The Transformation of Regulatory Cooperation Through Its Inclusion in Free Trade Agreements: What Is Its Added Value?

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ABSTRACT: The nature of trade relations in the EU is changing. Free trade agreements (FTAs) are expanding their utility, turning into governance mechanisms of the EU armoury instead of pure trade-relation regulators. This transformative capacity primarily stems from the inclusion of commitments in FTAs that go beyond pure economic governance, such as the chapters on regulatory cooperation. Although regulatory cooperation does not constitute a new trend in EU trade, under the present state, it represents an original shift. Indeed, the placement of regulatory cooperation within a legally binding treaty is at odds with the past choices of negotiation and commitment. This Article addresses this dichotomy. By analysing the inclusion of regulatory cooperation in a legally binding treaty, the Author seeks to understand its contribution to the implementation of these commitments, drawing arguments from the past and present, intra and extra EU experiences.


I. Introduction

The nature of trade relations in the EU is changing. Free trade agreements (FTAs) are expanding their utility, turning into governance mechanisms of the EU armoury instead

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of pure trade-relation regulators. This transformative capacity primarily stems from the inclusion of commitments in FTAs that go beyond economic governance, such as the chapters on regulatory cooperation. Although regulatory cooperation does not constitute a new trend in EU trade, under the present state, it represents an original shift. The positioning of regulatory cooperation within an FTA is an element of such importance that it could be considered a characteristic of this re-established regulatory cooperation because it defines and places it on a different playing field than before. This is primarily because, until recently, regulatory cooperation has been considered a matter of low politics\(^1\) and has been attempted outside a strictly legal environment based on political agreements and declarations. The placement of regulatory cooperation within a legally binding treaty is at odds with the past choices of negotiation and commitment. On the first level, one could see a better match between the less rigid forms and complex regulatory dialogues that require some flexibility.

This Article addresses this dichotomy. By analysing the inclusion of regulatory cooperation in a legally binding treaty, the Author seeks to understand its contribution to the implementation of these commitments, drawing arguments from the past and present, intra and extra EU experiences. In Section II, the Article provides an overview of the highlights of previous activities on regulatory cooperation outside an FTA. The analysis begins with the past, reaching the present status of regulatory cooperation activities through their inclusion in an FTA in Section III, which examines the compatibility of the two, essentially by asking whether an FTA structure can properly accommodate such activities, fulfilling their trade liberalising effect, while also adjusting to the imperatives of regulation, as the latter are mandated by contemporary trade structures. Having set the background by taking the previous two Sections as a basis, the rest of the Article locates where the added value of the inclusion lies, relying on the concepts of institutionalisation and legalisation for this exercise. Section IV goes against arguments of institutionalisation based on the plethora of activities mentioned in Section II. Section V proposes that the added value of the inclusion lies in the concept of legalisation. Finally, Section VI concludes the work.

II. Transatlantic regulatory cooperation outside an FTA structure

Before including it in an FTA structure, the EU made various efforts to begin a regulatory dialogue, in particular in the transatlantic realm. For a holistic regulatory cooperation initiative of the EU, the most comprehensive case study to examine would be the EU–US regulatory cooperation. Transatlantic regulatory cooperation between the EU and the US serves as a good case study because it not only illustrates three decades of history

dating back to the Transatlantic Declaration of the 1990s, it also provides a comprehensive overview of regulatory cooperation activities along a continuum, ranging from low profile to highly coordinated activities. Hence, based on this plurality of initiatives and the relevant successes and failures that accompanied them, one can safely derive conclusions on the effectiveness of the regulatory cooperation policy of the EU at that time and juxtapose it with more recent developments with its inclusion in an FTA, which will be examined later.

The first steps on regulatory cooperation in the context of EU–US relations were taken after the end of the Cold War, which set the economic collaboration between the two superpowers on a new basis. Triggered by the determination of the Bush Administration to observe the transformation of the European integration closely, transatlantic relations expanded beyond security matters to trade issues. Since then, transatlantic economic relations have been shaped by the two political declarations of utmost importance for the design of economic transatlantic relations, namely the Transatlantic Declaration and the New Transatlantic Agenda, and are still developed within their context.

Regulatory cooperation, considered an indispensable tool of economic integration, held a high position in the agenda in political talks, to which the various summits later gave substance. The choice of vocabulary chosen to describe the ambition of the transatlantic declarations reveals the commitment and belief that regulatory cooperation was the answer to the emerging nonregulatory tariff barriers to trade. Since then, regulatory cooperation has monopolised the interests of various initiatives that followed. It constituted the central axis of separate agreements and has been examined through the lenses of horizontal and sectoral mechanisms. Most importantly, the 1998 Transatlantic Economic Partnership (TEP), the agreement that actually shaped transatlantic economic relations, viewed regulatory cooperation activities as part of its core activities. In fact, being part of a compromise, TEP’s significance for transatlantic economic relations was enormous because it carried the weight of the failure to reach an agreement on an FTA. Moreover, its strong orientation towards the abolition of nonregulatory barriers to trade was informing for the necessity of regulatory cooperation at the time. All subsequent regulatory activities of sectoral and horizontal nature, the most important of which are briefly outlined below, were materialised under the auspices of the TEP.

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6 See J. Peterson, Get Away from Me Closer, cit., p. 53.
The absence of a cooperation framework brought disputes, such as the one on hush kits, to the centre of attention. To avoid new transatlantic adventures, the Early Warning Mechanism initiative was the first step in this direction. The subsequent Guidelines on Regulatory Cooperation and Transparency gave clearer direction to the regulatory authorities by mapping the landscape of the promoted horizontal cooperation. Seeking coordination on a higher political level, the establishment of the High Level Regulatory Cooperation Forum was a more coordinated effort to group existing sectoral and horizontal dialogues. Finally, the creation of the Transatlantic Economic Council made an ultimate effort to revitalise the dialogue built upon past mistakes, providing high political oversight and bringing hidden actors, such as legislators and stakeholders to the epiphany. As for sector-specific dialogues, they were established and enhanced mainly under the roadmaps of 2004 and 2005.

Despite the absence of an FTA framework and the regulation of trade relations on a political level, the efforts to invigorate regulatory cooperation activities were numerous and continuous. However, the existence of systemic problems rooted mainly in the legally fragile nature of the initiatives impeded the implementation of regulatory cooperation.

### III. FTA Structures Regulatory Cooperation and Regulation Imperatives: Conflict or Harmony?

Responding to those systemic failures and choosing to initiate regulatory cooperation on more legalistic terms, the EU abandoned the legally weak “political treaties”, a term that captures the general quality of previous forms of regulatory cooperation. Regulatory cooperation as it now stands in the new FTAs is seen again as an ensemble of commitments targeting unnecessary, duplicative, and trade-disruptive regulatory barriers to trade, only this time addressed in more legalistic terms and grouped under a chapter of a legally binding treaty. As discussed, until recently, the idea was quite mature in other fora and under different forms. However, the auspices of an FTA advocate for a different understanding in the context of an FTA. Before any discussion on the possible advancement

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11 The term “political treaties” is borrowed from Judge Baxter from his contribution on the variability of international law. According to this Article, political treaties, such as joint communications and joint declarations, are a category of soft law, as opposed to treaties that introduce hard law. R.R. Baxter, *International Law in Her Infinite Variety*, in *International and Comparative Law Quarterly*, 1980, p. 549.
through the inclusion in an FTA, one must first assess the compatibility of the FTA structure with the nature of regulatory cooperation, as the latter is influenced by the imperatives of contemporary regulations. One could pose the question regarding whether a legally rigid environment can properly accommodate such activities, given that contemporary and effective regulation transcends borders and requires the participation of many actors. Compatibility is thus assessed from that perspective. In other words, regulatory cooperation in this case cannot be understood distinctly from the FTA in which it is situated. The same applies for the reverse. The FTA structures must be equally informed by the nature and sequence of the regulation they try to control. Hence, during the process of reflection upon the appropriateness of an FTA to incorporate such a process, one should examine these structures in light of the regulation they address.

iii.1. The changing nature of regulation

The nature of regulation follows the imperatives of the production organisation because it is influenced by technological developments and increasing specialisation, according to Hoekman and Sabel. The key to their analysis is the dominance of value chains, in other words the disintegration of production and its organisation into vertical structures where the design and production of each component of a final product constitutes a different task run by different actors. Globalisation has further disintegrated the nature of production by allocating various production areas across the world on the basis of cost-saving criteria. Production has become a global multi-step process. Regulation follows these characteristics closely, covering each step of this long process because every component of production is regulated, and it is global because each step falls under different regulatory jurisdictions. Eventually, the time comes when different components produced according to different regulations must cross borders to be assembled into the final product. While regulatory competition implies that differences in regulation mirror differences in preferences, instances where different regulations are duplicative generate unnecessary extra conformity costs that are reflected on the final price. Such cases require effective and efficient regulation. Given today’s architecture of trade relations, it is imperative that regulations not only fulfil their primary purpose to regulate markets but also facilitate efficiently adopted and applied trade.

Vertical disintegration and the resulting dominance of supply chains not only aim for effective results but have also exercised considerable influence on the way regula-

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13 Ibid.
14 Ibid., p. 1. According to Hoekman and Sabel, non-tariff measures may be exclusionary in the sense that they restrict a certain activity. They also may be the result of successful lobbying by enterprises, may be duplicative, and may reflect different preferences.
tion is created. Earlier considered an exclusive task of regulators based on scientific data, regulation now forms part of a learning factory, a chain that implicates the presence of major actors in the production. In principle, regulation aims to express a society’s tolerance towards risks. Risk allocation can be based on scientific facts. It can also be a task burdening mass producers acting within the organisational structure of global value chains, where producers are required to hold rigorous controls over their production and determine and fix issues before they affect the final product or part of the supply. The chance of risk increases, and the risk allocation exercise becomes even more demanding as the evolution of technological innovation increases and becomes an integral part of production activities. In this continuously uncertain environment, enterprises choose to collaborate together and rely on the expertise of experienced suppliers when a new design is in the making. This inevitably creates a continuum of cooperation between non-regulators of doing by learning, where risks are minimised through a systematic collection and analysis of data. These results are further reported to the regulators that must translate the risks into concrete regulations. This collaborative system of reporting and learning has been captured under the term “meta-regulation”.16

The concept of “meta-regulation”, a facilitating mechanism arising out of the need for regulation to keep pace with the advancement of production, is thus changing the character of regulation. Regulation is not static but is a fluid concept that must closely assess the dangers and risks that innovation of production may hide. Considerable information asymmetry exists between the regulator and the cause of risks, a gap that production actors are called to address by reporting potential hazards to regulators. Inevitably, this kind of regulation must be taken into consideration in the context of an FTA.

iii.2. Compatibility of regulation and FTA structures for regulatory cooperation

Due to the differences regarding the sought priorities, trade objectives and domestic regulation have proven difficult to reconcile. However, the contemporary organisation of production and the associated risks make them mutually dependent and mandate their harmonious coexistence, characteristically called a “21st Century approach to regulatory coherence” by Bollyky. To what extent FTA structures can reconcile trade objec-

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18 Ibid., p. 180.
tives and regulation is thus the central question. As mentioned, scholars have raised this question of the suitability of an FTA to host regulatory cooperation on the described level of such complexity and interdependence. According to them, the emerging presence of these information chains that demand the input of non-traditional actors for regulatory purposes was not initially present in the regulatory cooperation chapters that seem to coordinate the dialogue channels between regulators.\(^\text{19}\) They argue that the commitments enshrined in the chapters focus on drawing parallels between the established practices by mandating the adoption of certain practices within the regulatory procedure that aim to create frameworks that are interchangeable and that this aim inevitably places key actors that are situated on a governmental level at the epicentre.\(^\text{20}\)

Indeed, the explicit reference to a “regulatory authority” as the addressee of the commitments in the chapter on regulatory cooperation of the EU-Japan FTA is indicative of its orientation towards the activities of actors that are subject to the regulatory mandate.\(^\text{21}\) The wording depicts regulators as the main subject of cooperation. However, this does not necessarily mean that the chapters overlook the complex task of regulation and the plurality of the actors implicated therein. This is true for two reasons. First, despite the detailed enumeration of the activities to take place, the organisational and institutional parts of both chapters have been outlined with laconism. Indeed, the chapters provide a framework for regulatory cooperation. Within this framework, regulators are expected to be the de facto protagonists, as the regulators are officially given the much-anticipated legal mandate to initiate dialogue as official representatives. Beyond that, the nature of relations and interdependencies that develop within frameworks that handle such sensitive and complex issues is unpredictable, which is the reason why their implementation cannot be predicted. While regulators are situated within a territorial environment, industry presumably is not.

Second, the linkage between regulation and production is highlighted through various commitments. Representative of this is the case of the 2016 Comprehensive and Economic Trade Agreement (CETA), where the instruction of consultation procedures with private entities, which may include, \textit{inter alia}, business representatives, is mandated in a sole article.\(^\text{22}\) Beyond this particular article, industry’s role varies within the chapters and can range from substantial input to a regulation under preparation, contacts on an informal basis, and participation in the committee’s workings.\(^\text{23}\) The participation of production actors is thus spread within the chapters’ workings and can appear

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\(^{20}\) Ibid.


\(^{22}\) Art. 21 of CETA.

\(^{23}\) Art. 21.8 of CETA and Art. 18.7 of the EU-Japan EPA.
in various important instances, as are the development of a regulation and the orienta-
tion of the cooperation activities through invitations to the meetings of the coordinating
body. Their presence in the regulatory process and the necessity of their contribution
as directly implicated entities is thus not ignored; on the contrary, it is welcomed.

IV. Tighter institutionalisation through inclusion in an FTA

Nowadays, scholars that conduct research in the various EU external relations increasing-
ly aim to describe the intensification of the actions through the creation of entities using
the term “institutionalisation”. In addition, in the area of trade, with the rise of the “living”
FTAs that the EU has been signing with its trade partners, this term has been used to sig-
nify the sudden appearance and proliferation of institutions that accompany and frame
the actions included therein.24 Especially in the realm of regulatory cooperation, claims of
the “institutionalisation” of regulatory cooperation through FTAs contrast with the failures
of the previous transatlantic efforts.25 In essence, it is argued that the “added value” of
FTAs is their contribution to a better institutionalisation of regulatory cooperation. How-
ever, many cases lack a description of the term and understanding of institutionalisation
and how it fits into their positioning on the institutionalisation of regulatory cooperation,
partially due to the recent appearance in the field of EU external relations.

This Section opposes those arguments and depicts the institutionalisation of regula-
tory cooperation even before its inclusion in an FTA. It begins by analysing how institu-
tionalisation has primarily been understood in social, legal, and international relations lit-
erature, particularly regarding European integration. The understanding of institutionali-
sation has been applied to the previous transatlantic developments to make the argu-
ment that FTAs do not contribute to tighter institutionalisation but to something different.

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

The concept of institutionalisation is a term primarily used as a conceptual tool in social
and behavioural sciences.26 It has been promulgated in recent years by legal and politi-
cal science scholars studying European integration to capture and explain in an inter-
disciplinary manner the constant changes in governance both within and beyond the

24 See D.P. Steger, Institutions for Regulatory Cooperation in “New Generation” Economic and Trade
25 E. Fahey, Introduction: Institutionalization Beyond the Nation State: New Paradigms? Transatlantic Rela-
tions: Data, Privacy and Trade Law, in E. Fahey (ed.), Institutionalization Beyond the Nation State, Cham:
Springer, 2018, p. 8 et seq.
26 The process of institutionalisation lies at the core of neo-institutionalism in organisation theory.
For example, see T.B. Lawrence, M.I. Winn, P. Deveraux Jennings, The Temporal Dynamics of Institutionaliza-
nation state. According to its understanding in organisation theory, institutionalisation is the process by which certain structures are consolidated, and it is a process triggered by persistent normative, mimetic, and coercive forces. This process often leads not only to consolidation of practices but also to their legitimisation, and this is also how institutionalisation has been described within the nation state, as the process by which a practice gains general acceptance.

A similar understanding is also present in the literature dealing with the institutionalisation of European integration. In fact, there are two elements on which analyses have heavily focused. The first one is the concentration on European institutions. Mark Pollack discussed connecting the EU's dense institutionalisation in comparison to other supranational settings to the proliferation of intergovernmental and supranational institutions that surround it and the augmenting body of EU legislation, known as acquis communautaire. The second and most important element is, as mentioned, the perception of institutionalisation as a process of formalisation. The gradual process of institutionalisation coincides with the consolidation of a set of norms and formalities that create particular communication dynamics and shape the routines in the European sphere within structures. Thus, relevant institutionalisation debates tend to concentrate on the process of formalisation and stabilisation of formal or informal institutions and procedures. Similarly, institutionalisation has been used regarding implicated actors in expressing their establishment within a given field. In the realm of the changing landscape of EU regulation for example, institutionalisation and de-institutionalisation have been employed to describe the gradual establishment of agencies and networks as regulatory actors.

According to another strand of the literature, institutionalisation as a notion in the EU context has been detached from its process-centric character and is considered the result

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29 E. FAHEY, Introduction, cit.


33 See S. SAURUGGER, F. MÉRAND, Does European Integration Theory Need Sociology?, cit., p. 7.

of the consolidation of procedures and structures that are difficult to change.\textsuperscript{35} Others have highlighted the constant change that came with European integration with higher levels of institutionalisation.\textsuperscript{36} Recently, academics have tried to capture the essence of the general notion beyond the nation.\textsuperscript{37} Their analysis begins from the new European governance trend of promotion of international institutions in various instances and extends accordingly to capture the associated procedures that these institutions promote. Institutionalisation beyond the nation state is understood as a sign of the times, as an “antidote to concerns about the delegation of authority beyond the Nation State”, a factor that establishes a certain practice and legitimises it.\textsuperscript{38} According to Fahey, institutionalisation beyond the nation state should better be described as the process of intense cooperation and interaction rather than its outcome, institution, or situation.\textsuperscript{39}

As outlined above, there is a cross-disciplinary convergence in treating institutionalisation as a process, with a few scholars instead viewing it as a result. Institutionalisation, however, has also been treated independently of the process/result debate of institution/procedure building. According to Bélanger and Fontaine-Skronski, institutionalisation depicts “the degree to which institutional rules govern more the actions of the actors”, in other words “the degree to which state behavior, in a particular area of cooperation, falls within the scope of particular rules”.\textsuperscript{40} The focus is not on whether institutionalisation is to happen during the development or with the creation of an institution. Institution-building, either as a process or result, does not have any significance. What matters is the range of activities covered by these institutional rules.\textsuperscript{41} The richer the range, the greater the institutionalisation of the particular area of cooperation.

\section*{iv.2. Was transatlantic regulatory cooperation institutionalised?}

Institutionalisation, understood in one way or another, was not absent from the transatlantic paradigm of regulatory cooperation. The institutionalisation of regulatory cooperation, understood as rule coverage, under the theory of Bélanger and Fontaine-Skronski, cannot be disputed because the various initiatives described above range

\textsuperscript{35}\textit{P. Petrov, Early Institutionalisation of the ESDP Governance Arrangements: Insights from the Operations Concordia and Artemis}, in \textit{S. Vanhooakacker, H. Dijkstra, H. Maurer (eds), Understanding the Role of Bureaucracy in the European Security and Defence Policy}, in \textit{European Integration online Papers (EIoP)}, 2010, eiop.or.at.


\textsuperscript{37} See generally \textit{E. Fahey (ed.), Institutionalization Beyond the Nation State}, cit.

\textsuperscript{38}\textit{M. Zurn, Opening up Europe: Next Steps in Politicization Research}, in \textit{West European Politics}, 2016, p. 164.

\textsuperscript{39} See \textit{E. Fahey, Introduction}, cit., p. 4.


\textsuperscript{41} Ibid.
from horizontal to sectoral initiatives, comprising diverse rules and many emergent actors, covering a wide range of regulatory cooperation activities. For example, the regulatory cooperation guidelines were as comprehensive content-wise as the contemporary FTA chapters, while the mutual recognition agreements (MRAs) were the product 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. As far as sector-specific dialogue is concerned, its highlight until today is the MRA, which concerns mutual recognition of the conformity assessment procedures over six sectors: telecommunications and information and communications technology (ICT) equipment, sport boats, medical devices, pharmaceuticals, electronics, and electromagnetic compatibility. With actual, although limited results, it is difficult to argue that regulatory cooperation activities were not regulated. They were indeed regulated but were not under strict legal terms.

Second, turning to the literature debate on the process and result of institution-building, one can observe the development of institutional structures through the 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 Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Directive by the EU and the 2002 Sarbanes-Oxley Act by the US.

Under both scenarios, institutionalisation could not provide 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 the 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, meaning that 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,


who are called to conciliate their main internal regulatory tasks, as these are mandated by their own constitutional framework with cooperation mandated by executive agreements with foreign counterparts. These two tasks may be contradictory in nature. When called to choose between the fulfilment of their constitutional mandate and cooperation with foreign counterparts, regulators will choose to proceed with complying with 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. That may happen because regulators are not accustomed to considering trade interests during the development of regulatory acts due to the structure of the regulatory system, which may not provide them with this possibility. This is the case of the US, which, unlike the EU regulatory system, is not accustomed to reconciling regulatory objectives with an internal market. Regulatory action in the US is divided between the varying agencies, which follow a strict mandate and are isolated from trade matters. 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 are dedicated for internal purposes. Finally, apart from these institutional problems, the lack of legal bindingness can also stand behind certain attitudes. The example of the lack of coordination for the development of the REACH Directive and the Sarbanes–Oxley Act in the US, despite existing available cooperation mechanisms, is indicative of the attitude of regulators towards regulatory dialogue. In the end, the particular soft law nature of the experiment could not provide enough reasons for regulators to cooperate, even though the political willingness at higher levels to activate and advance a regulatory dialogue was apparent.

V. Stronger Legalisation through Inclusion in an FTA

The conceptualisation of impediments to the successful operation of regulatory cooperation indicated the lack of legally strong rules as the weakest element. As noted, this feature does not substantially coincide with the concept of institutionalisation as examined above, even though it has been associated in the literature. Interestingly, legal bindingness has been used as one of the measurement units that builds the concept of “legalisa-
Legalisation is a conceptual tool developed by international relations scholars. Legalisation as a concept is associated but not equated to institutionalisation. Legalisation is a particular form of institutionalisation, characterised by three components: obligation, precision, and delegation. According to this construction, the element of obligation measures how binding the undertaken commitments are, the element of precision refers to how precise the rules are, and the element of delegation is used to depict whether a third party has a delegated authority, *inter alia* on issues of interpretation, implementation, monitoring, and dispute settlement. Legalisation, composed of these three components is a concept that is empirically built and inspired by characteristics found in institutions. More specifically, it examines the degree to which these components are to be found in each institutional structure. Legalisation of institutions can take several forms and can range from low to high; its form and intensity depend on the combination of the degrees of the various components. The following Section will firstly examine how the "obligation" part is strengthened in the chapters of Regulatory Cooperation and will discuss how similar levels of obligation have proven effective.

### V.1. The "Obligation" Element

Based on this concept, considering the lack of legal bindingness that characterised the previous efforts on regulatory cooperation, when analysing the contribution of FTAs to the development of the legalisation of regulatory cooperation, particular attention should be paid to "obligation", which measures the legal bindingness of the commitments. In other words, one should examine whether the inclusion in an FTA strengthens the obligation criterion, the weakness of which lies behind the implementation problems during past initiatives. This Section, after locating provisions that could be argued to weaken the enshrined obligation, argues for a high degree of obligation due to the commitments' qualification as international obligations.

However, before any analysis we should first become acquainted with the fundamental provisions of the chapters on regulatory cooperation, the formulation of which aims to weaken the obligation established by the inclusion of the chapters within FTAs, which are legally binding international treaties. Despite this qualification, the strength of the obligation has been questioned on the basis of existing reserve clauses that highlight the voluntary character of the activities and the non-submission of the EU-Japan chapter on the agreement's dispute settlement mechanisms.

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53 Ibid., p. 403.

On the voluntary character of the activities, Art. 21.2.6 CETA states the following: “The Parties may undertake regulatory cooperation activities on a voluntary basis. For greater certainty, a Party is not required to enter into any particular regulatory cooperation activity, and may refuse to cooperate or may withdraw from cooperation. However, if a Party refuses to initiate regulatory cooperation or withdraws from cooperation, it should be prepared to explain the reasons for its decision to the other Party”.

Moreover, Art. 18.6.2 of the 2019 EU-Japan Economic Partnership Agreement (EU-Japan EPA) states the following in a similar fashion: “The Parties may engage in regulatory cooperation activities on a voluntary basis. A Party may refuse to engage in or withdraw from regulatory cooperation activities. A Party that refuses to engage in or withdraws from regulatory cooperation activities should explain the reasons for its decision to the other Party”.

Such protective clauses, along with the careful formulation of other provisions, have provided fertile ground for the development of arguments on the “soft” law nature of the commitments. However, a detailed discussion of the said debates not only exceeds the purposes of the argument, but also comes at odds with it. And this is because for the purposes of this Section, that of discussing the nature of the obligation envisaged in the regulatory cooperation chapters, obligation is not viewed as it does originally, as having various nuances, ranging from high to low. Instead, this Section adopts a binary distinction of legality, as does Kal Raustalia in his influential piece of work, thus rejecting the usefulness of the concept of “soft law”. According to this view, the concept of soft law is redundant, because evidence suggests that legality should better be seen on a binary scale. Soft law (qualifying neither as hard law nor as non-law) can only exist as a phenomenon if we understand legality as obligation in legalisation is understood, on a spectrum. Only then is it possible to place soft law somewhere between law and non-law. However, such a view would obscure rather than help us to assess

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55 Apart from these clauses, other provisions have tried to secure the prerogatives of the regulators, as they are established by the respective legal orders, by highlighting the nonlimiting character of regulatory cooperation. An example of this is Art. 21.2.4 CETA, which begins “Without limiting the ability of each party to carry out its regulatory, legislative and policy”.

56 K. RAUSTALIA, Form and Substance in International Agreements, in American Journal of International Law, 2005, p. 581 and p. 586 et seq.

57 Indeed, Prosper Weil argues that “whether a rule is hard or soft does not, of course, affect its normative character. A rule of treaty or customary law may be vague, ‘soft’, but as the above examples show, it does not thereby cease to be a legal norm”. See P. WEIL, Towards Relative Normativity in International Law?, in American Journal of International Law, 1983, pp. 413-414.

58 Soft law is not always perceived as something between hard law and soft law. For example, Guzman in his influential contribution equates soft law with non-binding agreements. See A.T. GUZMAN, The Design of International Agreements, in European Journal of International Law, 2005, p. 580.
legal bindingness at the international level, since, as it will be shown, the determination on the quality of a rule as hard or soft comes from elements other than its form.59

Indeed, as Raustalia demonstrates, there is no evident state practice that grounds the existence of soft law in the reality of international treaty-making; soft law thus does not appear as a distinct category, instead, states negotiate and conclude either binding or non-binding agreements.60 This strict dichotomy does not allow room for new categories of law as is soft law, hence, scholars tend to judge the “softness” based on criteria other than the legal form of the agreement. They rather focus on the substance of a commitment instead, as is for example the consequential and influential nature of a rule based on its preciseness61 or on the structure of an agreement, as is its ability to be enforced.62 Indeed, it has been widely argued in the literature that the text of a treaty may not necessarily encompass exclusively legal obligations, an example constituting the preambles of a treaty that serves among others as normative guidance to the main body.63 Regarding the main treaty body, for these commentators it is thus not uncommon that a treaty comprises apart from solid legal obligations also declarations of intent and aspirations regarding the objectives to be fulfilled, that are of sub-legal, and even non-legal nature.64

Making a judgement on the legality of each separate provision65 based on its substance and its ability to influence behaviour66 and on its ability to be enforced conflates three distinct notions.67 Substance and structure along with legality of course constitute

59 See K. RAUSTALIA, Form and Substance in International Agreements, cit., p. 586.
60 Ibid., p. 587.
61 Regarding commitments included in human rights treaties, Judge Baxter insisted on their vague formulation to rule out any possibility to influence State behaviour. See R.R. BAXTER, International Law in Her Infinite Variety, cit.
62 Ibid., p. 562.
67 For those who understand soft law as the type of commitment that is not subject to a dispute settlement mechanism, treaties can include both hard and soft law commitments, the hard being the ones that
three components on the basis of which the design of international agreements is exam-
ined, however, they represent different aspects of each agreement and thus should not
be muddled. In other words, the status of a rule as law, represented by the dimension
of “legality” is by no means dependent on how effective a rule is. Of course, some rules
may bring better results than others, but this does not deprive them of their status as law.
That said, when it comes to the type of obligation in the case of regulatory cooperation
commitments, particular attention should be given to whether these “reserve clauses” be-
long to the Legality or form part of the substance or structure of the agreement.

a) Legality and substance.
As far as the examination of the design of an international agreement is concerned, “sub-
stance” reflects the extent to which states have agreed to change their behaviour. “Sub-
stance” encompass of course how vaguely or precisely the rules are defined; however, its
scope though reaches beyond that. Its best proxy would be the description of the “depth”
of the agreement, signaling the “the extent to which an arrangement requires states to
depart from what they would have done in its absence”. Such an indicator constitute the
provisions that outline the voluntary character of regulatory cooperation in FTAs. By giving
a voluntary character to the initiation of cooperation, these provisions are an indication of
how much the parties are called upon to alter their behaviour.

In this case, parties are called to voluntarily change their behaviour. The fact that the
voluntary initiation of cooperation does not give much “depth” to the commitments, given
the margin of discretion bestowed to the parties, is a different issue, one of depth and
substance and not of legality. It is through the practice of “reserving” that the parties
manage the “depth” of their commitments, that is why international arrangements pre-
sent significant variations with regard to their depth. Depth can also be a relative unit,
with the same obligation being deep for the one party but shallow for the other. Be it as
it may, in any case “depth” does not impinge upon the legality of the commitments.

are enforceable through an adjudication mechanism and the soft being the ones that range from non-
adjudication to milder forms of reconciliation procedures. However, this vision of soft law is only acknowl-
68 Also in the legalisation concept, obligation, precision and delegation are three distinct elements, which,
although seen together as an overall concept, each one taken separately is viewed and assessed on its own.
69 Effectiveness should also not be muddled with compliance. As explained by Kal Raustalia, compliance
and effectiveness should be viewed separately, because effectiveness provides the causal linkage
between a rule and a behaviour; compliance only demonstrates the conformity between the rule and the
behaviour. See K. RAUSTALIA, Compliance and Effectiveness in International Regulatory Cooperation, in Case
Western Reserve Journal of International Law, 2000, pp. 387 and 398.
70 See K. RAUSTALIA, Form and Substance in International Agreements, cit., p. 584.
71 G.W. DOWNS, D.M. ROCKE, P.N. BARSOOM, Is the Good News About Compliance Good News About Coop-
72 One example is the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights
(TRIPS Agreement), that on the one hand required substantive changes to the IP regime of many developing
states, which was not the case for the US or Europe for example.
b) Legality and structure.

The same framework, the need to distinguish between legality and the various design elements, in this case, structure, applies to the exclusion of the regulatory cooperation chapter in EU-Japan from the dispute settlement mechanism.\(^\text{73}\) Leading scholars apart from Raustalia, on whose framework the present analysis heavily relies, also separate the designation of an adjudication mechanism from legality, agreeing that it remains a design element, which is different and independent from the legal form of a commitment.\(^\text{74}\) Even commentators that accept the dichotomy between soft and hard law and equate it to binding and non-binding commitments, understand and present adjudication on a separate basis.\(^\text{75}\) Adjudication is thus not associated with legality, but with an enhancement of credibility instead, where also the design element of “hard law” aims as well.\(^\text{76}\)

The irrelevance of this element for the presence of an international obligation has been also confirmed by jurisprudence of the Court of Justice. Interestingly enough, the case under consideration, *France v. Commission*, dealt with another regulatory cooperation chapters initiative, namely the 2002 EU-US Guidelines which were agreed as a political declaration during one of the various bilateral summits.\(^\text{77}\) These Guidelines outlined in a quite detailed and coherent manner a series of activities that regulators were encouraged to undertake in order to initiate a sustainable dialogue. Quite alarmed by the content of the Guidelines and the impact they could have on the Commission’s right of initiative, France brought an action for annulment against the Commission before the Court of Justice arguing that in fact the Guidelines were concluded as an international agreement, not falling under the Union’s competences, the binding character of which could have a serious impact on the Commission’s right of initiative.\(^\text{78}\) Before deciding on the compatibility of the Guidelines with the legislative prerogatives of the Commission, the central question that had to be answered was whether the Guidelines were in fact an international agreement, concluded outside the scope of the Commission’s competences, and could as such be challenged as a legal act of the Commission under Art. 230 EC Treaty. To answer this question, AG Alber went beyond the form of the agreement, and looked into the content of the Agreement, developing an analytical framework which included various dimensions upon which it based its Opinion. AG Alber com-

\(^\text{73}\) Art. 18.19 of the EU-Japan EPA.

\(^\text{74}\) See A.T. GUZMAN, *The Design of International Agreements*, cit., p. 581, presenting the design elements of “hard law, dispute resolution and monitoring as three self-standing design elements”.

\(^\text{75}\) For example Guzman who uses hard/soft law as synonyms for binding/non-binding agreements respectively himself, admits that one cannot distinguish these two categories of commitment, the kind of legality in other words (hard/soft – binding/non-binding) neither on the basis of an adjudication clause nor on the effects on the behaviour. See A.T. GUZMAN, *The Design of International Agreements*, cit., p. 583, note 21.


\(^\text{77}\) *Court of Justice*, judgment of 23 March 2004, case C-233/02, *France v. Commission*.

mented on the following elements in order to assess the legal nature of the Guidelines: a) the context that placed the Guidelines; b) the intention of the parties; c) the use of language; d) the objectives pursued.79

79 Shortly, the Opinion of AG Alber argued the following. Regarding what is relevant, as mentioned above, the inclusion into a legally binding Treaty is of importance, even though not decisive on its own. AG's "context" criterion confirms that the choice of venue is indicative of the intention of the parties to dress their commitment in more formal clothes. Indeed, by arguing for the weak character of the cooperation activities as introduced in the Guidelines, due to the fact that they were founded in the context of a political arrangement, the Transatlantic Economic Partnership (Opinion of AG Alber, France v. Commission, cit., para. 59) one can expect some added value through the inclusion in a legally binding agreement, which changes the negotiating and decision-making environment, and thus influences the character of the agreement as a whole. This "upgrade" carries the history of countless efforts to promote the regulatory dialogue through the soft, legally fragile "political treaties", to quote Judge Baxter and signals the intention to commit further along more legalistic lines. Judge Baxter uses the term "international agreements" in order to expand his analysis also to agreements other than binding treaties (as understood for the purposes of 1969 Vienna Convention on the Law of Treaties). One of the categories of international agreements that he discerns are the "political treaties". These political treaties, examples of which are joint communications and joint declarations, are, according to his analysis, a category of soft law, as opposed to treaties that introduce hard law. See R.R. Baxter, International Law in Her Infinite Variety, cit., p. 551. This venue also instructs that cooperation is not taking place in a legal vacuum. FTAs create a whole new structure of trade relations between the parties – which is of course juxtaposed to the multilateral one, but which also functions independently on some issues – and constitute a new source of authority themselves. Martha Finnemore and Stephen J. Toope make the same argument with regard to legalisation of monetary affairs and the impact of the element of obligation to the decisions taken under Art. VIII of the 1944 IMF Agreement, in order to argue that authority and normativity do not derive exclusively from the obligation imposed by a single provision, but also from the wider legal environment that frames these actions, which encompasses the activities and supports them with a firm legal background and relevant expertise. See M. Finnemore, S.J. Toope, Alternatives to Legalization: Richer Views of Law and Politics, in International Organization, 2001, p. 752. Regarding the intention of the parties, it is, according to the AG, an important factor that guides about the legal nature that the parties intended to ascribe to an international arrangement; however, it is not decisive. He noted particularly that the intention of the parties to give voluntary character to the Guidelines should be read in conjunction with other elements as well (Opinion of AG Alber, France v. Commission, cit., para. 80). The voluntary character of the commitments, stated clearly in both FTAs, is to a certain extent informative, however, not decisive about the legal value of the commitments as such. Another dimension that merits consideration is, according to AG Alber, the use of language. "Legalization implies a discourse primarily in terms of the text purpose and history of the rules, their interpretation, admissible exceptions" (K.W. Abbott, R.O. Keohane, A. Moravcsik, A.-M. Slaughter, D. Snidal, The Concept of Legalization, cit.) note the instigators of legalisation while unfolding the different dimensions and content of the obligation criterion. Applying this framework to the regulatory cooperation chapters, and beginning from the discourse in terms of language, the vocabulary according to which the main provisions are formulated, the use of the obligatory "shall", is indicative of the mandatory nature of the terms, and the hard type of obligation. Such vocabulary is used for example in CETA with regard to Art. 21.5 dealing with the compatibility of regulatory measures ("each Party shall, when appropriate, consider the regulatory measures or initiatives of the other party on the same or related topics") and Art. 21.7 on further cooperation dealing with information exchange ("the Parties shall periodically exchange information of ongoing or planned regulatory projects in their areas of responsibility"). Similar language is used repeatedly in outlining the procedure of regulatory cooperation to be un-
However, it is the starting point of the AG's thoughts that confirms our argument. Indeed, AG Alber commenced his assessment by stating what is irrelevant for the characterisation of a commitment as a legally binding one. According to his analysis, the presence or absence of dispute settlement and liability provisions is irrelevant to the qualification of the Guidelines as an international agreement. Indeed, it is interesting that the same argument raised at the time by the Commission to argue against the legal value is raised also today for the same reason. The choice to subject a commitment to dispute settlement may instead influence the level of effectiveness, as a matter of enforcement, but not its qualification as an obligation as such.

Based on the argumentation provided in the previous two Sections, confirming the existence of a binding international obligation raises significantly the “obligation” criterion. As outlined above, the insistence of a voluntary cooperation and the choice in EU-Japan to exclude the provisions from dispute settlement refers to the substance and structure of the chapters, not their legality, and thus must not be seen as a factor to deprive the commitments from their quality as a legal obligation. As an international obligation created through its inclusion in an FTA, certainly the conditions under which regulatory cooperation activities are conducted are altered. Indeed, such an obligation carries a heavier legal significance, one that has the power to oversee, prevent and give solutions to internal implementation problems, as the one faced in earlier efforts, exactly because of the weight it carries as an international commitment.

V.2. Evidence from regulatory cooperation included in FTAs beyond the EU

Apart from the theoretical question on 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, an empirical connection seems to exist 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 the FTA structure has supported regulatory cooperation activities. One example is that of the 1992 North American Free Trade Agreement (NAFTA). Regulatory cooperation between the NAFTA partners, although initiated by the FTA, was only advanced later. The NAFTA saga begins with the inability of the NAFTA institutional structures to have any result. The trilateral Committee on Standards-Related Measures and the working groups comprising it, established under the FTA, did not advance the works on regulatory cooperation due to a lack of political oversight. The Security and Prosperity Partnership (SPP) did manage to incorporate to a certain extent the kind of cooperation envisaged in NAFTA. In a way, it completed it. Thus, the subject was treated once more under the SPP, an executive-type cooperation, with greater success. Later, to intensify the ongoing success, the parties established an even tighter form of cooperation, bilateral this time, the US-Canada Regulatory Cooperation Council, which also implicated the direct participation of regulatory agencies.

This case eventually demonstrated better achievements than the EU regarding regulatory cooperation. Regulatory cooperation was based on a firm background, a legal instrument that regulated solid trade relations. It is not a coincidence that, in the realm of NAFTA, the SPP brought far better results in the branch of regulatory cooperation than in security, which was not supported by a previous legal instrument. Hence, should regulatory cooperation operate more efficiently under an FTA structure, its inclusion in the EU FTAs is heading in the right direction.

VI. Conclusion

More than one factor led to the inclusion of regulatory cooperation in FTAs. In the multilateral setting, legal commitments of low cooperation that concentrated on non-

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81 Another example of regulatory cooperation based on an FTA is the example of Australia and New Zealand, built within the 1983 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. 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 D.P. Steger, *Institutions for Regulatory Cooperation in “New Generation” Economic and Trade Agreements*, cit., p. 115.


84 Ibid., p. 31.

discrimination (Art. 2.1 of the 1995 Technical Barriers to Trade Agreement, hereinafter TBT Agreement, and Art. 2.3 of the 1995 Sanitary and Phytosanitary Measures Agreement, hereinafter SPS Agreement) and rationality requirements (Art. 2.2 TBT and Art. 2.2 SPS) were inadequate to trigger a substantial regulatory dialogue. Apart from that, other efforts primarily in the bilateral political arena were condemned to failure because of their legal weaknesses. To cure both weaknesses, the coordination of regulatory cooperation activities under the premises of an FTA marks the beginning of a different era for their materialisation, mainly through its contribution to the “legalisation” of regulatory cooperation. With a stronger focus on obligation, it remains to be examined how strong the other constituents, precision and delegation, are in FTA regulatory cooperation. However, it is safe to argue that, with inclusion in a legally binding treaty, cooperation activities are placed on a different playing field, and commitments are vested with the armoury of an international obligation, an armoury that better and more effectively serves implementation and enforcement.