Regulatory Cooperation in EU FTAs: Characteristics of the Reestablished Practice

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REGULATORY COOPERATION IN EU FTAS: CHARACTERISTICS OF THE REESTABLISHED PRACTICE

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Keywords: regulatory cooperation, bilateralism, multilateralism, characteristics, FTAs

Abstract: Regulatory cooperation is a complex and multifarious concept. Its multimodality applies not only to the forms it can take but also to the fora where it may appear. Although regulatory cooperation does not constitute a new trend in EU trade, its current state represents an original development. Regulatory cooperation is now treated as a separate phenomenon in the new generation of free trade agreements (FTAs), raising several questions. What is the significance of this change? How does bilateralism as an external relations tool fit into a concept that partially falls under trade and partially under rule-making? Since regulatory cooperation is considered a trade-related concept that views domestic regulation through the prism of a beyond-the-borders dialogue, is bilateralism the best venue, considering the nature and sensitivities of the regulatory activity itself? What is the status of regulatory cooperation activities in the context of multilateralism, which is a *de facto* extension of bilateralism? This contribution will answer these questions through the concept of the 'characteristics' of contemporary regulatory cooperation, as the latter is envisaged in the new generation of European FTAs. The two identifiable characteristics upon which our analysis shall be based are bilateralism and inclusion in an FTA structure.

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I. Introduction

Regulatory cooperation is a complex, multifarious concept. Its multimodality applies not only to the forms it can take but also to the fora where it may appear. Although regulatory cooperation does not constitute a new trend in European Union (EU) trade, its current state represents an original development. Bilateral regulatory cooperation has not been as fully developed in EU trade relations as in other bilateral trade schemes. Until recently, it has primarily been governed by the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) chapters under the aegis of the World Trade Organisation (WTO) or by various international standardising organisations. This has begun to change with the new generation of Free Trade Agreements (FTAs) that typically introduce advanced chapters on regulatory cooperation, separate from those on TBT and SPS, which are also relevant. What is the significance of this change? Most importantly, what constellation of events in the existing multilateral and bilateral scene of regulatory cooperation caused the *de facto* extension of this particular type of bilateralism?

This contribution will give answers to the said questions through the concept of the 'characteristics' of contemporary regulatory cooperation, as the latter is envisaged in the new generation European FTAs. I refer explicitly to 'characteristics' since, in my view, the elements under analysis give a particular meaning to regulatory cooperation and distinguish it from previous forms. These features, which underpin the totality of the chapters, provide a basis for an improved understanding of legislators' choices and are analysed in the present paper. The strong interdependence of past experiences and present choices, which constitutes the main source of the identified characteristics, provides a solid ground to explore the historical background of this change, and especially how political circumstances and market imperatives contributed to regulatory cooperation as it is found today in European FTAs.

Overall, this Working Paper identifies and analyses two main features that place regulatory cooperation on a different playing field. Each of these characteristics is discussed in a separate section, despite their circumstantial and historical interconnection. The first characteristic, bilateral regulatory cooperation, is discussed in Section 2.2. The preference for bilateralism over multilateralism is not based on existing literature explaining bilateralism as a general preference of EU trade regulation, but rather on the basis of the TBT and SPS provisions to the extent that they introduce regulatory cooperation as such. Section 2.3 reflects upon the inclusion of regulatory cooperation in an FTA as the second characteristic. When positioned within a legally binding treaty, regulatory cooperation acquires a different meaning from a legal point of view. Section 2.3 draws upon this legal significance and examines past regulatory cooperation initiatives (the most prominent example being the transatlantic paradigm), examining their origins and pitfalls and comparing them to the chapters present in the FTAs.

II. Bilateralism as the First Characteristic of Regulatory Cooperation

The history of multilateral trade relations and negotiations highlights the central role of regulatory obstacles. Referencing such obstacles was unavoidable at a point when tariff reductions had reached historically low levels.[1] Thus, negotiators felt the need to dedicate separate agreements to the issue, leading to the introduction of regulatory cooperation by the Tokyo Round Standards Code in the era of the General Agreement on Trade and Tariffs (GATT era).[2] Regulatory cooperation under the GATT regime began with the Standards Code, the ancestor of the TBT and SPS Agreements, and was later concluded under the WTO scheme. While its scope was limited to technical regulations, standards and conformity assessment procedures covering goods (as contemporary agreements now do), the Standards Code was the first to introduce segments discussing regulatory cooperation and coherence.[3] On the one hand, regulatory cooperation provisions mainly highlighted the importance of international standards as such, which had to be taken into account by national legislatures during the formation of national technical regulations. On the other hand, they emphasised the need for Member States to participate actively in international organisations responsible for their formation; as for regulatory coherence, the Agreement introduced

1 KOEBELE Michael, *Preamble TBT in* Rüdiger Wolfrum, Peter-Tobias Stoll and Anja Seibert-Fohr (eds) "WTO – Technical Barriers and SPS Measures", Max Planck Commentaries on World Trade Law, Max Planck Institute for Comparative Public Law and International Law/Martinus Nijhoff Publishers /2007.

2 The introduction of the Standards Code was particularly advocated by the United States.

3 NAKAGAWA Junji, *Regulatory Cooperation and Regulatory Coherence through Mega-FTAs: Possibilities and Challenges in* Julien Chaisse and Tsai-yu Lin(eds) "International Economic Law and Governance: Essays in Honour of Mitsuo Matsushita" Oxford University Press/ 2016, p. 395.

obligations to notify and tolerate comments on national regulations deviating from international standards and to allow a reasonable time between their publication and entry into force.[4]

Soon, however, several defects limited the actual effect of these provisions. Firstly, the Agreement was plurilateral and was essentially a club for developed countries, which resulted in its fragmented application.[5] The shortcomings of the GATT Dispute Resolution System also hindered the Agreement's application, namely the requirement for consensus and the non-provision of appellate procedures.[6] Last but not least, the growing number of barriers in food and agriculture revealed the inability of the provisions to cover them sufficiently and underlined the need for a separate agreement specific to these issues.[7]

The Uruguay Round resulted in two agreements dedicated to product regulation, the TBT and SPS, as well as various regulatory provisions in the sectoral agreements (the GATS and TRIPS Agreements). Although formerly grouped under a sole agreement, the Uruguay negotiations resulted in a separation of SPS and TBT measures, due to the inherent particularity of the former.[8] These two Agreements, which form the evolution of the Standards Code, introduced similar provisions, albeit slightly more elaborated, clarified, and with some additions. Their added value can be found in the fact that they were adopted under Annex 1A of the Agreement Establishing the World Trade Organisation, which renders them part of the multilateral system.[9] In contrast, the Standards Code was formatted separately from the GATT and thus is open for 'acceptance by signature.'[10] Their exposure to the Dispute Settlement Mechanism counted as an additional advantage in the overall picture of the Agreements' potential.

After a short analysis of how these disciplines came to exist, the following section embarks on a twofold mission: on the one hand, it aims to discuss the extent to which regulatory cooperation is found in the multilateral setting, and on the other hand, it highlights the shortcomings of its existing elements through a legal analysis. The reasons will be explored in an analysis of the status and the core provisions of the TBT and of the relevant GATS provisions. When necessary, parallels to the SPS Agreement shall be drawn. Other agreements such as TRIPS will not be analysed in this instance, as the purpose of the section is not to go deep into the details of each regulatory discipline in the WTO, but rather to comment on their general nature and philosophy.

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4 MIDDLETON R. W., *The GATT Standards Code*, Journal of World Trade (1980) p. 201–219, p.205ff.

5 MARCEAU Gabrielle and TRACHTMAN Joel P., *The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement and the General Agreement on Tariffs and Trade: A Map of the World Trade Organisation Law of Domestic Regulation of Goods*, Journal of World Trade (2002) pp.351–432, p. 354.

6 See KUDRYAVTSEV Arkady, *The TBT Agreement in Context in* Tracey Epps and Michael J. Trebilcock (eds) "*Research Handbook on the WTO and Technical Barriers to Trade, Research Handbook on the WTO"* Edward Elgar/ 2013.

7 MARCEAU Gabrielle and TRACHTMAN Joel P. *supra* no 5, 355.

8 See KUDRYAVTSEV *supra* no 6, 25.

9 *The WTO Agreement Series, Technical Barriers to Trade*, <https://www.wto.org/english/res_e/publications_e/tbttotrade_e.pdf> accessed 13 October 2017, p. 11.

10 See MIDDLETON *supra* no 4, 201.

A. Core multilateral disciplines: Regulatory coherence or regulatory cooperation?

As a term, 'regulatory cooperation' in trade has been connected with activities and initiatives undertaken to tackle unnecessary regulatory trade barriers. These barriers form distinct categories of their own, as they may reflect societal values, present intrinsic characteristics and reflect measured solutions in the environment where they occur. In the multilateral setting, where they turn from a development into an imperative, they necessitate a special regime. The TBT and SPS Agreements establish such a regime, as they were tailor-made to combat such barriers through alternative measures. Each of these measures has a unique impact and establishes various ways through which the heterogeneity of national regulations can be addressed, thus achieving approximation. However, this does not necessarily mean that these measures reflect regulatory cooperation as the latter is addressed in the present thesis. On the contrary, the core disciplines build upon GATT provisions. The chosen legal tools which are to be found under both Agreements are disciplines that prohibit discriminatory treatment and those that develop a rationality test. Using the TBT provisions as the first material to interpret their functioning, this section provides a grasp of the main orientation of these Agreements, which, in combination with the findings of the next section, upholds the turn to bilateralism.

2. Non-discrimination or something more?

Article 2.1 TBT requires that 'in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.' This provision combines so-called national treatment and most-favoured-nation treatment. The focus of Article 2.1 on non-discrimination provisions can be deduced from the wording of the Agreement, as it aims to address discriminatory behaviours that foreign products could face regarding the technical regulations that they would have to follow. This Article aims to extend the existing non-discriminatory provisions to cover measures that otherwise would not be caught by the GATT.[11] The Appellate Body (AB) has confirmed the GATT's reach on regulatory measures. In the US — Tuna II case,[12] Article 2.1 TBT was found to expand the anti-discriminatory provisions through a specialised legal regime that also applies to voluntary standards and conformity assessment procedures, concerning not only the products themselves but also their production and processing methods.[13] Similarly, SPS Article 2.3 adjusts both non-discrimination principles to the particularities of the SPS Agreement by requiring that SPS measures do not discriminate between areas that are characterised by similar or identical conditions.

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[11] This has been further recognized first in the EC — Asbestos case, where the AB concluded that 'the TBT Agreement imposes obligations that are different from and additional to, the obligations imposed on the Member States under GATT 1994' Appellate Body Report, WT/DS135/AB/R, *EC v Asbestos*, par. 80.

[12] The AB found that in contrast to the SPS Agreement, conformity under the TBT cannot exclude examination under the GATT, which can be found to have been violated. This finding of the AB on the relation between the two Agreements does not follow closely the rule of *lex specialis* principle. According to the latter, the specific rule (here the TBT rules) is considered first, and the general one (the GATT) second and only if this is necessary. The AB seems to suggest that while TBT rules come first, GATT rules must be also taken into consideration, also in the case of non-violation. See in this regard MARCEAU Gabrielle, *The New TBT Jurisprudence in US-Clove Cigarettes, WTO US- Tuna II, and US-Cool*, Asian Journal of WTO & International Health law and policy (2014).

[13] DU Michael Ming *Domestic Regulatory Autonomy under the TBT Agreement: From Non-discrimination to Harmonization*; Chinese Journal of International Law (2007), pp. 269–307, p. 279.

In general, non-discrimination provisions fall short of introducing regulatory cooperation. Their impact on normative approximation is, at best, through negative integration. To this point, AB's judicial reading of provision 2.1 TBT confirms that its focus remains purely non-discriminatory and does not acquire a different meaning within the TBT Agreement. As a general acknowledgement, the AB admitted in the US — Clove Cigarettes case that 'the TBT and GATT overlap in scope and objectives.'[14] Moreover, as this was the first case to necessitate the interpretation of the Article, it is worth mentioning that the AB held that relevant jurisprudence of the GATT was 'instructive.' Key concepts such as the 'likeness' of the products and the understanding of 'treatment no less favorable' borrowed their essence from the corresponding GATT concepts.[15] The judiciary's reliance upon previous jurisprudence on the neighbouring GATT provisions as a source for inspiration and argumentation is indicative of the similarity between the TBT's legal construction and the anatomy of GATT. Considering the AB' s emphasis on the structural similarities of the TBT and SPS, there is no reason to argue that SPS Article 3.2 is to be interpreted differently than TBT Article 2.1. It is no coincidence that these provisions find their roots in Article 2.1 of the Standards' Code, an agreement born into GATT's committees, which proved a decisive factor that maximised the influence of the latter on the former.[16]

2. Substantial control through rationality requirements?

Since regulatory diversity can be pertinent and unnecessary even if non-discriminatory, a first control of the substance of neutral regulatory measures is realised through the so-called rationality requirements. Found under both TBT Article 2.2 and SPS Article 2.2, these provisions introduce 'necessity tests' that aim to discipline domestic regulations by imposing a rationality requirement that serves as the thin line separating legitimate regulation and protectionism.[17] The rationality test is implemented by the use of certain values that function as benchmarks, against which the rationality of the measures is assessed during the development stage.

In TBT Article 2.2, the value of necessity as a benchmark is enshrined in the first limb of the provision, which states that technical regulations shall not 'be prepared, adopted or applied with a view or with the effect to unnecessarily restrict trade.'[18] The second limb has a double significance. On the one hand, it mitigates the effects of the first limb and provides a gloss of 'legitimacy.' A technical regulation is allowed to be trade-disrupting as long as it serves a legitimate objective but is not allowed to be more trade-restrictive than necessary. On the other hand, the second limb serves as a mechanism to determine which measures qualify as 'unnecessary': when a measure is more trade-restrictive than necessary to fulfil a

[14] Appellate Body Report, WT/DS406/AB/R, *United States — Measures Affecting the Production and Sale of Clove Cigarettes*, p. 91.

[15] As far as 'likeness' is concerned, the AB overruled the findings of the Panel that had argued for an understanding of 'likeness' based on the objectives and purposes of the regulations. In fact, it copied the concept of 'likeness' of products as found in jurisprudence of Article III:4 GATT, based on the nature and extent of the competitive relationship between the products. Moreover, the concept 'treatment no less favorable' was also given a similar meaning as in the GATT, encompassing both de facto and de jure no-less-favorable treatment. See VAN DEN BOSCHE Peter, ZDOUC Werner, *The Law and Policy of the WTO*, Cambridge University Press/2017.

[16] For a detailed background on the roots of Articles 2.1 and 2.2 see LESTER Simon, STEMBERG William, *The GATT Origins of TBT Agreement Articles 2.1 and 2.2.*, Journal of International Economic Law, pp. 215–232.

[17] Wolfgang Weiß, *WTO Law and Domestic Regulation* (forthcoming), Nomos Verlagsgesellschaft, Baden-Baden und Hart Publishing, Oxford, Chapter 4 , sub I.

[18] The same obligation extends to standards and conformity assessment procedures, on the basis of Annex 3.E and Article 5.1.2 of the TBT Agreement.

legitimate objective, it will be found to violate the first limb. With regard to the SPS Agreement, a similar need to weigh the necessity of an SPS measure against the corresponding objectives is found under SPS Article 2.2, which assesses measures' rationality not only on the basis of a necessity test but also upon scientific principles and evidence.[19] As far as the GATS is concerned, given the even more demanding impetus to rationalise regulation in the services area (see supra B.ii), a comparable rationality requirement can be extracted from the rudimentary GATS Article VI:5, read in conjunction with Article VI:4.[20] According to this joint reading, Member States shall apply licensing and qualification requirements and technical standards that nullify or impair already-undertaken commitments in a manner that, inter alia, is based on objective and transparent criteria and is not more burdensome than necessary to ensure the quality of the service.[21] Thus, Member States undertake the responsibility of applying certain objectivity principles, even if those apply only where restrictive regulation comes into play.

The input of these disciplines to the substance of domestic measures certainly extends beyond non-discrimination, but only to the point of imposing a rational, objective and appropriate criterion to the proposed regulation.[22] Such disciplines could be seen as a primitive form of positive integration because they set a common standard of rationality with which all future TBT and SPS measures must comply if the WTO Judiciary chooses to interpret the rationality criteria in a restrictive way.[23] However, despite any impact they may have by setting a requirement that regulations have to meet, these provisions cannot ultimately be seen as introducing regulatory cooperation in the form of approximation, as they only indirectly and marginally influence the substance of the regulations. Under these rules, regulations can remain divergent and rational at the same time.

B. Regulatory Cooperation with Limits

Despite the primary standing of the aforementioned principles, the WTO has sought to implement an approach that shies away from them and aims towards the substantial approximation of regulations through regulatory cooperation. In the TBT and SPS Agreements, this approach is implemented by the importance of international standards during the development of the regulations. In TBT Article 2.4 and SPS Article 3.1, it is demanded that the Member States depart from a common regulatory starting point—an international standard of relevance, appropriateness and efficiency—when designing their national regulations. In the GATS, approximation is mandated on the basis of Article VI:4 through the creation of common rules upon which certain regulations will be based. Both types of commitments can fall within the scope of regulatory cooperation activities, in particular those that aim for harmonisation.[24]

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19 See WEISS *supra* no 17, Chapter 4, sub. 2b.

20 DELIMATIS Panos, *Determining the Necessity of Domestic Regulations in Services*, EJIL (2008) pp. 365–408, p.390ff.

21 The Article spells out two additional requirements. The first limb includes a requirement on licensing procedures, that must not in themselves restrict the supply of services. The second limb requires that the manner by which Members choose to proceed must not come into contrast to the legitimate expectations created to other Members, Articles VI:4 and VI:5 of the GATS Agreement.

22 KRAJEWSKI Markus., *Recognition, standardisation and harmonisation: Which rules for GATS in times of crisis in* Panizzon, Pohl, Sauvé (eds), "GATS and the Regulation of International Trade in Services", Cambridge University Press (2008), pp 407–433, p. 415.

23 See WEISS *supra* no 19.

24 Harmonisation is not understood as an absolute and flat process. Harmonisation may as well occur partially or to a certain degree.

However, this process of regulatory approximation encounters certain limits that are decisive when it comes to the materialisation, implementation and impact of the provisions. Firstly, limitations can be established by the lack of implementation by the Member States themselves. GATS Article VI:4 provides an illustration of this, as the internal incapacity to reach a decision has impeded the provision's harmonising potential. The judicial understanding of provisions can be another equally important source of limitations. Based on the degree of deference that the judiciary wishes to give to the Member States, an interpretation can either restrict or expand the harmonising potential of a provision. In general, the issues that WTO addresses as a single undertaking are very often found to balance trade liberalisation and the protection of other values. Given their sensitive nature, this balance is both necessary and difficult to achieve. In the TBT Agreement, the balance is first spelt out at the sixth recital of the Agreement's preamble, which upholds the sovereign right to regulate for the protection of legitimate interests.[25] TBT's provision on international standards follows a certain pattern. On the one hand, Member States have a positive obligation to follow the content of their regulations and the conformity assessment procedures of international standards issued by relevant organisations,[26] which recognises international standards as vehicles for reconciling regulatory cultures and minimising unnecessary barriers to trade. On the other hand, the affirmation of Members' sovereign right to regulate as they see fit is expressed through the possibility of deviating from the obligation stated above when international standards do not correspond or correspond only partially to the objectives pursued. Similarly, the SPS Preamble begins by mentioning the balance at stake: it opens by reaffirming the national right to regulate but immediately places that right in the context of non-discrimination.[27] Both Agreements are affected by this inherent battle between the two competing values of sovereignty and harmonisation. However, some interpretative inconsistencies can be found. It is in the context of this inherent battle that the WTO judiciary interprets the provisions according to the degree of deference it wishes to grant to the Members. The greater the deference, the less potential there is for harmonising. This section will try to delineate the limits of the provisions that prescribe harmonisation through international standards, namely TBT Article 2.4 and SPS Article 3.1, through a judicial reading. However, the reading and the interpretation of the examined provisions by the AB (through the few decisions relevant to them) have provided neither a complete nor a consolidated view of how the competing values should be balanced.

1. The limits of TBT Article 2.4 and SPS Article 3.1

As mentioned, in the case of TBT Article 2.4 and SPS Article 3.1, the limits of the provisions depend on the judicial understanding of the articles' key concepts. The significant sections for assessing the balance at issue are already apparent from a first reading of the provisions. Before any assessment, it should be remembered that, since the provisions go beyond mere encouragement by using the word 'shall,' the Member States are expected to implement them according to a hard law obligation they have undertaken. The judicial understanding of the instrumental terms 'international standards' and 'basis' is crucial for the estimation of the Members' legal obligations. Moreover, the choice regarding the placement of the burden of proof is indicative of the emerging balance, as is the amplitude of the objectives that justify deviations from them. Indeed, which standards qualify as international and to what extent do Member States need to comply with them? How easily can a Member State

[25] 6th Recital of the Preamble of the TBT Agreement.
[26] In comparison to the SPS Agreement, the TBT Agreement does not provide with a list of the international organisations whose standards are to be followed.
[27] Recital 1 of the Preamble of the SPS Agreement.

deviate from its obligation? Is the burden of proof positioned for or against the regulating party?

Answers to these questions and an effort to locate the appropriate balance will be sought in the relevant case law of the provisions under consideration. While an illustration of the emerging balance between the regulatory margin of manoeuvre of the Members and the depth of the judiciary's assessment could be based on a standard of review of the regulatory measures, this is not an option for the Agreements at stake; according to the AB in EC — Hormones, a standard of review has only been chosen for the Anti-Dumping Agreement.[28] Moreover, a clear standard of review has not emerged through a systematic analysis of the jurisprudence either. On the contrary, a case-by-case assessment has been observed. Given the lack of a standard of review, it is by answering the questions posed above that the following section, based mostly on case law, will try to locate the interests and determine towards which interest the scale tends to lean.

The obligation to substantially base regulations on international standards

As far as the TBT Agreement is concerned, the EC — Sardines and US — Tuna cases are important to the answers to the first two questions posed above. On these occasions, when the AB was given a chance to initiate the interpretation of TBT Article 2.4, a pro-trade, liberalising interpretation was chosen. In the EC — Sardines case, Peru challenged an EU Regulation which delineated which species of sardines could be marketed as such in the European market. Peru's main argument relied on the inconsistency of the EU Regulation with a relevant and available international standard issued by the Codex Alimentarius Commission on sardine labelling.[29] In its assessment of the case, the AB discussed (among other topics) which standards qualify as 'international standards' and which are relevant to the Article. Having confirmed the Panel's view on the question of the 'relevance' of an international standard as being one that 'bears upon, relates to the matter in hand; is pertinent to,'[30] the AB rejected the argument raised by the European Communities that standards need to be adopted by consensus within international bodies in order to qualify under the terms of TBT Article 2.4. This conclusion has been characterised as unfortunate, as it creates a paradoxical dynamic between the WTO and international standardising organisations. With this decision, the WTO seems to grant a high legal value to non-consensual standards; this value is higher than that which the standardising bodies ascribe to their own decisions.[31] Put differently, the WTO upgraded international standards as values against which national choices are assessed, while completely disregarding their initial legal status and per se enforceability.[32]

The US — Tuna case continued the crystallisation of the term 'international standards' by shedding light on a different angle of the process of their creation: the environment within which they are adopted, namely, the international bodies that issue them. In the EC —

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[28] Appellate Body Report, WT/DS26/29 European Communities — Measures Concerning Meat and Meat Products (Hormones), par. 114.

[29] TREBILCOCK Michael J., *Advanced Introduction to International Trade Law*, Edward Elgar (2015) p. 160.

[30] The WTO Panel built upon the literal dictionary meaning of the word 'relevant.' See generally LUDIVINE Tamiotti, *Article 2 TBT in* Rudiger Wolfrum, Peter-Tobias Stoll, Anja Seibert-Fohr (eds) "WTO – Technical Barriers and SPS Measures" Max Planck Commentaries on World Trade Law, Martinus NIjhoff Publishers (2007).

[31] HORN Henrik, WEILER Joseph, *European Communities – Trade Description of Sardines: Textualism and its Discontent*, World Trade Review, (2005) pp. 248–275, p. 254.

[32] ZLEPTING Stephan, *Non Economic Objectives in WTO Law*, Martinus Nijhoff Publishers, (2010) p. 383.

Sardines case, the EC never questioned the capacity of Codex Alimentarius to set international standards as an international standard-setting body. This question arose in the US — Tuna case, where Mexico challenged a US measure that regulated the use of a private voluntary standard, 'dolphin-safe' labelling.[33] Mexico made claims against the measure on the basis of several TBT provisions, including Article 2.4. Specifically, Mexico argued that the measure was inconsistent with a relevant international standard issued by AIDCP, a regional intergovernmental regime for dolphin protection.[34] Altering the Panel's analysis on this argument, which accepted the existence of an international standard but denied its application on the basis of its inappropriateness for the legitimate objective that the United States was pursuing,[35] the AB rejected the Mexican argument in its totality by denying the presence of an international standard in this case. In assessing the definition of 'international standards,' the AB described the nature of relevant international standards by defining 'international standardising bodies.' It essentially developed two criteria that international standardising bodies should meet: openness and recognition. Regarding the criterion of openness, the AB insisted on the necessity of including only standards that come from international organisations that do not set criteria on future membership. Indeed, as the AB argued, membership should be automatic and not subject to time restrictions. It was on this ground that AIDCP was disqualified as an international standardisation body, since new memberships required an invitation, and this requirement was judged to be substantial and not merely formal. Regarding the criterion of recognition, the AB, having already reached its decision based on the openness criterion, did not proceed with a substantive examination. However, it provided some guidelines on what recognition under TBT could entail. In short, a standardisation body is recognised when its standardising action is acknowledged by the Member States through reference to them in their national regulatory actions.[36] The massive adoption of a body's standards is not necessary for it to be recognised, and even bodies with only one developed standard can be recognised,[37] provided that standardisation is recognised as part of their activity by the Member States.[38]

The double-limbed test for the determination of the international character of a standardising body seems to create a peculiar balance. While many bodies can be recognised for their standardising action given the width of the set criteria, which are fair but far from stringent, the openness criterion could pose serious obstacles to the acceptance of the international character of a body, and eventually to the inclusion of its work in the TBT Agreement. For example, several WTO Members, such as Hong Kong, are not recognised states, and thus, cannot participate in this capacity regarding standard-setting bodies.[39] Interestingly, it has been pointed out that this strict requirement is not jurisprudential, but instead a limitation that the Member States themselves posed in the text. Indeed, Annex provision 1.4 describes an international body as one 'whose membership is open to the relevant bodies of at least

[33] HOWSE Robert, LEVY Philip, *The TBT Panels: US-Cloves, US-Tuna, US-COOL*, World Trade Review, (2013), pp. 327–375 p. 332.
[34] Ibid.
[35] Ibid.
[36] See WIJKSTRÖM Erik, MCDANIELS Demin, 'International Standards And The WTO TBT Agreement: Improving Governance For Regulatory Alignment' available at: https://www.wto.org/english/res_e/reser_e/ersd201306_e.pdf, pp. 1–30, p.13.
[37] Appellate Body Report, United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products
WT/DS381/AB/R, par. 392–394.
[38] Ibid, par. 390.
[39] See MARCEAU supra no 12, p. 24.

all Members.'[40] Scholars have tried to mitigate the constraining effects of this provision. It has been argued that the requirement of openness only determines which standards have a binding effect, while all other standards that do not satisfy the openness requirement are encouraged to be taken under consideration by the Member States without benefiting from the beneficial presumption of TBT Article 2.5.[41] As it stands now, however, it cannot be denied that the interpretation given in combination with the Annex provision limits the application of Article 2.4, revealing the AB's cautious approach.

The qualification of a standard as international is a simpler task under the SPS Agreement. According to Annex A:3 of the Agreement, international standards, guidelines and recommendations are defined by explicit reference to three specific standardisation bodies. Although this enumeration is not exclusive, the identification and addition of other bodies belong to the SPS Committee, depriving the WTO Judiciary of enjoying a role in the selection process similar to that which it plays under the TBT Agreement. Nevertheless, it cannot go unnoticed that both Agreements set clear limits on what is considered an international standard. These limits should be regarded as reflecting a fair level of selectivity, but should not be interpreted as overly restrictive, so as to deprive the provision of its *effet utile*.

The width of the term 'international standards' is undoubtedly a crucial element for the depth of TBT Article 2.4. However, it is not exclusive. The final reach of Article 2.4 is to be viewed holistically after taking into consideration the extent of the Member States' obligation to consider international standards during their regulatory activities. Article 2.4 provides that Member States must use international standards or the relevant parts of them 'as a basis' for their technical regulations. The literature has approximated this requirement via a procedural and substantial alternative. Through the procedural lenses, international standards are the initial piece, the 'basis,' upon which national legislators are called to work. Horn and Weiler have mirrored this procedural approach to the Union's legislative concept, where the Union's legislators, the Council and the Parliament use the Commission's legislative proposal as a basis; in both cases, the final regulation may differ substantially from the original proposal, which *procedurally* served as a basis.[42] On the contrary, the substantial alternative would use the international standard as a yardstick for a post hoc conformity examination of the national measure.[43] The first, advocated by the Panel and later affirmed by the AB's textual interpretation based on dictionaries,[44] leans towards the substantial alternative.[45] The AB uses the phrases 'principal constituent,' 'fundamental principle,' 'main constituent,' and 'determining principle' to understand the term 'basis,' noting the necessity of a substantial relationship between the two notions that should not, in any case, be contradictory.[46]

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[40] Ibid.
[41] Ibid.
[42] See HORN and WEILER *supra* no 31, 256.
[43] Ibid.
[44] Horn and Weiler have criticised this textualistic interpretation by the jurisprudence of the WTO as an unfortunate choice aiming to legitimise their authority. See generally ibid.
[45] The probability of the substantive alternative is supported also by the fact that the TBT provisions apply to both previous and new measures. While a procedural approach could be adopted for new measures, existing measures could only be altered substantially. See ibid.
[46] Appellate Body Report, WT/DS231/AB/R European Communities – Trade Description of Sardines, par. 244–248.

While it is made clear that international standards must impact the substance of the regulation, the AB has not ruled on the desired degree of this impact nor on the extent to which international standards must be followed. After all, despite acquiring a strong and substantial significance, the requirement to 'use as a basis' does not amount to a conformity requirement. In the EC — Hormones (Canada) case, the AB reversed the Panel's finding and established a different meaning for the two requirements. It based its finding upon a dictionary citation and upon the use of the terms in different paragraphs in Article 3, a fact that revealed the differing significance of the two.[47] The AB passionately argued against a total harmonising effect of Article 3.1 by stating that such a scenario would turn international standards into legally binding norms, thus contradicting the initial intention of the parties.[48] In the end, 'to base' does not mean 'to conform,' but it also cannot exclude a close relationship between international standards and national regulations. It would be far-fetched to claim that the requirement 'to base' is equivalent to 'not contradict'; in the end, if this were the case, it would be reflected in the wording of the provision.

Requirements for deviation and burden of proof

Up until this point, the analysis has revealed a highly consistent approach towards the interpretation of the main points of both provisions under analysis. This does not hold true for the circumstances that allow deviation from the international standards in each case, nor for the corresponding burden of proof in cases of litigation. TBT Article 2.4's conditions allow a much more favourable environment. Deviating from TBT Article 2.4 is easier not only because it is not accompanied by extra obligations (as in the case of deviation in the SPS) but also because in cases of litigation the AB has created a procedurally favourable environment for the deviating party.

In general, the SPS Agreement's stance regarding the requirements for deviation from harmonising obligations and the burden of proof is more consistent and convincing than that of the TBT Agreement, although it is also stricter. According to the AB in the EC — Hormones case, Article 3 contains three independent cases, rather than cases with a rule–exception relationship as the Panel had argued.[49] Provision 3.1 comprises the obligation to harmonise 'on the basis of' international standards, while provision 3.2 grants a rebuttable presumption of necessity and conformity to measures that 'conform to' international standards. The third option is to be found under Article 3.3, which allows deviations from international standards provided that two conditions are met. First, it must be established after a scientific justification and risk assessment that the chosen measure grants a higher degree of protection than the international standards. Secondly, the international standards must not suffice in order to reach the desirable higher level of protection. In short, Member States can either use international standards as a basis, conform with them, or disregard them. However, the option to disregard international standards is conditioned by scientific justification and risk assessment, which is arguably a rather demanding task under Article 5 of the SPS Agreement. This requirement makes a possible deviation more complicated in the SPS than in the TBT, where Member States are allowed to deviate when international standards are proven ineffective or inappropriate, though this claim must be proved.

In the context of the SPS Agreement, the burden of proving the inconsistency of a measure to international standards rests, according to Article 3.3, with the complaining party. The

47 Appellate Body Report WT/DS26/AB/R, WT/DS28/AB/R, European Communities — Measures Concerning Meat and Meat Products (Hormones) par. 163, 164.

48 Ibid, par. 165.

49 See WT/DS26/AB/R, WT/DS28/AB/R, European Communities — Measures Concerning Meat and Meat Products (Hormones) supra no 47, par. 169ff.

burden of proof is distributed in this way because, as mentioned above, the three provisions are not connected with a rule–exception relationship. According to the AB, Article 3.1 is not the rule, and hence Article 3.3 is not its exception.[50] All three provisions, 3.1, 3.2. and 3.3, are self-standing and disconnected from the others, as each covers a different situation. Thus, the burden of proof rests with the party invoking the violation of Article 3.3, and not with the party that has made use of it.

However, things are more complicated when allocating the burden of proof in the second recital of TBT Article 2.4. Article 2.4 is a complex construction that combines in the same provision both the obligation to base national TBT regulations on international standards and the conditions under which a deviation is allowed. Accordingly, there is a corresponding burden of proof for these two situations, which was addressed in the EC — Sardines case. Beginning with the obligation to use international regulations as a basis, it is the complaining party that has to prove the inconsistency of a national regulation with the relevant international standard, just like in the SPS Agreement. This is procedurally sound since standard procedural theory holds that it is the complaining party that has to prove the truth of its allegations. Surprisingly though, the AB also ruled that the complaining party not only had to prove the disregard of the international standard but also to prove its appropriateness and effectiveness for the public policy concern that the regulating party wishes to address. Thus, the ruling certainly favoured the Member State against which proceedings are running, since after having proven the inconsistency of the measure with international standards, the complaining party also needs to provide reasons supporting the correspondence of the international standard to the legitimate objectives that the other state tries to pursue. This mirrors the burden of the defending party to demonstrate the inappropriate fit of the international standard for its legitimate objectives, as found by the WTO Panel. It is the other side of the same argument, and this is the point that achieves the balance.

One of the considerations that guided the AB's decision in this direction was that, as in the EC — Hormones case where the rule–exception question arose in the SPS framework (see above), we are not in the presence of a rule–exception relationship, which would indeed reverse the burden of proof to the EU. In particular, it argued that the obligation to use international standards and the margin of manoeuvre to disobey as expressed in the last sentence do not have a rule–exception relationship but rather that 'the circumstances envisaged in the second part of Article 2.4 are excluded from the scope of application of the first part of Article 2.4.'[51] The AB further justified its opinion by recalling the existence of transparency provisions within the TBT, namely the obligation to justify national choices under Article 2.5 and the requirement of Article 10.1 to set up 'enquiry points' that would facilitate the exchange of information.[52] According to the Panel's view, these provisions enable the complaining party to acquire information on the legitimate reasons behind a certain regulation and actually argue for the suitability of an international standard against them. The AB rested upon the facilitating character of these provisions, taking as a fact that, according to the principle *pacta sunt servanda* and the Members' States good faith, one should depart from the point that Member States will actually abide by their international obligations.[53]

[50] See WT/DS26/AB/R, WT/DS28/AB/R, European Communities — Measures Concerning Meat and Meat Products (Hormones) par. 172.
[51] Ibid, par. 276.
[52] Appellate Body Report, WT/DS231/AB/R European Communities – Trade Description of Sardines, par. 277–280.
[53] Ibid, 278.

The reasoning of the AB seems partially unpersuasive, and, in my view, the AB cleverly escaped basic procedural principles through the creation of legal fictions. Regarding the first argument, the AB contended that the first and second parts of TBT Article 2.4 do not have a rule–exception relationship, but instead 'the circumstances envisaged in the second part of Article 2.4 are excluded from the scope of application of the first part of Article 2.4.' Following the WTO Judiciary's favoured practice, I rely on a dictionary definition for the purposes of the following argument. The Cambridge Dictionary defines 'exception' as 'someone or something that is not included in a rule, group, or list or that does not behave in the expected way.'[54] If the second part is *excluded* from the scope of application of the first, does this not mean that it is supposed not to 'behave' or to 'fit' in a particular way? Is this not a clear exception? Apart from that, the reasoning of the AB contrasts with its ruling in the EC — Hormones case. There, in order to exclude any kind of relation between SPS Articles 3.1 and 3.2, the AB raised the argument that they constituted different provisions, implying that if they were to be somehow connected, they would be positioned in the same paragraph. This is exactly the case of Article 2.4, where requirement and deviation are united under the same provision, which the AB completely disregards. If this is not a rule–exception relationship, why is it included in the same Article, the second part being the continuation of the first? If this were the intention of the parties (a principle that the AB clearly ignored), it should be positioned in a different Article.

Regarding the second argument, the reasoning of the AB is sound and rightly builds upon fundamental international law principles such as *pacta sunt servanda*. However, it is also safe to argue that, despite the transparency provisions, the complaining party might not always possess the necessary information about the background that led to a particular regulation. Indeed, according to the EU Report of 2012, many countries are not diligent with their obligations, in the sense that they either report their regulations at an advanced stage or they avoid answering the questions posed to them by other Members.[55] Lastly, let us not pretend that the regulating Member State can handle the available information in such a way so as to conceal a protectionist measure under a legitimate objective.

Behind this flawed argumentation stands the AB's effort to grant more deference to Members States' choices and provide them with legal advantages that aim to secure part of their regulatory sovereignty and freedom, at least as far as Article 2.4 is concerned. The same could be argued for all the interpretative points towards which the AB chose to take a more restrictive stance. However, the inconsistencies that are to be found between the SPS and TBT Agreements are quite remarkable, not only because of the similarity of their provisions on harmonisation but also because of the difference between the level of deference that each Agreement supports. Apart from the term 'international standards,' which is to be understood differently in each Agreement, their substantial importance as standards to be used 'as a basis for' remains the same for both Agreements and widens their potential. However, the exigencies for deviation and the litigation terms are decisive regarding the divergence of the two Agreements. While stringent conditions must be met for deviation under the SPS Agreement, the TBT Agreement loses in efficacy mainly because of the unfortunate verdict over the burden of proof. The latter is a clear illustration

54 https://dictionary.cambridge.org/dictionary/english/exception.

55 PREVOST Denise, *Transparency obligations under the TBT Agreement in* EPPS Tracey and TREBILCOCK Michael J. (eds) "Research Handbook on the WTO and Technical Barriers to Trade" Edward Elgar, 2013, p. 160.

of support for Members' States regulatory sovereignty, which is a welcome approach that nevertheless should be built upon sound argumentation.

2. Services: Multilateral regulatory cooperation in the making or in the waiting?

In contrast to agreements on goods, GATS's promises regarding regulatory cooperation have been more far-reaching, mainly due to the saliency of regulatory barriers to services. Indeed, regulatory intensity and complexity are inherent to the nature of services. This is not only due to the plurality of objectives that may be sought through regulation but also due to services' peculiar nature. To begin with the latter, services' multimodality makes them susceptible to over-regulation. The very concept of trade in services consists of four different modes of supply, according to GATS Article I:2. Hence, the number of measures that could potentially affect them and prove trade-disturbing is multiplied by four. Moreover, certain modes of supply, Mode 3 on commercial presence and Mode 4 on the movement of natural persons, have proven to be easier targets for protectionist regulations. Such regulations may, for example, impose restrictions on structural elements, such as capital for commercial supply and people for the movement of natural persons.[56] Apart from the over-regulation that follows service provision's anatomy, service provision comes hand in hand with a growing amount of regulatory intervention that is necessary in order to safeguard the controlled, risk-free and efficient provision of the services concerned.[57] Given the inapplicability of border measures to their cross-border trade in services, protectionism in services is rooted in national regulations that sooner or later, to a greater or lesser extent, are susceptible to have an unjustified diverting effect. This holds true especially for discriminatory measures, which are properly controlled under the non-discrimination GATS provisions.[58]

However, a different solution had to be found for non-discriminatory regulations that have been found to be equally trade-disturbing.[59] Here is where regulatory cooperation comes into play. Member States felt the need to negotiate a provision that would positively control non-discriminatory trade-impeding regulations that were not justified on public policy grounds.[60] However, the Uruguay Round failed to provide an agreement on the substance of such a provision. Thus, the issue was left upon Article VI:4, a provision that falls under Article VI on domestic regulation. Article VI:4 therefore provides a mandate to create disciplines on the matter. Such disciplines should tackle non-discriminatory provisions by ensuring that measures addressing the quality and safety of service provision-qualification requirements and procedures, licensing requirements and procedures and technical standards do not constitute unnecessary barriers to trade. In the absence of the successful negotiation of such disciplines, the rather rudimentary and limited (applicable only where commitments are made, rather than horizontally like GATS Article VI:4) provision of Article VI:5 (analysed above) addresses the issue. As such, Article VI:4 constitutes the first

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56 DELIMATSIS Panagiotis, *Due Process and 'Good Regulation Embedded in the GATS—Disciplining Regulatory Behaviour in Services Through Article VI of the GATS*, Journal of International Economic Law, pp. 13–50 , p. 16.

57 Ibid.

58 KRAJEWSKI Markus, *Services Trade Liberalisation and Regulation: New Developments and Old Problems in* HERRMANN Christoph., TERHECHTE Jorg Phillip. (eds) *European Yearbook of International Economic Law 2010*, Springer (2010), p. 162.

59 For a holistic analysis see TANS Simon, *Service Provision and Migration: EU and WTO Service Trade Liberalization and Their Impact on Dutch and UK Immigration Rules*, Brill Publications (2017), pp. 24–138.

60 DELIMATSIS Panagiotis, *Concluding the WTO Services Negotiations on Domestic Regulation- Walk Unafraid* , TILEC Discussion Paper Series, (2009), p. 3.

provision that introduces 'segments of positive integration' by setting minimum standards that these types of regulations must meet.[61]

The mandate of Provision VI:4 led to the first Working Party on Professional Qualifications, which indeed developed disciplines specific to the accountancy sector. Currently, negotiations on the basis of the mandate are ongoing in relation to horizontally applicable disciplines addressing regulations on qualification requirements and procedures, licensing requirements and procedures and technical standards. Their potential should not be underestimated. It has been argued that they could create a stepping stone for the conclusion of MRAs through the ongoing approximation of regulations on the basis of the mandates of those disciplines.[62] Be that as it may, one should also admit that negotiations have been ongoing for almost a decade, which indeed leads to the conclusion that so far, multilateral regulatory cooperation in services is not in the making, but rather in the waiting.

III. Inclusion in an FTA Structure as the Second Characteristic of Regulatory Cooperation

The positioning of regulatory cooperation within a free trade agreement is discussed in this section as the second characteristic of regulatory cooperation. It is primarily considered as such because regulatory cooperation was seen until recently as a political matter and was addressed outside a strictly legal environment through political agreements and declarations. Indeed, the establishment of regulatory cooperation conflicts with past negotiation choices and commitments, and, on a first level, one could see a better match between those less rigid forms and complex regulatory dialogues that require some flexibility by nature. The following section will provide an overview of these existing accounts and highlight their weaknesses. It will conclude by discussing the possible added value of FTAs as a new venue that now hosts regulatory cooperation activities.

A. Transatlantic Regulatory Cooperation in the EU Absent an FTA

The European Union has made various efforts to begin a regulatory dialogue, in particular in the transatlantic realm. The most comprehensive case study of regulatory cooperation initiatives of the EU is the EU–US relationship. Indeed, regulatory cooperation between the EU and the United States not only dates back to the Transatlantic Declaration of the 1990s but also demonstrates a wide range of regulatory cooperation activities ranging from low profile to highly coordinated. It is exactly the plurality of the initiatives and the various successes and failures that accompany them that offers a valuable background from which one can extract several arguments about the effectiveness of the regulatory cooperation policy of the EU.

Regulatory cooperation in the context of EU–US relations bloomed after the end of the Cold War, which marked the beginning of a new era of economic collaboration between the two superpowers. Inspired by the determination of the Bush administration to keep a close eye on the transformation of European integration, transatlantic relations, which until then had

[61] Ibid, p. 4.
[62] See DELIMATSIS supra no 58, p. 36.

been limited to security matters, expanded their horizon to trade issues.[63] Since then, transatlantic economic relations have been shaped by the two political declarations of utmost importance for the design of transatlantic economic relations: the Transatlantic Declaration and the New Transatlantic Agenda.

Ever since these developments, regulatory cooperation has been a necessary tool of economic integration and was highlighted as a priority of political negotiations, which later materialised as parts of the various Summits. The commitment and belief that regulatory cooperation was the answer to the then-emerging non-regulatory tariff barriers are apparent from the positioning and the vocabulary chosen at the various transatlantic declarations. Since then, it has been treated as the central subject matter of many initiatives. It has been the central idea of separate agreements as well as the subject of various dialogue mechanisms, examined both horizontally and with regard to specific sectors. Regulatory cooperation was of such importance that it constituted the central figure of the Transatlantic Economic Partnership (TEP), the agreement that actually shaped transatlantic economic relations. Being part of a compromise, TEP's significance for transatlantic economic relations was enormous, as it carried the weight of the failure to reach an agreement on an FTA.[64] Moreover, its concentration on the abolition of non-regulatory barriers to trade is revealing for the importance of regulatory cooperation at the time. All subsequent regulatory activities were carried out mainly within the framework of TEP.

The initial step to establish a sustained horizontal dialogue began with the introduction of the Early Warning Mechanism, aimed to avoid the transatlantic adventure over the dispute of hush kits.[65] The subsequent Guidelines on Regulatory Cooperation and Transparency gave a clearer direction to the regulatory authorities by holistically describing the spirit and methodology of horizontal cooperation that regulators are asked to undertake.[66] The establishment of the High-Level Regulatory Cooperation Forum was a more coordinated effort to consolidate existing sectoral and horizontal dialogues. Last but not least, the last effort to revitalise dialogue was the Transatlantic Economic Council, which was built upon past mistakes and provided high-level political oversight, bringing hidden actors such as legislators and stakeholders together.[67] Sector-specific dialogues were established and enhanced mainly under the Roadmaps of 2004 and 2005.[68]

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63 PETERSON John, *Get Away from Me Closer, You're Near Me Too Far: Europe and America after the Uruguay Round in* POLLACK Mark A. and SCHAFFER Gregory C. (eds) "Transatlantic Governance in the Global Economy", Rowman & Littlefield Publisher (2001) pp. 45–73, p. 54.

64 See PETERSON supra no 65, 53.

65 STEFFENSON Rebecca, *Managing EU–US relations: Actors, institutions and the new transatlantic agenda*, Manchester University Press (2005) p. 61.

66 *Guidelines on Regulatory Cooperation and Transparency*, <https://ustr.gov/archive/assets/World_Regions/Europe_Middle_East/Transatlantic_Dialogue/asset_upload_file350_5680.pdf>.

67 TAKACS Tamara *Transatlantic Regulatory Cooperation in Trade in* Elaine Fahey, Deirdre Curtin (eds) "A Transatlantic Community of Law: Legal Perspectives on the Relationship between the EU and US Legal Orders", Cambridge University Press (2014) pp.158-185, p. 177.

68 *Section I: Specific Sectoral Cooperation, 2004 Roadmap for EU–US Regualtory Cooperation and Transparency*, <https://ustr.gov/archive/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/2005_Roadmap_for_EU-US_Regulatory_Cooperation_Transparency.html>.

B. Breaking the Myth: The Need for Tighter Institutionalisation through inclusion in an FTA

Especially today, scholars that conduct research in the various EU external relations to describe the intensification of the actions through the creation of entities use the term 'institutionalisation.' In the area of trade, with the rise of the 'living' FTAs that the EU is currently signing with its trade partners, this term has been used to signify the sudden appearance and proliferation of institutions that accompany and frame the actions included therein.[69] Especially in the realm of regulatory cooperation, the arguments about the 'institutionalisation' of regulatory cooperation through the FTAs have been opposed to the failures of previous transatlantic efforts.[70] In essence, it is argued that the 'added value' of FTAs is their contribution to better institutionalisation of regulatory cooperation. However, many cases fail to provide a description of the term, their understanding of institutionalisation, and how it fits into their claims about the institutionalisation of regulatory cooperation. This is partially due to the term's recent appearance in the particular field of EU External Relations, even though it is methodologically incorrect.

This section counters those arguments and tries to depict the institutionalisation of regulatory cooperation even before its inclusion in an FTA. It begins with an analysis of the term 'institutionalisation' in the literature and goes on to present and justify the chosen understanding of the term. Then, the various understandings of institutionalisation are applied to the previous transatlantic developments in order to make the argument that FTAs do not contribute to tighter institutionalisation, but to something different.

1. On the nature of institutionalisation in European integration and beyond

Recently, academics have generally tried to capture the essence of the notion of institutionalisation beyond the nation.[71] Institutionalisation is indeed a curious term, analysed previously in contexts other than EU External Relations. However, it is exactly because of this lack of common understanding of the notion that this new strand of literature tries to develop an individual framework, and it still finds inspiration in concepts of institutionalisation used in other instances. Institutionalisation beyond the nation-state is understood as a sign of the times, an 'antidote to concerns about the delegation of authority beyond the Nation State,' a factor that establishes a certain practice and legitimises it.[72] This is also how institutionalisation has been described within the nation-state, as the process by which a practice gains general acceptance. Similarly, institutionalisation in the EU context is seen as the result of the consolidation of procedures and structures that are difficult to

[69] See generally STEGER Debra P., *Institutions for Regulatory Cooperation in 'New Generation' Economic and Trade Agreements*", Legal Issues of Economic Integration, (2011), pp. 109–126.

[70] FAHEY Elaine, *Introduction: Institutionalization beyond the Nation State: New Paradigms? Transatlantic Relations: Data, Privacy and Trade Law in* Elaine Fahey (eds) "Institutionalization beyond the Nation State", Springer International Publishing (2018) pp. 1–27, p.8ff

[71] See generally FAHEY Elaine (eds) *Institutinoalization beyond the Nation State*, Springer International Publishing (2018).

[72] ZUERN Michael, *Opening up Europe: next steps in politicization research*, West European Politics, (2016), p. 164-182, p. 164.

change.[73] However, according to Fahey, institutionalisation beyond the nation-state better describes the process of intense cooperation and interaction than its outcome.[74]

After only a short introduction, the academic debate around the concept of institutionalisation creates more questions than answers. The approach chosen for the purposes of this argument, which abstains from both conflicting branches of the literature, disconnects institutionalisation from the process vs result debate of institution building. Instead, it understands it as a term that depicts 'the degree to which institutional rules govern more the actions of the actors,' in other words, 'the degree to which state behaviour, in a particular area of cooperation, falls within the scope of particular rules.'[75] The focus here is not whether institutionalisation happens during the development or with the creation of an institution. Institution building, either as a process or a result, does not have any inherent significance. What matters here is the range of activities covered by those institutional rules.[76] The richer the range, the greater the institutionalisation of this particular area of cooperation. This approach not only helps to escape the process vs result dilemma but also serves to precisely identify the missing element, which is not institutionalisation.

2. Was Transatlantic regulatory cooperation institutionalised?

Institutionalisation, however it is understood, was not absent from the Transatlantic paradigm of regulatory cooperation. Let us begin from the ending. The institutionalisation of regulatory cooperation, understood as rule coverage under the theory of Belanger and Fontaine-Skronksi, cannot be disputed. The various initiatives described above ranged from horizontal to sectoral, comprised diverse rules and engaged many actors, thus covering a wide range of regulatory cooperation activities. For example, the Regulatory Cooperation Guidelines were as comprehensive as contemporary FTA chapters with respect to content, while the Mutual Recognition Agreements were the fruit of sectoral cooperation. In the context of the Guidelines, the High-Level Regulatory Cooperation Forum eventually proceeded to a joint examination and comparison of their impact assessment procedures.[77] As far as sector-specific dialogue is concerned, its highlight remains the Mutual Recognition Agreement, which concerned mutual recognition of the conformity assessment procedures over several sectors: telecommunications and ICT equipment, sport boats and medical devices, pharmaceuticals, electronics and electromagnetic compatibility.[78] As they have produced actual, if limited, results, it is difficult to argue that regulatory cooperation activities were not regulated. They were indeed regulated, but not under strict legal terms.

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[73] PETROV Petar, *Early Institutionalisation of the ESDP Governance Arrangements: Insights From the Operations Concordia and Artemis in:* VANHOONACKER Sophie, HYLKE Dijkstra and MAURER Heidi (eds). *Understanding the Role of Bureaucracy in the European Security and Defence Policy*, (2010) European Integration online Papers (EIoP), (2010) available at: http://eiop.or.at/eiop/texte/2010-008a_htm, pp. 1-33. p. 3.

[74] See FAHEY *supra* no 72, 4.

[75] BELANGER Louis, SKRONSKI Kim Fontaine, *Legalization in International Relations: A conceptual analysis*, Social Science Information (2012) pp.238–262, p. 240.

[76] Ibid.

[77] MEUWESE Anne, *EU–US horizontal regulatory cooperation: Mutual recognition of impact assessment? In* VOGEL David, SWINNEN Johan F.M "Transatlantic Regulatory Cooperation: The Shifting Roles of the EU, the US and California" Edward Elgar (2011).

[78] SCHAFFER Gregory, *Managing US–EU Trade Relations through Mutual Recognition and Safe Harbor Agreements: 'New' and 'Global' Approaches to Transatlantic Economic Governance? in* PETERSMANN Ernst-Ulrich and POLLACK Mark A. (eds) "Transatlantic Economic Disputes: The EU, the US and the WTO" Oxford University Press (2003), p. 303.

Secondly, turning to the literature debate on the process vs result of institution building, one will observe the development and appearance of institutional structures through consecutive agreements. Indeed, the functioning of initiatives such as the Early Warning Mechanism, the High-Level Regulatory Forum or the Transatlantic Economic Council came along with institutional development and establishment, despite being disregarded during the formation of two major regulatory acts, the REACH Directive by the EU and the Sarbanes–Oxley Act by the United States.[79]

In both cases, institutionalisation could not produce adequate results, and neither rule coverage nor weak institutions are to blame. On the contrary, both adequate rule coverage and institutional structures were unable to perform due to their legally weak method of regulation. The latter can be confirmed by existing literature, which has associated these shortcomings with a variety of reasons deeply rooted in the lack of legal bindingness and its implications. Indeed, the lack of legal bindingness lies at the root of the problem, as it causes inconsistency between several mandates, provides no base for additional funding and places no substantial pressure on regulators. Regarding the inconsistency of mandates, regulatory cooperation is a task largely left to regulators. They are required to reconcile their main internal regulatory tasks, as these are mandated by both their own constitutional framework and cooperation with foreign counterparts, mandated by executive agreements.[80] These two tasks may be contradictory in nature, and regulators, when called to choose between the fulfilment of their constitutional mandate and cooperation with foreign counterparts, will choose to comply with the internal requirements. Furthermore, the lack of a formal mandate means that the internal regulatory environment may not always be structurally ready to accommodate regulatory cooperation. Regulators may not be accustomed to considering trade interests during the development of regulatory acts due to the very structure of the regulatory system, which may not provide them with this possibility. This is the case in the United States, which, unlike the EU regulatory system, is not accustomed to reconciling regulatory objectives with an internal market.[81] Regulatory action in the US is divided between various agencies that follow strict mandates and are quite isolated from trade matters.[82] Furthermore, regulators usually have no further funding for the accomplishment of regulatory cooperation and are called to cover potential costs from their existing funds, which of course are dedicated for internal purposes.[83] Last but not least, apart from these institutional problems, the lack of legal bindingness can also stand behind certain *attitudes*. The lack of coordination for the development of the European REACH directive and the Sarbanes–Oxley Act in the United States despite existing available cooperation mechanisms is indicative of the attitude of regulators towards regulatory dialogue. In the end, the soft law nature of the experiment could not provide enough reasons for regulators to cooperate, despite political willingness at the higher levels to activate and advance a regulatory dialogue.

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79 Ibid.

80 PAUL Joel R., *Implementing regulatory cooperation through executive agreements and the problem of democratic accountability* in BERMANN George A., HERDEGEN Matthias, and LINDSETH Peter L. (eds) *Transatlantic Regulatory Cooperation: Legal Problems and Political Prospects*, Oxford University Press (2001).

81 See SCHAFFER *supra* no 80, 309.

82 Ibid.

83 JENSEN Kim, *International Trade and Negotiations in Global Value Chains* (2017) Conference Report, Centre for International Governance Innovation, available at: https://www.cigionline.org/sites/default/files/documents/2017_Washingtonweb.pdf.

C. Stronger legalisation through inclusion in an FTA?

From the conceptualisation of impediments to the successful operation of regulatory cooperation until today, the inadequate degree of legal obligation is of fundamental importance. As noted above, this feature does not substantially coincide with the concept of institutionalisation, even though it has been associated in the literature.[84] Interestingly, legal bindingness has been used as one of the measurement units that build the concept of 'legalisation.'[85] Legalisation is a conceptual tool developed by international relations scholars. The concept of legalisation is associated with but not equivalent to institutionalisation. Legalisation is, according to its creators, a particular form of institutionalisation that is characterised by three components: obligation, precision and delegation.[86] According to this construction, the element of obligation measures how binding the undertaken commitments are, precision refers to how precise the rules are, and delegation describes whether a third party has a delegated authority. This authority can relate to issues of interpretation implementation, monitoring and dispute settlement, inter alia.[87] Legalisation, as composed by these three components, is an empirically developed concept, inspired by characteristics to be found in institutions.[88] More specifically, it examines the degree to which these components are to be found in each institutional structure. The legalisation of institutions can take several forms and can range in every point of a scale from low to high; its form and intensity depend on the combination of the degrees that the various components may themselves take.[89]

Based on this concept, and taking into account the lack of legal bindingness that characterised the previous efforts on regulatory cooperation, the question to be explored is to what extent the inclusion of regulatory cooperation in an FTA strengthens its legalisation. In other words, the question to be answered is to what extent the legal obligation is harder under a Free Trade Agreement. This includes not only the 'obligation' part, which measures the legal bindingness of the commitments. The next chapter embarks on an extensive analysis of the legalisation of regulatory cooperation through FTAs.

Apart from the theoretical question of the legalisation of regulatory cooperation, it is worth mentioning that practice has associated the presence of an FTA and the achieved results of regulatory cooperation activities. In other words, there seems to exist an empirical connection between the existence of an FTA and the advancement of regulatory cooperation activities, the latter taking place either within or outside the FTA structures. These preliminary assumptions can be extracted from regulatory cooperation efforts beyond the EU, where regulatory cooperation activities were supported by an FTA structure. Australia and New Zealand provide a brilliant example of regulatory cooperation based on an FTA, built within the Australia–New Zealand Closer Economic Relations Trade Agreement. With its final goal being the establishment of a single market, this FTA approached regulatory cooperation via joint accreditation based on international standards, harmonisation, various MRAs and the creation of a joint regulator, the Australia–New Zealand Food Authority.[90]

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84 See FAHEY *supra* no 72, p. 8.

85 ABOTT Kenneth W., KEOHANE Robert O., MORAVCSIK Andrew, SLAUGHTER Anne-Marie, SNIDAL Duncan, *The concept of Legalization*, International Organization, (2000), pp. 401–419.

86 GOLDSTEIN Judith, KAHLER Miles, KEOHANE Robert O., SLAUGHTER Anne-Marie, *Introduction: Legalization and World Politics*, International Organization (2000), pp. 385–399, p. 396.

87 See generally ABOTT, KEOHANE, MORAVCSIK, SLAUGHTER, SNIDAL *supra* no 87.

88 Ibid, p. 403.

89 See GOLDSTEIN, KAHLER, KEOHANE, SLAUGHTER *supra* no 88, p. 388.

90 The joint regulatory authority was the result of the 1995 Agreement on Establishing a System for Development of Joint Food Standards. This Agreement finally led the adoption of a joint Australia–New Zealand Food Standards Code in 1999. See STEGER, supra no 71, p. 115.

The second example, although slightly more complicated, is NAFTA. Regulatory cooperation between the NAFTA partners, although initiated by the FTA, was only advanced later. The NAFTA saga begins with the inability of NAFTA's light institutional structures to produce any results. The trilateral Committee on Standard Related Measures and the working groups of which it was comprised established under the Free Trade Agreement did not advance regulatory cooperation due to a lack of political oversight.[91] The Security and Prosperity Partnership (SPP) managed to incorporate, to a certain extent, the kind of cooperation envisaged in NAFTA.[92] In a way, it completed the latter agreement. For this reason, the subject was treated once more under the SPP, an executive-type cooperation, with greater success.[93] Later, in order to build on the ongoing success, the parties established an even tighter form of bilateral cooperation: the US–Canada Regulatory Cooperation Council, which also implicated the direct participation of regulatory agencies.

Both cases demonstrated better achievements than the EU regarding regulatory cooperation sooner or later. In both cases, regulatory cooperation was based on a firm background: a legal instrument that regulated solid trade relations. It is not actually a coincidence that in the realm of NAFTA, the SPP produced far better results for regulatory cooperation than for security, which was not supported by a previous legal instrument.[94] Hence, should regulatory cooperation operate more efficiently under an FTA structure, its inclusion in EU FTAs is heading in the right direction. However, as mentioned, the question of the degree of legalisation that regulatory cooperation enjoys in its new clothes is a more complicated one, and many other factors need to be taken into consideration.

IV. Conclusion

Several factors have led to the inclusion of regulatory cooperation in FTAs. The multilateral setting had legal commitments of low cooperation depth that concentrated mainly on non-discrimination (TBT Article 2.1 and SPS Article 2.3) and rationality requirements (TBT Article 2.2 and SPS Article 2.2). These were inadequate to trigger a substantial regulatory dialogue. Apart from that, other efforts made mainly on the bilateral political arena were condemned to failure, exactly because of their legal weaknesses. To cure both weaknesses, the coordination of regulatory cooperation activities under the premises of an FTA certainly marks the beginning of a different era for their materialisation, mainly through its contribution to the 'legalisation' of regulatory cooperation. Should this assumption be confirmed, regulatory cooperation will meet the success that other examples outside the EU have already achieved.

91 Ibid, p. 112.
92 BÉLANGER Louis, *Governing the North American Free Trade Area: International Rule Making and Delegation in NAFTA, the SPP and Beyond* Latin American Policy, pp. 22–51, p. 31.
93 Ibid.
94 BÉLANGER Louis, *Le régionalisme "soft" en Amérique du Nord: le cas du Partenariat pour la sécurité et la prospérité, in* LACROIX Jean-Michel et MACE Gordon (eds), "Politique étrangère comparée Canada/États-Unis" Peter Lang, (2012), pp. 145–159, p. 157.

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