be rejected by a wider public in the EU. The continued leaks, and the critical information they reveal, nurture this public perception of intransparency, undermining trust and ultimately putting at risk the consent of the European Parliament.

[64] David E. Pozen, "The Leaky Leviathan: Why the Government Condemns and Condones Unlawful Disclosures of Information", 127 *Harvard Law Review* (2013), pp. 512 *et sqq.*, at p. 514.

How Confidential Negotiations of the Transatlantic Trade and Investment Partnership Affect Public Trust

Vigjilenca Abazi[*]

TTIP negotiations take place in a legal context that has been continuously developing and come after a line of EU negotiations of international agreements that have shifted the legal grounds of acceptable level of confidentiality in negotiations. Notwithstanding the salient legal developments in favour of more transparent EU negotiations, the underlying justification of institutions in favour of secrecy has remained unchallenged: confidentiality, as a tool to build trust between negotiating partners, takes prevalence over transparency as a means to foster public trust in the negotiating process.

I. Introduction

When EU Heads of States and Governments unanimously gave the European Commission a mandate to negotiate the EU-US Transatlantic Trade and Investment Partnership on 17 June 2013, they understood that these talks would become the leitmotiv of a new era in EU trade policy. However, few people would have guessed that it would *primarily* be because of transparency.[65]

The public demands for more transparent EU negotiations have significantly increased, especially with regard to the EU-US negotiations of the Transatlantic Trade and Investment Partnership. For many pundits transparency in negotiations comes as a surprise, as the candid statement by the Commissioner's Malmström cabinet member illustrates, since traditionally EU negotiations almost exclusively take place behind closed doors and with almost no public disclosure of documents.[66] Scholars have also noted how 'remarkable' the TTIP negotiations are for the fact that the negotiating directives were publically released,[67] which was not a common practice before, leading some Members of European Parliament to initiate adjudication for public disclosure of documents.[68] Not least important for the public availability of documents are

[*] Postdoctoral Researcher at Maastricht University

[65] Jolana Mungengová (Member of Cabinet at the EU Trade Commissioner), *The EU Enhanced Transparency in TTIP: A successful Shift in Paradigm* (CERiM blog, 1 March 2016).

[66] See generally Deirdre Curtin, 'Official Secrets and the Negotiation of International Agreements. Is the EU Executive Unbound?' (2013) 50 *Common Market Law Review* 423.

[67] Marise Cremona, Negotiating the Transatlantic Trade and Investment Partnership (2015) 52 *Common Market Law Review* 351, *361.*

[68] See Case C-350/12 P, Council v. Sophie In 't Veld, Judgment of the European Court of Justice (First Chamber) of 3 July 2014, EU:C:2014:2039.

leaks, i.e. unauthorised disclosure of information, with the most recent disclosure made by Greenpeace Netherlands.[69]

TTIP negotiations take place in a legal context that has been continuously developing and come after a line of EU negotiations of international agreements that have already shifted the legal grounds of acceptable level of confidentiality. For example, the European Parliament vetoed international agreements (partly) due to lack of access to information, such as the Anti-Counterfeiting Trade Agreement and the EU-US Agreement on Passenger Name Records.[70] In addition, a set of cases before the Court of Justice of the European Union (CJEU) has led to an enhanced legal protection of both public and parliamentary access to information regarding international negotiations.[71] Seen in this broader legal context, the TTIP negotiations are another step to more transparent negotiations, especially in light of the active efforts of the Commission to share information with the European Parliament and national parliaments,[72] even if this is done to 'dispel rumour and shape the argument in the face of widespread anxiety and campaigning'.[73]

However, it is problematic that the underpinning argument in favour of secrecy remains unchallenged, i.e. confidentiality, as a tool to build trust between negotiating partners, is more prevalent than transparency as a means to foster public support in the negotiating process.[74] In the context of the TTIP negotiations, this type of justification in favour of secrecy is particularly disconcerting as the negotiations touch upon issues that have quasi-legislative character and address regulation in the public interest. What is furthermore remarkable is that while some TTIP chapters such as those on regulatory cooperation or technical barriers to trade emphasize public notice and other measures for transparency, the negotiations of the rules of general application

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69 See Greenpeace Netherlands, Press Release, Greenpeace Netherlands releases TTIP documents (2 May 2016), available online <http://www.greenpeace.org/international/en/press/releases/2016/Greenpeace-Netherlands-releases-TTIP-documents/> [accessed 30 May 2016] See also in this issue, Ronny Patz, 'Just the TTIP of the iceberg? Dynamics and effects of information leaks in EU politics'.

[70] See Christina Eckes, How the European Parliament's participation in international relations affects the deep tissue of the EU's power structures (2014) 12(4) *International Journal of Constitutional Law* 904.

[71] See Vigjilenca Abazi and Maarten Hillebrandt, 'The Legal Limits to Confidential Negotiations: Recent Case Law Developments in Council Transparency: *Access Info Europe* and *in 't Veld'* (2015) 52 *Common Market Law Review* 825.

[72] Evelyn Coremans, Negotiating TTIP: The Impact of Transparency on Working Practices in EU Trade Policy, Paper presented at the workshop 'The Law and Politics of Confidential EU Negotiations', Brussels, 12 February 2016.

[73] Cremona, *Negotiating the Transatlantic Trade and Investment Partnership*, 361.

[74] For an elaborate discussion on trust and transparency see, Vigjilenca Abazi and Eljalill Tauschinsky, 'Reasons of Control and Trust: Grounding the Public Need for Transparency in the European Union' (2015) 11 *Utrecht Law Review* 78.

lack transparency necessary for public trust. Against this background, the paper maps the salient legal developments that limit confidentiality in negotiations but also critically questions the justification in favour of secrecy.

II. Legal Context of Negotiating TTIP: Limits to Confidentiality

In a post-Lisbon legal context, EU international negotiations take place in accordance with Article 218 of the Treaty on the Functioning of the European Union (TFEU), which stipules different roles for EU institutions. Whereas the Commission acts as the negotiator and ensures the EU's external representation,[75] the Council is entrusted with the power to sign and conclude the agreement. Article 218(10) TFEU affirms the prerogative of the European Parliament to be informed on international agreements, providing a democratic scrutiny role for the only directly elected EU institution. Important for the legal context of negotiations are also Treaty provisions stipulating EU's constitutional commitment to principles of openness and representative democracy that provide an overall framework of how the EU is supposed to act.[76]

In practice, most of the EU's international negotiations take place behind closed doors and with very few publically available documents. Nevertheless, a series of developments both in the case law of the CJEU as well as the institutional practice of the European Parliament in light of its veto powers have shifted the legal limits of accepted extent of confidentiality in international negotiations leading to more accessibility to documents. Salient in this respect is the distinction on whether such access is public or parliamentary, i.e. whether the document is disclosed to the public (and hence is accessible also for representatives) or whether the document is only disclosed to the parliament within the context of their institutional prerogatives of oversight. In the latter case, such access to documents may be desirable from an accountability perspective, however it is less likely to foster public debate and public trust in a particular process.[77] Overall, the legal context of negotiations is shaped by limits deriving from: public access to document based on Regulation 1049/01,[78] parliamentary access to information and powers to veto an international agreement on basis of Article 218 TFEU.

[75] In all those areas not covered by the CFSP, see Article 17(1) TEU.

[76] See Art. 1 TEU, see also Title II of TEU, particularly Articles 10, 11, 12 TEU.

[77] See V. Abazi 'Parliamentary Oversight Behind Closed Doors' (2016) 5 *Cambridge Journal of Comparative and International Law, Forthcoming.*

[78] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43.

Institutions cannot deny public access to information requests regarding international negotiations without explaining how disclosure could 'specifically and actually' undermine international relations. In the recent case of *Council* v *In 't Veld*, the European Court of Justice for the first time explicitly affirmed that even in international relations the institutions are obliged to explain whether disclosure could 'specifically and actually' undermine a protected interest.[79] The facts of this case are similar to the Council's initial position with regard to the secrecy of the negotiating mandate of the TTIP agreement. Namely, Ms In 't Veld, MEP utilising the public access regime in her personal capacity, requested a document containing an opinion of the Council's Legal Service regarding a recommendation from the Commission to the Council about the initiation of negotiations between the EU and the USA for an international agreement making available to the US Treasury Department financial messaging data to prevent terrorist financing (TFTP agreement). Whereas her initial request was denied in full, her confirmatory request yielded only limited access to the introductory and general parts of the documents, leading her to take the case to the Court. Significantly, the Court required the Council to demonstrate the claimed risk of the harm in international negotiations if the document is disclosed and it is particularly noteworthy that the Court did not accept broad claims invoked on the basis of the exception in international relations, as used to be the case,[80] and pointed to the relevance of the context of the issues at stake and their possible implications when deciding on disclosure.[81] The Court in this regard maintains the distinction between the specific content of the document relating to the substance of negotiations and the choice of legal basis regarding those negotiations. The latter according to the Court has constitutional significance and hence must be public.

Another set of limits to confidentiality derives from case law regarding parliamentary access. In the landmark case of *European Parliament* v *Council,*[82] the Council did not send the decision for the adoption of the EU-Mauritius Agreement until 17 October 2011 – more than three months after the adoption of that decision and the signing of that agreement, which took place on 12 and 14 July 2011, respectively, and 17 days after their publication in the *Official Journal of the European Union.*[83] Significantly, in this case the Court held that the information requirement laid down in Article 218(10) TFEU applies to any procedure for concluding an international agreement, including agreements relating exclusively to the Common Foreign and Security Policy.[84] Moreover,

[79] Case C-350/12 P, Council v. Sophie in 't Veld, para 53, 64.
[80] See Case C-266/05 P *Sison v Council* (known as *Sison II*), EU:C:2007:75, paras 34-35.
[81] Abazi and Hillebrandt, 'The Legal Limits to Confidential Negotiations, 837.
[82] C-658/11, EU:C:2014:2025,
[83] C-658/11, para 65
[84] C-658/11, para 85

informing the European Parliament is a mandatory procedural requirement within the meaning of the second paragraph of Article 263 TFEU and its infringement leads to the nullity of the measure.[85] It is also noteworthy that the Court held that the procedure covered by Article 218 TFEU is of general application and is therefore intended to apply, in principle, to all international agreements negotiated and concluded by the European Union in all fields of its activity, including the CFSP.[86]

Lastly, besides adjudication, the European Parliament in the post-Lisbon context has powers to demand more transparent negotiations and access to information through its veto powers. For example, the European Parliament refused consent to the EU-US SWIFT Agreement and delayed consent to the USA and Australia Passenger Name Records Agreements. Regarding the SWIFT Agreement, the European Parliament gave its consent at a later stage but as some scholars note there were 'no remarkable differences between the first and second SWIFT agreements'.[87] Rather, the difference was that on the second round, the European Parliament was fully informed at all stages of the negotiations.[88]

These legal limits to confidentiality in international negotiations are important; however the institutions continue to defend the necessity of secrecy in international negotiations. For example, the Council's self-perceived need for discretionary space and its institutional design that might necessitate such discretion have been pointed to as Council's significant arguments in favour of secrecy.[89] Yet, a crucial aspect to the rationale for secrecy, according to both the Council and the Commission, is the necessity of trust between negotiating parties.

III. Secrecy and Trust between Negotiating Partners

Secrecy in the conduct of international relations is not unique to the EU. Indeed, historically, international negotiations have always meant that a certain extent of secrecy will be practiced.[90] As it has been noted, 'if an ambassador had to appear in the bright light of the royal court, he became constantly preoccupied by secrecy. He needed to find ways to protect his own secrets from third parties and

[85] C-658/11, para 80

[86] C-658/11, para 72

[87] Juan Santos Vara, 'The Role of the European Parliament in the Conclusion of the Transatlantic Agreements on the Transfer of Personal Data after Lisbon' (2013) CLEER Working Papers 2013/2, <http://www.asser.nl/upload/documents/20130226T013310-cleer_13-2_web.pdf> [accessed 30 May 2016]

[88] Ibid., 20.

[89] Abazi and Hillebrandt, 'The Legal Limits to Confidential Negotiations, 838.

[90] Aurélien Colson, The Ambassador Between Light and Shade: The Emergence of Secrecy as the Norm for International Negotiation, Koninklijke Brill NV, Leiden, 2008.

uncover the secrets of others'.[91] Early studies of diplomacy illustrate the importance of secrecy in international negotiations as well. For example, Frangois de Callieres, in his study on diplomacy, *De la Maniere de Negocier avec les Souverains,* first published in 1716, dedicated an entire chapter to 'Letters in Cypher' explaining secret (coded) letters that were meant to be understood only by very few negotiators. [92]

Some level of *necessary* secrecy in negotiations may be justified on basis of 'positionalism' and strategic bargaining, but also for the confidence it creates between the negotiators. Secrecy in negotiations is defended as important due to the so-called 'limit position' of the negotiators. If negotiating is to be conceived as a series of information exchanges, then each exchange takes the form of 'bids and counterbids'. In this sense, it has been argued that while the exchange of bids and counterbids happens openly, 'each negotiator has a 'limit' position, which has to be kept concealed from the other negotiator(s)'.[93] Besides providing discretion to the negotiators to keep their limit position concealed towards one another, secrecy is also related to candour in the exchanges between negotiators. Secrecy leads to trust between secret-keepers. Confidence as a function of secrecy is accepted in many professional norms, such as the relation between a lawyer and client or a doctor and patient.

Defending trust with an international partner is particularly prominent in the context of EU negotiations. For example, in the case of *In 't Veld* vs *Commission*, the Commission defended the nondisclosure of documents pertaining to the negotiations of the Anti-Counterfeiting Trade Agreement by arguing that

> "It goes without saying that the success of international negotiations requires cooperation among the parties involved which depends to a large extent on the atmosphere of mutual trust."

Ultimately, in the view of the Commission, disclosure of documents in the context of international negotiations would undermine the EU's credibility in the negotiations and the trust of the negotiating partner.[94] The Council presents similar arguments when arguing in favour of nondisclosure of documents due to the trust relation with international partners. For example, in the case of *Jurasinovic* vs *Council*, the Council maintained that nondisclosure of documents is

[91] *Ibid.*

[92] L. N. Rangarajan (1998): Diplomacy, states and secrecy in communications, Diplomacy & Statecraft, 9:3, 18-49

[93] *Ibid*.

[94] In 't Veld vs Commission, para 117.

a 'key factor in strengthening trust'[95] in this case more specifically between the EU and countries of the Western Balkans.
However, an argument by the institutions that documents must remain secret because their disclosure would jeopardise the trust relationship with specific partner is liable to rouse suspicions among the uninformed outsiders. What if the institutions only use this confidentiality as a shield against the public interest in transparency?

Transparency is consistently emphasized to be of paramount importance for public trust[96] and EU policy makers see the latter as core to better regulation.[97] Information is a precondition of choice; citizens need a certain amount of information in order to be able to choose from different alternatives, to understand enough of their implications to be able to distinguish among them and hold institutions accountable on this basis. The latter are significant aspects to citizens' trust, yet secrecy obstructs this function of information since citizens do not have the information and hence cannot make an informed choice. It is quite remarkable therefore that the institutions seem to hold public trust of secondary value when trust between negotiating partners is at stake. This is quite evident in the negotiations of TTIP that begun in secrecy as the Council did not release the negotiating mandate. It took the Council a year to do so, arguably until it was too late, as the secrecy surrounding TTIP had already given rise to deep suspicions in the general public about this 'new generation' *preferential* trade agreement. Secrecy gives rise to suspicion and distrust[98]: it separates the institutions, as holders of information, from the citizens, as uninformed outsiders. In fact, even the word secrecy derives from the Latin *secernere* that originally meant to set apart, to separate.[99] The question in the case of TTIP becomes whether this separation and suspicion have become so large that could block the agreement.

IV. Conclusions

TTIP negotiations bring the question of citizen trust and transparency to the fore. Not only is the EU institutional practice of closed door negotiations and secret documents no longer acceptable for citizens but it also leads to deep dissatisfaction with the agreement itself. Whereas the legal context in which the

[95] T-63/10 Jurasinovic vs Council, para 9.

[96] This is true for both, EU policy documents and (legal) literature. Cf, for example, Com(2016) 117final or Com(2013) 0864 final, see Koen Lennaerts: 'In the Union we Trust: Trust Enhancing Principles of Community Law', 41 *Common Market Law Review* (2004), pp. 317-343.

[97] Communication from the Commission, Better regulation for better results, Com(2015) 215 final.

[98] See generally Georg Simmel, 'The Sociology of Secrecy and of Secret Societies' (1906) 11 *American Journal of Sociology* 441.

[99] Sissela Bok, *Secrets: On the Ethics of Concealment and Revelation* (Pantheon Books 1982), 6.

TTIP negotiations take place has already moved forward in terms of limitations to confidentiality, as elaborated in public access to information, parliamentary access and parliamentary veto powers, TTIP negotiations are nevertheless bringing a new dimension to transparency. Namely, it is becoming evident that it is not enough for citizens' trust that only their national parliaments or the European Parliament receive information about the negotiations, notwithstanding that such access is partial and does not yield a meaningful public debate. For citizens to build trust in what the EU is negotiating on their behalf transparency and public access to information is crucial. However, when the disclosed information is not coming through authorised disclosure by the institutions themselves, but rather citizens are informed via leaks, the potential for trust is further hindered, as the leaks only become an illustration of the lack of institutional will to disclose information. Overall, TTIP negotiations show that EU institutions disproportionally favour confidentiality necessary for trust between negotiating partners instead of transparency necessary for public trust. It remains highly questionable whether TTIP leaks are able to close this gap of trust.

TTIP Leaks: A Welcome Opportunity for More Homework

Christian Häberli[*]

So the damage is done: both emperors go naked, and this at a particularly sensitive stage of the negotiations. Worse, the hegemons sit on an applecart already so full that only a "TTIP light" seems to save it from toppling, albeit at a price of losing its most precious apple: regulatory coherence, now and forever![100]

But wait! We may already have given up hope for transatlantic agreements on financial cooperation and data protection. Hormone beef and biotech seeds, if not feed, also look rather far away from good and risk-free regulatory solutions. And car makers in Asia and South America may have chuckled with relief when the efforts of US and EU manufacturers of automobiles failed to define a fully harmonised, standardised and mutually recognised "TTIP Car" – after which they would have had little if any leeway for their own motors, emission limits, windscreens and safety standards.

This is where the leaks may have opened a welcome window of opportunity for third countries, blinded as they apparently all are by the prospects of trade liberalisation racing ahead with megaregional steps too big for them to buy in with any hope for negotiating power. Let's first have a look at the old horse called WTO where – apart from the Trade Facilitation Agreement 2014 and a few plurilateral deals – two decades of negotiations produced nothing serious since its birth in the Marrakesh desert, in March 1995.

OK, there is little the WTO can do about preferential rules of origin by which regional trade agreement partners of all sizes shield off their reciprocal tariff concessions from what they consider (often wrongly) as free-riders. This also means that without further MFN tariff reductions the world risks becoming rather uneven with a TPPA and, perhaps later, with a TTIP. Especially for outsiders like developing countries having successfully fought for ceiling bindings of two hundred percent across-the-board when joining the WTO. Who will now talk to them? Mind you, without a TTIP, and if TPPA enters into force, even Europe will become an island with many tariff peaks, not only for foodstuffs, garments, computer parts and some raw materials – not to mention the ridiculously outdated GATS schedules countersigned in 1995 by the other

[*] PhD (Law), Senior Research Fellow, World Trade Institute, Bern University (Switzerland). Research for this paper was funded by the Swiss National Science Foundation under a grant to the National Centre of Competence in Research on Trade Regulation, based at the University of Bern's World Trade Institute. Web: http://www.wti.org / http://www.nccr-trade.org/people/haeberli/. Mail: christian.haeberli@wti.org.

[100] As for *investor-state dispute settlement* (ISDS), the other big apple on that cart, it may already have fallen off. As matters stand, especially when looking at the difficulties WTO now has to reappoint Appellate Body members and to fill vacancies, this is perhaps not a big drama... but that is another story unrelated to this paper.

WTO founding members, and not really updated ever since. The leaked EU "flexibilities" for GIs and services can hardly come as a surprise to anyone.[101]

So much for the tariffs and some other peanuts. Yet, at least for third countries there is something worse than tariff freedom for the hegemons: *regulatory close-off* threatens to restrain their effective market access, if their accession offers are spurned by Washington or Brussels. Indeed, even if they accept the whole future TTIP package and offer *at least* commensurate concessions in all fields of interest to the TTIP partners, the remaining non-tariff barriers (NTB) will become a moving target, for which further liberalisation is envisaged in *new* negotiating rounds between the US and the EU. Non-TTIP members won't sit at those future tables, but stand by and then buy the new regulations without access even to a toned-down litigation procedure, let alone investor-state dispute settlement for their operators without EU or US subsidiaries.

Now what? Does the holy Article XXIV of the GATT (and Article V GATS) really shield all mutual standard recognitions and agreements from all MFN and NT obligations? Will equivalence recognition demands for technical regulations based on Article 2.7 TBT fail as quickly as Article 4 SPS without a proof of an equivalent "ALOP"? Will third countries really be unable, after the conclusion of the TTIP, to invoke their WTO rights to non-discrimination – as they have rarely but successfully done in a few cases of mutual recognition agreements and autonomous standards *outside* RTA?[102]

Here is my advice for TTIP addicts: instead of playing haruspex with TTIP leaks – or paying lobbyists in Brussels and Washington to find out what's in the cards – start identifying your goods and services for exports to the EU and the USA mostly affected when elephants mate. And look not at tariffs (if you want to join the biggies you will have to abolish yours anyhow, except for a few agricultural quotas). Rather look at those non-tariff barriers which according to the TTIP leaks are up for complex deals.

Regulatory cooperation is indeed the name of the game, and academia has enthusiastically embraced it. Too quickly? We applaud the efforts and first "WTO Plus" results obtained at the regional level: megaregionals (TPPA), especially among "like-minded" partners (TTIP), will make the most inroads in lifting the NTB which remain despite their prohibition by default under various WTO agreements. In their report commissioned by the European Commission, Parker and Alemanno carefully describe the legislative and regulatory differences to be

[101] "TTIP Round Produces Signs Of New Flexibilities On GIs, Services Exceptions", 34/17 *Inside U.S. Trade* (29 April 2016), at p. 2.

[102] Consider, for example (i) *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, Report of the Appellate Body, WTO Doc. WT/DS381/AB/R, 16 May 2012, at p. 133 *et sqq.* (ii) *European Communities – Trade Description of Sardines,* Report of the Appellate Body, WTO Doc. WT/DS231/AB/R, 23 October 2002, at p. 61 *et sqq*.

addressed in the negotiations.[103] In another study requested by the European Parliament, Alemanno highlights the parliamentary dimension of such regulatory cooperation.[104] Rudloff sees "enormous" prospects for economic growth, particularly for non-tariff barriers for food trade.[105] Yet, for regulatory cooperation Lester and Barbee rightly suggested, back in 2013, to look for the "low-hanging fruits".[106] Josling and Tangermann agree, recalling the long history of transatlantic conflicts just for food, that the effort is certainly worthwhile.[107]

Most observers thus welcome regulatory cooperation (and enhanced intellectual property protection) under TTIP, pointing out to the competitive advantage for EU and US products resulting from the joint risk assessment and risk management this implies. The transatlantic differences in risk attitudes and regulatory cultures are recognised. Nonetheless, in their report from two major conferences on new approaches to international regulatory cooperation, Bull et al reiterate the promises of newly agreed standards and technical regulations, as well as of *procedural* regulatory cooperation, for 'more competitive markets, lower prices, broader diffusion of innovations, and enhanced consumer welfare, as well as other benefits from liberalization of countries' domestic economies and regulatory governance structures.'[108] Wiener and Alemanno consider the TTIP as a learning process whereby interest groups may find alliances, and solutions for joint risk management, across borders. They point to empirical studies contradicting the stereotype notion that Europeans favour "precaution" whereas Americans readily embrace "science-based" standards, concluding that overall, U.S. and European risk regulation over the past four decades has exhibited average parity. Hence, regulatory cooperation, involving stakeholders with common interests and political leverage on both sides of the Atlantic, represents a new form of collective action for shared risk management.[109]

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[103] Richard Parker and Alberto Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems* (Brussels: European Commission, 2014), cf. Annex: Process for developing laws and regulations in the EU and the US.

[104] Alberto Alemanno, *The Transatlantic Trade and Investment Partnership and the parliamentary dimension of regulatory cooperation*. Brussels, Doc. EXPO/B/AFET/2013/32, April 2014, at p. 46 *et seqq*.

[105] Bettina Rudloff, "Food Standards in Trade Agreements: Differing Regulatory Traditions in the EU and the US and Tips for the TTIP", *German Institute for International and Security Affairs, SWP Comments 49* (November 2014), at p.4 *et seqq*.

[106] Simon Lester and Inu Barbee, *The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership*. 16 *Journal of International Economic Law* (2013), pp. 847–867, at p. 849.

[107] Timothy E. Josling and Stefan Tangermann, "*Transatlantic Food and Agricultural Policy: 50 Years of Conflict and Convergence*. Edward Elgar Publishing (2015), at Chapter 6

[108] Reeve T. Bull et al., "New Approaches to International Regulatory Cooperation: The Challenge of TTIP, TPP, and Mega-Regional Trade Agreements", 78 *Law and Contemporary Problems* (2015), pp. 1-29 at p. 3.

[109] Jonathan B. Wiener & Alberto Alemanno, "The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory". 78 *Law and Contemporary Problems* (2015), pp. 103-136, at pp. 104 and 114.

The already signed TPPA provides a good template – its NTB extent and content has surprised us all. And then there is the CETA, with a new attempt for dispute settlement allowing for ratification which might also inspire TTIP negotiators. It also has several risk management features of interest to observers, and a new formula for the protection of geographical indications: "Schwarzwälder Schinken" remains protected for dried ham producers in Germany's Black Forest – but "Black Forest Ham" will be available for both European and Canadian produce. Does the prosciutto war story in Europe ring a bell?

What is now required first and foremost is political leadership – not only in Germany.[110] But this leadership needs guidance. The homework menu proposed here requires close cooperation with standard-setting bodies and operators across the whole range of a country's exports to either the US or the EU. Of course, a special risk assessment will be necessary not only as in Articles 5 and 6 SPS and for all sorts of contentious foods such as chlorine-treated chicken. The same goes for the EU prohibition of the veterinary drug ractopamine: the maximum residue limit (MRL) for traces of ractopamine in muscle cuts of meat, razor-thin adopted in a most unusual Codex alimentarius vote as a new standard, henceforth dividing the membership, and with an uncertain outcome in a WTO/SPS case.[111]

We are on new risk assessment grounds here. And risk management is not made easier by the fast-evolving production standards and technical regulations churned out weekly by the National Standardization Bodies of 33 European countries federated in CEN and CENELEC, *ex ante* recognised and mandated as official standard-setters by the European Commission. Of course, there are pros (efficiency) and cons (competition) in joint standard-setting and privileged information-sharing between CEN/CENELEC and the American National Standards Institute (ANSI). But their support to regulatory harmonisation is definitely a plus to a future TTIP.[112] Which means risk assessments and conformity presumptions will have to play both for food and non-food, child safety requirements, and even for services such as maintenance works in mode 4: anything goes in a "transatlantic internal market" – and non-members beware!

And, again, do keep an eye on your WTO rights. Trade "concerns" can be addressed to the SPS and TBT and other WTO bodies, but the lead time is long and nowhere near the foreseeable TTIP hotlines between like-minded and transatlantic regulators. Networking, nudging, and then acceding to new

[110] Peter Sparding, "Germany's Pivotal Role on the Way to TTIP", *Europe Policy Paper*, November 2014, at p. 10.
[111] "EU Stance On Food Safety in TTIP Makes Resolving Irritants Tough Road" 32/16 *Inside U.S. Trade* (18 April 2016), at p. 2
[112] "CEN-CENELEC, ANSI Negotiate Deal That Could Aid TTIP Regulatory Effort" *Inside U.S. Trade* (Daily News, 8 October 2013), at p. 1

standards will be the available avenues. For third countries, most important of all the WTO rights will be a new assessment of the provisions in Article XXIV:5(b) GATT specifying that "other regulations of commerce [...] shall not be higher or more restrictive than the corresponding duties and other regulations of commerce [...] prior to the formation of the free-trade area". Admittedly, the scarcity of case law and the historic context especially in this 1947 formulation do not allow a safe prediction of the outcome of a challenge under SPS, TBT and the GATT or the GATS Agreements. Perhaps significantly, neither of the three "regulatory" WTO agreements has a RTA exception like in Article XXIV GATT and Article V GATS: Howse suggests that since neither the SPS nor the TBT Agreement allow exceptions for RTA, preferential regulatory cooperation in RTA 'must be opened up to all WTO members where the conditions are appropriate for their participation' in order to be consistent with WTO norms.[113] A more differentiated approach is found in Article 4 TRIPS which prescribes MFN treatment for any concession made by a Member to foreign nationals – except for four specific cases enumerated in lit.(a) to (d) of that article. There is no case law for MFN violations in respect of technical regulations based on legitimate (here, regional) regulatory distinctions. At any rate, it is always useful to remind big powers that they too are bound by their WTO obligations, and that their present, exclusive mutual recognition agreements (MRA) e.g. for wines and spirits, and for organic agriculture, may not pass all WTO compatibility and necessity tests forever. In my view, this might even happen when they come in the shape of treaty annexes, in order to better fulfil the 'basically all the trade' requirement in Article XXIV for MFN exceptions.

All of this means a lot of work, perhaps facilitated as the TTIP negotiations now enter a cold phase for some months. The impasse must be used for more and better structured consultations.[114] Negotiators do not give up because demonstrators try to change or to annul their ministerial and parliamentary terms of reference. A recent online survey by YouGov, commissioned by the Bertelsmann Stiftung, does show important differences in attitudes towards trade liberalisation and risk between Germany and the United States.[115] But nobody should be over-impressed by the countless impact assessments on trade, growth, income and employment – often contradictory even from pro-traders.[116] In a recent study commissioned by the American Chamber of Commerce to the European Union (AmCham EU), Francois, Hoekman and Nelson show, in macro-

[113] Robert Howse, "*Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?*" 78 *Law and Contemporary Problems* (2015), pp. 137-151, at p. 151.
[114] European Commission, "*Report on the Online public consultation on investment protection and investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement*". Commission Staff Working Document SWD(2015) 3 final, Brussels, 13 January 2015
[115] Christian Bluth, "*Attitudes to global trade and TTIP in Germany and the United States*". GED-Team, Bertelsmann Stiftung (2016), Gütersloh
[116] Matthias Bauer and Fredrik Erixon, "*Splendid Isolation as Trade Policy: Mercantilism and Crude Keynesianism in "the Capaldo Study" of TTIP*" (2015). *ECIPE Occasional Paper* 03/2015, at p. 17.

economic terms, GDP increases under a TTIP for all but one EU Member State; it should also lead to export increases, wage increases, consumer price decreases for the majority of EU Member States, and to a small decline in income inequality.[117] In respect of TTIP climate risks, environmental and development lawyers Porterfield and Gallagher are sceptical[118] while the trade lawyers Holzer and Cottier point out that a lot of home work is still required for a trade rules review.[119]

The famous last night, with the long knives out, all chips on the table and Champaign with a GI in the fridge, may have to be postponed. But especially the present bystanders, and third countries intending to benefit from a TTIP "right" (rather than "light")[120], can and should act now. "Science-based" is the word dividing the Atlantic, but "fact-based" is more than ever a must, for both sides of the divide.

[117] World Trade Institute, "TTIP and the EU Member States" (2016). World Trade Institute, University of Bern, Bern, January 2016

[118] Matthew C. Porterfield and Kevin P. Gallagher, "*TTIP and Climate Change: Low economic benefits, real climate risks*" (2016). International Institute for Sustainable Development, posted 1 December 2015, at p. 1-2.

[119] Kateryna Holzer and Thomas Cottier, "*Addressing climate change under preferential trade agreements: Towards alignment of carbon standards under the Transatlantic Trade and Investment Partnership*". 35 *Global Environmental Change* (2015) 514–522, at p. 515.

[120] Laura von Daniels, "*»TTIP right« geht vor »TTIP light«*". *German Institute for International and Security Affairs*. SWP-Aktuell 33, April 2016, at p. 5.

Food Safety Regulation in TTIP: Much ado about nothing?

Alan Matthews[*]

I. Introduction

Disputes over food safety standards – what in the language of trade policy are called sanitary and phytosanitary standards (SPS) – have been at the heart of many transatlantic trade rows between the US and the EU. Examples include the EU bans on the import of hormone-treated beef, on pork treated with growth-promoting additives, or on poultry washed in antimicrobial rinses to reduce the amount of microbes on meat.[121] As a result, the potential impact of the ongoing negotiations to reach a Transatlantic Trade and Investment Partnership (TTIP) free trade agreement between the US and EU on EU food standards has, rightly, attracted a lot of attention and no little anxiety. [122] Opposition to "Chlorhühnchen" has become the rallying-call for anti-TTIP activists in many countries.

NGOs argue that "TTIP will sacrifice food safety for faster trade".[123] Critics highlight possible procedural rules requiring transparency of decision-making and early warning mechanisms which would give interested parties (including of course business firms and lobby groups) the opportunity to comment on planned rule-making which it is argued are likely to lead to 'regulatory chill'. Proposals for a joint committee of the competent regulatory authorities to exchange information and discuss SPS issues which the other side believes are a trade concern are viewed as tantamount to "transferring power from national

[*] Alan Matthews is Professor Emeritus of European Agricultural Policy, Trinity College Dublin, email: alan.matthews@tcd.ie.

[121] Timothy Josling and Stefan Tangermann, *Transatlantic Food and Agricultural Trade Policy: 50 Years of Conflict and Convergence* (Cheltenham, UK: Edward Elgar Publishing), 2015.

[122] See, for example, BEUC, "Food and the Transatlantic Trade & Investment Partnership (TTIP)", 7 May 2014, available on the internet at http://www.beuc.eu/publications/beuc-x-2014-030_ipa_beuc_position_paper_ttip_food.pdf (last accessed 29 May 2016); Friends of the Earth Europe, "How TTIP undermines food safety and animal welfare", 4 February 2015, available on the internet at https://www.foeeurope.org/how-TTIP-undermines-food-safety-animal-welfare-040215 (last accessed 29 May 2016); GRAIN, "Food Safety in the EU-US Trade Agreement: going outside the box", 10 December 2013, available on the internet at https://www.grain.org/article/entries/4846-food-safety-in-the-eu-us-trade-agreement-going-outside-the-box (last accessed 29 May 2016).

[123] James Crisp, "TTIP will sacrifice food safety for faster trade, warn NGOs", 28 August 2014, available on the internet at http://www.euractiv.com/section/health-consumers/news/ttip-will-sacrifice-food-safety-for-faster-trade-warn-ngos/ (last accessed 29 May 2016).

authorities to a committee of experts, potentially including industry representatives".[124]

These claims are, unsurprisingly, rejected by the official side. The EU Commissioner for Trade Cecilia Malmström affirmed during her confirmation hearing before the European Parliament and many times since that TTIP "cannot be about lowering standards, but about avoiding extra costs – the costs entailed for example in the duplication of factory inspections and unnecessary divergences of approach."[125] Referring to criticism by Greenpeace following its leak of the consolidated texts of a number of chapters of the TTIP agreement under negotiation,[126] Commissioner Malmström reiterated, once again, that "No EU trade agreement will ever lower our level of protection of consumers, or food safety, or of the environment. Trade agreements will not change our laws on GMOs, or how to produce safe beef, or how to protect the environment."[127]

Nonetheless, the fears among consumers that TTIP will lead to changes in EU food safety standards to accommodate US export interests are understandable in the light of the injudicious and over-ambitious early claims made by advocates for TTIP in their attempt to build political momentum behind an agreement. The claim that the negotiations would lead to a transatlantic internal market suggested, analogous to the EU single market, that US goods would have automatic access to the EU. The assertion that TTIP rules would be the gold standard for health, safety and environmental protection for trade for the world as a whole implied that TTIP negotiators would set harmonised rules across these areas. Nor did economists help by defining all regulatory differences in their economic modelling as 'non-tariff barriers' which should be swept away if the potential economic gains from an agreement were to be achieved.

The leak of the consolidated text of the SPS chapter provides an opportunity to examine these opposing viewpoints.[128] It is important to keep in mind that the consolidated text is not a negotiated outcome. A consolidated text simply

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[124] Friends of the Earth Europe supra, note 3.

[125] European Parliament, "Highlights from the European Parliament Hearing of Cecilia Malmström European Commissioner for Trade", 29 September 2014, available on the internet at http://www.europarl.europa.eu/RegData/etudes/BRIE/2014/536417/EXPO_BRI(2014)536417_EN.pdf (last accessed 29 May 2016). See also the DG Trade Fact Sheet, "Food safety and animal and plant health in TTIP", 7 January 2015, available on the internet at http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153004.3%20Food%20safety,%20a+p%20health%20%28SPS%29.pdf (last accessed 26 May 2016).

[126] Greenpeace, "TTIP Leaks", 1 May 2016, available on the internet at https://ttip-leaks.org/ (last accessed 29 May 2016).

[127] Cecilia Malmström, "Negotiating TTIP", 2 May 2016, available on the internet at https://ec.europa.eu/commission/2014-2019/malmstrom/blog/negotiating-ttip_en (last accessed 29 May 2016).

[128] The consolidated texts leaked by Greenpeace Netherlands refer to the state of play in March 2016 prior to the 13th round of negotiations at the end of April 2016.

arranges in a systematic way the negotiating positions of both Parties under each topic. Nonetheless, the text allows us to see what each side is demanding and how it is approaching the negotiations. It allows us to see the size of the gap that exists, but not necessarily where, and whether, that gap will be bridged.

While this viewpoint examines the rights and obligations that might be created by the TTIP SPS chapter, commitments made in this chapter must be read in the light of other chapters in a possible TTIP agreement, particularly the chapter on Regulatory Cooperation or Regulatory Coherence (RC) and the chapter on Dispute Settlement to the extent that it will cover commitments in the SPS chapter. The latter chapter mainly describes the institutional procedures to handle disputes and the approaches of both Parties are closely modelled on existing WTO procedures. As in the WTO, if there is a finding against a Party, it is expected to bring itself into compliance but there is no fully effective way to force it to do so. A trade panel cannot force a Party to change its regulations against its will, although as in the WTO an adverse finding allows the other Party to suspend concessions to an equivalent value in retaliation.

The main purpose of the proposed RC chapter is to affirm that both Parties will adhere to good regulatory practice.[129] This includes giving information on planned regulatory acts, providing opportunity for stakeholder consultation, undertaking an impact assessment, engaging in regulatory exchanges of information, encouraging the pursuit of regulatory compatibility where mutual benefits can be realised without compromising the achievement of legitimate public policy objectives, and promoting international regulatory cooperation. The US proposal on these matters is more detailed and prescriptive than the EU one, but as the EU's tactical assessment of the state of the negotiations in March 2016 notes: "it is safe to say that provisions tabled by both the EU and US are complementary in many respects and could form the basis for identifying common ground".[130]

II. The SPS chapter

The March 2016 consolidated text contains 22 articles plus an introduction setting out the objectives of the chapter which has been proposed by the EU. In addition, the EU has proposed an article on anti-microbial resistance within the

[129] Alexia Herwig, "TTIP Regulatory Cooperation: Changes in Transnational Risk Regulation from WTO Law and WTO-Consistency", this volume, discusses the potential consequences of the RC chapter in detail.
[130] Greenpeace, "Note – Tactical State of Play of the TTIP Negotiations – March 2016", 1 May 2016, available on the internet at https://ttip-leaks.org/ (last accessed 29 May 2016).

SPS chapter which does not appear in the consolidated text.[131] A brief summary of the content of each article follows.

Objectives. The EU's proposal for chapter Objectives sets out its view that the purpose of the SPS chapter is to facilitate trade by removing unnecessary barriers while "while preserving each Party's right to protect human, animal or plant life and health in its territory and respecting each Party's regulatory systems, risk assessment, risk management and policy development processes".

1. **Scope and coverage.** This article specifies that the chapter applies to all SPS measures between the parties while the EU wants animal welfare matters also to be covered.

2. **Affirms each Party's rights and obligations under the WTO SPS Agreement.** The EU wants to add "Nothing in this Chapter shall limit the rights or obligations of the Parties under the Agreement established by the World Trade Organization and its Annexes." This could be read as making WTO law, and possibly also judicial interpretations of its agreements, applicable in TTIP.

3. **Competent Authorities.** This article commits each Party to notify the other of the competent authorities for SPS matters.

4. **Equivalence.** Both parties recognise that determining equivalence can facilitate trade. Both parties agree to an annex which would set out the procedures to be followed to determine equivalence (though the annex itself is not yet agreed). The EU, in addition, would like an annex setting out specific areas where agreement on equivalence has been reached. This annex would presumably contain the 1998 Veterinary Equivalency Agreement and the Organic Equivalency Agreement agreed in 2012, but is unlikely to contain more at this point in time,

5. **Science and risk.** This article is tabled by the US with the proviso that additional provisions aimed at improving the use of science in SPS decision-making will be considered. Because of the sensitivity of this issue, I discuss it in more detail later.

6. **Adaptation to regional conditions in case of a pest or disease outbreak.** In principle both Parties are in favour and seek to operationalise better how this should work in practice.

[131] DG TRADE, "EU proposal to include an article on Anti-Microbial Resistance within the SPS Chapter of TTIP", 6 November 2015, available on the internet at http://trade.ec.europa.eu/doclib/html/153936.htm (last accessed 26 May 2016).

7. **Transparency.** This is mainly about notifying the status of SPS issues and communicating the results of SPS decisions to the other Party. The US side, in addition, proposes that the text of proposed SPS regulations should be made available for comment prior to adoption in line with its general approach to science and risk set out in Article 5.

8 and 9. **Elimination of redundant control measures and audits and inspections.** The EU proposes that each Party would accept that the other Party's competent authority is responsible for ensuring that products and establishments meet the SPS standards of the importing Party and would not require re-inspection, third party certification or additional guarantees. Of course, this could not be a carte blanche, and hence Article 9 provides for a system of audit and verification of the control systems implemented by these competent authorities.

10. **Export certificates.** This article deals with the matter of certificates that should accompany the export of an agri-food product (e.g. health certificates for live animals) and aims to ensure that certificates should be as simple as possible and only used when necessary.

11. **Trade facilitation.** This article proposed by the EU deals with trade facilitation procedures, or what happens to an agri-food consignment when it enters the importing country. Inspection and control procedures should be kept to a minimum. Specifically, the EU proposes that the Parties would adopt the tolerances and maximum residue levels adopted by the Codex Alimentarius Commission unless the importing Party has signalled a reservation in the Codex.

12. **Regulatory approvals for products of modern agricultural technology.** This article proposed by the US deals with GMOs (or what the article refers to as the products of modern agricultural technology). As fears that TTIP would overturn EU rules on GMOs are widespread, I also discuss this proposal in more detail later.

13. **Import checks and fees.** This article deals with the question of import checks, and sets out principles for the frequency rate, notification obligations and the level of fees that can be charged.

14. **Application of SPS measures.** This article proposed by the EU seeks to make clear that SPS decisions apply across the whole territory of each partner. The EU wants to avoid a situation where individual US states might introduce additional SPS restrictions.

15 and 16. **Joint SPS Committee and technical working groups.** These articles set out each Party's views of how a joint committee on SPS matters might function, with the US proposing (in Article 16) a number of additional technical working groups on specific issues (the EU also proposes technical working groups but in Article 15). The intention is that the Committee and/or its working groups would provide a forum where trade concerns arising from SPS measures could be discussed. The Committee would not be a decision-making body but it would be expected to trigger initiatives which would be taken up by the competent authorities of both Parties using their regular procedures.

17. **Technical consultation.** Alternative proposals are made by the EU and the US. Technical consultations are essentially the same idea as regulatory exchanges in the RC chapter although the obligations would go further for SPS exchanges. The article proposed by the EU proposes that the other Party can request technical consultations if "it has significant concerns regarding food safety, plant health, or animal health, or regarding a measure proposed or implemented by the other Party". However, under the EU proposal not only is the Party required to give a response, but this should be made within 15 days. Also, there would be an obligation that "Each Party shall endeavour to provide all relevant information necessary to avoid unnecessary disruption to trade and to reach a mutually acceptable solution".

The US proposal is more prescriptive. Apart from a longer timeframe for consultations than in the EU proposal, it introduces the idea of a facilitator (an idea borrowed from the US process of negotiated rule-making).[132] This would be an expert brought in to help the parties to resolve the concerns expressed. However, this expert would be expressly forbidden from commenting on the consistency of the measure at issue with either the TTIP or WTO Agreements. The only obligation on a Party is to seek to resolve concerns over an SPS measure through technical consultations prior to initiating dispute settlement proceedings under the TTIP Agreement.

18. **Emergency measures.** Allows for provisional emergency measures necessary for the protection of human, animal or plant health.

19. **Animal welfare.** This is of course an EU proposal. It is a short article with three substantive obligations based on the recognition that animals are sentient beings. Parties would undertake to respect trade conditions for live animals and animal products that are aimed to protect their welfare. Parties would undertake

[132] On negotiated rule-making in the US, see Richard Parker and Alberto Alemanno, Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems, Special Report No. 88, (Brussels, Centre for European Policy Studies), 2014.

to exchange information, expertise and experiences in the field of animal welfare with the aim to align regulatory standards related to breeding, holding, handling, transportation and slaughter of farm animals. And Parties would strengthen their research collaboration in animal welfare. Even if the US were to accept these objectives, it might still query whether the SPS chapter is the appropriate place in the agreement for this article.

20. **Collaboration in international fora.** This EU proposal commits the Parties to collaborate in international fora with a view to reaching mutually satisfactory outcomes.

Articles 21 and 22 are technical articles which terminate the Veterinary Agreement and set out definitions, respectively.

Anti-microbial resistance (AMR). Though not included in the consolidated text, the EU made a proposal on AMR at the end of 2015. This recognises the serious and transnational nature of AMR, and proposes a technical working group charged with a dedicated work plan on reduced use of antibiotics in animal production to combat antibiotic resistance.

III. Science and Risk

The US proposal on science and risk deals both with risk assessment (identifying the extent of any risk) and risk management (identifying the appropriate response to the risk). In the EU these responsibilities are divided between EFSA (responsible for risk assessment) and the Commission supervised by the member states and the European Parliament (responsible for risk management), together referred to as the competent authorities.

The US article would require the competent authorities (a) to take into account comments from interested parties (b) to discuss comments made by the other Party (c) and give reasons when making their decisions including why alternatives put forward by other parties were rejected. Note that there is no reference to eliminating the precautionary principle in the US proposal; indeed, there is no reference to the precautionary principle at all.

NGO critics are alarmed that this consultation requirement "would allow American firms to influence the content of EU laws". They fear that allowing US firms and lobby groups to submit comments to EFSA during its risk assessment process and requiring the EU Commission publicly to state the reasons for adopting one form of regulation rather than another will lead to a weakening of EU standards of food safety. While it would be naïve to dismiss the self-interest of US firms and their formidable lobbying capacity, the EU accepted obligations

in the WTO SPS Agreement (e.g. Article 5.4 provides that when adopting SPS measures Members should take into account the objective of minimising negative trade effects, while Article 5.8 provides that a Member must provide an explanation where another Member disagrees with an SPS decision that it has made and requests it) without any evident diminution of food standards since 1995 (when these obligations took effect).[133]

If there is a fear that the EU risk analysis system (including risk assessment, risk management and risk communication) can be unduly influenced by industry lobbying, this surely applies to EU firms as much as US firms. The solution should be to strengthen the independence, integrity and democratic oversight of the EU risk analysis system where this is warranted, rather than to exclude particular viewpoints from the process *ex ante*. It also needs to be underlined that these obligations would be a two-way street. The provision (which at this stage is just a US proposal) would also give EU firms (and NGOs) the right to intervene in the US rule-making process which would be an important benefit from an agreement.

A rather intrusive proposal (paragraph 6 of this Article), in cases where "a regulatory authority of a Party submits a proposal for an SPS measure for approval by a committee comprising national representatives" (which is a clear reference to the EU comitology procedure for risk management), and the committee rejects or modifies the proposal, would require each individual member of the committee to give a public explanation of why it has rejected or modified the proposal. Although this is often the case at present, it should be sufficient for the regulatory authority itself to provide this explanation on behalf of the body as a whole.

IV. Regulation of GMOs

The US proposal is that each Party should make its risk assessments of GM traits publicly available (as is already the case in the EU) and to keep to the timeline set out for authorisation or approval (which in the EU process has been prone to arbitrary delays).[134] It also proposes a joint working group on products of modern agricultural technology made up of officials from the competent authorities including the regulatory agencies to discuss trade issues that might arise as well as to consult on future standard-setting efforts.

[133] Herwig (supra, note 10) notes with respect to similar provisions in the RC chapter that the requirement to lay out the basis for a specific regulation could make it easier for a complainant to attack regulatory measures as unnecessary for the regulatory objective. Also, the WTO Article 5.8 is a soft law obligation which refers to "should" rather than "shall" which leaves room for other concerns to be taken into account.

[134] Complaints about undue delays in the completion of the EC approval procedures were upheld by the WTO panel in the *EC-Biotech* case.

It is hard to make the case that these US proposals would overturn the existing EU GM regulatory regime or even significantly affect it. While maintaining the prescribed timeline for approvals would be a departure from current practice, in the case where this does not happen the draft US text merely requests that the other Party should provide an explanation for the delay and update the timeline for the remaining steps.

One potentially controversial element in this article is that the US proposes that each Party should participate in the Global Low Level Presence Initiative (GLLPI) to develop an approach to manage low-level presence in order to reduce unnecessary disruptions affecting trade. The GLLPI was initiated by Canada in 2012 and now has 14 member countries, with the EU currently participating as an observer. Low-level presence (LLP) refers to the unintentional or inadvertent mixing of a transgenic crop (for example, through dust or residues in a transport container) not approved in the importing country in a shipment that otherwise would be permitted. With a growing number of GM crop varieties being approved around the world, risks of LLP increase.

The EU currently has a zero-tolerance of LLP for GM varieties approved in other countries but not approved in the EU (technically, the threshold is set at 0.1% as the lowest amount that has to be reliably detected). Countries in the GLLPI are pushing for significantly higher thresholds, perhaps up to 5% under specified conditions. Whether the EU should take a more relaxed view of LLP in future is clearly a matter for the competent authorities in the EU. Obligating the EU to take part in GLLPI discussions on this issue might be seen as the thin end of the wedge by those opposed to any relaxation of the current zero-tolerance threshold, even if it does not in itself predetermine the outcome.

V. Concluding Thoughts

In discussing the significance of the SPS Chapter in the proposed TTIP Agreement for EU food safety standards, one cannot emphasise enough that all we have at the moment is a consolidated text setting out the views of both Parties. We do not have a final negotiated outcome. In a final agreement there could be issues that are not yet flagged in the consolidated text. On the other hand, the positions in the consolidated texts are the initial starting points of both parties in the negotiations. We might expect the US position in the consolidated text to be even more demanding and extreme that what the EU might accept as part of the final outcome while, conversely, the EU may not succeed in having its proposals incorporated into the final text.

With these qualifications in mind, my initial response to reading the consolidated SPS chapter is how banal it all is compared to the fears expressed by anti-TTIP activists as well as the claims of TTIP advocates. It is not the case, as often alleged, that either the TTIP Agreement or trade officials in the future under a TTIP Agreement would make decisions on food safety standards. These will continue to be taken, as of now, by the member states or the Commission taking into account the advice of the European Food Safety Agency (EFSA). What TTIP seeks to do is to agree common rules on how aspects of the standard-setting process in each Party might work in the future, particularly in terms of good regulatory practice, and to encourage regulatory exchange and co-operation to try to minimise unnecessary differences in standards in the future.

This is not to say that the process obligations would not have implications for EU decision-making on food safety. It is possible to see bogeymen behind every paragraph where particular obligations are mentioned, and this seems the preferred approach of anti-TTIP activists. The new procedures would provide for more information and regulatory exchange, more consultation and more reasoned evidence, but, in the language of the EU proposal, they would respect "each Party's regulatory systems, risk assessment, risk management and policy development processes".

On the other hand, a TTIP agreement holds out the opportunity to reduce some of the unnecessary costs from trade procedures that do nothing to enhance food safety on either side of the Atlantic. The provisions would help EU firms, for example, to challenge US rules which add additional costs to EU exports without contributing to improving food safety in the US. And for these benefits a balanced agreement is worth pursuing.

TTIP Regulatory Cooperation: Changes in Transnational Risk Regulation from WTO Law and WTO-Consistency

Alexia Herwig[*]

I. Introduction

The leaked TTIP documents reveal that the EU and US are discussing the introduction of a detailed set of procedural requirements for the adoption of regulatory measures. Default provisions are set forth in the chapter on regulatory cooperation, applicable to goods and services.[135] More specific provisions are being negotiated in the chapters on technical barriers to trade and on sanitary and phytosanitary measures. If they conflict with the regulatory cooperation chapter, they prevail.[136]

This article analyses the regulatory cooperation chapter insofar as it pertains to trade in goods but to the exclusion of SPS matters and anything provided in the TBT chapter itself.[137] The questions this article examines are to what extent the TTIP proposals expand upon the obligations the two parties have already taken on under WTO law and to what extent the resulting regulatory coordination is consistent with WTO law. It will be shown that the US proposals on procedure may constrain substantive regulatory discretion beyond what applies under the GATT and TBT Agreement of the WTO. It will also be shown that the needs to conduct trade impact assessments and a detailed explanation of the necessity of measures anticipate a legal challenge to necessity and will provide information of much use to complainants in meeting their burden of proof. Transatlantic regulatory cooperation at EU level will remain largely an affair of regulators without significant parliamentary involvement. It is furthermore argued that the envisaged regulatory cooperation and any MFN-violations stemming from it could be difficult to justify under the GATT exception for FTAs. Lastly, the US proposal on Article X.5 may create third-party rights in non-TTIP states that regulatory procedures be designed with the objective of ensuring consistency with trade and investment law obligations. As a result of the increasing internationalization of supply chains and foreign direct investment, EU and US companies would benefit from such third-party rights. Full domestic regulatory

[*] Assistant Professor at the University of Antwerp.

[135] Greenpeace Netherlands, " Initial Provisions for CHAPTER [ ] [EU: REGULATORY COOPERATION] [US: REGULATORY COHERENCE, TRANSPARENCY, AND OTHER GOOD REGULATORY PRACTICES]" [hereafter: Leaked, consolidated TTIP chapter on regulatory cooperation/good regulatory practices], available on the Internet at https://ttip-leaks.org/ (last accessed on 31 May 2016), Article X.3.

[136] Ibid., Article X.4.

[137] For an elaborate discussion of the SPS chapter, see Alan Matthew's "Food safety regulation in TTIP: much ado about nothing?" in this volume.

sovereignty increasingly seems to be challenged by a new paradigm of shared regulatory sovereignty to which WTO law is not fully receptive.

The second section reviews the obligations of the EU and US under the WTO's GATT and TBT Agreement in respect of their design of national regulatory procedures. The third section analyses whether the proposals by the EU and US on the design of national regulatory procedures and on regulatory cooperation significantly alter the way risk regulation will be conducted and expand on their WTO obligations. The fourth section examines whether regulatory cooperation would be consistent with WTO law. The fifth section concludes.

II. The WTO Obligations in Respect of the Design of National Regulatory Procedures

The GATT only imposes a very limited set of procedural obligations. Its Article X creates an obligation to publish regulations once they are adopted. Article III:4 on national treatment of like imported products through domestic laws, regulations and requirements cannot be interpreted as applying to procedures for making regulations. Its reference to laws, regulations and requirements being applied in paragraph 1 suggests that paragraph 4 only refers to the substantive requirements applicable to the product and not to procedures for making regulations. As per the Decision on Notification Procedures, quantitative restrictions, product bans but also technical regulations have to be notified to the WTO.

The requirements imposed by the TBT Agreement are more far-reaching. Its Article 2.1 does not contain any qualification that it only concerns the application of technical regulations. It speaks about treatment 'in respect of technical regulations', which could be interpreted to include procedures, especially if Article 2.2 is taken as interpretive context. Article 2.2 makes clear that it applies to the preparation and adoption of technical regulations in its introductory first sentence. The first sentence does not set forth level obligations but it is nevertheless relevant as context for the interpretation of the TBT Agreement. However, the following operative obligation stipulates that technical regulations may not be more trade-restrictive than necessary to fulfil a legitimate objective. Annex 1 defines technical regulations as mandatory requirements on product characteristics or their related processes and production methods and including applicable administrative provisions. The obligation of Article 2.2 therefore extends to substantive regulatory requirements and not to procedures for defining such requirements. This suggests that Article 2.2 does not impose independent obligations on the design of regulatory procedures and that a dependent complaint about preparation or adoption procedures could at best be

made only if it has led to the adoption of technical regulations not meeting the operative legal provision.

Article 2.5 mandates WTO members to explain the justification of a technical regulation in terms of avoiding unnecessary obstacles to trade at the stage of preparation or adoption of a technical regulation but only upon the request of another WTO member. Article 2.9.2 imposes an obligation to notify proposed technical regulations not based on international standards or with significant effect on trade and to provide a *brief* indication of the rationale and objective of each one. Article 2.9.4 makes it mandatory for WTO members to allow other WTO members reasonable time to make comments in writing, discuss these and take the comments and discussions into account without discrimination. A shortcoming of Article 2.9.4 is that it does not require explicitly the comment procedure to precede the adoption of the measure and that it allows a WTO member to take account of the comments but also the discussion, suggesting that there is wide discretion of the WTO member in selecting the reasons upon which it bases its technical regulations.

Demonstrating substantive compliance with the provisions of the GATT and of TBT Agreement is therefore in essence deferred to the stage of dispute settlement, entailing legal risks and costs for a complainant. It is the complainant's burden to suggest that the regulating WTO member could have taken less-trade restrictive alternatives that would also achieve that WTO member's level of protection. The defending party's right to set the level of protection autonomously has been upheld in a number of cases.[138] Absent detailed information from the regulator, it will often be difficult for the complainant to meet its burden. TTIP could possibly change these difficulties by requiring the regulating party to undertake trade impact assessments and to explain a regulation in detail prior to its adoption.

III. Rights and Obligations in the Leaked, Consolidated TTIP Chapter on Regulatory Cooperation/Good Regulatory Practices

The chapter on regulatory cooperation begins with a proposed preamble by the EU, which indicates the objective to strike a balance between economic objectives and regulatory protection but without compromising each party's right to adopt its own level of protection.[139] This language goes further than the objectives of the GATT and TBT Agreement because the right to regulate extends

[138] *Korea-Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, Report of the Appellate Body, WTO Doc. WT/DS161, 169/AB/R, 10 January 2001, para. 180, *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WTO Doc. WT/DS135/AB/R, adopted 5 April 2001, paras. 168, 172-174.

[139] Leaked, consolidated TTIP chapter on regulatory cooperation/good regulatory practices, *supra* note 1, Article X.1.

to each party's regulatory framework and principles, thereby encompassing the EU precautionary principle, which is not explicitly mentioned in the GATT and TBT Agreement.

The US proposes an Article X.5 on good regulatory practices, which would require each party to put in place mechanisms of internal coordination, consultation and review of regulations being developed with the objective of, inter alia, complying with international trade and investment obligations. Amongst other things, these obligations require that a measure is necessary to achieve the regulatory objective because it promotes its attainment and uses effective measures least-restrictive of trade. It is noteworthy that the objective is not limited to inter se trade and investment obligations of the EU and US but to all their trade and investment law obligations.[140] The EU or US as complainant could hence argue that even procedures which fail to pursue trade or investment law obligations in treaties with third states violate Article X.5. Article X.5 suggests that legal claims could be made purely on the basis of procedural defects, regardless of whether they actually lead to the adoption of substantively illegal regulations. It should, however, be noted that legislatures will likely be outside of the scope of the regulatory cooperation chapter as per US Annex X.B(2) but that the definition of 'regulation' in Annex X.A applies to EU Regulations and Directives.

Recall that Article X.5 mentions compliance with trade and investment law obligations as the objective to be pursued. This raises the question whether regulatory procedures which pursue objectives in conflict with the objective of trade and investment law compliance would violate this provision. This question can become particularly relevant if a party foresees direct participation of the public in regulatory procedures for the sake of allowing democratic input into regulatory decision-making. If such participatory procedures allow for the disregard of scientific evidence or the choice of more trade-restrictive alternatives because the public demands it, they could violate Article X.5 just as procedures. Such a result would obtain especially if the terms of Article X.5 are interpreted without giving much weight to the countervailing affirmation of the right to regulate in the preamble, which may also not be adopted in the end. Another instance where the stipulation of trade and investment law compliance as the goal to be pursued through regulatory procedures could become significant is in respect of procedures which lead to frequent regulatory changes as such procedures might be inherently unsuitable to protect an investor's legitimate expectations pertaining to the stability of the regulatory environment, which is an element of the fair and equitable treatment obligation in international investment agreements. Article X.5 might thus interfere with a

[140] Ibid., Article X.5 (b).

party's well-recognized right in the GATT and TBT to select its level of protection autonomously insofar as they occur in regulation. An interesting legal question pertaining to a possible loophole will be whether violations of Article X.5 are possible if legislative acts such as framework legislation mandate the inconsistencies of regulatory procedures with Article X.5 since it does not apply to legislatures.

As regards the development of regulations, Articles X.6 and X.7 proposed by the EU go beyond Article 2.9.4 of the TBT Agreement only insofar as they have the effect of extending its disciplines to non-TBT regulations. The proposed Article X.7 refers to taking account the results of public consultations in general, thereby encompassing contributions from US companies but also EU companies and citizens and therefore leave maximal discretion to the regulator to identify the reasons upon which it will base a regulation.

Article X.8 on domestic regulatory transparency would require the regulator to make public data, scientific and technical analyses and regulatory impact assessments it relied upon and an explanation of how the regulation is supported by this evidence. Additionally, the regulating party has to provide an explanation of the regulation, its objectives, how the regulation achieves them and any alternatives being considered. This provision evokes the necessity test in GATT Article XX. The first part of Article X.8 would require the regulator to explain the scientific basis of regulations already at the stage of regulatory decision-making rather than only at the stage of dispute settlement, as is the case under WTO law. Although the reference to analyses and impact assessments relied upon suggests that this is voluntary, the US proposes to make regulatory impact assessments mandatory through its Article X.13.

The US' proposal on Article X.13 requires parties to have procedures that promote the consideration of a number of factors studied by the impact assessment, which include the need for the regulation, its costs and benefits and the availability of regulatory alternatives.[141] The EU's proposal notably is weaker because it states that parties affirm their intention to carry out regulatory impact assessments, which is not the same as stating that parties must carry out such impact assessments. The actual goal of the impact assessment pursuant to the EU's proposal would be to consider how options for proposed regulations relate to relevant international instruments and impact on international trade or investment and take account of the other party's measures. These obligations are relatively weak because they do not require regulators to study the legality of the proposed measures nor do they require the final measure to be based on the

[141] Ibid., Article X.14(3) creates an obligation for post hoc follow up on the regulatory impact assessments' estimate of costs and benefits and possibilities for regulatory improvements.

result of the impact assessment. If Article X.5 were also adopted, there would thus appear to be a mismatch between the EU's proposal which allows for disregarding the results of impact assessments and the obligation in Article X.5 to put in place procedures whose goal is to comply with trade and investment obligations.

Concerning evidence-based decision making, the US is merely proposing soft law according to which each party should adopt mechanisms to seek robust evidence but for final decisions, the party shall publicly explain the rationale for the regulation, its relationship with the evidence and the reason for selecting the measure chosen amongst alternatives.[142] This provision, together with proposed Article X.5 and X.13 is an interesting attempt to introduce more science-based decisions into non-SPS and non-TBT measures through the backdoor of non-binding language and the cumulative effect of several provisions. Recall that the purpose of the regulatory impact assessments for the US should be to reveal 'the need for a proposed regulation, including the nature and the significance of the problem the regulation is intended to address.' This can of course best be demonstrated by scientific evidence but once it is available, the duty to explain the link between the evidence and the measure, coupled with the need to maintain procedures that promote compliance with trade and investment law obligations will likely make it very difficult to disregard that evidence. At a minimum, the three articles together will considerably facilitate the task of a complainant to attack regulatory measures as unnecessary for the regulatory objective.

Article X.15 proposed by the US would require each party to provide for any interested person to petition for the introduction, amendment or repeal of a regulation if it has become ineffective at protecting health, welfare of safety, if it has become unnecessarily burdensome for trade, if it fails to take account of changed circumstances or if it relies on outdated or incorrect information. Note that this provision could be used to petition for the introduction of stricter regulations. Its broad reference to 'any interested person' seems to include ordinary citizens. It would thus significantly lower the hurdles for Citizens' Initiatives in the EU, which are the current instrument to petition the EU to introduce new regulations but which require at least one million people from seven Member States and do not oblige the Commission to propose legislation.[143] At first, this democratic strengthening of risk regulation through a trade agreement might seem odd. It may, however, be the case that US companies have

[142] Ibid., Article X.14(1) and (2).
[143] European Commission, "A New Right for EU Citizens. You can set the Agenda. Guide to the European citizens' initiative.", available on the Internet at <http://ec.europa.eu/citizens-initiative/public/welcome?lg=en> (last accessed 31 May 2016), pp. 3 and 26.

an interest in upward regulatory change in the EU in certain cases because they already comply with stricter regulations at home.

The subsequent parts of the leaked consolidated TTIP chapter on regulatory cooperation/good regulatory practices concern bilateral regulatory cooperation.[144] The EU proposes a bilateral cooperation mechanism (BCM) to support regulatory cooperation, bilateral information and exchanges on planned regulatory acts between regulators and competent authorities.[145] These can lead to a joint examination of mutual recognition, simplification of regulatory acts or harmonization based on international standards or bilateral approximation of laws where mutual benefits can be realised, without, however, compromising the level of protection of public policies.[146] An interesting legal question is who is to be considered a 'competent authority responsible for the regulatory acts' in the case of the EU. The general definition of a competent authority at central level in Article X.2(b) refers only to the European Commission but not the Council and European Parliament. As principals, they must hence take care to constrain a mandate of the Commission adequately in the regulatory cooperation.

Lastly, the EU proposes the establishment of the Regulatory Cooperation Body (RCB) to monitor and facilitate the implementation of the regulatory cooperation chapter and of specific sectoral provisions.[147] The RCB will draw up a work plan and consider new initiates for regulatory cooperation based on input from the parties or stakeholders.[148] It will also engage in the technical preparation of proposals for the update, modification or addition of sectoral provisions but without enjoying the power to adopt legal acts.[149] In terms of transparency and participation, minutes of the RCB are to be made public and there is to be at least one annual meeting with stakeholders who have the right to make submissions to the RCB and receive replies.[150] The mechanism where the real work on regulatory cooperation will be done will hence be the BCM and the RCB's sectoral committees and it is significant that there is no public access to these mechanisms. The democratic concern Alemanno has expressed in a recent publication hence has potential merit.[151] The argument that neither mechanism has power to adopt legal acts and that the outcomes require transposition is not

[144] Leaked, consolidated TTIP chapter on regulatory cooperation/good regulatory practices, *supra* note 1, Article X.22(1).
[145] Ibid., Article X.18(1) and X.19(2) and (3).
[146] Ibid., Article X.21.
[147] Ibid., Article X.23.
[148] Ibid., Article X.23(2) (a) and (d).
[149] Ibid., Article X.23(2)(c).
[150] Ibid., Article X.23(5) and X.24.
[151] Alberto Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences", 18 *Journal of International Economic Law* (2015), pp. 624 et sqq, at pp. 627, 635-637.

enough to fend off an argument for greater democratic embedding where the EU transposition provisions do not foresee parliamentary involvement.[152]

IV. Consistency of Regulatory Cooperation with WTO Law

It has been argued that regulatory cooperation under TTIP would either lead to highest common denominator harmonization or diversity but not a lowering of standards.[153] Harmonised requirements between the EU and US could violate the Most-Favoured Nation obligation in Article I:1 of the GATT if they produce disparate impacts on other WTO countries or if they are accompanied by recognition of each other's testing systems that is denied to other WTO members.[154] Inconsistencies with GATT obligations can be justified if compliance with Article I:1 were to prevent the formation of a free trade area or in respect of an interim agreement necessary for the formation of a free trade area, which has on the whole not imposed more restrictive regulations of commerce vis-à-vis the other WTO members than those which existed prior to the free trade agreement.[155]

It is unlikely that MFN violations would be constitutively necessary for the formation of TTIP since the trade liberalization achieved absent the MFN violation is likely sufficient to induce the parties to sign TTIP and keep it going.[156] If TTIP were considered as an interim agreement, it would have to be shown that TTIP is necessary for the formation of a free trade area but this does not imply that a possibility for regulatory harmonization it creates and the precise results thereof are also justified. Moreover, if TTIP leads to a systematic harmonization at the highest level of protection in some areas and otherwise preserves the status quo of regulatory diversity, it will impose greater restrictions on trade with non-members to TTIP.[157] If so, an Article XXIV defence might not be available to TTIP regulatory cooperation. If Article XXIV is unavailable common, harmonized standards between the EU and US would have to be justified under the general exceptions in GATT Article XX as being necessary to protect health or human lives, for instance. At least in respect of the TTIP party which converts to the more restrictive regulation as a result of harmonization, this required substantive justification in terms of risk may fail whenever no new evidence emerges about higher risks or lesser effectiveness of

[152] Ibid., at 636.
[153] Jonathan B. Wiener and Alberto Alemanno, "The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory", 78 *Law and Contemporary Problems* (2015), pp. 101 et sqq., at p. 102.
[154] More advantageous procedures might violate Article 2.1.
[155] GATT, Article XXIV:5.
[156] For an explanation of this requirement in the WTO Turkey-Textiles case, see Robert Howse, "Regulatory Cooperation, Regional Trade Agreements, and World Trade Law: Conflict or Complementarity?", 78 *Law and Contemporary Problems* (2015), pp. 137 et sqq., at 142.
[157] Ibid..

the laxer risk mitigation measures previously deemed suitable. To avoid this, the TTIP parties have every interest in producing convergent expert assessments confirming the necessity of more restrictive regulations in both parties.

Turning to the TBT Agreement, its Article 2.1 might encompass MFN discriminations through differences in regulatory procedures since it refers to treatment in respect of technical regulations as opposed to treatment *through* technical regulations or their application. If distinctions or disparate impacts stem from legitimate regulatory distinctions, they would not violate Article 2.1. However, the TBT Agreement does not contain any exceptions for free trade areas or a reference to free trade areas as legitimate objectives. Howse has convincingly argued that discriminations imposed by free trade areas cannot be seen as being based on legitimacy regulatory distinctions through a careful contextual analysis of the TBT Agreement.[158] It is also unlikely that violations of Article 2.1 of the TBT Agreement on MFN grounds in the pursuit of a free trade agreement could find a justification through an application of GATT Article XXIV to the TBT Agreement.[159]

Relatedly, an interesting international law question emerges from the proposed obligation in Article X.5 to design regulatory procedures in pursuit of the objective of compliance with trade and investment obligations. Since this reference is not limited to obligations between the two parties, it might be read as a provision creating rights in third parties. The Vienna Convention on the Law of Treaties' Article 36(1) assumes these are assented to unless explicitly rejected.[160] It should also be noted that these rights would actually become judicially enforceable in front of the International Court of Justice in respect of measures of general applicability developed by agencies or ministries of those EU Member States that have accepted its compulsory jurisdiction as per Article 36(2) of the Statute of the International Court of Justice since certain national regulatory measures are within the scope of the TTIP regulatory cooperation/good regulatory practices chapter.[161] Only France, Croatia, the Czech Republic, Latvia and Slovenia have not accepted and neither has the EU itself. Note also that the US has not accepted the ICJ's compulsory jurisdiction and has therefore taken on a lesser obligation.

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[158] Ibid., at pp. 143-148.

[159] The fact that the Appellate Body crafted the legitimate regulatory distinctions test onto TBT Article 2.1 in *United States-Measures Affecting the Production and Sale of Clove Cigarettes,* Appellate Body Report, WTO Doc. WT/DS406/AB/R, 4 April 2012, paras. 175, 181-2 suggests that it does not consider that a TBT violation could be 'cured' through the application of GATT and in casu Article XX.

[160] 22 May 1969, in force 27 January 1980, United Nations Treaty Series 331.

[161] The list of states which have recognised the compulsory jurisdiction of the ICJ is available at <http://www.icj-cij.org/jurisdiction/?p1=5&p2=1&p3=3> (last accessed 31 May 2016). The scope of application of the TTIP regulatory cooperation chapter is defined in Annex X.A and X.B(1)(b)(ii).

When it comes to the regulatory procedures for transposition of the outcomes of regulatory cooperation, the two parties might thus be under an obligation to design the procedures in such a way that the outcomes can be reviewed for their WTO-legality in terms of GATT Articles I:1, XXIV:5 and XX and the other Annex A1 Agreements and adjusted if they would be WTO-illegal. For regulatory acts by agencies or ministries at the level of EU Member States and conceivably also for their transposition of EU Directives, this obligation would even be judicially enforceable. Additionally, where harmonization results from a transposition of regulations previously enacted by one TTIP party to which the duty to conduct trade impact assessments already applied as per TTIP, its disciplines on the design of national regulatory procedures contribute to generating evidence for the GATT Article XXIV:5 assessment on whether restrictive regulations of commerce become higher than prior to the formation of TTIP. Ironically, the regulatory cooperation/good regulatory practices chapter thus carries the seeds of making the under-enforced WTO disciplines on preferential free trade agreements more effective. The regulatory cooperation chapter should thus undoubtedly limit the potential for GATT MFN-violations at least in respect of regulatory acts at EU Member State level. This alone cannot make the outcomes of regulatory cooperation compliant with GATT Article XXIV:5(b), however, firstly because its obligations pertain to the substantive trade-effects of regulations and not their procedures of adoption and secondly because neither the US nor the EU itself are subject to the compulsory jurisdiction of the ICJ, which might prevent inconsistencies with GATT Article XXIV:5(b) through the shadow of enforcement.

V. Conclusion

The leaked document reveals the EU's emphasis on the right to regulate and its interest in regulatory cooperation while the US wants to be tougher on observing trade law disciplines including through cost-benefit analysis but also champions the right to petition for new or amended legislation. If the US proposals go through, the analysis of trade impacts in regulation will acquire greater weight relative to other concerns[162] and necessity discipline in trade law will become much more justiciable. The democratic credentials of the BCM and RCB are of some concern. Lastly, regulatory harmonization between the EU and US could lead to MFN violations under WTO law, for which an Article XXIV defence and possibly an Article XX defence may not be available. It has also been suggested that Article X.5 might create rights for third states related to the design of EU and

[162] Similarly, Christiane Gerstetter, "Regulatory Cooperation under TTIP- A Risk for Democracy and National Regulation?", Heinrich Böll Stiftung TTIP Series, 2014, available on the Internet at <https://www.boell.de/sites/default/files/ttip_study_regulatory_cooperation_under_ttip_1.pdf> (last accessed 31 May 2016), pp. 2 and 32.

US regulatory procedures. Making TTIP's benefit non-exclusive might seem odd from a strategic perspective of enticing third states to join the 'TTIP club' later on. However, thanks to foreign direct investment in third states, the claimant whom such rights might actually benefit could be US or EU companies investing in third states. Additionally, thanks to the internationalization of supply chains and trade in tasks, US and EU domiciled companies might have an interest in getting market access for inputs from third states. This raises the interesting, more conceptual question whether the notion of domestic regulatory sovereignty still is much of a concept for the future or whether trade in tasks and investment flows inaugurate shared regulatory sovereignty[163] and how to assess WTO law constraints on regulatory cooperation in that respect *de lege ferenda*.

[163] Bernard Hoekman, "Trade Agreements and International Regulatory Cooperation in a Supply Chain World", EUI Working Paper RSCAS 2015/04", available on the Internet at < http://cadmus.eui.eu/bitstream/handle/1814/34207/RSCAS%202015_04.pdf?sequence=1> (last accessed 31 May 2016) pp. 6-8 argues shared sovereignty is needed because of the internationalization of supply chains.

Two Continents, Divided by Deep Philosophical Waters?
Why Geographical Indications Pose a Challenge to the Completion of the TTIP

Benjamin Farrand[*]

I. Introduction

The May 2016 leak of draft texts produced within the context of the on-going Transatlantic Trade and Investment Partnership negotiations has provided an interesting insight into the positions of the EU and US with regard to different dimensions of regulatory cooperation, with some chapters being complete or near completion (as other articles in this symposium discuss), and others still in a more rudimentary format. One such field of regulation, covered in the leaked 'Tactical State of Play' document, covers geographical indicators (hereafter GIs). However, this coverage is very brief, stating that 'discussions focused on the preparation of an intersessional discussion prior to the next round'[164]. GIs, marks identifying the geographical origin, and by extension (so the argument goes) quality of goods, have continued to be a source of consternation in international trade regulation, with states unable to see eye-to-eye on how they should be protected, if at all. The EU and US in particular reflect two very different philosophical approaches to the concept of a GI, and its application to foods in particular[165]. For the EU, cheeses such as *Feta* are culturally and geographically distinct, attributable to a certain region within Greece[166], with a long, established history. For the US, feta is a generic type of 'white' cheese, and not deserving of special recognition. As this paper will demonstrate, the substantially different conceptions of GIs, combined with two distinct regulatory approaches being exported through other trade agreements by both the EU and US, appear to render the negotiating positions of the two regions incompatible. The impact of this may be that GIs are excluded from the scope of TTIP, or that TTIP may fail to be concluded at all.

II. Geographical Indications as a Source of Conflict between the EU and US

[*] Assistant Professor, University of Warwick, contactable at b.farrand@warwick.ac.uk. The author would like to thank the reviewers for their helpful comments and advice in redrafting this article.

[164] Greenpeace Netherlands TTIP Leak, 'Note - Tactical State of Play of the TTIP Negotiations' (2016) at p.21.

[165] It must be stated that there are specific additional regimes for the protection of wines and spirits – in the interests of brevity, and to focus on this core issue of controversy, these additional regimes are not considered here.

[166] *Feta* being the name for a traditional cheese produced in Greece since 'ancient times', using either ewe's milk exclusively, or a mixture of ewe and goat milk, as per Regulation No 1829/2002 amending the Annex to Regulation (EC) No 1107/96 with regard to the name 'Feta'

A GI is a *sui generis* form of intellectual property right, concerned with identifying a good as originating in a specific country, territory or locality[167]. First given specific definition in international trade rules under the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter TRIPS), this identification is of relevance 'where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin'[168]. For Blakeney, the novelty of a GI comes in the explicit linkage of the concept of geography to that of quality[169], the idea that a particular location, soil, climate or type of vine will influence the quality of produced agricultural goods, whether they be meats, cheeses or grains. Recognition of a GI, it would therefore follow, relies upon accepting the initial presumption that these geographical factors, as well as developed knowledge of techniques of preparation and production *do* indeed influence the quality of those goods. The idea of attaching specific qualities to produce of a particular region is by no means new, with examples dating back to Egypt's Old Kingdom and the Ancient Greek city-states[170]. Their inclusion within TRIPS as a form of intellectual property right, however, was. While reference to appellations of origin is made in the Paris Convention of 1883, and the Lisbon Agreement of 1958 does make specific reference to GIs[171], it was only with TRIPS in the mid 1990s that the concept of a geographical indicator became recognised as a legal right with effective dispute settlement[172]. Yet when compared to the more considerable harmonisation of patents and trademarks, the TRIPS provisions on GIs dictate little substantively, allowing states to choose for themselves the specific means of protection under Article 22(2)[173]. Described by Ganjee as constituting an 'unstable compromise'[174], the minimally harmonised nature of GIs at the international level is the result of significant conflicts between states regarding the legitimacy, and indeed necessity, of their protection. Whereas much of the discussion of TRIPS relates to

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[167] Bernard O'Connor, 'The Legal Protection of Geographical Indications' Intellectual Property Quarterly (2004) pp.35 *et seqq*, at p.35.
[168] TRIPS, Article 22(1)
[169] Michael Blakeney, 'Geographical Indications: What Do They Indicate?' 6 WIPO Journal (2014) pp.50 *et seqq*, at p.50.
[170] Vadim Mantrov, *EU Law on Indications of Geographical Origin: Theory and Practice* (Berlin: Springer 2014) at p.32.
[171] Although it must be stated that membership of this agreement is low, limiting upon its international impact, as indicated by Justine Pila and Paul Torremans, *European Intellectual Property Law* (Oxford: OUP 2016) p.469; William A Kerr, 'Enjoying a Good Port with a Clear Conscience: Geographic Indicators, Rent Seeking and Development' in William A Kerr (ed), *Conflict, Chaos and Confusion* (Cheltenham: Edward Elgar Publishing 2010) p.88.
[172] See Kerr (n 6) p.88.
[173] On this point see Gail E Evans, 'The Protection of Geographical Indications in the European Union and the United States under Sui Generis and Trade Mark Systems: Signs of Harmonization?' Intellectual Property Quarterly (2013) pp.18 *et seqq*, p.20; Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (Cambridge: Cambridge University Press 2012) pp.77–78.
[174] Dev Gangjee, *Relocating the Law of Geographical Indications* (Cambridge: Cambridge University Press 2012) p.184.

the 'global North-global South' conflict[175], particularly as concerns issues such as access to medicines[176], the protection of GIs can be conceptualised as a conflict between the 'Old World' and 'New World'[177]. As Sanders puts it, there 'is not a single IP right that has so consistently led to heated debates in international trade other than GIs'[178]; this debate can be understood in terms of the significant divergences in perception of the role of GIs in international trade, and subsequently the ways in which they are protected in the IP system. In order to demonstrate how this may negatively impact upon the likelihood of successful TTIP negotiations, it is necessary to consider the competing narratives over GIs in the EU and US.

GI protection has been afforded a key role in the EU's agricultural policies[179], particularly as they relate to external market relations with other states and their respective consumer bases[180]. GIs are perceived to promote the cultural heritage of the EU Member States, linking issues of trade to issues of authenticity and traditional knowledge[181], as well as serving an additional goal of promoting the EU's agricultural regions economically, penetrating new markets for EU produce[182]. For the EU, goods protected by a GI constitute a useful 'value-added' regime, with the consumer perceptions of increased quality through originality and speciality[183] meaning that higher prices can be afforded to such products[184]. According to a 2012 report commissioned by the European Commission, the value of sales of GI-protected foodstuffs (excluding wines and spirits) was €15.8

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175 See for example Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Abingdon: Earthscan 2002); Carlos María Correa and Abdulqawi Yusuf (eds), *Intellectual Property and International Trade: The TRIPs Agreement* (Aalphen aan den Rijn: Kluwer Law International 2008).

176 FM Scherer and Jayashree Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Nations' 5 Journal of International Economic Law (2002) pp.913 *et seqq*.

177 Taubman, Wager and Watal (n 8) p.77.

178 Anselm K Sanders, 'Geographical Indications of Origin: When GIs Become Commodities, All Gloves Come off' 46 International Review of Intellectual Property and Competition Law (2015) pp.755 *et seqq*, p.755; see also Meir Perez Pugatch, 'Intellectual Property Policy-Making in the 21st Century' 3 WIPO Journal (2011) pp.71 *et seqq*, p.72; Tim Josling, 'The War on Terroir: Geographical Indications as a Transatlantic Trade Conflict' 57 Journal of Agricultural Economics (2006) pp.337 *et seqq*, pp.339–340.

179 O'Connor (n 2) p.35; Luisa Menapace and others, 'Consumers' Preferences for Geographical Origin Labels: Evidence from the Canadian Olive Oil Market' 38 European Review of Agricultural Economics (2011) pp.193 *et seqq*.

180 Andreas Dür, 'Bringing Economic Interests Back into the Study of EU Trade Policy-Making' 10 The British Journal of Politics & International Relations (2008) pp.27 *et seqq*, p.35.

181 Tesh W Dagne, 'Beyond Economic Considerations: (Re)conceptualising Geographical Indications for Protecting Traditional Agricultural Products' 46 International Review of Intellectual Property and Competition Law (2015) pp.682 *et seqq*, pp.684–685; Matteo Ferrari, 'The Narratives of Geographical Indications' 10 International Journal of the Law in Context (2014) pp.222 *et seqq*, p.225.

182 Ferrari (n 16) p.225; O'Connor (n 2) p.36.

183 For more on this see Menapace and others (n 14).

184 Arete Research & Consulting in Economics, 'Study on Assessing the Added Value of PDO/PGI Products' (Commissioned by the European Commission 2013) pp.5–6.

billion with an increase in sale value between 2005 and 2010 of 19%[185]. Due to their value (and indeed the EU's prime position to maximise the international recognition of foods such as *mozzarella di bufala* and *jamón de serón*) EU protection afforded to GIs is particularly broad. The 2012 Quality Schemes Regulation[186] reflects these perceptions regarding the role of GIs, stating their existence is necessary to both raise commercial awareness of these high-quality products, as well as achieve rural development policy objectives[187]. To gain Protected Geographic Indicator (PGI) status, Article 5(2) states that only the one of the production steps for that good[188] need take place in that geographical area[189], allowing for a broad range of products to be afforded protection. While Article 6 specifies that a term that is considered generic cannot receive protection, jurisprudence of the Court indicates that this is a comparatively low barrier to surmount, with *Feta* cheese gaining protected status, contrary to arguments that the name was considered generic by consumers in the EU, in addition to the fact that the name *Feta* refers to a cutting technique rather than a geographical location[190].

Rather than promoting luxury agricultural products, however, critics of the EU GI regime, and in particular 'New World' producers such as the US and Australia, consider it to be a form of market protectionism[191], or in the words of one US Commerce Department official, 'nothing less than a subsidy of European agriculture interests through claw back of generic terms'[192]. Furthermore, critics in the US dispute the inherent linking of geography with quality, noting that waves of immigration to the US from Europe resulted in the 'know-how' of many of these traditional foods being transferred and applied in US territory, resulting in the same processing and production methods[193]. Instead of a broad *sui generis* regime, the US protects GIs generally as a discrete subcategory of its trademark laws[194], as certification or collective marks under the Lanham Act[195]. A certification mark allows for a certain mark to be used subject to certain

[185] Tanguy Chever and others, 'Value of Production of Agricultural Products and Foodstuffs, Wines, Aromatised Wines and Spirits Protected by a Geographical Indication' (European Commission 2012) p.16.
[186] Regulation No 1151/2012 on quality schemes for agricultural products and foodstuffs
[187] Ibid, Article 1
[188] Defined in Article 3(7) as processing, production and packaging
[189] Although for the stronger Protected Designation of Origin (PDO) protection, all three steps must take place within that area.
[190] Joined cases C-465/02 and C-466/02 *Federal Republic of Germany and Kingdom of Denmark v Commission of the European Communities* EU:C:2005:636
[191] Kal Raustiala and Stephen R Munzer, 'The Global Struggle over Geographic Indications' 18 European Journal of International Law (2007) pp.337 *et seqq*, p.351.
[192] As quoted in Molly Torsen, 'Apples and Oranges (and Wine): Why the International Conversation Regarding Geographic Indications Is at a Standstill' 87 Journal of the Patent and Trademark Society (2005) pp.31 *et seqq*, p.52.
[193] Blakeney (n 4) p.52.
[194] Evans (n 8) p.23.
[195] The Lanham (Trademark) Act 15 USC § 1054

specifications, which can include production methods and places of origin[196], or even as a trademark where the geographic terms used have acquired distinctiveness through consumer identification of those terms with a particular company or producer[197]. Furthermore, the US is stricter than the EU when it comes to determining whether a particular product is generic, and so ineligible for trademark, certification or collective mark protection[198]; whereas *parmigiano reggiano* is a protected GI in the EU, 'parmesan' is considered a generic in the US, referring to a hard, aged cheese[199]. The US considers the EU approach to GIs to be unnecessarily broad, arguing that trademark law is sufficient to protect these goods, while preventing overreach when considering generic terms[200]. US agricultural producers in particular are opposed to the EU *sui generis* system, considering it a potential threat to their own business interests[201]. The US is particularly concerned that the EU grants priority to the *sui generis* GI over trademarks, preventing the registration of a trademark that may conflict with a pre-existing GI[202], and being permitted to co-exist with a pre-existing trademark in the event that the application for a GI is filed subsequent to a successful, good-faith trademark registration[203]. As well as representing a substantial incompatibility in economic interests, the conflict between the EU and US also reflects an incompatibility in the philosophical and legal approaches to the protection of GIs[204], which may have considerable implications for TTIP.

III. International Manoeuvring and Norm Exportation: Divergences in the Protection of Geographical Indicators in Regional Trade Agreements

The EU and US have been engaged in the formulation of other trade agreements in addition to the TTIP negotiations, in which they have sought to implement their respective norms and legal approaches to GIs, creating an atmosphere of

196 Josling (n 13) p.347.
197 ibid.
198 Evans (n 8) p.26.
199 ibid.
200 Michael Blakeney, 'Scope of the Intellectual Property Chapter of the Trans-Pacific Partnership Agreement (TPPA)' 21 International Trade Law & Regulation (2015) pp.14 *et seqq*, p.16; see also Dwijen Rangnekar and Sanjay Kumar, 'Another Look at Basmati: Genericity and the Problems of a Transborder Geographical Indication' 13 The Journal of World Intellectual Property (2010) pp.202 *et seqq*.
201 Dermot J Hayes, Sergio H Lence and Bruce Babcock, 'Geographic Indications and Farmer-Owned Brands: Why Do the US and EU Disagree?' 4 EuroChoices (2005) pp.28 *et seqq*.
202 Regulation No 1151/2012, Article 14(1)
203 Ibid, Article 14(2); see also WTO Disputes WT/DS/174 and WT/DS/290 *EC - Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (2005)
204 See also Cerkia Bramley, Delphine Marie-Vivien and Estelle Biénabe, 'Considerations in Designing an Appropriate Legal Framework for GIs in Southern Countries' in Cerkia Bramley, Estelle Bienabe and Johann Kirsten (eds), *Developing Geographical Indications in the South* (Berlin: Springer 2013); Stephan Marette, Roxanne Clemens and Bruce Babcock, 'Recent International and Regulatory Decisions about Geographical Indications' 24 Agribusiness (2008) pp.453 *et seqq*.

regulatory competition. The US has recently agreed the final text of the Trans Pacific Partnership, a comprehensive trade agreement between the US, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. Chapter 18 of this agreement concerns intellectual property rights, including trademarks and GIs. The position of the US is made clear by the chapter summary provided by the Office of the United States Trade Representative, which states that the intention of TPP in this regulatory sector is to 'address the potential for inappropriately "overprotecting" GIs in ways that shut out US agricultural and food producers, including [...how to] determine whether a term is generic in its market'[205]. The US preference for protection within the context of the trademark system is apparent under Article 18.19, which concerns collective and certification marks. This Article states that each party 'shall also provide that signs that may serve as GIs are capable of protection under its trademark system'. While Article 18.30 states that GIs may also be protected through a *sui generis* system, in comparison to the EU regime, strict limitations are placed upon its operation. Article 18.32(1) outlines the grounds of opposition to a grant of a GI, which can take place if it would cause confusion with a trademark that is the subject of a pre-existing application or registration, it would cause confusion with a pre-existing mark granted, or the GI is a 'term customary in common language as the common name for the relevant good' in that territory. Article 18.32(2) states that these grounds for opposition can also be used as the grounds for the *cancellation* of an existing GI, indicating that the position of the US is that trademarks have prime position in the intellectual property regime[206]. Calboli has referred to this as a 'first in time, first in right' approach to registration, in which a new GI cannot be used to supplant a pre-existing trademark[207] – however, the fact that a GI can be *cancelled* on the grounds of a competing mark suggests this goes beyond 'first in time, first in right' to afford trademarks a higher standard of protection than GIs. The approach in TPP mirrors that of the US-South Korea Free Trade Agreement, which specifies at Article 18.2(2) that GIs are to be protected as trademarks, and that trademark holders can prevent the use by other economic actors of 'identical or similar signs, including GIs' at Article 18.2(4). It becomes quickly apparent that the US position is that GIs should be protected at the international level as a category of trademark, rather than under a *sui generis* system.

The EU, in comparison, is rapidly exporting its norms and laws through its own trade agreements. In the finalised Comprehensive Economic and Trade Agreement (CETA) negotiated with Canada, the EU has ensured that its

[205] Office of the United States Trade Representative, 'Intellectual Property Chapter Summary' (2015) p.3.
[206] A view supported by Blakeney (n 35) p.16.
[207] Irene Calboli, 'Geographical Indications of Origin at the Crossroads of Local Development, Consumer Protection and Marketing Strategies' 46 International Review of Intellectual Property and Competition Law (2015) pp.760 *et seqq*, p.765.

definition of GIs as part of a *sui generis* system of protection is reproduced in Article 20.16, including a list of protected EU-based GIs in Annex 20-A. Furthermore, CETA grants priority to the *sui generis* GIs over trademarks, stating in Article 20.19(6) that any trademark applications that contains elements of the protected GI shall be refused, and that pre-existing trademarks can be invalidated at the request of an interested party. Interestingly, the list in Annex 20-A includes cheeses that are the source of EU-based frustration (to say nothing of US concerns) such as *Feta*, in addition to *parmigiano reggiano* and *mozzarella di bufala*. The EU-South Korea Free Trade Agreement contains similar terms, albeit allowing for the co-existence of a prior trademark under Article 10.22, but preventing the registration of a trademark incorporating an element of a GI under Article 10.23. As with CETA, Annex 10-A of the Agreement includes protection for products argued by the US to be generic, such as *Feta*. According to Engelhardt, DG Agriculture and Rural Development considers protection of GIs under a sui generis system in trade agreements as a 'must-have'[208], with the EU pursuing (somewhat successfully) a policy of 'securing protection of EU-based GIs through bilateral and regional general trade agreements'[209]. In the case of South Korea, however, the adoption of two trade agreements that present radically different approaches to the issues of GI creates the potential for significant regulatory clashes[210], as well as demonstrating the seemingly incompatible positions of the EU and US.

IV. What Does this Mean for TTIP?

It is clear that the regulatory approaches taken by the EU and US to GIs in trade agreements differ in substance and underlying rationale. This does not bode well for future negotiations on this chapter of TTIP. The EU has made it clear that it considers GI protection, including of some foodstuffs that the US considers generic, as constituting its 'offensive trade interests'[211], including in Annex I of its textual proposal products such as *Feta* and *parmigiano*. The EU is making its position clear regarding negotiations, and indeed prospects for a successful deal. Commissioner for Agriculture and Rural Development Hogan has stated that

[208] Tim Engelhardt, 'Geographical Indications under Recent EU Trade Agreements' 46 International Review of Intellectual Property and Competition Law (2015) pp.781 *et seqq*, p.783.
[209] ibid p.816.
[210] Billy A Melo Araujo, 'The EU's Deep Trade Agenda: Stumbling Block or Stepping Stone Towards Multilateral Liberalisation?' in Christoph Herrmann, Markus Krajewski and Jörg Philipp Terhechte (eds), *European Yearbook of International Economic Law 2014* (Springer: Berlin 2013) p.281.
[211] European Commission, 'Follow Up to the Strategy for the Protection and Enforcement of IP Rights in Third Countries - GIs' (2015) 2; Alan Matthews, 'Geographical Indications (GIs) in the US-EU TTIP Negotiations' <http://capreform.eu/geographical-indications-gis-in-the-us-eu-ttip-negotiations/> accessed 19 May 2016.

unless the US gives satisfactory protection for EU GIs, 'there will be no deal'[212], and that there will be no sacrifice of GIs 'for the sake of a deal with the US or anyone else'[213]. This causes considerable difficulties for the realisation of a successful deal – in response, US negotiators have stated that the EU 'has aspirations for changing the U.S. system that are not going to be met in TTIP'[214]. These views are supported by those in the US agricultural community, including the president of the US National Milk Producers Federation, who stated that the GI issue 'is a horrific overreach by the EU that undermines the entire EU interests in these negotiations […] there won't be a TTIP agreement passed by the Congress that is detrimental to U.S. agriculture'[215]. As argued above in the previous section, the incompatibilities between the EU and US on this issue are not 'merely' economic, but represent two distinct legal and philosophical conceptualisations of the role and function of GIs. Given such divergences, GIs may end up excluded from the scope of TTIP, or potentially result in its abandonment. Given the desire for regulatory harmony as a facilitator of increased trade between the two regions, neither result is particularly auspicious.

And, to conclude, what was one of the key products causing such consternation? *Feta* cheese.

[212] Hans von der Burchard, 'POLITICO Pro's Morning Trade: EU Flexes Muscles on Food Protection in TTIP — Wallonians Reject CETA' (*POLITICO*, 29 April 2016) <http://www.politico.eu/newsletter/morning-trade/politico-pros-morning-trade-eu-flexes-muscles-on-food-protection-in-ttip-wallonians-reject-ceta/> accessed 19 May 2016.
[213] ibid.
[214] Hans von der Burchard and Emmet Livingtstone, 'Transatlantic Trade Deal Could Be Bogged down ... by Feta Cheese' (*POLITICO*, 12 May 2016) <http://www.politico.eu/article/transatlantic-trade-deal-could-be-bogged-down-by-feta-cheese-ttip-champagne/> accessed 19 May 2016.
[215] ibid.

TTIP as a Platform for Progress in Pharma and Medtech Regulations

Bart Van Vooren and Charlotte Ryckman[*]

I. Introduction

Opponents of the transatlantic trade and investment partnership treaty (TTIP) fear that, the EU might lose the capacity to protect public health as it deems appropriate.[216] The freedom to regulate would be jeopardized because TTIP would bind the EU to the United States' regulatory interests, which are expressly or implicitly assumed to live up to a 'lower' standard than those in the EU. The '*TTIP-leaks*' provide a good opportunity to examine the potential impact of the agreement on EU public health regulation. This brief contribution uses as its starting point the document "*Tactical State of Play of the TTIP negotiations*" of March 2016,[217] and will focus on pharmaceuticals and medical devices. In light of the statements in this document, we query what would change for the EU consumer, and what would be the impact on the EU regulators' role in protecting public health.

II. Mutual Recognition of Good Manufacturing Practices for Pharmaceuticals

1. Introduction

The Tactical Document states that a significant step forward was made on the mutual recognition of Good Manufacturing Practices (GMP) for pharmaceuticals. In the following paragraphs we shall explain that, in our view, such mutual recognition could indeed be a step forward for all stakeholders on both sides of the Atlantic: the consumer would benefit from increased safety of pharmaceutical products with shorter lead-times to market, the regulator could re-focus inspections where needed the most, and pharmaceutical companies would benefit from reduced cost by eliminating double inspections. Finally, it is only in the context of TTIP that the EU and the USA are progressing rapidly towards mutual recognition, after two decades of efforts in that direction.

2. Good Manufacturing Practices in the European Union

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[*] Both authors are lawyers in the Food & Drug practice of Covington & Burling LLP. They are writing in a personal capacity. Bart Van Vooren is also honorary associate professor at the University of Copenhagen.

[216] Editorial, *Warning: TTIP could be hazardous to your health*, Journal of Public Health, Vol 37 No 3, pp 367-369 .

[217] Author not specified, *Note - Tactical State of Play of TTIP Negotiations - March 2016.* This negotiation document was leaked in March 2016. It is accessible via https://www.ttip-leaks.org/ (consulted 27 May 2016).

Under EU law, manufacturers of pharmaceuticals must respect GMP. In order to obtain a marketing authorization for a medicinal product, the applicant must prove that manufacturing complies with the principles and guidelines of GMP.[218] Similarly, holders of a manufacturing authorization must "*comply with the principles and guidelines of GMP for medicinal products and to use only active substances which have been manufactured in accordance with GMP.*"[219]

The GMP Directive 2003/94/EC defines GMP as "*the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use.*"[220] In substance, GMP includes effective quality assurance, employing qualified personnel, maintaining suitable manufacturing premises and equipment, establishing appropriate documentation procedures, maintaining quality control, and so on. According to Article 3 of the GMP Directive, the supervisory authorities of the EU Member States are responsible for conducting audits of manufacturers. This is because the European Medicines Agency (EMA) does not have inspectors of its own. Instead, the role of the EMA is coordination and support, and the national authorities must take account of the compilation of Community procedures on inspections and exchange of information, drawn up by the Commission with support from the EMA.

3. Mutual Recognition of GMP

The EU currently has active mutual recognition agreements (MRAs) for GMP of pharmaceuticals with the following countries: Australia, Canada, Israel, Japan, New Zealand and Switzerland. The agreement between the EU and Canada appropriately explains their purpose. The text expressly states that the underlying idea behind the MRA for GMP compliance certification, is that both Canada and the EU Member States have 'equivalent' GMP compliance programmes. Therefore, the issuance of a certificate by an authority of one Party certifying that a facility is in compliance with GMPs, should suffice so that the other party accepts that facility as GMP-compliant.[221] The EU-Canada MRA explicitly states that "*It should be understood that equivalent does not mean identical but it does mean leading to the same result.*"[222] To achieve their objective, the success of MRAs is significantly dependent on the successful

[218] Article 8 (ha) of Directive 2001/83/EC.
[219] Article 46(f) of Directive 2001/83/EC.
[220] Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.
[221] Agreement on mutual recognition between the European Community and Canada, OJ 16 October 1998 L280/3, chapter 6 on good manufacturing practices, points 3.1, 3.2 and 3.3 general considerations.
[222] Idem.

completion of a confidence building exercise and subsequent evaluation of its results. This is a process integrated in all of the EU's MRAs.

That last point is where the EU and the USA have failed in the past. Article 5 of the EU-USA MRA of 1999 established a three-year transition period, and article 9 established that equivalence would be determined by having in place regulatory systems respecting a pre-defined set of pre- and post- approval quality criteria. The transitional period lapsed in November 2001 largely because the FDA had concerns that GMP practices on the EU Member States' side were not sufficiently harmonized, and that overall divergence with the USA was too significant. Of course, fifteen years ago, the European Medicines Agency had not yet attained its current mature role in coordinating principles of GMP.

It is against that background that we should read pages 12 and 13 of the Tactical Document. On mutual recognition, it confirms that both the EMA and the FDA intend to establish an MRA under TTIP that includes all 28 EU Member States, provided that the FDA receives reports of the audits conducted under the Joint Audit Program (JAP). The JAP is essentially a peer review system covering all GMP inspectorates of the European Economic Area (EEA) to ensure harmonised inspection standards and interpretation of GMP requirements. The Tactical Document states that the FDA now accepts to receive these JAP audit reports, together with some additional information, and that it will take a decision on mutual recognition within three months of receiving the JAP report. The Tactical Document adds that "*in comparison with the process followed for the other MRAs on GMP, it is remarkable that the FDA would essentially rely on the JAP since it is an EU MS internal system of audits*". The Tactical Document thus confirms that the Commission wishes to accelerate the program so that all audits of all Member States are completed before the signature of TTIP.

These developments have clear benefits for patients, regulators and the industry.

The point of cost-reduction for EU and US pharmaceutical companies is the most obvious. An MRA reduces the need for double GMP inspections, eliminating fees and waiting times. This argument often seems to ring hollow to critics of TTIP, and it is certainly not the only reason to have an MRA.

For the regulator, MRAs have significant benefits too. Indeed, GMP inspections do not only occur in manufacturing plants in the EU or the USA, but throughout the world. Many Asian companies manufacture finished drugs and Active Pharmaceutical Ingredients (APIs), which all need to comply with GMPs. Since

the EMA and FDA are by far the most active in conducting GMP inspections,[223] an MRA will allow both agencies to collaborate towards leveraging inspection resources on a global scale. The main benefit here is not cost-reduction, but greater efficacy through joint EU and US identification of the highest risks in urgent need of inspection, as well as an overall increase in inspections of manufacturers around the globe. That, in turn, increases the safety of medicinal products brought to the USA and EU markets.

Finally, an MRA is not about 'lowering' the good manufacturing practices of EU pharmaceutical companies to the detriment of the consumer. Substantively, on the EU side the so-called 'Qualified Person' will still have to certify that each batch of finished product has been manufactured in line with the marketing authorization. On the USA side, the 'Quality Unit' of the marketing application holder remains similarly responsible to determine compliance. Thus, the MRA is about recognizing the equivalent substantive outcomes of systems, which may vary in structure or format. It is also telling that such MRAs are already in place with countries that have advanced inspectorates and pharmaceutical industries. In this area, TTIP is about tried-and-tested rapprochement between partners with equivalent regulatory challenges and solutions, even if the benefit is difficult to quantify.

4. Do we need TTIP to get these Benefits?

It could be argued that TTIP is not necessary in order to achieve mutual recognition of GMP between the EU and the USA. This argument is not without merit. Past efforts towards mutual recognition between 1998 and 2001 failed. An MRA is now possible in part because of global regulatory convergence in GMP, those promoted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)., According to the Tactical Document, TTIP negotiations, if anything, created momentum and time-pressure to complete the work that had been on-going for two decades. The Tactical Document expressly states that it "*is of the utmost importance that member states deliver JAP audit reports within a shorter time frame, so that the 28 audits can be completed by the time of signature of TTIP*". Additionally, the Tactical Document shows that the GMP MRA does not exist in isolation, and is linked to negotiations over TTIP as a legal basis for the exchange of confidential and trade secret information. Thus, an MRA can certainly function as a standalone legal instrument. Hence, in our reading the Tactical Document shows that TTIP provided the platform and momentum needed to finalize a process which had been on-going for 20 years. Given the interconnectedness of TTIP

[223] S. Milmo, *Collaborating on GMP inspections*, Pharmaceutical Technology, Volume 39, Issue 9, September 2015.

negotiations, it is not guaranteed that the MRA could be salvaged in case TTIP as a package-deal would fail.

III. Medical devices.

1. Introduction

In the medical devices sector, the Tactical Document shows that negotiations are progressing, but that US authorities are requesting further measures in relation to some of the three main priorities for the medical devices sector under TTIP, which are the single audit system, the unique device identification ('UDI') system, and the regulated product submission. The following paragraphs address these three topics and explain that while these are "light" measures that are unlikely to compromise patient health (on the contrary), they may still create significant benefits for industry and regulators alike.

2. Medical Devices in the European Union

The current EU regime on medical devices comprises three directives.[224] This contribution focuses on the Medical Devices Directive 98/42 ("the Directive"). The regime is currently undergoing revision, in an effort to address some of its shortcomings. The new Medical Device Regulation is still being negotiated, and its adoption is expected around mid or late 2016.[225] It will start applying three years after its adoption. Below we briefly outline the rules of the Directive (and the new Regulation) that are relevant to the TTIP negotiations.

First, medical devices in the EU are not subject to a pre-marketing authorization. Instead, the system is based on a combination between self-certification by the manufacturers, or a conformity assessment procedure conducted by a so-called "notified body". Notified bodies are entities that have been accredited by the competent authority of an EU Member State to assess the conformity of products with the relevant legislation. Their legal status varies from public bodies to associations and commercial undertakings.

The applicable conformity assessment procedure depends on the risk presented by the product class. For low-risk devices, manufacturers may self-certify compliance with the requirements of the Directive. Higher risk devices are subject to inspections by the notified bodies. The new Regulation tightens the

[224] The Active Implantable Medical Devices Directive 90/385/EEC, the Medical Devices Directive 93/42/EEC, and the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

[225] The future legislative package on medical devices consists of the new Medical Devices Directive and the new Regulation on Invitro Diagnostic Medical Devices. The latest texts data from the Council's so-called "General Approach", adopted in September 2015. Once adopted, the new rules on medical devices will enter into force three years later; those on invitro medical devices five years later.

rules on notified bodies, but essentially keeps the principle of self-certification or notified body involvement depending on class.

The USA use a very different system, where all new devices require prior approval from the FDA. Hence, the EU and US regimes impose different substantive requirements *and* apply different inspection procedures. Currently, when a US company wants to market a medical device in the EU or vice versa, a given manufacturing facility is audited by both the FDA and (if applicable) by EU notified bodies. This is one area where TTIP is trying to increase convergence (see below, point 3).

Second, traceability of medical devices is currently not required at EU-level, although there is a Commission Recommendation on the use of a unique device identification (UDI) system.[226] This Recommendation calls for the inclusion of unique identifiers in the database of the EU country where the device is marketed, facilitating device safety monitoring and reporting, recalls and other field safety corrective actions. While the Recommendation was a step in the right direction, it is non-binding and certainly did not create an EU-wide system for tracing medical devices. The new Regulation does include specific traceability provisions and envisages a mandatory internationally compatible UDI system for the EU.[227]

3. The TTIP Agenda for Medical Devices: a Threat to Public Health?

TTIP critics often voice concerns that the treaty would lower the EU's capacity to protect public health in that it would "lower the standard". In our view, however, the proposed medical devices measures could strengthen cooperation, encourage the sharing of best practices, increase traceability and reduce red-tape.

The TTIP agenda for medical devices essentially consists of three points.

(i) Quality Management System Audits:, manufacturing facilities for the EU and US markets are subject to audits by both US and EU inspectors. Under TTIP, parties are discussing the creation of a "single audit" system. The single audit system already exists at international level. The Medical Devices Single Audit Programme (MDSAP) is currently being tested within the framework of the International Medical Device Regulators Forum (IMDRF). At the moment, the EU

[226] European Commission, Recommendation (2013/172/EU) of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union.
[227] See Annex V Part C of the Council's General Approach to the Medical Devices Regulation, 21 September 2015, 2012/0266 (COD).

is merely an observer to the IMDRF and is therefore not fully participating in the MDSAP. Instead, three European Commission experts and experts from three Member States (UK, Ireland and - more recently - Poland) are observing the MSDAP Pilot. Despite repeated US requests to formally join the MSDAP, the European Commission indicated it would not decide on further steps until at least the end of 2016. Because of the central role of notified bodies, EU Member States are closely involved in this debate, and the European Commission will discuss further involvement in the MSDAP with the EU Notified Body Operations Group (NBOG).

Significantly, the aim of a single audit is not to harmonise EU and US QMS regulatory requirements. It is not a mutual recognition mechanism either. Instead, the aim is to put in place a single audit whereby auditors can check compliance with the requirements of several jurisdictions at the same time. [228]

In our view, a single audit system could put an end to double auditing and reduce the burden on manufacturers and regulators. The proposed mechanism is not likely to lower the EU standard. On the contrary., one single audit would test compliance with both regimes, leaving the applicable requirements as they are, but streamlining and increasing efficiency of the inspections. Furthermore, for certain devices the FDA pre-marketing authorization system imposes stricter audits -- and higher standards, as civil society is keen to remind us of[229] -- than the self-certification and/or notified body checks in the EU. A single audit system involving experts from both sides of the pond may very well become a platform for the FDA to share best practices with EU notified body inspectors.

Furthermore, it is clear that the European Commission is not willing to rush this, as it is holding off on becoming a full member to the MDSAP. From an EU law perspective, formalizing a single audit also requires the establishment of a legal basis, a process which in and of itself will require further debate and consideration. This cautious approach suggests that the parties are weary about repeating mistakes from the past. Indeed, the 1999 MRA between the USA and the EU meant to put in place a system of mutual recognition of inspections, but instead led to distrust and more, not less, inspections.

(ii) Unique Device Identification (UDI): As explained above, the new Regulation will create a mandatory UDI system. While the USA UDI system has been operational since 2014, the EU mechanism will only start to apply in a few years-time (*i.e.*, not before the new Regulation enters into force). The Technical

[228] See, for example, European Commission, *EU Position Paper on Medical Devices*, 15 April 2015, which states that "*there is no intention to use TTIP to harmonise EU and US QMS regulatory requirements.*"
[229] See, for example, BEUC, *How will TTIP affect the health of Europeans?*, 21 September 2014.

Document confirms that European Commission experts are reviewing the US UDI database and are making the technical preparations for integrating the (future) EU UDI system in that database. The aim is that both systems are "*aligned and interoperable*", allowing data exchanges. Hence, if and when the EU-wide UDI system becomes operational, TTIP negotiations will have contributed to technical compatibility of this system with the existing USA databases. Interoperability of both systems is crucial for the protection of public health: it can play a key role in the fight against counterfeit goods, and traceability is a fundamental pharmacoviligance component.

(iii) Regulated Product Submission: Negotiators are discussing the use of a common template for regulatory submissions. That template is being tested and developed at international level, under the auspices of the IMDRF. The EU and USA experts are currently testing the table of contents agreed within the IMDRF, which shows that the project is taken one step at a time and is subject to multiple test phases. In our view, the regulated product submission is not merely *presented* as a "harmless measure to reduce red-tape",[230] but actually aims to reduce red-tape, nothing more, nothing less.

IV. Conclusion: The Fallacy of Splendid Isolation

Negotiations or pharmaceuticals and medical devices do not suggest that public health in the EU is threatened. In both areas, negotiations focus on relatively technical-procedural issues where benefits are clearly mutual. Discussions over 'lowering standards' may not be that relevant after all. On pharmaceuticals, the benefits of mutual recognition for GMP exist for consumers, regulators and business alike. Such mutual recognition necessarily draws on an element of trust between regulators, which is currently being built up between the EMA and the FDA during the TTIP negotiations. In our view the facts on GMP mutual recognition speak for themselves: regulators can more efficiently leverage resources to the benefit of public health, and medicines can be brought to market more efficiently. This can only be the result of trans-Atlantic regulatory trust, and any criticism thereof tends to result from either an aversion for globalisation, or a (latent) anti-Americanism, or both.

The same conclusion can be drawn from our analysis of medical devices. Traceability of medical devices should necessarily be seen in the context of a global menace of smuggling and counterfeiting. Falsification of sunglasses or handbags is often dismissed as a fait-divers, but counterfeiting also occurs in the medical sector. Since counterfeit goods often originate outside the EU or the

[230] Some non-governmental associations warn that TTIP measures may be presented as harmless while in fact harming patient health.

USA, it is crucial that both parties set up a compatible and interoperable system to track and trace genuine products. Cooperation supports public health protection, it does not detract from it.

Admittedly, both examples are very specific, and it can be argued that these benefits can be reaped on an individual basis. Therefore, TTIP is allegedly not necessary and cherry-picking the benefits should suffice. However, in our view such argument misses the point of TTIP. Take the example of GATT, which progressed in a piecemeal fashion for several decades. However, by the end of the 1980's times had changed, and the regime of global trade required a qualitative leap forward - the World Trade Organization, gathering negotiation momentum linking multiple issues towards a holistic deal that ties them together on a new legal foundation. In our view, TTIP negotiations are no different from the Uruguay round in terms of historical significance. Continuing the WTO comparison, the debate surrounding TTIP similarly reflects the ideological rift that was the basis for the 1999 'Battle of Seattle' during the WTO Ministerial Conference. This obviously does not bode well for the future of TTIP. However, when we look back at the experiences of the 20th century, splendid isolation and a retreat from international trade have only worsened global problems, not resolved them.

Thoughts on Transatlantic Regulatory Cooperation in Pharmaceuticals after #TTIPleaks

Marco Rizzi[*]

I. Introduction

The leak of confidential documents on 2 May 2016 by Greenpeace Netherlands allows some preliminary conclusions on both the scope and success of the negotiations so far. As regards the pharmaceutical market,[231] the current state of affairs combines the promise of steps forward with the prospect of concerning standstills. This short opinion follows key points emerging from the leaked documents n.9 ("Regulatory Cooperation") [232] and n.16 ("Tactical State of Play")[233] that are directly relevant to the pharmaceutical market.

The themes that will be briefly discussed are, first, the regulatory cooperation mechanisms emerging from doc. n.9 in comparison to current cooperation processes in pharmaceutical regulation. The leaked papers suggest positive and commendable (yet far from conclusive) developments towards a more transparent and regulated framework for cooperation, while perpetuating concerns regarding fundamental policy choices and prevalence of mercantile imperatives over competing public interests.

Secondly this paper examines the sector-specific issues identified in paragraph 2.4 of doc. n.16. Concerns over general policy choices in regulatory cooperation are reflected in discussion of the progress of the negotiations as regards mutual recognition of Good Manufacturing Practices (GMP), on one hand, and the standstill on generic medicines and exchange of confidential trade secret information (CTSI), where the distance between the parties is substantial (recognising that cooperation in these areas is a priority for the EU while of minor interest to the US).

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[*] Senior Lecturer in Law, University of Seychelles.

[231] Identified as a relevant sector in EU Commission, "EU position on pharmaceutical products", 14 May 2014, available on the internet at <http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152471.pdf> (last accessed 19 May 2016).

[232] TTIP leaks, Document n.9, "Initial Provisions for CHAPTER [ ] [EU: REGULATORY COOPERATION] [US: REGULATORY COHERENCE, TRANSPARENCY, AND OTHER GOOD REGULATORY PRACTICES]", available on the internet at <https://ttip-leaks.org/#docdoc9> (last accessed on 19 May 2016).

[233] TTIP leaks, Document n.16, "Note – Tactical State of Play of the TTIP Negotiations", available on the internet at <https://ttip-leaks.org/#docdoc16> (last accessed on 19 May 2016).

Finally a brief set of conclusions is offered on the persistent divergence of regulatory styles between the parties, underpinning the weakest links in the negotiation results (to date).

II. ICH and RCB: Steps forward but in which Direction?

1. An Element of Novelty: Towards Accountable Regulatory Cooperation…

Transnational regulatory cooperation between the US and the EU (the Parties) in the pharmaceutical sector has ben practiced for more than 25 years.[234] The regulatory cooperation chapter of TTIP attempts to institutionalise in a publicly accountable shape and under a cross-sectoral umbrella the *rapprochement* of regulatory regimes on both sides of the Atlantic. Doc. n.9 offers a rare opportunity to compare the EU and US positions.[235] To begin on a positive note, it transpires that the EU is making a sincere effort to transpose its schemes of "non-majoritarian" [236] accountability and legitimacy into this partnership. Looking specifically at Section III and parts of Section II of the chapter, one can identify a skeleton of "procedural democracy" that sounds familiar to EU lawyers. It is not clear what exactly is the US contribution, in particular regarding the design and functioning of the proposed Regulatory Cooperation Body (RCB). In a nutshell what emerges from the leaked papers confirms the model that has been analysed in detail in a number of contributions.[237] The pillars of this model are transparency and stakeholder consultation duties that are owed without discrimination to institutions, legal and natural persons of both Parties throughout the cycle of proposal, discussion and approval of regulatory acts.

It is possible to contrast the main features of the TTIP's RCB against those of the current preferred platform for cooperation on pharmaceutical regulation, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH is itself undergoing a process of organisational change the extent of which is yet to be fully publicised.[238] The

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[234] ICH, "History", available on the internet at <http://www.ich.org/about/history.html> (last accessed 19 May 2016).

[235] Alberto Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Inverstment Partnership: Institutional Structures and Democratic Consequences", 18 *Journal of International Economic Law* (2015), pp. 625 *et sqq.*, at 628, observing that the US do not share as much TTIP material as the EU.

[236] Using the terminology first adopted by Giandomenico Majone, *Regulating Europe* (London: Routledge, 1996), at pp 12 *et sqq*.

[237] See among which in particular Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Inverstment Partnership", *supra* note 5; Peter Chase and Jacques Pelkmans, "This time it's different: Turbo-charging regulatory cooperation in TTIP", Special Report no. 110 *CEPS* (2015); Alberto Alemanno, "The Regulatory Cooperation Chapter of the TTIP – Challenges and Opportunities", 20 *European Policy Analysis* (2015), at pp. 7 *et sqq*.

[238] ICH, "Organisational Changes", available on the internet at <http://www.ich.org/about/organisational-changes.html> (last accessed 19 May 2016).

following comments are therefore based on the structure as it operated until the end of 2015. So far there is no reason to anticipate changes to the *modus operandi* of the ICH Steering Committee. This leaves the essence of the following comments intact. ICH has operated for 25 years as a hybrid public-private platform for regulators and regional representatives of the pharmaceutical industries of the EU, the US and Japan to harmonise regulatory requirements for marketing authorisation in their respective markets. The ICH machinery[239] is characterized by the "behind closed doors" nature of the Steering Committee's decision-making. In essence, consultative steps are required at the level of regional administrative agencies (FDA and EMA in particular) at an early stage of the "five-step" procedure leading to the adoption of harmonised guidelines to ensure local stakeholders' involvement.[240] However the decision-making process within the Steering Committee is not transparent. The fate of regional comments cannot be traced; there is no duty to justify the adoption, dismissal or modification of said comments in the final product.[241]

The TTIP's RCB as it emerges from the leaked papers, in combination with the provisions laid down in Section II of the chapter, confirm a strong adherence to principles of deliberative democracy. Article X.23 and X.24 in conjunction with Articles X.6, X.7 and X.8[242] are a textbook application of those principles. From this perspective an RCB structure dealing with pharmaceutical regulatory cooperation would represent a significant attempt at claiming back transnational (in this case transatlantic) regulatory decision-making to a public sphere with clear accountability mechanisms. Admittedly, while stakeholder participation is emphasized, legislatures are missing from the equation. The role of domestic democratic institutions is pushed back to the adoption of regulatory instruments emerging from the transnational cooperation within the Parties' own legal frameworks. In this sense, the lack of involvement of the European Parliament (EP), raised by civil society observers and commentators,[243] is largely an EU issue and not a TTIP one (as further discussed below). However, we do learn from the leaked Article X.23.6 that the negotiators are contemplating the introduction of "provisions on the interaction of the RCB with legislative bodies", thus leaving the door open to a role for Parliaments within TTIP (which would

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[239] Marco Rizzi, "Non-Measurable Negotiations: The EU between Transnational Regulation of Pharmaceuticals and Private Law", in Marise Cremona and Hans-W. Micklitz (eds.), *Private Law in the External Relations of the EU* (Oxford: Oxford University Press, 2016), pp. 273 *et sqq.*, at pp. 283 *et sqq*.

[240] ICH, "Formal ICH Procedure", available on the internet at http://www.ich.org/about/process-of-harmonisation/formalproc.html (last accessed 19 May 2016).

[241] Rizzi, "Non-Measurable Negotiations", *supra* note 9, at p. 285.

[242] TTIP leaks, Document n.9, *supra* note 2, Artt. X.23 "Establishment of the Regulatory Cooperation Body", X.24 "Participation of stakeholders", X.6 "Early Information on Planned Acts", X.7 "Stakeholder Consultation", X.8 "Transparent Development of Regulation".

[243] Alemanno, "The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership", *supra* note 5, at pp. 636 *et sqq.*, describing the mechanisms under Art. 218 TFEU.

be an interesting platform for the EU to bring back the EP in decision-making involving technical regulatory matters). This observation is a useful *trait d'union* with the remarks in the following paragraph.

2. ...or much of the same?

Whether or not TTIP will introduce a mechanism allowing the EP to gain an active role within the RCB, the issues with the proposed architecture lie elsewhere. While a greater involvement of the only truly representative institution of the EU could certainly constitute a positive development, it would also depart from EU consolidated models of non-majoritarian governance.[244] Therefore, should legislative institutions' involvement fail to find its way into the negotiations, a "representative democracy deficit" would hardly be attributable to TTIP. The concerns are of different nature and we can focus on two specifically.

First, there is a general issue: is a trade partnership the correct instrument to set up a general mechanism of regulatory cooperation? It has been eloquently argued that using a trade and investment partnership to build regulatory cooperation bears the risk of implying a "discursive shift in favor of economic and trade interests"[245] over competing policy objectives such as, in our case, patient and consumer welfare. While obviously speculative (the partnership is far from being operative, if it will ever be) this observation deserves attention especially in conjunction with the linked issue of having a sole umbrella mechanism of cooperation (the RCB) for regulated sectors. The precise architecture of the RCB and its relationship to sectoral regulation remains to be determined.[246] Should the structural obstacles and uncertainties be overcome, the risk would be that RCB's role to "monitor and facilitate implementation of the provisions set out in [the Regulatory Cooperation] Chapter" could translate into a cross-sectoral catalyst for economic and trade interests in EU policy. To give substance to this concern let us turn to a second objection.

The issue revolves around the centrality of the so-called "international instruments" as defined in Article X.2(d): "documents adopted by international bodies or fora in which both Parties' regulators [...] participate", including guidelines of the sort produced by ICH for the registration of pharmaceuticals.

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[244] A wonderful account of the perils of such models can be found in Peter Mair, *Ruling the Void – The Hollowing of Western Democracy* (London: Verso, 2013).

[245] Christiane Gerstetter, "Regulatory Cooperation under TTIP – A Risk for Democracy and National Regulation?", *Heinrich Böll Stiftung – TTIP Series* (2014), at pp. 6 *et sqq.*

[246] TTIP leaks, Document n. 9, *supra* note 2, Art. 23(2)(c); and TTIP leaks, Document n.16, *supra* note 3, para. 2.1 "Regulatory Coherence": "a number of important issues remain to be addressed: scope (both in terms of measures and authorities covered), the question of how to identify the cooperation activities that should be covered, and the architecture (relationship of the regulatory cooperation chapter with sectors), including the institutional mechanism, which will be crucial to the future operability of regulatory cooperation."

The combined reading of Articles X.21 ("Promoting Regulatory Compatibility") and X.22 ("Promoting International Regulatory Cooperation"), together with Article X.6 of doc. n. 10 ("Technical Barriers to Trade") on "Standardisation" (or "Standards" in the US version, which adopts a much sharper wording than the EU one),[247] suggest a potential picture in which the RCB works as the tipping point of strategic discussions to determine areas of cooperation while *de facto* delegating the discussion on substance to those international fora. In other words, while the RCB with its inclusive and transparent structure throws the "accountability deficit" of ICH-like bodies out of the window, it welcomes it back through the front door by promoting prompt adoption of "international instruments". This brings us back to the original objection. If RCB is to be a point of strategic discussion for the identification and development of areas of regulatory cooperation, having it operate under the umbrella of a partnership primarily aimed at facilitating trade and investment runs the risk of a discursive shift in EU policy catalysing economic and trade interests.[248] This would contradict the spirit of recent EU reforms in pharmaceutical regulation that constitute a serious legislative attempt to enforce public accountability on a market where private economic interests have traditionally played a dominant role.[249]

III. "Tactical state of play" of Sector-specific Negotiations on Pharmaceuticals

Against the backdrop of the general observations suggested above we can now turn our attention to three areas of specific cooperation in the pharmaceutical sector identified in doc. n.16: GMP inspections, generic medicines and CTSI.

1. Something new: Moving forward on GMP

The leaked document shows encouraging steps forward in an area that has traditionally seen divergence between the US and EU: the Good Manufacturing Practices. Over the past ten years, GMP has been an object of debate as the EU always understood GMP to be an integral part of the Good Clinical Practice (GCP) requirements, whereas the US have been separating the two both conceptually and in the relevant regulatory instruments.[250] What emerges from the tactical

[247] TTIP leaks, Document n.10, "Chapter [_] Technical Barriers to Trade", Art. 6, available on the internet at < https://ttip-leaks.org/#docdoc10> (last accessed 19 May 2016).
[248] On the accountability deficit of such a prospect see Ernst-Ulrich Petersmann, "Transformative Transatlantic Free Trade Agreements without Rights and Remedies of Citizens?", 18 *Journal of International Economic Law* (2015), pp. 579 *et sqq.*
[249] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ 2014 L 158/2.
[250] John Simmons and David Bernstein, "Navigating Differences between FDA and EMA for Regulatory Compliance During Drug Development", 2 *BioPharm International* (2006), available on the internet at <http://www.biopharminternational.com/navigating-differences-between-fda-and-emea-regulatory-compliance-during-drug-development> (last accessed 19 May 2016).

state of play is that both regions have agreed that mutual recognition of GMP inspections would be highly beneficial. If taken in isolation from broader considerations of the place of GMPs in the overall regulatory architecture, inspections on GMPs can be a relatively straightforward and "mechanical" exercise, requiring less controversial and sensitive evaluation than those required in GCP inspections:[251] in light of the limited resources at the disposal of regulatory agencies, mutual recognition of GMP inspections would result in a net gain for everyone. This seems to be appreciated by both Parties, with the FDA showing willingness to rely on the results of Joint Audits Program (JAP), an internal peer review mechanism used by Member States (MSs) authorities, while the Commission is putting pressure on MSs to accelerate the JAP process. This is certainly a comforting sign of trust that could speed up a fruitful partnership.

2. At a Standstill: Generic Medicines and CTSI

While GMP cooperation is progressing, other key areas appear to be at a standstill. Generic medicines have been identified by the EU as a key strategic area for cooperation to be pursued alongside the TTIP negotiations.[252] Yet "the FDA did not show interest in working on generics",[253] claiming on the one hand a lack of resources to examine the EU proposal and on the other hand the intention to exclude scientific work from TTIP. The latter consideration is particularly surprising given the insistence of US negotiators on evidence-based decision-making spelled out for instance in Article X.14 of doc. n.9.[254] As regards CTSI, while the Parties agree that "this is an important matter", the hang-up is the legal instrument to be used for the exchange of such information. The question on the table is whether it should be via a separate instrument to be signed by each MS and EU institution (Commission and EMA) individually, as the FDA is requesting, or whether the circulation of CTSI could be governed directly via TTIP as proposed by the Commission.

It is entirely possible that both of these obstacles are temporary and attributable solely to the material and procedural constraints recalled above, that is, resources and appropriate legal formula (though the FDA's position on the latter begs the question: what is the point of promoting regulatory cooperation in the first place if key issues are subject to further burdensome bureaucratic requirements…?). It is however possible that a more profound divergence is at play both in regulatory styles and in pharmaceutical product litigation. While the

[251] On the controversial nature of the GCP guidelines see Rizzi, "Non-Measurable Negotiations", *supra* note 9, at p. 283.
[252] EU Commission, "Technical Paper for Regulatory Cooperation on Generic Medicines – Proposal of the European Union", 26 January 2016, available on the internet at <http://trade.ec.europa.eu/doclib/docs/2016/january/tradoc_154172.pdf> (last accessed 19 May 2016).
[253] TTIP leaks, Document n.16, *supra* note 3, para. 2.4.
[254] TTIP leaks, Document n.9, *supra* note 2, Art. X.14 "Decision-Making Based on Evidence".

EU is committed to move towards full transparency in marketing authorisation data availability with the new Clinical Trials Regulation,[255] commercially sensitive information in the US is still very much proprietary and confidential, with the result that availability is largely based either on voluntary release or as a result of litigation.[256] This is not the place to analyse the role of litigation in American regulation, but the volume and relative accessibility of private judicial remedies are among the key factors making business-friendly CTSI regulations relatively sustainable in that jurisdiction.[257] Litigation in the EU does not play a comparable role with the result that transparency in the pharmaceutical sector has to be pursued principally through regulatory means. It is not just a matter of technicalities: the philosophies underpinning the two regulatory architectures remain fundamentally different. Conversely, generic medicines in the US receive a special protection from litigation in the form of a federal pre-emption of state tort law (where FDA approval shields manufacturers from liability under certain circumstances).[258] It is not therefore entirely surprising that the US would wish to maintain a higher degree of domestic control over approval of products benefitting from such special treatment (thus explaining the lack of interest in discussing the EU proposal on the matter).

The intention of these quick thoughts is not to identify litigation as the sole factor slowing down negotiations. Litigation is rather a tell-tale sign of persisting sectoral divergence between US and EU approaches to regulation.

IV. Conclusion

Sector-specific divergence still permeates regulatory styles. This is true as regards the specific architecture of pharmaceutical regulation as recalled above, but it also applies to key elements of the general cooperation mechanism devised in doc. n.9, such as Article X.13 on regulatory impact assessment (RIA). Here the US version makes reference to "not regulation" as an implicitly preferred option, whereas the EU limits itself to a requirement of measuring impact on international trade while being more proactive in advocating for a cooperative spirit mindful of each Party's regulatory approach.[259] Limiting our observations to the pharmaceutical sector, the impression is that for the partnership to take a

[255] Regulation (EU) No 536/2014, *supra* note 19.

[256] Marco Rizzi, "The Complex Case for Another Hard Look – Transnational Pharmaceutical Regulation and the Pedagogical Role of Courts" (PhD thesis on file at the European University Institute, 2015), pp. 155 *et sqq*.

[257] Ibid.; for a recent discussion on the comparatively smaller role of product liability in the EU see Barend Van Leeuwen and Paul Verbruggen, "Resuscitating EU Product Liability Law?", 5 *European Review of Private Law* (2015), pp. 899 *et sqq*.

[258] As established for failure to warn claims by the US Supreme Court decision *PLIVA, Inc. v Mensing* 131 S. Ct. 2567, 2581 (2011) on the basis that if federal law requires generic manufacturers to use the same labeling as their brand-name counterparts it is impossible for them to simultaneously comply both with federal law and a state tort law duty to provide an enhanced label.

[259] TTIP leaks, Document n.9, *supra* note 2, Art. X.13 "[EU: Analytical Tools] [US: Regulatory Impact Assessment]".

shape better suited to EU objectives it is paramount that obstacles are overcome in generics and CTSI. Generics are too central to healthcare systems and patients of both sides of the Atlantic[260] to be justifiably ignored if the partnership is to take multifaceted interests seriously. As for CTSI the EU has spent too much political capital towards transparency in recent times to have the issue stall on technicalities. If the EU's vision is to gain substance, the degree of cooperation in both areas can be subject to negotiation but not so their inclusion.

Are aggregate convergences[261] in risk regulation sufficient to prompt the creation of a general cross-sectoral cooperation mechanism or are sectorial specificities still too pronounced to make it a successful (or desirable) project? To embrace the full scope of regulatory cooperation, a partnership needs a shared analytical frame of reference and (at least as regards pharmaceuticals) the proposed regulatory mechanism, with its potential catalyst effect on the adoption of "international instruments", appears better tailored for the US architecture, where litigation plays a prominent role, than for the EU. The leaked papers reveal that there is still significant scope for negotiation and we identify two specific issues where the EU could push to capitalise on the positive aspects of the RCB design and lessen the risk of it becoming a catalysing tool for minimally accountable transnational practices. First, the promotion of international regulatory cooperation should be more clearly framed within the procedural context and mechanisms of the RCB. In particular, implementation as described in Article X.22.1 and 2 could benefit from clearer wording and more direct reference to the overall deliberative scheme. Secondly, the EU could push for a watchdog role of the EP under Article X.23.6. While many would raise an eyebrow at seeing the legislature directly involved in this area, one must concede that relying on stakeholders alone is not necessarily an optimal choice. In particular, civil society's ability to effectively and competently represent its interests is not always a realistic prospect. At least if the frantic debate surrounding TTIP is anything to go by…

[260] EU Commission, "Technical Paper for Regulatory Cooperation on Generic Medicines", *supra* note 22, at p. 1.

[261] Jonathan Wiener and Alberto Alemanno, "The Future of International Regulatory Cooperation: TTIP as a Learning Process Towards a Global Policy Laboratory", 78 *Law and Contemporary Problems* (2015), pp. 103 *et sqq.*, at p. 104: "empirical research finds that U.S. and European risk regulation over the past four decades has exhibited overall average *parity*, with occasional divergences as selective precaution is applied on *both* sides to *particular* risks".

Divergences between EU and US in the Financial Regulation

What Effects on the TTIP Negotiations?

Sara Pugliese[*]

I. Introduction

Financial regulation is an issue where differences between the EU and US are highly sensitive. Indeed, EU and US apply in a different manner the financial standards adopted at international level by the Basel Committee and have different systems of financial supervision.

Due to these significant differences between the two systems, it is very difficult for the EU and US to reach an agreement on common financial standards within the TTIP negotiations.

Actually, as the differences in regulation between the two systems are an obstacle to the access of the financial operators of each Party to the market of the other Party, the absence of common standards in this sector could nullify the efficacy of norms of market access that will be probably contained within the TTIP.

Moreover, in a risk regulation perspective, considering the weight that the US and EU financial relationship have on the global system and taking account of the effect of destabilization that could be generated by the divergent requirements imposed to the credit institutions on the two sides of the Atlantic, the lack of common financial standards between the EU and US could have a great impact on global financial stability.

The aim of this short paper is to underline the differences between the EU and US financial regulatory and supervisory systems, in order to verify if there is room to find common issues within the TTIP negotiations or if it is possible at least to prefigure mechanisms of regulatory cooperation.

II. The Financial Global Standardization by the Basel Committee

Since the 1980s the international financial sector has been the object of the standard-setting activity by the Basel Committee, where both US and EU banking

[*] Researcher of EU Law, University of Naples "Parthenope".

authorities are represented. The three so called Basel agreements[262] have contributed to diversify the relevant risk typologies (credit risk, operational risk, market risk, funding risk, default risk) and to impose on financial operators more and more rigorous standards aimed at avoiding the crisis of a single institute and the systemic effect that it could generate.

Today, the most important standards established by the Basel Agreements to avoid banking crisis are: 1) minimum capital requirements, aimed at finding a balance between core capital and risk-weighted assets[263]; 2) the risk assessment methods; 3) the so called liquidity risk monitoring tools, useful to assess the capability of a credit institute to face an unexpected shock[264].

As is well-known, the Basel Agreements contain non – binding standards[265]. If national authorities consider such standards sufficiently rigorous to guarantee the stability of the domestic financial system, they will transpose them into the national law. On the contrary, they could establish more rigorous requirements for their credit institutes.

III. Divergences between EU and US in the Financial Regulation: Are Basel Standards enough to Contain Risk of Financial Crisis?

On the side of regulation, the EU and US confer different relevance to the Basel standards. Actually, EU financial regulation has a very close relationship with Basel standards. Indeed, since the 1980s EU has established with the Basel Committee a sort of "osmotic" relation and the two have often worked in a parallel way[266]. The EU influenced in a significant way the elaboration of Basel standards and, consequently, once approved, these standards were inserted rather accurately in the EU financial directives and regulation.

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[262] See Basel Committee on Banking Supervision, "International convergence of capital measurement and capital standards", July 1988; Basel Committee on Banking Supervision, "International Convergence of Capital Measurement and Capital Standards: A Revised Framework", June 2004; Basel Committee on Banking Supervision, "Basel III: A global regulatory framework for more resilient banks and banking systems", December 2010 (rev June 2011) and all the integrating documents available on the Internet at <https://www.bis.org/bcbs/> (last accessed on 31 May 2016). On the Basel agreements, Jeffery Atik, "Basel II: A Post-Crisis Post-Mortem", 19 *Transnational Law and Contemporary Problems* (2011), pp. 731 *et sqq.*; Panagiotis Delimatsis, "Financial Innovation and Prudential Regulation: The New Basel III Rules", 46 *Journal of World Trade* (2012), pp. 1309 *et sqq*.

[263] The principal instruments to obtain this balance are the so called minimum reserves.

[264] These tools consists in two ratios (The Liquidity Coverage Ratio and the Net Stable Funding Ratio). The same aim is pursued by the so called "countercyclical buffers", that are supplementary reserves useful to face unexpected shock.

[265] See Basel Committee on Banking Supervision, "Charter", January 2013, art. 3, available on the Internet at https://www.bis.org/bcbs/charter.htm (last accessed on 31 May 2016).

[266] On the "osmotic" rapport between EU regulation and Basel standards, see Sara Pugliese, "L'unione bancaria europea tra esigenze d coerenza interna e risposte alle sfide globali", 19 *Il Diritto dell'Unione europea* (2014), pp. 831 *et sqq.*

On the contrary, the US has always maintained a sort of independence from the Basel standards, elaborating an autonomous financial regulation and insisting within the Basel Committee to affirm its rules within the "Basel agreements". When the US was unable to impose its financial rules as global standards within the Basel Committee, it maintained its own regulation for domestic firms but accepted foreign operators that conformed themselves at least to the Basel standards. Indeed during the 1980s and 1990s the US financial regulation followed was oriented towards de-regulation and liberalization.

This approach has significantly changed after the 2007 financial crisis. The financial crisis propelled a change towards more rigorous requirements placed on its financial institutions, as established by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010[267].

During the negotiations for the adoption of the so called "Basel III", the US made a great effort to impose the new rules as global standards but it was not able to obtain completely this result[268].

Considering new requirements absolutely necessary to assure the domestic financial stability, the US has become more restrictive towards foreign financial operators since 2010, admitting to operate in its market only the credit institutions that complied with US rules, when they were more rigorous than Basel standards[269]. So, many EU financial operators that have conformed their minimum capital and risk assessment methods with Basel standards and EU regulation were excluded from the US market. At the same time, the suspicion against the US operators, considered the principal responsible of the crisis, created barriers to the access of US financial operators to the EU market.

As a consequence, during the TTIP negotiations the different approaches on the weight to confer to the Basel standards have progressively emerged as a potential obstacle for the achievement of an agreement on common standards. The US considers that Basel standards concerning credit institutions' capital are not sufficient to assure their stability. Two examples are particularly significant.

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[267] Pub. L. 111–203 , H.R. 4173, July 21, 2010, 124 STAT. pp. 1376 *et sqq*.

[268] Eugene Goyfnan, "Let's be Frank: Are the Proposed US Rules Based on Basel III an Adequate Response to the Financial Debacle?", 36 *Fordham International Law Journal* (2013), pp.1062 *et sqq*.

[269] K. Kathryn C. Lavelle, "The Foundations of Regulatory Convergence and Divergence Between the Federal Reserve and European Central Bank", 45 *Georgetown Journal of International Law* (2014), pp. 1165 *et sqq*.

First, the US imposes capital requirements, as for example the "leverage ratio"[270], stricter than the Basel standard[271]. On the contrary the EU regulation is based on the Basel standard[272].
Second, the US adopted the so called "Volcker Rule", that limits the "proprietary trading" (purchase of stocks, bonds, coins, commodities, derivatives, hedge funds shareholdings through bank core capital more than deposits) imposing a maximum of 3% to the banking speculative operations. The Vulcker Rule has the objective to forbid commercial banks to do too risky operations and it pursues the aim to protect their account holders[273]. The EU does not yet have a regulation on proprietary trading, even if Commission presented a proposal about this issue in 2014[274].

Increased capital requirements and the "Volcker Rule" represent good examples of the different approach of the EU and US to financial risk: while the EU establishes norms that lower the banking risk exposure without excessively braking their activity, the US forbids all the operations that could expose credit institutes to higher risks in order to prevent the crisis of its domestic financial system.

IV. Divergences between EU and US in the Financial Supervision: Differences between "Multilevel" and "Federal" Systems

The US and EU differ both in the weight they confer to supervision and in the method they apply to control the credit institutes' performances.

First, the two systems have a different history and tradition. The US supervisory system is based on the centrality of the Federal Reserve (FED), established in 1913 by the Federal Reserve Act[275] and charged with the function of supervision since 1917. At first, the FED control was limited to the banks of federal

[270] The "leverage ratio" is the index of indebtedness of a credit institute and is based on the ratio: total amount of credit institutes activities/credit institute's core capital. Erik Jones, Huw Maccartney, "TTIP and the "finance exception": Venue-shopping and the breakdown of financial regulatory coordination", 17 *Journal of Banking Regulation* (2016), pp. 4 *et sqq*, at p. 15 *et sq*.
[271] Basel Committee on Banking Supervision, "Basel III", *supra* note 1, pp. 61 *et sqq*.
[272] Regulation (EU) No 575/2013 of the European Parliament and of the Council on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012, OJ 2013 L 176/1; Commission Delegated Regulation (EU) 2015/62 amending Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to the leverage ratio, OJ 2015 L 11/37.
[273] Laura Puccio, *Le PTCI et la réglementation des marches financiers. Autonomie réglementaire contre fragmentation,* (Bruxelles : Service de recherché du Parlement européen 2015), pp. 12 *et sqq*.
[274]Commission Proposal for a Regulation of the European Parliament and of the Council on structural measures improving the resilience of EU credit institutions Brussels, COM (2014) 43.
[275] Ch. 6, 38 Stat. 251, enacted December 23, 1913, 12 U.S.C. ch. 3.

dimension. The Banking Act (known also as the Glass-Steagall Act) of 1933[276] articulated the Federal Reserve System on a multilevel structure and established the Federal Deposit Insurance Corporation (FDIC), an independent agency charged with assuring the bank deposit guarantee. During the Great Depression, Federal Reserve System supervision has been extended to the overall credit institutions system. The Financial Service Modernization Act (so called Gramm-Leanch –Biley Act) of 1999[277] devolved to the FED the overall responsibility for the financial market system[278]. After the financial crisis, the FED gained a stronger role both as a regulator and as a supervisor. Indeed the Dodd-Frank Wall Street Reform and Consumer Protection Act established the *C*onsumer Financial Protection Bureau and the Financial Stability Oversight Council (FSOC) (the so called "twin peack system"), strictly connected to the FED. These two bodies have the role to coordinate all the sectorial agencies and the supervisory authorities of the federal States[279].

Differing from the US system, the EU supervisory system is rather young. Even if the EU has adopted directives aimed to approximate the national supervisory systems since the 1980s[280], only since 2010 the EU has established a system of European Supervisory Authorities (ESAs)[281] and since 2013, with the so called "banking union", the EU has established a Single Supervisory Mechanism. Indeed the Regulation 1024/2013[282] confers to the ECB the exclusive competence to fulfill the supervisory functions that were previously exercised by the national authorities on all the credit institutes of the eurozone, except on "those that are

[276] Pub.L. 73–66, 48 Stat. 162, enacted June 16, 1933.
[277] Pub.L. 106–102, 113 Stat. 1338, enacted November 12, 1999.
[278] The Financial Service Modernization Act conferred to the system a four level structure: Board of Governors, composed by seven members appointed by the President after approval by the Senate, with a function of monetary and supervision policy; the Federal Open Market Committee, composed by the members of the Board and by the 12 Presidents of the Federal Reserve Banks; the 12 Regional Federal Reserve Banks; the Boards of Directors of Federal Reserve.
[279] K.Kathryn C. Lavelle, "The Foundations of Regulatory Convergence and Divergence Between the Federal Reserve and European Central Bank", *supra* note 8, at pp. 1141 *et sqq*.
[280] Council Directive 83/350/EEC, OJ 1983 L 193/18; Council Directive 92/30/EEC, OJ 1992 L 110/52*;* Directive 2000/12/EC of the European Parliament and of the Council, OJ 2000 L 126/1; Directive 2006/48/EC of the European Parliament and of the Council, OJ 2006 L 177/1; Directive 2013/36/EU of the European Parliament and of the Council, OJ 2013 L 176/338 .
[281] Regulation (EU) No 1093/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Banking Authority), OJ 2010 L 331/12; Regulation (EU) No 1094/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), OJ 2010 L 331/48; Regulation (EU) No 1095/2010 of the European Parliament and of the Council establishing a European Supervisory Authority (European Securities and Markets Authority), OJ 2010 L 331/84.
[282] Council Regulation (EU) No 1024/2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions, OJ 2013 L 287/63; Mario Sarcinelli, "The European Banking Union: Will It Be a True Union Without Risk Sharing?", 66 *PSL Quarterly Review* (2013), pp. 137 *et sqq.*; Rosa M. Lastra, "Banking Union and Single Market: Conflict or Companionship?", 36 *Fordham International Law Journal* (2013), p. 1190 *et sqq*.

less significant"[283]. The ECB has a role of overall supervision of the well-functioning of the system and a function of coordination and orientation of national authorities, which it exercises in cooperation with the European Banking Authority (EBA)[284].

The Single Supervisory Mechanism is completed by the Single Resolution Mechanism[285] and by the Single Deposit Guarantee Mechanism[286], proposed by the Commission but not approved yet.

As the "banking union" has centralized at EU level all the problems concerning not only the prevention and management of banking crisis and the reaction to them, it has tried to make the EU supervisory system more similar to the US one.

Nevertheless, the two systems present still many differences. First, while the FED exercises the supervisory functions taking account of its principal objectives of economic growth and price stability, the ECB focuses mainly on the last objective. Second, while the US sectorial agencies are strong independent from the US government, the ESA are strictly linked to the Commission. Third, since their establishment in 2010, in the US system the two bodies of the "twin peak system" (the Consumer Financial Protection Bureau and the Financial Stability Oversight Council) acquired a more and more intense function of coordination and control on the other sectorial and national agencies and they contributed to concentrate the supervisory action on prevention of systemic crisis and especially on consumer protection[287]. Instead in the EU, with the exception of the Directive on the deposit guarantee schemes, the financial consumer protection is still conferred to national authorities[288]. Finally, while in the US the Dodd Frank

[283] Art. 6, §4-6. Gunnar Schuster, "The Banking Supervisory Competencies and Powers of the ECB", in 25 *Europäische Zeitschrift für Wirtschaftsrecht* (2014), pp. 3 *et sqq*.; Kerstin Neumann, "The supervisory powers of national authorities and cooperation with the ECB – a new epoch of banking supervision", 25 *Europäische Zeitschrift für Wirtschaftsrecht* (2014), pp. 9 *et sqq*.

[284] Regulation (EU) No 1022/2013 of the European Parliament and of the Council amending Regulation (EU) No 1093/2010 establishing a European Supervisory Authority (European Banking Authority) as regards the conferral of specific tasks on the European Central Bank pursuant to Council Regulation (EU) No 1024/2013, OJ 2013 L 287/5. Elke Gurlit, "The ECB's relationship to the EBA", in 25 *Europäische Zeitschrift für Wirtschaftsrecht* (2014), pp. 14 *et sqq*, at p. 16 *et sqq*.

[285] Regulation (EU) No 806/2014 of the European Parliament and of the Council establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010, OJ 2014 L 225/1.

[286] Commission Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 806/2014 in order to establish a European Deposit Insurance Scheme, COM (2015) 586.

[287] Pablo Iglesias-Rodríguez, *The Accountability of Financial Regulators. A European and International Perspective*, (Alphen aan den Rijn: Wolters Kluwer Law & Business, 2014).

[288] Directive 2014/49/EU of the European Parliament and of the Council on deposit guarantee schemes, OJ 2014 L 173/149. Directive fastens at 100.000 euro the deposit guarantee limit.

Act limited the role of credit rating agencies, in the EU system, compliant with the Basel standards, credit rating agencies continue to carry out an important role of risk assessment and orientation of financial operations[289].

In conclusion, the US supervisory system has evolved towards a federal model, with the allocation of a systemic coordination role to the federal supervisory bodies and an operative role to the decentralized supervisory bodies. On the contrary, although the banking union confers also on the EU supervisory system a centralized structure[290], national supervisory authorities maintain significant autonomous power so that the EU supervisory system could be defined rather" multilevel" than "federal".

Due to the decentralized structure of the EU supervision system, US considers it unable to assess properly the risk whom European credit institutes are exposed to and fears the spill-over effects that its system could suffer if European credit institute would be admitted to the US market.

So, as the US is oriented to exclude the EU operators from its financial markets and tends to confer extraterritorial value to its more stringent norms, the EU reacts in the same way (as for example in the derivative regulation[291]), with a cost-burden of duplicative regulatory requirements. Therefore, differences in regulation and supervision become barriers to the market.

Laurie Buonanno, "Financial services regulation and the Transatlantic Trade and Investment Parnership Agreement", 14 *Journal of Transatlantic Studies* (2015), pp. 1 *et sqq*.

[289] Iris H.-Y. Chiu, "Regulating Credit Rating Agencies in the EU: In Search of a Coherent Regulatory Regime", 25 *European Business Law Review* (2014), pp. 269 *et sqq*..; Kern Alexander, "The Risk of Rating in Capital Regulation", in 25 *European Business Law Review* (2014), pp. 295 *et sqq*.

[290] On the potential effects of banking union on TTIP negotiations, Karel Lannoo, "The New Financial Regulatory Paradigm: A Transatlantic Perspective", *CEPS Policy Briefs* No 287, 21 March 2013, pp. 1 *et sqq*.; Sara Pugliese, *L'unione bancaria europea*, *supra* note 5, pp. 859 *et sqq*.

[291] For an example of US extraterritorial norms, Title VII del *Dodd-Frank Act*. For the EU extraterritorial rules, Regulation (EU) No 648/2012 of the European Parliament and of the Council on OTC derivatives, central counterparties and trade repositories, OJ 2012 L 201/1 (so called EMIR), art. 4, §4. See also Commission Delegated Regulation (EU) No 285/2014 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on direct, substantial and foreseeable effect of contracts within the Union and to prevent the evasion of rules and obligations, OJ 2014 L 85/1. Edward F. Greene, Ilona Pothia, "Issues in the Extraterritorial Application of Dodd-Frank's Derivatives and Clearing Rules, the Impact on Global Markets and the Inevitability of Cross-Border and US Domestic Coordination", 8 *Capital Market Law Journal* (2013), pp. 338 *et sqq*; Lucy McKinstry, "Regulating a Global Market: The Extraterritorial Challenge of Dodd-Frank's Margin Requirements for Uncleared OTC Derivatives & A Mutual Recognition Solution", 51 *Columbia Journal of Transnational Law* (2013), pp. 778 *et sqq*.; John.C. Coffe Jr, "Extraterritorial Financial Regulation: Why E.T. Can't Come Home", *European Corporate Governance Institute (ECGI) - Law Working Paper* n. 236/2014, pp. 1 *et sqq*.

V. The Effects of the US-EU Financial Systems Divergences on the TTIP Negotiations

Due to the divergences between systems, today both US and EU are quiet cautious to insert within the TTIP norms of market access and regulatory cooperation concerning the financial sector[292].

From the document "Note – Tactical State of Play of the TTIP Negotiations – March 2016" leaked by Greenpeace on 2 May 2016[293], it appears that the EU and the US agreed on the architecture of the financial services chapter according to the EU proposal on market access and they started a "process of negotiation, whereby horizontal disciples (such as national treatment) would be centralized for the sake of efficiency and to avoid undesired inconsistencies". Conforming to the "living agreement" idea, "Once these discussions reach sufficient maturity, we will discuss if and how to modify these provisions to the FS chapter".

The other controversial issues remain unresolved, as the definition of "financial services"[294], the text of the prudential carve-out[295] and regulatory cooperation in the sector[296].

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[292] Really the first EU approach was more ambitious. See DG Trade della Commissione europea, "EU - US Transatlantic Trade And Investment Partnership (TTIP). Cooperation on financial services regulation", 27 January 2014, available on the Internet at http://trade.ec.europa.eu/doclib/docs/2014/january/tradoc_152101.pdf (last accessed on 31 May 2016).

[293] The leaked documents are available on the Internat at https://www.ttip-leaks.org/ (last accessed on 31 May 2016).

[294] The US chapter on financial services covers only financial service suppliers, which are regulated and supervised as financial institutions (all other financial services suppliers are covered in the investment chapter), whereas the EU chapter covers all categories of financial service suppliers".

[295] "The EU prudential exception includes a necessity test as opposed to the US proposal which includes an anti-circumvention test as in the GATS". The necessity test has already been introduced within the prudential carve-outs included into the EU-Singapore Agreement (Art. 8.50), May 2015, available on the Internet at http://trade.ec.europa.eu/doclib/press/index.cfm?id=961 (last accessed on 31 May 2016), and into EU-Vietnam Agreement (p. 82), January 2016, available on the Internet at http://trade.ec.europa.eu/doclib/press/index.cfm?id=1437(last accessed on 31 May 2016). On the prudential carve-out within the TTIP, Inu Barbee, Simon Lester, "Financial Services in the TTIP: Making the Prudential Exception Work", 45 *Georgetown Journal of International Law* (2014), pp. 954 *et sqq*.

[296] In particular, "the US continues to oppose discussing this issue in TTIP, whereas the EU confirmed that its mutual access offer for Financial Services hinges upon the US satisfactory engagement in regulatory cooperation". The specificity of the regulatory cooperation in the financial sector is confirmed by the document "Initial Provisions For CHAPTER [ ] [EU: REGULATORY COOPERATION] [US: REGULATORY COHERENCE", Art. X-23 (EU: Establishment of the Regulatory Cooperation Body: 3.In the domain of financial services as set out under paragraph 2 (function of RCB) shall be performed by the {Joint EU/US Financial Regulatory Forum (FRF)}, which shall ensure that appropriate information is given to the Regulatory Cooperation Board. Any decisions concerning financial services should be taken by the competent authorities acting within the framework of the FRF". See also European Commission, Report of the 13th Round of Negotiations for the Transatlantic Trade and Investment Partnership

In conclusion, it is necessary to underline that, as EU and US are the two most important Members of the Basel Committee, divergences in their financial regulatory and supervisory systems have effects both on the transatlantic financial market and on the increase of global risks of financial crisis[297].

So, the establishment of an effective regulatory cooperation mechanism between US and EU, favoring the approximation of rules and standards, could contribute not only to open the transatlantic financial market, but also to strengthen global economic stability.

(New York, 25-29 April 2016), pp. 1 *et sqq*, at p. 5, available on the Internet at http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154581.pdf (last accessed on 31 May 2016). It is to remember that since 2002 the EU and US conduct a "soft" cooperation on financial service regulation within the EU-US Financial Markets Regulatory Dialogue. On the difficulty to conciliate EU and US regulatory methods and procedures, Richard Parcker, Alberto Alemanno, "Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems", *CEPS Special Reports* 88, 15 May 2014, pp. 1 *et sqq*.

[297] Ecorys, *Trade SIA on the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the USA Draft Interim Technical Report*, (Brussels: European Commission), May 2016, pp. 333 *et sqq*., at p. 373 *et sqq*.

Sustainable Development in TTIP: A Highest Common Denominator Compromise?

Ferdi De Ville, Jan Orbie and Lore Van den Putte[*]

I. Introduction

The impact of TTIPleaks on the negotiations of and debate about the Transatlantic Trade and Investment Partnership (TTIP) has been more limited than its name and announcement would lead us to expect. This is, first, because the leaked 'consolidated documents' only show the European Union's (EU) and United States' (US) positions on a number of negotiating areas but does not unveil concessions made by either side in the pursuit of a compromise. Therefore, it contains little surprising information for observers of the negotiations. But a second reason for the lack of uproar is that for only about half of the expected chapters in TTIP a text has been leaked, either because there is no consolidated text yet for the other issues in the negotiations or because Greenpreace did not get hold of it.

One of the chapters lacking in the TTIPleaks is on 'Trade and Sustainable Development'. This is an interesting issue area because the advocates often argue that this chapter will help ensure that TTIP upholds and strengthens social and environmental standards[298]. However, the credibility of this claim depends on how strong this chapter will eventually turn out to be. A leaked consolidated text could have given us an indication of this.

In this short piece, we will speculate about the possible outcomes in this area. In the remainder of this article we will focus primarily on labour provisions[299]. However, our conclusions to large extent also apply to environmental provisions in TTIP. While these provisions touch upon a wide variety of issues related to sustainable development, many concern areas of social and environmental risk regulation, such as with regard to health and safety at work or trade in and

[*] Ferdi De Ville is Assistant Professor at the Centre for EU Studies, Ghent University. Jan Orbie is Full Professor and Director of the Centre for EU Studies, Ghent University. Lore Van den Putte is a PhD Fellow funded by the Research Foundation Flanders (FWO), at the Centre for EU Studies, Ghent University.

[298] Cecilia Malmström, "TTIP – what's in it for labour, environment and sustainable development", 6 November 2015, available on the Internet at: <https://ec.europa.eu/commission/2014-2019/malmstrom/blog/ttip-whats-it-labour-environment-and-sustainable-development_en> (last accessed on 16 May 2016).

[299] We do this because of word constraints, because the literatures on labour and environmental provisions in trade agreements have been quite separated, because most scholarship on trade and sustainable development has focused on labour rights, and because the US has the tradition to deal with labour and environmental provisions separately (while the EU integrates them in a sustainable development chapter). This difference in structuring labour and environmental provisions could be accommodated by including chapters in TTIP on trade and labour, trade and environment and trade and sustainable development, as in the EU-Canada Comprehensive Economic and Trade Agreement.

environmentally sound management of chemicals and waste. We will, in the next section, explain that the EU and the US have different approaches to the inclusion of labour provisions in free trade agreements (FTAs). We will then argue that these two approaches can be integrated in a lowest common denominator or a highest common denominator way (this should rather be seen as a continuum of potential outcomes), and we will outline what we already know about TTIP in this area. We conclude that if the negotiators want to live up to their promise that TTIP will have beneficial social and environmental effects they should integrate the EU and US approaches at the highest level.

II. EU and US Approaches to Trade and Labour

Both the EU and the US started to include labour provisions in their FTAs in the mid-1990s. The US initiated this practice with the North American Agreement on Labour Cooperation (NAALC) as a parallel agreement to the North American Free Trade Agreement (NAFTA), which was signed in 1992 and entered into force in 1994. In the EU, this started with the agreements with countries at the southern shore of the Mediterranean, called Euro-Med Agreements, of which the EU-Tunisia Association Agreement signed in 1995 was the first.[300] Both entities developed this approach further in the coming two decades.

Labour provisions in EU and US FTAs not only evolved over time, both also adapted these provisions to some extent to the partner country in such treaties. However, a current template or approach can be discerned for both entities. The EU's approach to labour provisions in trade agreements is often called 'promotional' or 'soft' while the US template is often termed 'conditional' or 'hard'[301]. In more specific terms, how do the EU's and US' approaches to trade and labour differ?

In terms of the substantial provisions included in these agreements, EU FTAs incorporate multilateral instruments, most importantly the Core Labour Conventions of the International Labour Organisation (ILO) and more recently also the ILO's Decent Work Agenda. Its trade agreements stipulate that parties reaffirm their commitment to the Decent Work Agenda and commit to respecting, promoting and realising in their laws and practices, the fundamental rights of the 1998 ILO Declaration. Moreover, EU agreements require that the parties shall effectively implement the ILO Conventions that they have ratified and that they should make sustained efforts towards ratifying the other

[300] Lore Van den Putte and Jan Orbie, "EU bilateral trade agreements and the surprising rise of labour provisions", 31 *International Journal of Comparative Labour Law and Industrial Relations* (2015), pp.263 *et sqq*.

[301] International Institute for Labour Studies, "Social Dimensions of Free Trade Agreements", 6 November 2013, available on the Internet at: <http://www.ilo.org/global/research/publications/WCMS_228965/lang--en/index.htm> (last accessed on 18 May 2016).

fundamental Conventions as well as other Conventions classified as 'up-to-date' by the ILO. In the case of US trade agreements a new template for labour provisions was drafted in 2007 with the May 10 bipartisan Congressional-Executive agreement[302]. In contrast to the EU, the US does neither refer to ILO Conventions nor to the Decent Work Agenda, but only states that each party shall adopt and maintain in its statutes and regulations and practices the rights as stated in the 1998 ILO Declaration. The explanation for this is straightforward: the US has only ratified two out of the eight Core Labour Conventions. A non-lowering clause in both the EU's and US' FTAs stipulates that the parties shall not waive or otherwise derogate from (or offer to waive or derogate from) its labour laws in a manner affecting trade or investment between the parties[303].

Apart from this fixed template, the US often adds additional requirements to trade agreements that partners should successfully implement as a precondition for the FTA to enter into force. These are often very detailed requirements, such as the hiring of a specified number of labour inspectors and assigning a specified number of judicial police investigators to support prosecutors in charge of investigating criminal cases involving union members and activists, like in the Colombian Action Plan Related to Labor Rights[304]. The EU agreements also include labour rights commitments that go beyond the ILO Core Conventions. However, it concerns a general commitment without reference to specific laws or practices, and there is no pre-ratification conditionality[305].

With regard to enforcement, the EU opts for soft mechanisms such as dialogue, cooperation and naming and shaming. It foresees a civil society dialogue mechanism through which civil society organisations meet both domestically as well as transnationally to discuss the implementation of the sustainable development chapter. Besides, in case of an alleged labour violation, a party may request government consultations through which the parties shall make every attempt to arrive at a mutually satisfactory solution. If they don't, ultimately, a party (but not civil society organisations) may request that a panel of experts be

[302] Office of the United States Trade Representative, "Bipartisan Agreement on Trade Policy", May 2007, available on the Internet at: <https://ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf > (last accessed on 16 May 2016).
[303] The interesting question how these provisions may affect the interpretation of other chapters of TTIP, such as on investment (and investment protection in particular), is beyond the scope of this article. Similarly, we do not discuss provisions on sustainable development in other chapters than the one dedicated to this topic specifically.
[304] Office of the United States Trade Representative, "Colombian Action Plan Related to Labor Rights", April 7 2011, available on the Internet at: <https://ustr.gov/sites/default/files/uploads/agreements/morocco/pdfs/Colombian%20Action%20Plan%20Related%20to%20Labor%20Rights.pdf> (last accessed on 16 May 2016).
[305] Jeffrey Vogt, "The Evolution of Labor Rights and Trade—A Transatlantic Comparison and Lessons for the Transatlantic Trade and Investment Partnership", 18 *Journal of International Economic Law* (2015) pp.827 *et sqq*.

convened to examine the matter. This panel may issue recommendations on the implementation of the chapter on sustainable development. In EU FTAs, it is explicitly stipulated that parties only have recourse to the procedures mentioned above and, consequently, not to the general dispute settlement provisions of the agreement. This is the main difference with enforcement provisions for labour provisions in US agreements. US FTAs also foresee dialogue and cooperation (including, but to a more limited extent, with civil society) through a Labor Affairs Council and stipulate that the parties shall initially seek to resolve disputes through these consultative mechanisms. Contrary to the EU's approach, however, any person may file a submission with the US government regarding alleged non-compliance with the labour commitments. Ultimately, these procedures could lead to a case before the general dispute settlement mechanism of the agreement. This implies that non-implementation of labour provisions in US FTAs can result in sanctions, while this is not possible under EU agreements[306].

III. Labour Provisions in TTIP

How will these templates be integrated in TTIP? The differences between the EU and US approach to labour provisions can be combined in a lowest or a highest common denominator way. On the lowest common denominator side, substantially, the relevant chapter in TTIP would only require the parties to comply with the fundamental rights included in the 1998 ILO declaration (while only finding a violation if a failure to comply with this declaration affects transatlantic trade or investment), without the obligation to respect the Core Labour Conventions or the requirement to (strive to) ratify them, neither would other labour standards such as those included in the ILO Decent Work Agenda be mentioned. With regard to enforcement, no recourse to the dispute settlement, no possibility of sanctions and no extensive involvement of civil society would be foreseen. At the highest common denominator side, the clear obligation to comply with (and possibly even to ratify) Core Labour Conventions and the decent work agenda would be combined with enforcement provisions that would both seriously involve and empower civil society (including trade unions) in the implementation of the trade agreement. In addition, it would allow for sanctions as the ultimate instrument to ensure compliance.

As stated at the beginning of this article, TTIPleaks did not contain a document about labour provisions. What do we know about this issue area in TTIP, then?

[306] The possibility for sanctions remains largely hypothetical for now as only one public submission on labour violations in Guatemala has reached the stage of dispute settlement. At the time of writing, the outcome is still uncertain.

The European Commission made public its textual proposal on Trade and Sustainable Development on 6 November 2015[307]. This proposal starts with a disclaimer stating that 'additional proposals, including on institutional aspects, civil society participation and dispute settlement, will be developed at a later stage'. Hence, the provisional textual proposal of the EU mainly contains substantial provisions. Section I lays out the context (art. 1) and the objectives (art. 2) of the Chapter and reaffirms the parties' right to regulate in the area of sustainable development in a manner not inconsistent with the multilateral labour standards and agreements included in art. 4 and multilateral environmental governance and rules included in art. 10. Section II deals with the labour aspects of trade and sustainable development (arts. 4-9) while Section III is about the environmental aspects (arts. 10-16). Finally, Section IV deals with horizontal issues (arts. 17-21).

Art. 4 on multilateral labour standards and agreements contains the most important substantial obligations. It states (§1) that the parties agree to promote the development of their trade and investment relations in a manner conducive to the realisation of the Decent Work Agenda and its four strategic objectives (employment protection, social protection, social dialogue and fundamental principles and rights at work). With regard to the latter strategic objective, §2 stipulates that each party shall ensure that its laws and practices respect, promote and realise the fundamental ILO Conventions and in this context, to continue to make sustained efforts towards ratifying these Conventions and their Protocols, as well as other Conventions and their Protocols that are classified as up-to-date by the ILO. Paragraph 3 states that each party shall ensure to protect health and safety at work and decent working conditions for all, including with regard to wages and earnings, working hours and other conditions of work in order to ensure a minimum living wage. The remainder of art. 4 states that the parties: shall effectively implement the ILO Conventions they have ratified (§4); shall implement the recommendations adopted by the ILO where they exist in areas covered by up-to-date Conventions (§5); and recognise the need of an adequate system of labour inspections to ensure the effective enforcement of their labour laws (§6). The final paragraph (§7) of art. 4, balancing the prohibitions of social dumping and disguised protectionism, states that the parties recognise that the violation of fundamental principles and rights at work cannot be invoked or otherwise used as a legitimate comparative advantage and that labour standards should not be used for arbitrary or unjustifiable discrimination or protectionist purposes.

[307] European Commission, "EU Textual Proposal: Trade and Sustainable Development", 6 November 2015, available on the Internet at: <http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153923.pdf> (last accessed on 16 May 2016).

Articles 5 to 8 then specify in considerable detail the obligations that respect of the fundamental labour rights entails, namely with regard to: freedom of association and the right to collective bargaining (art. 5; ILO Conventions 87 and 98), elimination of forced or compulsory labour (art. 6; ILO Conventions 29 and 105), effective abolition of child labour (art. 7; ILO Conventions 138 and 182) and equality and non-discrimination in respect of employment and occupation (art. 8; ILO Conventions 100 and 111). Art. 9, finally, lays out a number of priority areas and activities for the parties to cooperate on the labour aspects of trade and sustainable development at bilateral, regional and global level.

Substantially, the EU textual proposal on labour aspects of trade and sustainable development is relatively ambitious. With the provisions on enforcement (institutional aspects, civil society participation and dispute settlement) not included yet, this leaves open the possibility for a highest common denominator compromise, if the US would accept this substantial EU proposal, and would itself put forward a proposal on dispute settlement that includes the possibility to have recourse to the general dispute settlement mechanism of the agreement in case of violations of labour provisions.

The US position can be derived from its 'Bipartisan Congressional Trade Priorities and Accountability Act of 2015'[308] (also known as Trade Promotion Authority, or TPA) and more specifically from Section 2 Trade Negotiating Objectives, (b) Principal Trade Negotiating Objectives, (10) Labor and the Environment. The TPA does not seem to preclude a highest common denominator compromise. It sets out as US negotiating objectives to ensure that the parties adopt and maintain measures implementing internationally recognized core labour standards and that they do not waive or derogate from their statutes or regulations implementing these core labour standards and do not fail to enforce their labour laws effectively in a matter affecting trade or investment. This is in line with the traditional US approach. It does not go as far as the EU textual proposal but the latter is also not in contradiction with the US TPA. With regard to enforcement, the TPA mandates the United States Trade Representative to ensure that enforceable labour obligations are subject to the same dispute settlement and remedies as other enforceable obligations under the agreement.

Hence it seems that a highest common denominator compromise on trade and labour should be possible in TTIP. What might still be problematic on the European side is that the European Parliament in its Resolution on TTIP of 8 July 2015 has asked the European Commission 'to ensure that the sustainable

[308] US Congress, "Bipartisan Congressional Trade Priorities and Accountability Act of 2015", 11 May 2015, available on the Internet at: <https://www.congress.gov/114/bills/s995/BILLS-114s995rs.pdf> (last accessed on 16 May 2016).

development chapter … aims at the full and effective ratification, implementation and enforcement of the eight fundamental International Labour Organisation (ILO) Conventions and their content, the ILO's Decent Work Agenda and the core international environmental agreements'[309]. This is also the position of the European Trade Union Confederation[310]. It has been argued that the difficulty for the US to ratify Core Labour Conventions is related to the US federal system. After the US rejoined the ILO in 1980, it was stipulated in a 1988 US Senate resolution that 'there is no intention to change State law and practice by Federal action through ratification of ILO Conventions'[311]. But as the European Parliament and ETUC also ask that labour provisions be enforceable before the general dispute settlement mechanism, a compromise seems plausible where the EU does not require the US to ratify the six Core Labour Conventions it has not ratified yet, the US agrees with the EU's more ambitious substantial provisions, and the EU accepts (in line with EP and ETUC demands) enforceability of labour provisions before the general dispute settlement mechanism. In its state of play after the 12th Round of negotiations, the EU seems to indicate that its strategy is to trade off ambition on substance for enforceability: '[d]iscussions about enforceability could be addressed as soon as there is sufficient common understanding on the substantive disciplines for the chapter'[312].

IV. Conclusions

The chapter on Trade and Sustainable Development, and its labour aspects in particular, are an important part of TTIP. The advocates of the agreement often refer to this chapter to argue that TTIP will uphold and strengthen rather than weaken labour and environmental standards. In this article, we have argued that to live up to this promise (and hence to help ensure trade unions' and other civil society actors' support of TTIP), the negotiators have to integrate the EU's and US' approaches to trade and labour in FTAs at the highest common denominator. While requiring the US to ratify the Core Labour Conventions seems politically difficult, this would imply that the US accepts the EU's more ambitious substantial provisions while the EU accepts the US' approach to dispute settlement, including the possibility of sanctions in case of non-compliance.

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[309] European Parliament resolution of 8 July 2015 containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership TTIP, 2014/2228(INI).

[310] ETUC, "Position on the Transatlantic Trade and Investment Partnership", 25 April 2013, available on the Internet at: <https://www.etuc.org/documents/etuc-position-transatlantic-trade-and-investment-partnership#.VzmPI0t2mSA> (last accessed on 16 May 2016).

[311] See United States Council for International Business, "Issue Analysis: U.S. Ratification of ILO Core Labor Standards", April 2007, available on the Internet at: <https://www.uscib.org/docs/US_Ratification_of_ILO_Core_Conventions.pdf> (last accessed on 16 May 2016).

[312] European Commission, "The Transatlantic Trade and Investment Partnership (TTIP) – State of Play", 27 April 2016, p. 6, available on the Internet at: <http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154477.pdf> (last accessed on 16 May 2016).

While this may still not be the most optimal approach from a social rights perspective (as ratification of ILO conventions does make a difference), it would have the advantage of combining the strengths of the EU's and US' approaches. Moreover, the new template might provide a 'gold standard' for future trade agreements concluded by the US and the EU.